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# A Bioethics Tool for the Implementation of Global Principles by the Pharmaceutical Industry

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A BIOETHICS TOOL FOR THE IMPLEMENTATION OF  
GLOBAL PRINCIPLES BY THE PHARMACEUTICAL INDUSTRY

A Dissertation

Submitted to the McAnulty College and Graduate School of Liberal Arts

Duquesne University

In partial fulfillment of the requirements for  
the degree of Doctor of Philosophy

By

Daniel J. Hurst, ThM, MDiv

December 2017

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Daniel J. Hurst

2017

A BIOETHICS TOOL FOR THE IMPLEMENTATION OF  
GLOBAL PRINCIPLES BY THE PHARMACEUTICAL INDUSTRY

By

Daniel J. Hurst

Approved August 31, 2017

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## ABSTRACT

# A BIOETHICS TOOL FOR THE IMPLEMENTATION OF GLOBAL PRINCIPLES BY THE PHARMACEUTICAL INDUSTRY

By

Daniel J. Hurst

December 2017

Dissertation supervised by Henk ten Have, MD, PhD

Due to scandals of scientific misconduct, a climate of mistrust of science exists amongst the general public. This becomes of concern when we acknowledge that it is difficult for science and technology to flourish without broad societal trust. The pharmaceutical industry has often felt the brunt of such mistrust and has suffered many reputational setbacks over the past several years. Such reputational decline has a strong moral dimension, as it stems from issues such as the questionable conduct of clinical trials, pricing schemas, and access to medicines for low- or middle-income countries. The end product of such issues is the public not viewing pharmaceutical and biotechnology companies favorably. Since pharmaceutical and biotechnology companies are intrinsically tied to health and human flourishing, an ethical framework to aid in resolving both the ethical issues facing the industry and the resulting

reputation it yields on both the industry as a whole and individual companies, could certainly be valuable.

The central supposition of this dissertation is that additional work needs to be done in the area of pharmaceutical ethics and corporate social responsibility. Currently, no specifically global bioethics tool exists to implement ethics principles into the business practices of pharmaceutical and biotechnology companies, which constitutes a glaring gap in the implementation of ethics principles. This dissertation thus aims to do the following: (i) clarify the ethical grounding of pharmaceutical corporate social responsibility, and (ii) develop a global bioethics tool that can be utilized by the pharmaceutical industry as a manner to aid in implementing global ethics principles. The global bioethics tool seeks to implement a global ethical framework on the basis of performance indicators and best practices, with a long-term goal of helping society regain its trust in the pharmaceutical industry. While there are numerous bioethical guidelines available, it is argued that the UNESCO Universal Declaration on Bioethics and Human Rights, as a global ethics document with the backing of the global community, can be utilized to create such a tool by which to measure the ethical practices of pharmaceutical and biotechnology companies.

## DEDICATION

*To my bride, Rachel.  
Your constant love, encouragement, and selflessness knows no bounds.  
And our son, Justus. May you exemplify your name.*

## ACKNOWLEDGEMENT

I would like to begin by thanking my dissertation director, Dr. Henk ten Have. You have believed in this project, and me, since its inception. You provided me with opportunities and insights that I will remember for a lifetime. Thank you for your mentorship, and in many ways, friendship. Your love of global bioethics is now deeply shared by me. Because of you, my thinking has been shaped in ways that I can only begin to understand.

Dr. Lise Holst, you tried to get the global bioethics tool off the ground. We share the vision of what pharmaceutical bioethics and corporate social responsibility could be, and I hope one day that will be realized. Thank you for giving this project a fighting chance.

Thanks also to Dr. Joris Gielen and Dr. Gerard Magill. Dr. Gielen, you provided me with numerous opportunities during the two years I worked for you that I would never have had otherwise. My qualitative research interests were spurred because of you. Rachel and I talk often and fondly about our trip to Leuven. Thank you for letting us be part of it. Dr. Magill, you challenged me to think deeply and provocatively. You always showed great interest in my work. Thank you for your guidance.

To Glory, you constantly pour yourself out for the sake of the Center and its students. Countless times I came to you for answers, and you were always there. You celebrated with Rachel and I in the good times, and cried with us in the tough. Your friendship has been cherished.

Mom and Dad, thank you for always supporting me to follow my interests, my academic pursuits, and instilling in me many of the values this work hopes to express. You have supported Rachel and I in countless ways along this journey.

And finally, words fail to express the gratitude I have for my beautiful bride, Rachel. Your encouragement throughout this degree has sustained me. You have unconditionally stood by me and allowed me to chase my dreams. Being your husband is the joy of a lifetime.

It is not hyperbole to say that this work would scarcely have been possible without the above people, as well as numerous others I have failed to mention. These words offer only a glimpse of your role. My sentiments echo those of Sebastian towards his friend Antonio in Shakespeare's *Twelfth Night*, which I first read in an undergraduate course nearly a decade ago:

I can no other answer make but thanks,  
And thanks; and ever thanks. (Act III, Scene 3)

Soli Deo Gloria



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## **Chapter 1: Introduction**

Due to scandals of scientific misconduct, a climate of mistrust of science exists amongst the general public. This becomes of concern when we acknowledge that it is difficult for science and technology to flourish without broad societal trust. The pharmaceutical industry has often felt the brunt of such mistrust and has suffered many reputational setbacks over the past several years. Such reputational decline has a strong moral dimension, as it stems from issues such as the questionable conduct of clinical trials, pricing schemas, and access to medicines for low- or middle-income countries (LMICs). The end product of such issues is the public not viewing pharmaceutical and biotechnology companies favorably. Since pharmaceutical and biotechnology companies are intrinsically tied to health and human flourishing, an ethical framework to aid in resolving both the ethical issues facing the industry and the resulting reputation it yields on both the industry as a whole and individual companies, could certainly be valuable.

The central supposition of this dissertation is that additional work needs to be done in the area of pharmaceutical ethics and corporate social responsibility. Currently, no specifically global bioethics tool exists to implement ethics principles into the business practices of pharmaceutical and biotechnology companies, which constitutes a glaring gap in the implementation of ethics principles. This dissertation thus aims to do the following: (i) clarify the ethical grounding of pharmaceutical corporate social responsibility, and (ii) develop a global bioethics tool that can be utilized by the pharmaceutical industry as a manner to aid in implementing global ethics principles. The global bioethics tool implements a global ethical framework on the basis of performance indicators and best practices, and the tool has a number of goals: 1) helping society regain its trust in the pharmaceutical industry through transparency

about bioethical concerns, 2) increase the bioethics agenda of the industry and, in turn, increase the trust and reputation of the industry, and 3) create a platform of defining and sharing industry best practices, generating global industry standards, and providing a forum for fellow stakeholders to dialogue. While there are numerous bioethical guidelines available, it will be argued that the UNESCO Universal Declaration on Bioethics and Human Rights, as a global ethics document with the backing of the global community, can be utilized to create such a tool by which to measure the ethical practices of pharmaceutical and biotechnology companies.

The request for and importance of responsible business practices are increasing, and recent high-profile scandals have led to decreased societal trust of pharmaceutical companies and resulted in poor reputation for the industry. This has spurred a number of private consultancy companies, non-governmental organizations (NGOs), and others to measure and benchmark the performance of the pharmaceutical industry. This initiative will provide more than that. The industry will develop a needed common voice and have the opportunity to collaborate and learn from each other. Furthermore, a great strength of such a tool is that it would come from inside the industry rather than being imposed on it by external forces. When the industry takes the lead rather than external parties it will send a strong signal to onlookers that particular firms are serious about ethical conduct and self-regulation.

Currently there is no tool for the measurement of bioethics implementation. Other such tools have been implemented for business and human rights,<sup>1</sup> as well as social responsibility and sustainability. Though there are overlaps between issues of human rights, social responsibility, and sustainability and what the proposed global bioethics tool aims to accomplish, this tool will be unique for being the first in the area of bioethics for pharmaceutical and biotechnology companies.

Chapter two discusses the relationship between global bioethics and human rights in order to provide the necessary foundation for discussing the UNESCO Universal Declaration on Bioethics and Human Rights, as well as the context in which the global bioethics tool operates. The gradual evolution of global bioethics will be first discussed. This will be followed by the status of the human rights discourse and the current relationship between global bioethics and human rights. The symbiotic relationship between global bioethics and human rights will be considered in detail.

The first section of chapter two examines the gradual evolution of global bioethics from the fields of medical ethics and bioethics. The history of medical ethics growing out of the atrocities committed during World War II has been well documented.<sup>2</sup> After the Allied victory, the Nuremberg Trials convened, which, in part, resulted in the Nuremberg Code.<sup>3</sup> The Nuremberg Code is centered on the research relationship between physician/researcher and patient/subject.<sup>4</sup> Since that time, medical ethics, and bioethics specifically, has been charged with, at times, placing the loci of focus too strongly on individual matters while neglecting the social context of medicine.<sup>5</sup> While focused on the individual rights and welfare of the research participant from the beginning, bioethics and a wave of personal autonomy became more distinct in the 1970s during debates over life-sustaining treatments, making headway into medical clinics and hospital units.<sup>6</sup>

It was in 1970 that the term bioethics was coined, marking a significant shift from the discipline of medical ethics that paved the way.<sup>7</sup> Yet, from its creation, the usage of the word had different meanings. One stream of thought, originating with Andre Hellegers at Georgetown University, saw bioethics as primarily an extension of medical ethics focused on medical issues and medical technology, with still a very individualized approach.<sup>8</sup> Yet the alternate stream,

though not as popular, attempted to incorporate social and global perspectives into the discipline.<sup>9</sup> This was largely due to the work of Van Rensselaer Potter who envisioned bioethics as a bridge between science and the humanities.<sup>10</sup> Indeed it was Potter who, heavily influenced by the work of Aldo Leopold, would later coin the term “global bioethics” because of his discontent with the lack of a social perspective incorporated into bioethics.<sup>11</sup> From the beginning of bioethics there were major differences and even clashes between the Potter and the Hellegers/Georgetown understandings of bioethics. Though the Hellegers/Georgetown approach came to be the more widely accepted, Hellegers also proposed a global approach to bioethics, bringing his vision much closer to Potter’s evolving view.<sup>12</sup>

Some scholars such as physician-philosopher Tristram Engelhardt have passionately argued that there is no such thing as a global or universal ethic due to the competing philosophies present in the world. Engelhardt has written that the Universal Declaration on Bioethics and Human Rights is marked by a “general vacuity of its principles, as well as a failure to take seriously the moral difference characterizing the contemporary age.”<sup>13</sup> Hence, no consensus on a variety of topics is achievable.<sup>14</sup> The most notable document within the field of global bioethics written in the past few years is arguably the UNESCO Universal Declaration on Bioethics and Human Rights. Critics have faulted the UNESCO declaration for excluding mainstream bioethicists, an absence of peer review, and failing to acknowledge socioeconomic and other factors, which have impeded its implementation.<sup>15</sup> Others have argued that there is no unified global field of bioethics,<sup>16</sup> and still others maintain that the UNESCO declaration merely reformulates existing principles of bioethics, does not lend much new, and could actually be harmful to the impoverished of the world.<sup>17</sup> These many critiques are serious, and the objections

will be thoughtfully considered and a response that argues it is possible to create a global ethical framework for bioethics will be provided.

In the second section of chapter two, the evolution of human rights is examined. The literary corpus of human rights declarations advanced in the aftermath of World War II. However, these documents have a much richer history. The rationales of 17<sup>th</sup> century philosopher John Locke can be seen in them, as it was Locke who laid a foundational theory of human rights.<sup>18</sup> The Lockean heritage can also be seen in the U.S. Declaration of Independence (1776) and the French Declaration of the Rights of Man and of the Citizen (1789), which were the first direct political statements to express the equality, universality, and naturalness of human rights.<sup>19</sup> At the formation of the United Nations over 150 years later, the framework of human rights ideologies expounded in the U.S. and French declarations would prove invaluable.<sup>20</sup> The claim that all human beings have a “right” to something (such as access to medicine, food, safety) can be both a moral/ethical claim based upon the intrinsic dignity of humans, and it can be a legal claim that is based on specific codified, enforceable law. Oftentimes the language of rights is used in conjunction with the moral/ethical dimension and does not necessarily align with an existing law. Yet, inscribing rights into law can be a difficult maneuver, for there is considerable debate about the content of human rights.<sup>21</sup> While the UN and other prominent organizations and states have been essential to advocating and furthering the idea of human rights, criticisms still arise. Jeremy Bentham is renowned for calling human rights “execrable trash” and simply “rhetorical nonsense, —nonsense upon stilts.”<sup>22</sup> A key concept in human rights is human dignity, which is often taken to be the foundation from which human rights emerge. However, amongst modern critics, a large number of ethicists and bioethicists have labeled human dignity a useless concept.<sup>23</sup> Further, dignity has been labeled “vacuous,”<sup>24</sup> and some have

labeled appeals to dignity as a “conversation stopper.”<sup>25</sup> The Canadian Supreme Court recently issued a ruling summarizing their disappointment at the role of human dignity in constitutional law, stating, “[It] has also proven to be an additional burden on equality claimants, rather than the philosophical enhancement it was intended to be” (*R. v. Kapp*, SCC 41 (2008), 2 S.C.R. 483, paragraph 22).<sup>26</sup> This is important for the human rights discourse because the secular iteration of human rights is generally grounded in the concept of dignity, as witnessed in the UN Universal Declaration of Human Rights<sup>27</sup>. Hence, a close examination of the critiques of human rights will be provided in this analysis.

While we must not gloss over the criticism, human rights treaties have proven valuable in disseminating the human rights discourse of the latter 20<sup>th</sup> century. Governments have joined international human rights treaties for different reasons, including with the goal of following the rules, as a way to set an example for other countries, or as a means of reassuring their own citizens of their seriousness in this matter. Some governments have been more ready to ratify treaties if their neighbors have done similarly.<sup>28</sup> Nonetheless, other countries commit to human rights treaties and violate their agreements at will. In early 2016 Amnesty International released a list of the ten worst attacks on human rights across the world in 2015.<sup>29</sup> Of the ten countries that Amnesty International listed as perpetrating the violations, all are UN member states, four were original signatories to the UN Universal Declaration of Human Rights in 1948, and four are current members of the UN Human Rights Council.<sup>30</sup> Hence, a state’s approval of certain declarations does not imply implementation or enforcement. Making human rights salient involves not only merely raising the issues to an international audience, but persistent campaigning, monitoring, and reporting to force governments to recognize shortcomings and acknowledge the validity of human rights agreements.<sup>31</sup> This section will also need to explore

some preliminary ideas of how to implement human rights, as the goal of the proposed global bioethics tool is to actually implement the principles in the pharmaceutical and biotechnology sector.

The preceding two subsections of chapter 2 examined global bioethics and human rights separately. This final section seeks to show their relation. Bioethics has not often been thought of in a human rights context and, conversely, human rights has only rarely taken great concern for bioethical issues.<sup>32</sup> Global bioethics and human rights stand in a symbiotic relationship. Whereas human rights law and cosmopolitan ideals inspired the development of a global bioethics discourse, the converse is similarly true; global bioethics contributes to human rights.<sup>33</sup> However, we should not get the impression that global bioethics can simply be reduced to the application of universal human rights norms to moral issues, for this would be a false view.<sup>34</sup>

The human rights discourse is attractive for global bioethics for a variety of reasons. A number of thinkers, such as George Annas, have argued that medicine must develop a global language and global strategy in order to help persons all over the world.<sup>35</sup> Individual nation-states are inadequate to address global health issues, and culturally or religiously specific principles are insufficient for addressing the growing issues in global bioethics. What is needed is a universal language and moral framework that is founded on universally shared, transcultural beliefs, which the human rights framework fulfills.<sup>36</sup>

Generally, human rights are invoked in three bioethics contexts: 1) the protection of humans from being harmed by medicine, 2) the discussion about humans as subjects to medical experiments, and 3) regarding the rights of patients relative to their healthcare services and providers.<sup>37</sup> The discipline of bioethics can learn from human rights due to the nature of human rights being grounded in the community and in nature itself. In this way, human rights cannot be



separated from economic and social rights, which is something bioethicists will need to explore internationally and interculturally.<sup>38</sup> Further, Lisa Forman and Stephanie Nixon have delineated at least three ways that bioethics and human rights complement each other, including how global bioethics can advance human rights and, conversely, how human rights can advance global bioethics.<sup>39</sup> These points are essential in order to understand rightly how the fields of global bioethics and human rights interplay and are can be utilized in ethics guidelines such as the UNESCO Universal Declaration on Bioethics and Human Rights.

Chapter three examines corporate social responsibility and the pharmaceutical and biotechnology industry. For the proposed global bioethics tool, corporate social responsibility is an integral component. Corporate Social Responsibility (CSR) is an increasingly important issue to stockholders and the general public. This section will first introduce the concept of social responsibility and will then turn to an examination of CSR applied to the pharmaceutical and biotechnology industry.

A key concept in global bioethics is the notion of social responsibility and health, which significantly broadens the agenda of bioethics so that the social and basic issues related to the provision of healthcare for populations all over the globe are taken into account.<sup>40</sup> This section examines the concept of social responsibility in global health and bioethics. Social responsibility and health combine two basic ideas: 1) several actors aside from states and governments are responsible for health, and 2) global problems reflect common challenges and, therefore, should be addressed through common action.<sup>41</sup> This concept has made it into prominent ethics documents such as the UNESCO Universal Declaration on Bioethics and Human Rights (UDBHR).<sup>42</sup>

The history of social responsibility is rather recent, with a majority of the formal writings only being traced back to around the 1950s.<sup>43</sup> Today, the concept focuses on the responsibility of the broader society, specifically private companies, toward not only property and profits but also to those who are affected by or involved in the activity of a company. In a broad sense, the term is meant to denote a change or enlargement of perspective in the strategies and aims of, specifically, firms, and calls on them not only to meet their legal duties but also to commit to improve the welfare of society.<sup>44</sup> In bioethics, the notion of social responsibility transcends the doctor-patient relationship and delves into issues of health economics, public policy, and social determinants of health.<sup>45</sup> Social responsibility in the bioethics context aims to redress the balance of the field towards a more global, collective approach that brings solidarity to the fore.<sup>46</sup> Assuming that society is partly responsible for the health of its members does not settle the question of how society should fulfill this responsibility. It has been argued that greater attention should be paid to strategies of promoting health in ways other than simply access to healthcare, such as environmental and public health and health research.<sup>47</sup> Indeed, these strategies are closely aligned with the field of global bioethics.<sup>48</sup>

Social responsibility cannot be adequately comprehended without an understanding of both solidarity and cooperation.<sup>49</sup> Émile Durkheim was one of the first social theorists to devote significant attention to the notion of solidarity, and he noted that societies are only constructed through social cohesion.<sup>50</sup> At a basic level, solidarity involves two aspects: caring for the defense and promotion of the conditions of social life for which members of a group are collectively responsible, and caring particularly for the needs and interests of the weaker members of the group.<sup>51</sup> Durkheim, Comte, and other thinkers will be interacted with on this topic. Cooperation is in many respects a similar concept to solidarity. In the UNESCO UDBHR, the two concepts

are combined into a single principle, not to argue that they are synonymous, but rather to highlight their closeness and complementarity.<sup>52</sup> John Stuart Mill was an early advocate of cooperation in the nineteenth century to solve social troubles. Reacting against the inequality and exploitation of labor he witnessed in his day, Mill proposed that such ills could be overcome through cooperative processes involving free associations between workers and other workers and between workers and capitalists.<sup>53</sup> Mill was onto the idea that human rights cannot be fully realized without cooperation, and that in order to see true change, joint action and cooperation is required.<sup>54</sup>

The second section of chapter 3 introduces the specific study of CSR and how it relates to the pharmaceutical and biotechnology industry. CSR has been defined by the UN, at its broadest, to signify the overall contribution of business to sustainable development.<sup>55</sup> There is not unanimous support for CSR. Since its early beginnings there have been notable critics. This section will first present a number of general criticisms leveled against CSR, initially focusing largely on the debate between Milton Friedman and those who hold to an opposite viewpoint, such as Edward Freeman and Peter Drucker. Friedman's repudiation of CSR was broadcast widely in a popular-level *New York Times Magazine* article in 1970, entitled, "The Social Responsibility of Business Is to Increase Its Profits."<sup>56</sup> This view was countered by thinkers such as Peter Drucker<sup>57</sup> and Edward Freeman.<sup>58</sup> The positions of both sides will need to be critically considered. Though there are many critics of CSR, the fastest growing cause for shareholders is sustainability.<sup>59</sup>

In regards to pharmaceutical and biotechnology companies, some commentators have made the case that the industry cannot merely be concerned for their own profit margins to the neglect of the very people who depend on their medications. That is, the business decisions of

pharmaceutical companies directly impact human health, which makes corporate social responsibility particularly important.<sup>60</sup> Prominent NGOs and international groups such as UNESCO, Oxfam, Save the Children, and Voluntary Service Overseas, have challenged the pharmaceutical industry to adopt a broader scope of responsibility and improve its efforts to tackle the health crisis affecting LMICs.<sup>61</sup> In particular, the pharmaceutical industry has recently been accused of exceedingly high prices. In an August 2015 poll completed by the Kaiser Family Foundation, one of the premier healthcare public policy think tanks in the US, it was found that most Americans feel that drug costs are unreasonable (72%) and that drug companies put profits before people (74%).<sup>62</sup> Further, in a 2012 Harris poll, only 12% of persons in the US believed that drug companies were generally honest and ethical.<sup>63</sup> These polls were taken prior to a succession of high-profile pricing scandals that rocked the industry, including the September 2015 price hike of Daraprim by Turing Pharmaceuticals,<sup>64</sup> the Valeant Pharmaceuticals controversy over price inflation at the same time,<sup>65</sup> and the August 2016 revelation that the price of EpiPen® produced by Mylan has increased 400% from 2007 to 2015,<sup>66</sup> and that Mylan falsely classified the drug in order to overcharge Medicaid for its reimbursement, resulting in a half-billion dollar fine by the US Department of Justice.<sup>67</sup> The importance of personal accounts, a tactic used for years by human rights and humanitarian NGO's,<sup>68</sup> was significant in the EpiPen® case, raising the visibility of the situation and causing public outcry.<sup>69</sup>

These scandals produce negative impacts on pharmaceutical reputation. A recent study estimates that it is the intangible assets of a company, including reputation, that currently represent as much as 40-60% of a company's market capitalization, leading to the conclusion that a company's reputation is among its most valuable assets.<sup>70</sup> Yet, reputation is at the very heart of a business. The reputation problem facing the pharmaceutical industry is currently too

sizeable for any one company to address alone. The industry must work together to rebuild trust.<sup>71</sup> Hence, the proposed dissertation seeks to build a tool by which the industry can collaborate and dialogue on issues of bioethics, including the sharing of best practices, and making their implementation of bioethics principles available to the general public and stakeholders in a transparent manner.

For the global bioethics tool to become a reality, we must answer the question of whether this is something that is truly needed. Is there sufficient demand for the type of information that the tool would provide to convince pharmaceutical and biotechnology companies to participate? Would the disclosure of the bioethical performance of a pharmaceutical or biotechnology firm influence an individual's decision on what products to use, how to invest, where to work, or how they perceive a specific company?<sup>72</sup> There may be numerous reasons why a pharmaceutical or biotechnology company would engage in CSR. Businesses have viewed CSR as a way to improve their reputation and legitimacy, brand image, gain a competitive advantage, reduce business risks and costs, and enhance shareholder value.<sup>73</sup> There is some empirical data regarding the impact of corporate social responsibility on a company's bottom line. Research suggests there is a positive relationship between a company's corporate social responsibility actions and consumer attitude about the company and its products.<sup>74</sup> However, when it comes to CSR and a firm's bottom line, the data is mixed. Between 1972 and 2002, over 100 studies that empirically examined this relationship were published.<sup>75</sup> To much dismay, the empirical studies have never been in agreement. Some studies found a positive correlation.<sup>76</sup> Others determined a negative association.<sup>77</sup> Still, others found no correlation at all.<sup>78</sup> Hence, there must be other reasons rather than financial for a company to participate in CSR. For the pharmaceutical and

biotechnology industry, reputational gains and restoring trust is a hugely beneficial effect of CSR.

Nonetheless, there is precedent for harnessing market forces to recognize and promote acts of social responsibility through a system of accreditation, certification, or rating. Surveys show that consumers are likely to avoid products that are linked to socially irresponsible and untrustworthy companies and will go so far as pay a premium to patronize ethical companies.<sup>79</sup> This will need to be further examined, as well as the current mechanisms of implementing CSR, such as the UN Global Compact,<sup>80</sup> UN Guiding Principles on Business and Human Rights,<sup>81</sup> Dow Jones Sustainability Group Index,<sup>82</sup> amongst others.

Chapter four examines the bioethics guidelines that have been produced since the end of World War II and the role of governance in bioethics. The purpose of such an undertaking is to analyze the evolution of bioethics guidelines, note where there are areas of convergence and divergence between documents, and to introduce the UNESCO Universal Declaration on Bioethics and Human Rights as well situated to be the foundation of the global bioethics tool. While no guideline is perfect, and changes occur within medicine, technology, and society to prompt changes to guidelines, the UDBHR, based upon a moral human rights framework and broad enough to cover many social dimensions of bioethics, is very well suited for this task.

Section 4.1 examines the ethics guidelines produced from 1947 to the present. Since World War II, a number of prominent bioethics guidelines have been produced, almost exclusively by a Western commission, leading to the conclusion by some that modern bioethics predominantly reflects the traditions of Western moral philosophy and political and social theory.<sup>83</sup> Some of these guidelines address a narrow aspect of bioethics, some have a degree of governmental authority, some are issued by non-governmental organizations, and others are

advisory.<sup>84</sup> The Nuremberg Code, as stated above, was a product of the aftermath of World War II and has been a staple of research ethics since its inception. However, it has exerted more rhetorical invocation rather than actual practice. This may be due to its blanket prohibition of any research that is not voluntary or for its lack of interpretive or enforcement mechanism.<sup>85</sup> While it was in many ways the beginning of medical ethics guidelines, many followed. The World Medical Association (WMA) appalled by the atrocities of WWII, issued a code of medical ethics in 1948 that was known as the Declaration of Geneva. This code proved very ambiguous and difficult to interpret.<sup>86</sup> The WMA adopted its more prominent Declaration of Helsinki originally in June 1964.<sup>87</sup> It has since undergone seven revisions, tripling its original size, with the most recent version being approved in 2013.<sup>88</sup> While the document is very prominent in the field of research ethics, it has been criticized for a number of reasons, including being contradictory, poorly phrased, and making unjustified and unethical recommendations.<sup>89</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78) produced a report that proved very significant for the direction of healthcare ethics.<sup>90</sup> They selected seven principles that should underlie biomedical human research. These seven would be reduced to three in the *Belmont Report* (1978): respect for persons, beneficence, and justice.<sup>91</sup>

The Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO) first issued guidelines on human experimentation and medical ethics in 1982. The current 2002 version of their guidelines is now the third installment of CIOMS guidelines for biomedical research, superseding the 1993 and 1982 guidelines. The present version consists of 21 guidelines with commentaries.<sup>92</sup>

Good Clinical Practice is an international quality standard that is provided by the International Conference on Harmonization (ICH), an international body that defines standards.<sup>93</sup> Governments can use these standards by transposing them into regulations for clinical trials involving human subjects, such as what the US Food and Drug Administration (FDA) has now done.<sup>94</sup> These standards for clinical trials are oftentimes referred to as ICH-GCP. ICH-GCP has been criticized by some commentators for lacking the breadth, depth, and moral authority of the Declaration of Helsinki.<sup>95</sup>

Indeed the past two decades have witnessed an upsurge of interest in international declarations on bioethics and, specifically, global bioethics and the governance of bioethics.<sup>96</sup> The 1997 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine is a notable example.<sup>97</sup> As this document preceded the Universal Declaration on Bioethics and Human Rights, it is lauded as “the first international treaty in this field.”<sup>98</sup> In this section, in order to make a concise and well-analyzed argument for the utilization of the Universal Declaration on Bioethics and Human Rights as the grounding for the global bioethics tool, these aforementioned bioethics guidelines will need to be systematically analyzed, their strengths and weaknesses analyzed, and conclusions drawn as to why they are less suited for the task of a global bioethics tool than the UNESCO Universal Declaration on Bioethics and Human Rights.

Section 4.2 analyses the UNESCO Universal Declaration on Bioethics and Human Rights. In order to solve global problems, global solutions and the commitment of the global community are necessary.<sup>99</sup> In 2001, the UNESCO Director-General was asked to look into the possibility of developing a universal bioethics instrument. On the basis of the International Bioethics Committee’s subsequent report, the 2003 General Conference declared the setting of



universal bioethical standards to be “imperative and desirable.” An extensive drafting and consultation period then ensued, involving member states and other stakeholders.<sup>100</sup> Because of the need to incorporate international and universal perspectives, the declaration is by necessity the result of compromise. Indeed, it is this compromise and internationality that provides strength to the declaration and its normative ethical standards. The declaration represents the views of the UNESCO Member States and not just scientists and ethics experts.<sup>101</sup>

The Universal Declaration on Bioethics and Human Rights is well positioned to be the framework upon which the global bioethics tool is built for at least the following reasons: 1) it is the first and only bioethics declaration to gain the approval of international governments (all UNESCO Member States), with the input of bioethics experts, rather than solely a group of individuals with bioethics or scientific expertise, 2) it efforts to incorporate major principles in bioethics, such as those included in the Declaration of Helsinki and ICH-GCP, 3) the Declaration also stretches beyond individual orientations to bioethics to a global perspective, focusing on issues such as the environment, respect for cultural diversity, capacity building, and future generations, and 4) the Declaration is very useful for countries that lack an infrastructure in bioethics. The need for worldwide standard-setting in bioethics has been strongly expressed by low- or middle-income countries (LMICs) who want to share the benefits of the developments of science and technology and not only be the providers of data and resources.<sup>102</sup>

Section 4.3 begins by elaborating on what is meant by “governance” and especially its role in global bioethics. Understanding the role of governance in bioethics requires the historical consideration of how bioethics became institutionalized into the specific forms of committees, regulatory bodies, and commissions.<sup>103</sup> Governance has developed alongside globalization and is no longer sufficient to be applied merely within states. Cooperation towards the oversight and

implementation of global bioethics principles cannot be considered the work of a particular state, but must be the doing of a coalition of partners, which may necessarily involve those who are regularly affected by bioethics, such as the pharmaceutical industry. There are many problems for global bioethics governance both at the international state level (between governments) and at the level of commerce (between companies) that will need to be discussed.<sup>104</sup> The need for greater cooperation at the state level and the level of commerce will be explained in this section. Further, different models for implementing governance upon companies externally (i.e. not from directly within the individual firm) will be presented and analyzed for the current proposed global bioethics tool.

The Commission on Global Governance has defined governance as follows:

Governance is the sum of the many ways individuals and institutions, public and private, manage their common affairs. It is a continuing process through which conflicting or diverse interests may be accommodated and co-operative action may be taken. It includes formal institutions and regimes empowered to enforce compliance, as well as informal arrangements that people and institutions either have agreed to or perceive to be in their interest.<sup>105</sup>

While governance is often thought of in terms of states and governments, it is also applicable to companies, foundations, and institutions. In the realm of bioethics, declarations and, specifically the applications of the principles, at local levels such as companies and research universities, as well as at national levels, is the idea of governance.<sup>106</sup> For global bioethics, if there are global ethical frameworks, how can they be applied at a global level in order to address problems on a global scale?<sup>107</sup> Some have proposed a system of accreditation, certification, or rating to validate how pharmaceutical companies are doing in regards to certain indicators.<sup>108</sup> This section will also examine systems of accreditation, certification, and rating.

In the literature and in practice there are differing models of accreditation, certification, and rating for companies in regards to implementation of ethical principles. Accreditation

systems date back around a century to when the Joint Commission was established. Certification systems are more recent and achieved popularity largely in response to activists who viewed the logging industry and population growth as threats to forests and the environment. Rating systems date back to around the turn of the twentieth century and have been notably used by the Access to Medicine Foundation in their biennial publication.<sup>109</sup> These different models will need to be considered for the proposed global bioethics tool. While some sort of rating system is certainly promising for the proposed global bioethics tool, a system of certification or accreditation is outside the bounds of the project at this time. That is, this tool is not currently designed to be a statement that participating companies have eliminated harmful bioethics practices and are certified as being upstanding bioethics citizens. Rather, the proposed tool is a measure of how well companies are doing in regards to applying and implementing certain principles. While it is envisioned that stakeholders and the general public will be able to compare how Company X is doing in comparison to Company Y, a system of certification or accreditation would be asking too much of the global bioethics tool at this stage. A model that is more promising at this stage is rating. While there have been shown to be many positive benefits of a rating system, such as stimulating companies towards competition within the industry and thus greater social responsibility,<sup>110</sup> rating does not inspire collaboration between competitors. The proposed project is based around the idea of generating best practices for the industry and spurring greater transparency rather than rating companies.

Chapter five presents the global bioethics tool, including methodology and the development of indicators. The proposed global bioethics tool involves four main steps: First, a preliminary phase, consisting primarily of desk research, is conducted to develop indicators, research the viability of the project, and determine the interest level of UNESCO. Second, an

exploratory phase seeks to gather interest from 4-5 top pharmaceutical and biotechnology companies so that a partnership can be formed. The exploratory phase also involves reaching out to the UN Global Compact to discover if there are partnership opportunities with them. The third phase commences once there is a commitment from 4-5 companies. This phase is also the longest and consists of refining the indicators, interviewing the companies, generating best practices, producing a functioning self-reporting website, and other activities in order to make the global bioethics tool eventually reach the point of sustainability. Finally, the fourth phase forms a non-profit foundation to house the global bioethics tool. To make the foundation financially sustainable, member organizations would pay into the foundation with a dues structure based upon the annual revenue of the organization. Such a system has been set up before, as similar dues structures are used by Business for Social Responsibility<sup>111</sup> and other industries have also set up similar foundations, such as IPIECA, the global oil and gas industry association for environmental and social issues.<sup>112</sup>

Section 5.1 begins by presenting the rationale and methodology behind the creation of the proposed global bioethics tool. In order to justify that the proposed global bioethics tool is needed, we must provide evidence that there is sufficient demand for this type of evaluation from stakeholders in order to convince pharmaceutical and biotechnology companies to participate. In other words, is there a strong business case for firms in the pharmaceutical industry to divulge aspects of bioethics implementation and assist the industry in developing best practices? Jennifer Miller has described the case for accreditation, certification, or rating within the pharmaceutical industry based upon consumer interest.<sup>113</sup> Similarly, this rationale is significant for the proposed global bioethics tool. We must remember that prescription sales are not the only products that pharmaceutical companies are concerned about. Many companies offer a vast array of over-the-

counter (OTC) medicines or home products. For instance, Bayer is known for their aspirin and Johnson & Johnson is known for numerous OTC medicines as well as medical supply products like Band-Aid. Hence, even persons who do not regularly take prescription medication are likely to use at least some of the non-prescription products from a pharmaceutical company. The benefits of a voluntary, transparent global bioethics tool reach beyond restoring reputation and positive public image for the pharmaceutical industry. Such a tool would aid the industry in better understanding and defining what good ethical practices look like, motivate companies to incorporate better ethical processes into their operations, and send a clear message to multiple stakeholders that they are serious about implementing bioethics into their business. Hence, this subsection begins by detailing the justification for the tool.

Following this, the methodology of creating the global bioethics tool from its inception to the present is explained. In January 2016 the bioethics division of Novo Nordisk awarded a 6-month grant to Duquesne University to work on developing a global bioethics tool for use by the pharmaceutical and biotechnology industry and to see if such a tool is viable for the industry. The Principal Investigators (PIs) on the study were Lise Holst, MD, PhD, Director of Global Bioethics Management at Novo Nordisk and Henk ten Have, MD, PhD, Director of the Center for Healthcare Ethics at Duquesne University. As chief researcher on this project, the author was deeply invested in the project from its origin. This section will describe the process that took place in beginning the project and the different phases, including trying to collaborate with multiple stakeholders, comprising major pharmaceutical and biotechnology companies and UNESCO. In July 2016 the grant was extended for an additional 6-month period as an “exploratory study” to investigate the feasibility of engaging primarily pharmaceutical and biotechnology companies in setting up this initiative. A number of major, top-20, pharmaceutical

and biotechnology companies were contacted to ascertain their interest in collaborating on this project. The entire methodology describing the process of how the project unfolded will be presented in detail in this subsection.

A primary goal of the global bioethics tool is to create a platform through which companies can discuss and develop industry best practices. To achieve this, a process of determining best practices and benchmarking will need to occur. Benchmarking is the systematic search for best practices that leads to superior performance.<sup>114</sup> The concept of benchmarking draws from the Japanese industrial practice *dantotsu*, referring to a method for finding the best practice that consistently yields the best results in that industry.<sup>115</sup> From its inception, benchmarking has been utilized to identify aspects of an organization's activity that could be more efficient/effective by comparison with the performance of other relevant organizations. The data regarding the other relevant organizations and their key processes are used to identify and implement changes.<sup>116</sup> There are four types of benchmarking: internal, competitive, functional, and generic. Each type has its specified outcomes and benefits depending on what the organization wants to achieve, and each will be discussed.<sup>117</sup>

Benchmarking is perceived by many as a strategic tool to increase productivity, enhance learning, assess performance, and continuously improve upon an operation.<sup>118</sup> While there is no single accepted method for making benchmark analyses, a frequently used model is proposed by Robert Camp, a pioneer in the field of benchmarking. Camp divides benchmarking into two main parts: practices and measures.<sup>119</sup> He delineates a twelve-step process on benchmarking that is split into five phases. The process starts with deciding what to benchmark and whom to involve, following up with planning and conducting investigations to collect data, determining performance gaps and projecting future performance levels, and communicating findings. The

final steps are focused on revising and improving performance goals, developing an action plan, and finally implementing action plans, monitoring results, refining benchmarks when necessary, attaining leadership position, and fully integrating the practices into the processes.<sup>120</sup> This model of benchmarking will be examined along with others, including the proposed set-up of Spendolini,<sup>121</sup> Watson,<sup>122</sup> Zairi,<sup>123</sup> and Letts.<sup>124</sup> A possible set-up for how to determine best practices and how best to utilize benchmarking for the proposed global bioethics tool will be presented.

Section 5.2 presents the development of indicators. Performance measurement is a fundamental principle of good management. The measurement of performance is significant because it identifies performance gaps between current and desired performance and provides indication of progress towards closing the gaps. The use of key performance indicators may identify precisely where to take action to improve performance. Key performance indicators represent a set of measures focusing on those aspects of organizational performance that are the most critical for the current and future success of the organization.<sup>125</sup>

A key performance indicator can be defined as an item of information collected at regular intervals in order to track or measure the performance of a particular system.<sup>126</sup> Qualitative and quantitative key performance indicators are used as a means of measuring and monitoring the progress towards particular goals and objectives.<sup>127</sup> In the UNESCO Universal Declaration on Bioethics and Human Rights, the core of the declaration is found in fifteen principles (Articles 3-17).<sup>128</sup> Indicators, in the form of questions, are developed based upon each of these principles so that one can qualitatively assess how a particular company is doing in implementing the international standards. In developing these indicators, the UNESCO UDBHR was first compared to the other prominent bioethics guidelines, such as those presented in 4.1. As an

example of this process, Article 15 of the UDBHR concerns benefit sharing and states the following:

- Chapter 6 Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms: (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research; (b) access to quality health care; (c) provision of new diagnostic and therapeutic modalities or products stemming from research; (d) support for health services; (e) access to scientific and technological knowledge; (f) capacity-building facilities for research purposes; (g) other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not constitute improper inducements to participate in research.<sup>129</sup>

As the Declaration of Helsinki also discusses sharing of benefits in Articles 22 and 34, the two documents were compared for similarities and to see the general requirements of benefit sharing in each document. Additionally, prominent, current literature on each of the principles was examined and will continue to be investigated during this process to better understand how each principle could be implemented by the pharmaceutical and biotechnology industry. For the principle of benefit sharing, the following three indicators have been developed based upon the principle of benefit sharing:

- Chapter 6 How does the company ensure that the benefits resulting from its scientific research are shared with society as a whole?
- 2) When conducting clinical trials, does the company ensure that in advance of the trial, provisions are made for post-trial access for all participants who still need an intervention identified as beneficial in the trial (DoH, Article 34, 2013)
- 3) How does the company ensure against improper inducements to participate in research?

Therefore, other prominent bioethics guidelines were consulted while forming these indicators, as well as the two Pis on this study, one of which is an expert in corporate social responsibility and pharmaceutical bioethics, and the other an authority in global bioethics. Moreover, the



importance of substantial stakeholder engagement to further refine these indicators cannot be overstated. Nonetheless, the developed indicators provide a good starting ground for the global bioethics tool.

The process for developing these indicators will be discussed in greater detail, and the indicators will be presented. To arrive at the indicators, the principles of the UNESCO declaration were closely examined. The principles of the UNESCO declaration were also examined alongside corresponding principles found within other prominent ethics guidelines, such as those presented in chapter four. The commentary on each of the UNESCO declaration principles found in both *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles and Application* and the *Handbook of Global Bioethics* were both initially consulted, as they are primary source material from those who helped craft the document. Additionally, experts both in the field of global bioethics and in the pharmaceutical industry were consulted. The result is a list of indicators for each of the core fifteen principles. Admittedly, the indicators that have been developed constitute a beta version of the global bioethics tool. In order to further verify the quality of the indicators, further consultation with global bioethics experts and industry stakeholders will need to take place, as well as applying the indicators to actual companies.

Chapter six develops the reporting framework for the global bioethics tool and applies the indicators that were presented in the previous chapter to major pharmaceutical and/or biotechnology companies. As implementation is an ongoing process, it is envisioned that the indicators discussed in the previous chapter will need revising on an ongoing basis in consultation with various stakeholders. Nonetheless, this first step of application is necessary in order to establish a baseline of where certain companies are in implementing the principles of the

Universal Declaration on Bioethics and Human Rights. In order to accomplish this, publicly accessible information has been utilized. Additionally, persons from each company are to be contacted for further information if needed.

Section 6.1 presents the reporting framework for the global bioethics tool. In regards to reporting, the global bioethics tool is envisioned as a set of questions with a self-reporting framework for companies. One problem with reporting frameworks in general is that they can become cumbersome. Every reporting framework that a company joins will require a separate report, which could result in numerous reports being filed annually with much manpower utilized.<sup>130</sup> The overabundance of reporting in the human rights realm by state actors has been shown to spread a government's available resources thinly rather than investing in high-quality reporting.<sup>131</sup> Global Reporting Initiative, an international independent standards organization that helps businesses and governments understand and communicate their impacts on issues such as climate change, human rights, and corruption, estimates that the cost for a company to report issues of sustainability can vary from as little as €2,000 to over €100,000.<sup>132</sup> For small and medium-sized businesses, such reporting may be especially onerous.<sup>133</sup> Hence, in order for an implementation mechanism such as the global bioethics tool to be maximally effective, a self-reporting framework that seeks to minimize the burden placed upon companies seems optimal.

The reporting frameworks of several organizations in the industry will be examined for their strengths and weaknesses in order to make a recommendation for this project. The reporting framework of the UN Global Compact is known as the "communication on progress" (COP). Signatories are required to submit an annual report on how they are implementing the ten principles of the UNGC in their practices.<sup>134</sup> Additionally, a collaboration between The Danish Institute for Human Rights, the Confederation of Danish Industry, the Ministry of Economic and

Business Affairs, and the Danish Investment Fund for Developing Countries has created a Global Compact Self Assessment Tool that is designed to help a company evaluate how they are doing in integrating and implementing the UNGC in their company. The tool contains indicators that are set up in the form of indicators so that companies can see how well they are doing in implementing the ten principles.<sup>135</sup> An entity named “Shift” in 2015 launched a UN Guiding Principles Reporting Framework that seeks to help companies self-report on their activities implementing the UN Guiding Principles on Business and Human Rights. The Reporting Framework takes the form of a questionnaire (31 questions) for companies to answer as they strive to meet their human rights responsibilities.<sup>136</sup> These reporting tools and others will be examined in order to make a recommendation for how to proceed with reporting for the global bioethics tool.

Section 6.2 seeks to apply the global bioethics tool, with the list of indicators developed in section 5.2 and the reporting framework developed in section 6.1, to at least two pharmaceutical and/or biotechnology companies—one of which is a major Western company and the second a firm based in a LMIC. The purpose of choosing a company both from a high-income country (HIC) and a LMIC is to demonstrate that the global bioethics tool is a useful instrument for any pharmaceutical or biotechnology company that is involved in research and development, not only large Western entities. In the exploratory phase of the study (July-December 2016), conducted in conjunction with Novo Nordisk, companies were initially screened for whether they were signatories to the UN Global Compact, if they were included in the 2014 Access to Medicine Index, Dow Jones Sustainability Indices, and whether they were a member of Business for Social Responsibility. If a company was found in multiple of these then

they were viewed as having interests in the area of CSR. Hence, this formed the initial criterion for contacting companies.

This section is largely hypothetical as it applies the indicators and benchmarks to different companies. In order to accomplish this, publicly accessible information is utilized. Public information found on the company's websites, available in academic literature, and reported through alternative mechanisms such as the UN Global Compact COP will be scoured. Additionally, representatives from each company are to be contacted for further information on an as needed basis. While this section is hypothetical, the purpose of applying the tool in this section is to demonstrate its viability. Hence, the global bioethics tool is not merely a curious academic exercise, but it is a practical way to more fully implement bioethical principles into the business practices of the pharmaceutical and biotechnology industry. Applying the tool to specific companies will also showcase areas where the tool is in need of refinement. However, refinement will best come through engagement with multiple stakeholders and having intimate knowledge of the workings and practices of specific companies, which is difficult to accomplish by an outsider.

Chapter seven is the concluding chapter, reviewing the dissertation and the need for a global bioethics tool in order to address issues within the pharmaceutical and biotechnology industry. While a model global bioethics tool was developed with specific indicators and benchmarks, the global bioethics tool is not a complete endeavor. To be most effective at achieving the aspired goals, the tool must continually be tested and altered if needed. This will happen in consultation with multiple stakeholders. The process of attempting to implement the UDBHR principles and gain pharmaceutical industry support around the tool is examined in this chapter, and the reasons for not implementing the tool in industry will be studied. Further options

for seeing the tool adopted by the pharmaceutical and biotechnology industry, such as alternate ways of promotion or seeking support from others in the industry, will be assessed.

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## **Chapter 2: Global Bioethics and Human Rights**

Chapter two discusses the relationship between global bioethics and human rights in order to provide the necessary foundation for discussing the UNESCO Universal Declaration on Bioethics and Human Rights, as well as the context in which the global bioethics tool operates. The gradual evolution of global bioethics will be first discussed. This will be followed by the status of the human rights discourse and the current relationship between global bioethics and human rights. The symbiotic relationship between global bioethics and human rights will be considered in detail.

### *2.1) Global Bioethics*

This section examines the gradual evolution of global bioethics from the fields of medical ethics and bioethics. The history of medical ethics growing out of the atrocities committed during World War II has been well documented.<sup>1</sup> In the aftermath of World War II the Allied powers established the Nuremberg tribunals (1946-47), which brought forth charges and convictions for many of those involved in the Nazi experiments and Jewish Holocaust.<sup>2</sup> Sixteen physicians were found guilty, and seven of those were hanged for their crimes.<sup>3</sup> Included in the Nuremberg judgment was the Nuremberg Code, ten statements of ethical rules to govern research, designed to protect the rights and welfare of those who participate in human research. The Nuremberg tribunals would assist in the revival of human rights and established the legal precedent that heads of state, governmental officials, and military members could be punished for crimes committed against humanity.<sup>4</sup>

The Nuremberg Code is centered on the research relationship between physician/researcher and patient/subject.<sup>5</sup> The Nuremberg Code required that research with human participants utilize voluntary informed consent, aim at positive results for society that

cannot be obtained another way, be designed on the results of animal experimentation, be set up in a way that avoids unnecessary physical and mental suffering and injuries, have risks/benefits adequately assessed, be conducted by qualified personnel in a proper facility, and, participants must be free to terminate their participation in the experiment at any point. Lastly, medical personnel are obligated to suspend and perhaps even terminate the experiment at any point when they observe that continuation would be unsafe.<sup>6</sup> These ten guidelines would prove influential in forming a foundation for the new discipline of medical ethics, and we cannot separate the root of modern bioethics from the atrocities committed during this period. It is important to note the initial response of the American judges to the horror of the Nazi doctors and the concentration camps was to articulate, in the first principle of the Nuremberg Code, the doctrine of informed consent. This is one of the key foundations of bioethics, and it was born at Nuremberg in 1947.<sup>7</sup>

By the end of World War II, the Allied nations recognized the need for a new international body to oversee world affairs and replace the largely ineffective League of Nations. A new intergovernmental organization, the United Nations (UN), was born in 1945.<sup>8</sup> To a large extent, the UN was formed as an attempt to reaffirm faith in the dignity and worth of all mankind, as well as the fundamental human rights that all persons globally share.<sup>9</sup> In spite of several countries initially opposing inserting human rights into the charter of the UN, eventually the constituents agreed and devoted a few lines of the document to reaffirming faith in fundamental human rights and in the dignity and worth of the human person. In hopes of curbing the scale of human atrocities witnessed in World War II from happening again, the UN retains a Security Council that is charged with maintaining international peace and security. Further, the UN charter provided for an International Court of Justice to be established at The Hague in the Netherlands as the primary judicial branch of the UN.<sup>10</sup>

In 1948 the UN adopted the Universal Declaration of Human Rights (UDHR) without dissent and with eight nations abstaining.<sup>11</sup> The UDHR was clearly impacted by the Nuremberg tribunals and the condemnation of physicians and scientists for horrific crimes committed against humanity. The UDHR opens with a statement recognizing “the inherent dignity of all members of the human family.”<sup>12</sup> While the UDHR is not legally binding on countries, it does carry significant moral authority.<sup>13</sup> Though it is erected on the footings of its eighteenth century predecessors, the UDHR was the first explicit human rights declaration of the contemporary system of international human rights law.<sup>14</sup> The UDHR proclaimed the equal rights and inherent dignity of all humanity by articulating a broad range of rights to be protected in pursuance of core human rights values.<sup>15</sup>

However, the UDHR did more than simply reaffirm the eighteenth century notions of equality and certain freedoms. The UDHR expressly prohibited slavery and called for a variety of other universal rights, including the right to marry, to right to education, the right to work with equality of pay, and many others.<sup>16</sup> The issue of universality—that there are rights that apply to all persons in all stages of life and in all contexts—is one of the topics understood by many to be a common feature in both bioethics and human rights.<sup>17</sup> This universality found within the modern discourse on human rights has been drawn largely from the paradigm shifting nature of both the US and French declarations. Therefore, it can be said that the UDHR presented a global framework that transcends culture, ethnicity, and religion.

What is more, the UDHR made specific, original contributions to efforts to achieve global health equality. It declared that the right to health was universal in scope and recognized that governments are responsible for the health of their people. Thus, the UDHR effectively recognizes every person’s right to a standard of living adequate for health and wellbeing. With

the intergovernmental backing of the UN, this empowers rights-holders.<sup>18</sup> An essential shift was occurring in which the language of the universal right to health transferred from appeals to charity to demands upon nation-states based in legally binding duties and justice. This approach is advantageous because humanitarianism is redefined from the language of compassion to a language of rights and dignity. This redefinition grounds humanitarianism in the moral-legal framework of international human rights law. In this regard, people are viewed as citizens of the world with the same claims and rights as everyone else. Thus, human rights make people equal and give them more power.<sup>19</sup> The effects of this would see governmental policy-makers viewing health as an area implicating legal and moral duties.<sup>20</sup>

Though many applaud the work of the UDHR and similar documents, some critics have taken issue with them, finding them inconsistent and overblown. They argue that a human rights framework cannot be imposed on healthcare. Thus, in their view, the principles of human rights work best as limitations on governments because they specify actions that they may not undertake.<sup>21</sup> While these criticisms should not be taken lightly, a human rights framework has been seen to work well when imposed on healthcare, for it empowers people and promotes equality and justice.

Unlike the focus of modern bioethics or the human rights discourse, the focus of medical ethics is relatively narrow, concerning itself chiefly with the relationship between doctor/researcher and patient/subject. This is predominantly seen in the Nuremberg Code, which was in many ways a template for how medical ethics developed in the years leading up to the birth of bioethics. While the focus of medical ethics was narrow, the link between bioethics and human rights is historically strong, as is seen in the relationship between the Nuremberg Code and the UDHR.<sup>22</sup>

Before the modern elaboration of bioethics, in the time period between Nuremberg and the early 1970s, there came the development of what is typically referred to as medical ethics. In the decades following WWII, medical ethics took a turn as medical science and medical technology advanced and became increasingly technical. Traditional duties of the physician were challenged, as it was no longer clear-cut what constituted benefit and harm. Medicine grew very technical and very expensive in Western nations. New intellectual resources were summoned to analyze and critique the novel questions: What is benefit? What is harm? How should expensive resources be distributed? What does justice mean in a healthcare context? Professionals that were hardly proficient in medicine—chiefly, theologians and philosophers—were called upon to enter into these discussions.<sup>23</sup> Theologians, with an extensive tradition of reflecting on life, suffering, and death, were already more accustomed to engaging in moral theory than many philosophers, steeped in the deontological and teleological theory of the day.<sup>24</sup> The works on healthcare ethics penned by Catholic moralists during the early twentieth century provided a discussion of fundamental moral principles that were underpinned by natural law, divine revelation, and magisterial instruction. The Catholic moral theologians also provided casuistic analysis of specific topics they saw as paramount to their day: abortion, contraception, et. Al. As the age of bioethics opened in the latter part of the twentieth century, such prominent Catholic moralists as Richard McCormick, a Jesuit priest, and Charles Curran would criticize these methods for their interpretations of both natural law and the magisterium. Therefore, by the time medical ethics was being formed, Catholic moral theology was in a state of disorder due to internal disagreements over its methods.<sup>25</sup>

McCormick was the main Catholic moralist to preside over this period of medical ethics. While faithful to the natural law heritage of the Church, he was also open to revision when

necessary. Thus, he entered the bioethical dialogue rather seamlessly as he held that moral judgments based on reason could be understood by all rational persons, irrespective of religious orientation. Perhaps his greatest contribution to bioethical theory came when he took up the discussion of double effect and both refined and expanded its principles. McCormick's legacy is that of helping to liberate Catholic moral theology from a rigid application of natural law that would form a method for moral analysis.<sup>26</sup>

Protestant ethics at the time focused considerably on personal morality and biblical obedience. Two chief Protestants presided over the formation of healthcare ethics: Joseph Fletcher and Paul Ramsey. Fletcher, an avowed act-utilitarian, deeply stressed situationism. His theory, essentially, posited that apart from the intention of an agent, which must be love, the rightness or wrongness of a moral action was only determined by the situation.<sup>27</sup> Thus, Fletcher easily championed the goodness of every advance in medicine, for he only found criticism when harm might outweigh the benefits for society collectively. Ramsey, starkly contrasting Fletcher, provided a deontological ethic to the conversation of healthcare ethics. Rigorous biblical principles support Ramsey's analysis of moral issues in medicine. Further, Ramsey promoted the work of casuistry because he saw the imperative for healthcare ethics to deal competently with concrete issues.<sup>28</sup>

For philosophers, in the years leading up to the birth of medical ethics, the chief theories of normative ethics were grouped into teleological and deontological categories. Utilitarianism, the central example of teleology, was presented as compelling for moral philosophy, yet suffered from many weaknesses. Similarly, deontological approaches would also be dismissed as relying too heavily on intuition. Moreover, logical positivism was highly favored in America as a method of analysis to be applied to disciplines outside philosophy. To be sure, no overarching



theory dominated the philosophical field. Thus, those philosophers who decided to cross into the bioethical realm were unlikely to bring an orthodoxy or collective methodology to the discussion.<sup>29</sup>

It was in 1970 that the term bioethics was coined, marking a significant shift from the discipline of medical ethics that paved the way.<sup>30</sup> The word “bioethics” has a somewhat contentious birth. Both Van Rensselaer Potter at the University of Wisconsin and Andre Hellegers at Georgetown University would begin using the word nearly simultaneously, leading some to argue for a bilocated birth of the term.<sup>31</sup> The stream of thought originating with Hellegers saw bioethics as primarily an extension of medical ethics focused on medical issues and medical technology, with still a very individualized approach.<sup>32</sup> Yet, Potter’s alternate stream, though not as popular, attempted to incorporate social and global perspectives into the discipline.<sup>33</sup> Potter, a research oncologist, envisioned bioethics as a bridge.<sup>34</sup> It was a bridge between the present and the future, science and values, nature and culture, and man and nature.<sup>35</sup>

It was Potter who, heavily influenced by the works of C. H. Waddington, a Scottish geneticist, Pierre Teilhard de Chardin, the French Jesuit philosopher and geologist, and Aldo Leopold, the American environmentalist, would later coin the term “global bioethics” because of his discontent with the lack of a social perspective incorporated into bioethics.<sup>36</sup> Potter stated at the time of coining the term “bioethics” that it was Waddington who influenced him more than any other individual. Waddington was concerned with the need to develop ethical theory in the light of biological knowledge and was, in Potter’s estimation, “essentially a bioethicist before the word was invented.”<sup>37</sup> It was Teilhard who anticipated what today is termed “globalization.” One of his main beliefs was that humanity would develop into a global community. Teilhard devoted his life to reflection on the place of human beings in the universe and the grand scheme of

evolution. These ideas resonated with Potter as he recognized that Teilhard, like himself, was absorbed in the problem of human progress and the survival of humankind.<sup>38</sup> Further, the works of Aldo Leopold intrigued Potter due to Leopold's environmental and conservationist efforts. Leopold also acknowledged that human survival depended on the maintenance of a healthy ecosystem and the regulating of human fertility. Potter saw these ideas as monumental for Leopold's thinking, yet also noted that Leopold's views on items such as the overconsumption of renewable and nonrenewable resources by an increasing human population were simply neglected and overshadowed by those who felt his love for nature was a more comfortable aspect of his philosophy on which to latch. These ideas were immensely important for Potter and greatly aided in informing and shaping his views on global bioethics.<sup>39</sup>

However, these views were at odds with other streams within bioethics. From the beginning of bioethics there were major differences and even clashes between the Potter and the Hellegers/Georgetown understandings of bioethics. Potter saw the field of bioethics addressing the pressing questions of the day: war, population growth, poverty, politics, and environmental concerns. He saw these concerns as of utmost priority for the survival of mankind.<sup>40</sup> Potter would term this "the science of survival".<sup>41</sup> The search for wisdom, according to Potter, should be promoted in terms of the survival and improvement of humankind.<sup>42</sup> However, the contemporary orientation of bioethics is oriented mainly around medical issues and technologies, which places it at odds with Potter's initial conception. Though the Hellegers/Georgetown approach came to be the more widely accepted, Hellegers also, surprisingly, proposed a global approach to bioethics, bringing his vision much closer to Potter's evolving view.<sup>43</sup>

Not at all satisfied with the restricted medical application of bioethics, in 1975 Potter stated that the word bioethics had become fashionable and not in line with what he had intended.

Potter saw the Georgetown interpretation of bioethics as simply medical ethics under a new name and as restricted to individual survival with little consequence for societies and populations. Further, Potter thought the direction of bioethics was emphasizing individual autonomy over the common good, was too specialized, and merely doing applied ethics rather than creating anything significantly new. Yet, perhaps his chief complaint was that the Georgetown definition of bioethics provided no global perspective for LMICs and displayed no interest in environmental or social concerns.<sup>44</sup>

Bioethics had been proposed by Potter to combine human values with ecological facts. Many forgot this.<sup>45</sup> Disappointed with the Georgetown interpretation of a narrow concept of bioethics taking priority over his broader conception, Potter would craft the term “global bioethics” in 1988 to broaden the scope of bioethics to address the concerns he saw as prominent. For Potter, the word “global” suggests that the approach should be unified, comprehensive, and worldwide in scope.<sup>46</sup> Global bioethics, in Potter’s view, would truly be worldwide in that it would go beyond international bioethics. Global bioethics is not merely a matter of simply crossing borders, but it concerns the entire planet as a unified whole. Hence, it is worldwide. Potter’s second meaning of global referred to bioethics as more encompassing and comprehensive, combining traditional biomedical ethics with concerns for the environment and ecosystem.<sup>47</sup> This new approach would also emphasize the problems that Potter saw as urgent concerns for the survival and progress of mankind.

Potter’s contention that bioethics is too insular rather than expansive is a common critique today. Since Nuremberg, medical ethics, and bioethics specifically, has been charged with, at times, placing the loci of focus too strongly on individual matters while neglecting the social context of medicine.<sup>48</sup> While focused on the individual rights and welfare of the research

participant from the beginning, bioethics and a wave of personal autonomy became more distinct in the 1970s during debates over life-sustaining treatments, making headway into medical clinics and hospital units.<sup>49</sup> Recently, however, particularly since the turn of the millennium, bioethical discourse has evolved to a degree and has been concerned with and characterized by a global perspective on issues and has been more closely linked with international human rights law.<sup>50</sup> Yet, for this to continue and truly see bioethics transformed into a global perspective, the field must expand into various directions. While modern-day bioethics has incorporated other fields into its perspective, such as human rights, others are lagging. A clear environmental ethic and deep social concern continues to be noticeably absent. Bioethics is nowadays primarily focused on the problems of HICs and how they affect individual persons. The plight of LMICs and general populations is most often grossly neglected. The Western view of bioethics also often assumes that it can merely be exported to other contexts around the world as a universal, one-size-fits-all framework.<sup>51</sup>

For much of the late twentieth century and early twenty-first century, following Potter's formulation of global bioethics, his idea were not influential and his publications not recognized by those in the influential bioethics community.<sup>52</sup> However, due to globalization, this is no longer true. Since the late 1970s, the global political economy and rules of trade have been transformed by neoliberal ideology and practices. The policies enacted under this ideology have supported the rise of globalization and global trade.<sup>53</sup> Though there is no standard, agreed upon definition for globalization, it has been described as encompassing transnational economics and politics and the transmission of knowledge.<sup>54</sup> Others have thought of globalization as the world getting "flat" in a sense due to the interconnectedness of peoples that makes geography and distance not seem quite real.<sup>55</sup> Human beings are interconnected now in a complex system of

interdependency with changes and developments on one side of the world affecting the other. Marshall McLuhan termed this phenomenon “the global village.”<sup>56</sup> Raúl Urzúa has proposed a multifaceted definition of globalization that is characterized by the acceptance of a set of economic rules for the entire world designed to maximize profits and productivity by universalizing markets and production, technological innovation and organizational change centered on flexibility and adaptability, the reduction of the welfare state, and the dissemination of common cultural values.<sup>57</sup> The field of economics and finance, with the integration of national economies into international or global ones, through trade, foreign direct investment, and capital flows is a key feature of globalization.<sup>58</sup> Nonetheless, while there is no agreement about how to define globalization, some common themes emerge from the definitions. It is agreed that advances in communications and technology have created greater interconnectedness with persons all over the globe. Further, globalization can be said to include at least the following five key dimensions: 1) economical, 2) political, 3) environmental, 4) cultural, and 5) ideological.<sup>59</sup>

The process of bioethics becoming a global enterprise has many causes, some of which are due to the changing context of globalization. There are at least four reasons why bioethics has become global. First, globalization has influenced how we perceive the world. Traveling and interacting with new cultures and ways of life has brought about the encounter of different worldviews and ethical reasoning. Ideas, philosophies, and worldviews do not stop at geopolitical boundaries, as the world is a global community. Second, globalization has changed decision-making in ethical and non-ethical matters by highlighting the interconnectedness of our world. A third reason deals with international cooperation. The existence of very contagious, communicable diseases that may cause pandemics, such as Ebola and the Zika virus, or issues such as clinical research in LMICs, warrants thoughtful dialogue and cooperation in problem

solving at an international level between nations. Fourth, bioethics has also become a global enterprise due to inequalities in health care. Unequal treatment in the access to health care addresses issues of social justice, and it is this social nature that is a defining characteristic of a global approach to bioethics.<sup>60</sup>

In addition to the above four reasons why bioethics has become a global enterprise, Henk ten Have has distinguished four stages in which this gradual process of globalization has taken place. The first stage of the globalization of bioethics witnessed a broader scope introduced into the agenda of bioethics. In this stage, the individual autonomy narrative is increasingly criticized as being too narrow and reductionist, without regard for the common good. Many bioethicists have criticized such a minimalist approach to bioethics. Daniel Callahan has been foremost among them since the early days of the field.<sup>61</sup> It was thanks in large part to the efforts of Norman Daniels for providing comprehensive commentaries on social responsibility for health, thereby broadening the traditional scope of bioethics. Daniels claims that society has an obligation to protect the opportunities of its members, an argument which he forms by examining theories of justice.<sup>62</sup> This has been a key development for the field of bioethics that has long been steeped in individual clinical medicine and medical technology, yet has struggled to address the social and institutional context of medical decisions. Hence, bioethics should become more global in the sense of more encompassing, which is gradually being seen.<sup>63</sup>

The second stage in this development has been the confrontation of bioethics with a new set of problems associated with globalization. As aforementioned, deadly communicable diseases, starting with the HIV/AIDS pandemic in the 1980s, made bioethics aware of its limited ethical framework and insufficiency to address problems of global magnitude. The emergence of the HIV/AIDS pandemic brought to the surface the significance of social determinants of health,

such as poverty and education. These global issues required global solutions, and thus necessitated the bioethics debate to broaden if it was going to be useful in addressing these pressing matters. Ten Have has noted that other issues in the 1990s, such as organ trafficking, the brain drain of doctors and clinicians from LMICs to HICs, and the trade and conduct of international corporations also began to crop up on the bioethical agenda. This reiterates Potter's vision of a global bioethics no longer solely focused on narrow individual concerns.<sup>64</sup>

The third stage of transforming bioethics into a global effort has been the abundant rise of international activities and collaborations. Since 1985 the Council of Europe has had a standing bioethics committee.<sup>65</sup> During the 1990s, prominent international organizations established bioethics programs, such as UNESCO in 1993.<sup>66</sup> The WHO also established a Global Health Ethics Unit and held its first biennial international summit in 1996.<sup>67</sup> Local and/or national centers and organizations of bioethics began springing up in the 1990s. The 1994 UNESCO Directory lists the names of 498 such centers outside the United States, and in 1995 the second edition of the *Encyclopedia of Bioethics* was published containing articles of bioethics from a variety of nations and cultures.<sup>68</sup> Ten Have credits the Human Genome Project as a major impetus for international cooperation in bioethics, as 5% of its annual budget was allocated to the research of ethical, legal, and social issues of human genomics.<sup>69</sup>

The final stage of transforming bioethics into a global endeavor has been the process of elaborating universal frameworks. For bioethics to address the problems generated by globalization sufficiently, proceeding as it has done in other cultures will not suffice. Bioethics will have to increasingly become more multicultural and incorporate a broader scope into its perspective. This does not necessarily equate to being in agreement with every particular culture's practices. Rather, respect for different cultures and being sensitive to other values,

while at the same time applying a global approach, is essential to protect individuals, minorities, and vulnerable populations.<sup>70</sup> Therefore, to deal with the challenges of multiculturalism and expand its scope, bioethics also needs to expand to a broader ethical framework. The 1997 European Convention on Human Rights and Biomedicine was an important step to seeing this goal actualized. In 2005 UNESCO went further by adopting the Universal Declaration on Bioethics and Human Rights.<sup>71</sup>

Global bioethics as a field has matured since Potter's introduction of the term in 1988. Both characteristics of global bioethics espoused by Potter are not likely to be disputed: bioethics has become both worldwide and comprehensive. Controversial to some, however, is the notion of global bioethics in general and, in particular, the question of whether global bioethics should advance a transcultural framework of ethical values and principles. Universal ethical theories that aim to transcend cultural differences are looked upon with suspicion.<sup>72</sup> Skeptics generally assume that "cultural relativism" is also present in the moral domain, and disagreement seems to be the norm in moral matters. Samuel Huntington has written that this clash between the major cultures and religions is unavoidable, due to cultural relativism.<sup>73</sup> Hence, it is questionable to some whether the entire enterprise of global bioethics is even possible.

Some scholars, such as physician-philosopher Tristram Engelhardt, have passionately argued that there is no such thing as a global or universal ethic due to the competing philosophies present in the world. Engelhardt has fervently contended that contemporary moral reflection is marked by prominent disagreement. This is seen in the way that moral philosophers support different moral theories. Further, Engelhardt acknowledges there are certain persistent concerns in bioethics, such as the morality of abortion and euthanasia, which have been troubling humanity for millennia without great consensus. He views this as confirmation of the lack of a



global bioethics. What is more, Engelhardt maintains that it is impossible through secular reasoning to resolve competing moralities and diverging views on bioethics.<sup>74</sup> In particular, Engelhardt has written that the Universal Declaration on Bioethics and Human Rights is marked by a “general vacuity of its principles, as well as a failure to take seriously the moral difference characterizing the contemporary age.”<sup>75</sup> Hence, no consensus on a variety of topics is achievable.<sup>76</sup> Engelhardt perceives numerous flaws in the UDBHR. First is the vacuity of its principles and lack of serious thinking on moral differences, as quoted above. Engelhardt sees this as a move to deny the challenge that moral diversity presents to governance and political stability. As an example, Engelhardt cites Article 10 of the UDBHR that states the equality and dignity of every human being should be respected. His qualm is that the Article is silent on the status of human embryos, the morality of abortion, and what justice and equality demand.<sup>77</sup>

Engelhardt’s intention here may be to protect embryos, fetuses, and the unborn. While this may be a worthy goal for Engelhardt, it misses the nature of the UDBHR. As an intergovernmental document, with some 190 countries with various cultures and mores adopting it, the principles of the UDBHR had to be, in some sense, general. If the UDBHR had made pronouncements on the moral status of embryos or the practice of abortion then it would have made it abundantly difficult to have any country adopt it. While the text of the UDBHR does not address embryos and fetuses, the 2009 commentary published on the process of how the UDBHR was prepared and giving more insight into each of the principles, does. The commentary recognizes that new technologies used at the beginning of life, as well frozen embryos, have brought a new set of ethical problems that may increase inequity, inequality, and injustice.<sup>78</sup> What is more, other international ethics guidelines, such as the very prominent Declaration of Helsinki, likewise does not mention fetus, embryo, or abortion anywhere in its

text. This is simply the nature of international documents. There must be compromise, enough generality, and appeal to a common denominator in order to achieve consensus among collaborators.

Second, Engelhardt criticizes the portrayal of cultural diversity in the UDBHR: “Though the Declaration acknowledges cultural diversity, it fails to appreciate the depth of moral diversity, for this would bring the very possibility of the Declaration into question.”<sup>79</sup> To back this claim, Engelhardt cites Article 12 of the UDBHR: “Respect for Cultural Diversity and Pluralism.” Engelhardt’s critique is that Article 12 announces a vaguely articulated view of human equality without much footing to back it up. He combines this critique with a misgiving about Article 13 on solidarity, stating that the nature and scope of solidarity claims are left undefined. Engelhardt concludes that the claims are “either platitudinous, ambiguous, or ungrounded.”<sup>80</sup> However, it is unclear what Engelhardt would like to see in Articles 12 and 13’s stead or how he would like to see them elaborated. The nature of an ethics declaration like the UDBHR is that it states the most general claim of which there can be consensus to adopt it. Each of these articles have been subsequently further articulated in both the 2009 commentary on the UDBHR<sup>81</sup> and in a subsequent 2014 publication entitled *Handbook of Global Bioethics*,<sup>82</sup> each of which was edited by the former director of the UNESCO Division of Ethics of Science and Technology at the time of the UDBHR’s creation and adoption.

Cheryl Cox Macpherson has faulted the UNESCO UDBHR for excluding mainstream bioethicists, an absence of peer review, and failing to acknowledge socioeconomic and other factors, which have impeded its implementation.<sup>83</sup> To answer the charge of excluding mainstream bioethicists, the vast majority of mainstream bioethicists hail from Western, HICs. However UNESCO, as a UN organization, must attempt to be representative of all nation-states

and regions of the world, not only the West. The activities of UNESCO must try to incorporate all perspectives that are relevant to all Member States. To develop the UDBHR, different bodies of experts were consulted, including the International Bioethics Committee (IBC) of UNESCO, the Intergovernmental Bioethics Committee of UNESCO (IGBC), and the meetings of governmental experts. The IBC is composed of 36 experts from different disciplines, including genetics, medicine, law, philosophy, and history.<sup>84</sup> The 2004-2005 committee was composed of 19 members from LMICs and 17 from HICs, with the late Edmund Pellegrino of Georgetown University, a very prominent bioethicist, representing the USA.<sup>85</sup> Hence, the committee was very diverse and simply because there was a lack of “mainstream” bioethicists, however that is defined, does not lead to the conclusion that there was an inherent flaw in methodology. Many of these persons involved in the crafting of the UDBHR are bioethics experts in their respective countries or regions, and being unknown to a Western audience does not lead to the conclusion that they are incompetent in the field of bioethics.

Further, Macpherson finds fault with a supposed lack of peer review for the UDBHR. Peer review is the evaluation of scientific, academic, or professional work by others working in the same field.<sup>86</sup> Yet, numerous expert groups had access to the drafts of the declaration and were able to comment. Macpherson seems to fault UNESCO for not eliciting public comments on the final draft. Yet, this would not technically be a peer review process, for peer review is an evaluative system amongst expert peers in the field. It is unclear whether establishing “channels for public comment,” as Macpherson would have liked to see, would have made any positive contribution upon the UDBHR.<sup>87</sup>

Others have argued that there is no unified global field of bioethics. Researchers in one study looked at the web-linking patterns of bioethics institutions, the citation patterns of

bioethics papers, and the buying patterns of bioethics books in order to determine if there was indeed a unifying global bioethics. The result was that they found that bioethicists do not link to each other's websites as much as expected, do not cite each other as much as expected, and do not converge on the same books as much as expected if bioethics were truly a global, unified field.<sup>88</sup> Yet, these results are now a decade old and they are not wholly surprising. Global bioethics is a growing field and has received greater attention since the adoption of the UDBHR, though in many ways is still a niche field. Still, others maintain that the UNESCO declaration merely reformulates existing principles of bioethics, does not lend much new, and could actually be harmful to the impoverished of the world.<sup>89</sup> It is true that many of the principles found within the UDBHR can be found in other ethics guidelines. However, a key feature of the UDBHR, as will be further expounded upon in 4.2, is that it was approved by governments rather than an organization. This marks new territory for bioethics and signals a truly global acceptance. Further, the charge that the UDBHR could be harmful to the impoverished of the world is only conjecture. Richard Ashcroft has written, "If the declaration is cited at all in litigation or policymaking, it will probably be as evidence that standards weaker than those in some existing international guidelines (such as the Helsinki Declaration) are legally and internationally acceptable." And if this happens, Ashcroft speculates, the vulnerable could fare much worse than before.<sup>90</sup> Ashcroft is purely speculating on this point and there is no case law or precedence to suggest this is actually plausible. Indeed, the request to develop a common framework of ethical principles, which would become the UDBHR, was explicitly made by developing countries that were fearful that with the rapid evolution and globalization of medical science and research they would insufficiently benefit from the advances and suffer too many harms as a result. A major concern of these countries was that international medical research and healthcare endeavors

would proceed along double standards so that persons in LMICs would receive substandard care and be involved in research trials deprived of the ethical protections that exist in HICs. This call from LMICs to craft a global normative framework demonstrates that global bioethics principles are not necessarily imposed upon the developing world by a small handful of powerful, rich nations.<sup>91</sup> Further, it will become clear in section 4.1 when various bioethics guidelines are examined that the Declaration of Helsinki is not greatly more specific than the UDBHR.

These many critiques of both global bioethics and the UDBHR are serious and responses to them have been offered while maintaining the argument that it is possible to create a global ethical framework for bioethics. However, we should be under no illusion that the field of global bioethics or the UDBHR is flawless. Yet, to deal with global issues in public health, healthcare, research, and advancing technologies, a robust, complex global bioethics that takes into account diverse perspectives will be required. This is due to the nature of the problems facing bioethics today. The problems facing the globe today are complex, transnational, and affect persons of many cultures and perspectives. Importantly, global bioethics is not a static field that is simply now finished. Rather, it is dynamic and must be continually changing in order to address the intricate, ever-changing issues of the day.<sup>92</sup>

Looking forward, the majority of LMICs in the world today have a limited bioethics infrastructure. They lack expertise, educational programs, bioethics committees, and legal frameworks to protect patients and human research participants. Yet, because of globalization, many of the similar ethical questions that have emerged in HICs where bioethics is firmly entrenched into medicine are now being seen in these LMICs with limited capacity. A great benefit of the UDBHR is that it has been developed in collaboration with these LMICs. Work still needs to be done in order to ensure that the principles of global bioethics are actually

enacted on the ground in these countries. However, great strides have already been made, which is very encouraging.

## *2.2) Human Rights*

This chapter now turns its attention to the development of human rights and the human rights discourse. It is difficult to discuss human rights without also discussing human dignity, as the two are often closely linked in the literature and human dignity is generally understood to be the bedrock of human rights. This section will proceed as follows: first, a history of the human rights discourse will be examined. Second, the relationship of human dignity to human rights will be assessed. Criticism of both the human rights discourse and human dignity will be evaluated. Third, the current state of human rights in the world and the problems associated with implementation will be presented. Finally, the increasing recourse to human dignity within bioethics will be explained.

The question, “What are human rights?” is generally taken as a request for an exhaustive catalogue of valid rights. This section will not so much focus on a list of individual rights as trying to understand the history of human rights and what a “human right” means. The Office of the UN High Commissioner for Human Rights (OHCHR) has defined human rights as follows:

Human rights are rights inherent to all human beings, whatever our nationality, place of residence, sex, national or ethnic origin, colour, religion, language, or any other status. We are all equally entitled to our human rights without discrimination. These rights are all interrelated, interdependent and indivisible.

Universal human rights are often expressed and guaranteed by law, in the forms of treaties, customary international law, general principles and other sources of international law. International human rights law lays down obligations of Governments to act in certain ways or to refrain from certain acts, in order to promote and protect human rights and fundamental freedoms of individuals or groups.<sup>1</sup>

This definition of human rights will be the working definition of this analysis. It is important to note how society has come to a place of accepting and generally respecting human rights, which comprises much of the rest of this section.

Historically, human rights can trace its roots to the time of the High Middle Ages—around the eleventh through thirteenth centuries. However, the contemporary usage of the term can be found in the seventeenth century with the influential work of John Locke. At the time, Europe was recovering from the ravages of the Thirty Years War and decades of religious conflicts. Locke laid the foundation for a theory of human rights that would remain significant to this day.<sup>2</sup> Newly established democracies would also find the human rights discourse important for their politics and foundations. The US Declaration of Independence, adopted by the Second Continental Congress in 1776, was one of the first governmental documents that argued for universal human rights. The Declaration would prove to be a lasting proclamation of human rights. Asserting that “all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness,” the Declaration would be paradigm shifting and affect the contours of human history.<sup>3</sup> Through the drafting of the Declaration of Independence, the framers created something radically novel: governments that are justified by their guarantee of universal rights.<sup>4</sup>

At the root of the Declaration of Independence's "unalienable Rights" is a respect for the worth and equality of every human life, which is known as a universalistic approach to human rights. Though this principle did not work itself out in practice as much in theory, with persistent attitudes of racism and sexism exceedingly prevalent in the government at the time of its passage, the principle of equality is nonetheless present. In a true universalistic approach human rights is seen to be both transcultural and transnational. It transcends ethnicity, geo-political boundaries, religion, encompasses the breadth of the human race, and is rooted in humanity's inherent dignity. This sketching of mankind's basic rights would have dramatic implications for later human rights discourse, which would service the development of global bioethics. Indeed, several key values have been identified as a basis required for global bioethics. These include such notions as respect for all human life, acknowledgment and defense of human rights, equity, freedom, and democracy.<sup>5</sup> These concepts are not original to the global health discourse, but rather are altogether present, to one degree or another, in the 1776 US Declaration of Independence. Thus, the connection between the robust emergence of conversation on human rights in the late eighteenth century to the modern-day development of global bioethics can begin to be seen.

The French Declaration of the Rights of Man and of the Citizen, a fundamental document of the French Revolution, would be fashioned just over a decade after the similar American manuscript, being passed by France's National Constituent Assembly in August 1789. Thomas Jefferson, the key framer of the US Declaration of Independence, would also prove instrumental in this rendition of human rights, which, notably, at the time, were referred to as natural rights. Jefferson was a regular consultant to General Lafayette, the French aristocrat and military officer who also fought in the American Revolution and introduced the original version of the French



Declaration. In the French Declaration, it was unabashedly declared that all men, not merely French, were born and remain free and equal in rights. Thus, quite similar to its American predecessor, the French Declaration proclaimed universal human rights and fundamental freedoms.<sup>6</sup>

John Locke in his *Two Treatises of Government* defended the claim that people have rights, such as the right to life, liberty, and property. These rights have a foundation independent of the laws of any particular society. In Locke's formulation, governments exist by the consent of the people in order to protect the rights of the people and promote the public/common good.<sup>7</sup> Locke was writing in a seventeenth century British context and his thoughts can be seen in the US and French Declarations. Locke's ideas continue to be influential for modern political thought and were re-confirmed at the 1993 Vienna World Conference on Human Rights, which proclaimed that it is the duty of states to promote and protect all human rights and fundamental freedoms, regardless of their political, economic and cultural systems.<sup>8</sup>

Before both the Americans and French declared the basic rights of mankind, the foremost champions of universal rights resided on the margins of powerful kingdoms in Western European countries such as Germany, the Netherlands, and Switzerland.<sup>9</sup> As a consequence of these two declarations, the use of rights language would increase dramatically after 1789 and human rights would be pushed to an international audience. Its philosophies would be spread across the Western world, and its principles would soon prove to be a hallmark of many modern societies.<sup>10</sup> At the formation of the UN over 150 years later, the framework of human rights ideologies expounded in the US and French declarations would prove invaluable. The imperative of framing human rights in public policy would become commonplace and be seen as a state's fundamental obligation to its citizens, just as it was viewed in the embryonic US and French

democracies. Global bioethics would likewise recognize the need for policy-making as a tool to ensure that human rights are being secured and justice is not scorned. An integrated framework of moral-legal international human rights law would prove <sup>57</sup>subsidized<sup>57n57</sup> for both the UN and global bioethics.

It is important to note that the claim that all human beings have a “right” to something (such as access to medicine, food, safety, housing) can be both a moral/ethical claim based upon the intrinsic dignity of humans, and it can be a legal claim that is based on specific codified, enforceable law. Oftentimes the language of rights is used in conjunction with the moral/ethical dimension and does not necessarily align with an existing law. While ethical precepts are oftentimes seen as primarily governing individual conduct, human rights are principally the rights that individual persons have against their government. They are negative rights in that they require governments to respect human rights by refraining from certain actions. Yet they are also positive rights in that they place a duty upon governments to provide for certain things, such as healthcare and education.<sup>11</sup> Nonetheless, inscribing rights into law can be a difficult maneuver, for there is considerable debate about the content of human rights.<sup>12</sup> Although there is debate about what may constitute a human right and the extent of rights, the basic notion of human rights has not changed since its foundations.

The human rights discourse has certainly at times been invoked hastily and abused. Some have used it as a trump card, seeing it overrule all other considerations. While the human rights discourse should not be used in such a flippant and reckless manner, human rights are independent of merit and are essential to an individual simply by nature of being human.<sup>13</sup> As has been iterated, the modern discourse of human rights has been greatly furthered by the UN, which has prescribed that human rights are “universal legal guarantees protecting individuals and

groups against actions and omissions that interfere with fundamental freedoms, entitlements and human dignity.”<sup>14</sup> The UN has also stated that duty bearers, most prominently states but also businesses, are legally bound to respect, protect, and fulfill human rights. This means that the state must refrain from interfering with a person’s enjoyment of human rights, it must prevent others from infringing upon that enjoyment, and it must take positive measures to ensure the realization of human rights.<sup>15</sup>

This section will now transition to an assessment of the relationship of human dignity to human rights. The UN has declared that the foundation of any human rights should be human dignity. This is most prominently seen in Article 1 of the UDHR: “All beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.”<sup>16</sup> Hence, the UDHR expresses rights as an existential entitlement—persons are entitled to them on the basis of their identity as human beings.<sup>17</sup> This is echoed in other documents, such as the International Covenant on Civil and Political Rights, which states that the rights detailed within “derive from the inherent dignity of the human person.”<sup>18</sup> Nonetheless, while there is large international consensus about the nature of human rights, and even the content of rights, this is not to dismiss that there is also criticism of the human rights discourse and the concept of human dignity, which will both be discussed in this section.

The concept of human dignity has been the subject of many centuries of philosophical discussion. Plato and Aristotle concluded that the essence of every human individual is not just pure matter, but a spiritual principle, which they termed the soul. They argued that, due to the spiritual capabilities of human beings, they are essentially spiritual beings and, based upon this premise, that humankind is fundamentally unique among living beings. Nonetheless, the modern

iteration of human dignity was not yet clearly extant in ancient Greek philosophy, as is exemplified by their justification of slavery. However, it has been noted that the thoughtful reflections on the spiritual dimension of human beings that is present in ancient Greek thought provided an invaluable basis for the later developments of Stoic and Christian philosophy and theology.<sup>19</sup>

Stoicism insisted particularly on rationality as the principal element of human dignity. Further, it was Roman Stoic philosophers who seem to have been the first to use the term dignity (*dignitas*) to indicate the intrinsic and universal worthiness of human beings. Further, the Judeo-Christian tradition founded universal dignity as a consequence of being made in the “image of God” (Gen. 1:26-27). During the Renaissance period and the rise of humanism, the Italian philosopher Pico della Mirandola insisted on the intrinsic moral worth of humankind based upon Greek philosophy and biblical sources. Additionally, Mirandola believed that human dignity consists in the freedom of choice that characterizes humankind in comparison to other living beings because the different possibilities open to the human person include the highest one. Near the end of the eighteenth century, Immanuel Kant would develop one of the most influential accounts of human dignity in the history of philosophical thought on the subject. For Kant, intrinsic human dignity is grounded on the capacity for practical rationality, especially the capacity for autonomous self-legislation under the categorical imperative. Hence, autonomy is the ground of human dignity for Kant.<sup>20</sup>

While the concept of human dignity has particularly developed within the Western world, the concept is not alien to other contexts. Human dignity is not purely a Western construct, for Islamic scholar Abdul Aziz Said has argued that “[i]n Islam as in other religious traditions, human rights are concerned with the dignity of the individual.”<sup>21</sup> Within Islam there is an

emphasis on the special place of human beings on earth. According to the Qur'an, Allah gave to humankind the best form (95:4), breathed into them their spirit (15:29; 38:72), gave intellect and freedom to humanity (16:78; 23:78), bestowed dignity on the progeny of Adam (17:70), placed humanity even above his angels (2:31), and made them his representative on earth (2:30; 33:72). Hence, it is commonly understood that the Qur'an assigns dignity to all human beings.<sup>22</sup>

Muslims are regularly and compellingly instructed to treat their fellow humankind with respect and dignity. The bases for these injunctions are not human rights but rather divine commands.<sup>23</sup>

Further, Roberto Andorno has noted that according to Chinese scholars there is a correlate of human dignity in the teachings of Confucianism. The important Confucian philosopher Xunzi (third century BC) believed that, though humanity is not innately good, all humans are born with the capacity to become good, and this is what makes each individual special.<sup>24</sup>

Human dignity has also been enshrined in international human rights law, the most well known being the UDHR. The relationship between human dignity and human rights in international law concerns providing equal respect for every human being while also attempting to apply concrete norms that are needed to flesh out that principle in social life. In international law there is near universal consensus that human dignity is the foundation of human rights. That is, equal rights for persons derive from human dignity simply by virtue of being human. Hence, at present, the entire international human rights system is founded on the supposition that people do really have inherent dignity, which has been questioned by many thinkers and will be discussed later in this section.<sup>25</sup> Further, the validity of human dignity and human rights is not conditional upon their explicit recognition and/or acceptance by states. Consequently, it can be stated that the idea of human dignity points to a requirement of justice toward every individual. John Rawls picked up on this and stated that this requirement presupposes that "each person

possesses an inviolability founded on justice that even the welfare of society as a whole cannot override”.<sup>26</sup>

Certainly there have been thinkers who have refuted the human rights discourse and the concept of human dignity. Jeremy Bentham is renowned for calling human rights “execrable trash” and simply “rhetorical nonsense, —nonsense upon stilts”.<sup>27</sup> At the time of his writing, Bentham was criticizing the 1789 French Declaration and also had some strong words for extravagant tenets found in the 1776 US Declaration. While he denounces human rights, surprisingly Bentham offers no constructive alternative theory of rights, such as one grounded in utilitarianism.<sup>28</sup> Bentham is not alone in his criticism of human rights or human dignity. Among modern critics, a large number of ethicists and bioethicists have labeled human dignity a useless concept.<sup>29</sup> Further, dignity has been labeled “vacuous”,<sup>30</sup> and some have labeled appeals to dignity as a “conversation stopper”.<sup>31</sup> The Canadian Supreme Court recently issued a ruling summarizing their disappointment at the role of human dignity in constitutional law, stating, “[It] has also proven to be an additional burden on equality claimants, rather than the philosophical enhancement it was intended to be” (*R. v. Kapp*, SCC 41 (2008), 2 S.C.R. 483, paragraph 22).<sup>32</sup>

This is important for the human rights discourse because the secular iteration of human rights is generally grounded in the concept of dignity, though this is also somewhat contentious as others view it as grounded more in the common humanity and universal interests of humankind.<sup>33</sup> The view that rights are founded in human dignity is central to the UDHR in which the first line of the preamble reads, “Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world” and a few lines later, “Whereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the

human person and in the equal rights of men and women.” This is further supported in Article 1 of the Declaration.<sup>34</sup>

However, even if dignity is accepted to be the foundation of human rights, it is not clear from where that dignity derives. That is, if the ground of human rights is human dignity, what is the ground of human dignity? From a Judeo-Christian theological perspective, dignity is found in simply being a member of the human race, as humans are endowed with dignity by their Creator and formed in the *imago Dei* (Genesis 1:26-27). Yechiel Barilan views human dignity as originating in the Hebrew Bible, and then being developed by Stoicism and Christianity.<sup>35</sup> Yet, from an atheological position, such a derivative is uncertain. Commentators will similarly argue that dignity is inherent to humankind, yet no further discussion of its origin is to be found. Too often the impression is given that dignity is an irreducible value, that we have burrowed deep below the rights that are recognized in the familiar human rights charters and that once we burrow down to human dignity it is not necessary to dig any deeper. Kantian thought states that the dignity of persons is based in metaphysical significance of our possession of moral capacity, the ability to act on principle even when every empirical impulse or inclination, every sentiment, and every element of self-interest pressures us to the contrary.<sup>36</sup> Hence, the very foundation of human dignity is not agreed upon universally. Nevertheless, though the grounding of dignity is disputed, most do not deny that humans possess dignity.

Additional criticism of human dignity comes from those who closely associate it with biblical and classical origins. However, there is nothing in the core of human dignity, from a secular perspective and how it has been used by organizations such as the UN, that allies it with specific ideologies or religions. Concepts of dignity can be found in antiquity, the monotheistic religions, and in secular enlightenment writings. Though it is found in varied contexts, dignity

still comes under attack as being too closely associated with conservative and religious ethics.<sup>37</sup> Hence, human rights and human dignity are not without their share of criticism.

While we must not gloss over the criticism, human rights treaties have proven valuable in disseminating the human rights discourse of the latter twentieth century. Governments have joined international human rights treaties for different reasons, including with the goal of following the rules, as a way to set an example for other countries, or as a means of reassuring their own citizens of their seriousness in this matter. Some governments have been more ready to ratify treaties if their neighbors have done similarly.<sup>38</sup> Nonetheless, other countries commit to human rights treaties and violate their agreements at will. In early 2016 Amnesty International released a list of the ten worst attacks on human rights across the world in 2015.<sup>39</sup> Of the ten countries that Amnesty International listed as perpetrating the violations, all are UN member states, four were original signatories to the UN Universal Declaration of Human Rights in 1948, and four are current members of the UN Human Rights Council.<sup>40</sup> Hence, again and again in the past century it has been demonstrated that human rights, in and of themselves, do not offer absolute protections for individuals against state and non-state actors. Examples of this include not only medical research in Germany and Japan during WWII, but also the Tuskegee Syphilis Study (1932-72) in the US, the Guatemalan Syphilis Study conducted by US researchers (1946-48), and the harassment of activists and stifling of religious freedom in China. Indeed, it has been demonstrated that states that have become signatories to numerous human rights treaties and declarations have at times been the greatest abusers of human rights. The mere adoption of certain principles is no assurance of implementation.



The problem of implementation is also apparent in the annual publication of US Department of State, entitled *Country Report on Human Rights Practices*. The preface to the 2015 edition, written by Secretary of State John Kerry, begins with a bleak assessment:

The 2015 edition of the Country Reports on Human Rights Practices points to a global governance crisis. In every part of the world, we see an accelerating trend by both state and non-state actors to close the space for civil society, to stifle media and Internet freedom, to marginalize opposition voices, and in the most extreme cases, to kill people or drive them from their homes.<sup>41</sup>

Indeed, state actors and non-state actors, such as ISIS, Boko-Haram, and the Taliban, alike, commit human rights atrocities. States that are signatories to international human rights treaties continue to commit human rights abuses. Hence, this leads to at least two conclusions: 1) adoption of a human rights instrument is no assurance of implementation, and 2) there is still much work to be done to ensure the implementation of human rights. Making human rights salient involves not only merely raising the issues to an international audience, but persistent campaigning, monitoring, and reporting to compel governments to recognize shortcomings and acknowledge the validity of human rights agreements.<sup>42</sup>

Implementation is not an easily achievable solution. The Office of the United Nations High Commissioner for Human Rights (OHCHR) has stated that the route from developing normative standards to operationalizing those standards largely depends on the availability of appropriate tools for policy formulation and evaluation within countries. OHCHR has also prescribed that both quantitative and qualitative indicators are an essential tool to seeing this accomplished. OHCHR has defined indicators as,

[A] human rights indicator is specific information on the state or condition of an object, event, activity or outcome that can be related to human rights norms and standards; that addresses and respects human rights principles and concerns; and that can be used to assess and monitor the promotion and implementation of human rights.<sup>43</sup>

However, indicators are not utilized in a systematic manner, which constitutes a gap in human rights implementation. The use of appropriate indicators is a key way to help countries assess their progress in ensuring the enjoyment of human rights by their people.<sup>44</sup>

As an intergovernmental organization, the UN generally takes a top-down approach to human rights (i.e. passing formal treaties and declarations at the international level, creating institutions, etc.). Fuyuki Kurasawa has argued that the top-down approach needs to be reversed by examining how groups and individuals caught in the struggle against abuses construct and enact human rights. Kurasawa does not make the case that normative endeavors, such as crafting universal ethical principles, or juridical constructs that seek to legally entrench human rights are wrong. These initiatives are necessary, he states. However, what these initiatives miss, in Kurasawa's estimation, is the substantive core of what constitutes global justice. For Kurasawa, the crucial question is less the specification of norms and rules and rather the interpretation of how global justice is enacted by persons and groups on the ground. It is the arduous process of making and doing global justice by individuals that Kurasawa sees as vital to actually implementing human rights.<sup>45</sup>

While organizations and individuals may differ on what is most needed to see human rights implemented on the ground so that humankind can enjoy these inalienable rights, there is no question that additional work needs to be done to ensure this enjoyment. The idea of creating indicators, briefly presented above, will play a major role in this dissertation, as it is the backbone of the global bioethics tool that will be presented in chapter five and then applied in chapter six. Before this section concludes it is also important to understand the increasing recourse to human dignity within bioethics.

Andorno has distinguished three stages of increasing recourse to human dignity in bioethics. The first stage initiated just after the end of the WWII and focused on issues relating to medical research on human subjects, particularly the requirement of free, uncoerced informed consent of participants. This culminated in the Nuremberg Code, as has been presented earlier. While the Nuremberg Code does not explicitly refer to human dignity, it is evident that it is inspired on this notion. According to Andorno, “The nonnegotiable nature of the code principles puts in evidence that the idea of an unconditional human worthiness was in the mind of the judges that formulated them.” Seven decades after the Nuremberg Code was drafted then it remains the bedrock of research ethics and the connection of how human dignity relates to bioethics. Andorno sees the second stage in the recourse to human dignity in the field of bioethics as starting near the end of the 1970s. This stage stretched beyond the domain of medical research and began to cover medical practices and techniques at both the beginning and end of life, such as assisted reproductive technologies, embryonic research, fertility, and questions regarding physician assisted suicide and euthanasia. This wider, multifaceted function of human dignity is visible in at least two global, intergovernmental declarations adopted since the end of the 1990s: the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration of Bioethics and Human Rights. The latter is perhaps the finest example of the significant and multifaceted role that human dignity plays in bioethics. Finally, the third stage began near the end of the 1990s and marked much more of a dramatic shift. Human dignity began to be appealed to in order to articulate concerns about biotechnological developments that may impact humanity as a whole. Not only is the dignity of existing individuals at stake in this third stage, but also the value attached to the integrity of the human species.<sup>46</sup>

The emerging global instruments relating to bioethics utilize the concept of human dignity as an overarching principle with the integration of the new commonly adopted standards into a human rights framework. These instruments present themselves as an extension of international human rights law into the specific field of bioethics. Several reasons seem to explain this strategy. First, because biomedical activities are directly related to the most basic human rights such as the right to life and to physical integrity, as was argued in the Nuremberg Code, having recourse to the large swath of human rights norms to ensure their protection is sensible and can be an invaluable tool for promoting human flourishing and the common good in the field of biomedicine. Second, because international human rights law is based on the supposition that basic rights transcend culture and state borders, the human rights framework can aid in facilitating the formulation of global standards. Third, human dignity is a rather abstract principle that alone is unable to provide concrete responses to many challenges raised by biomedical advances. This is why human dignity normally operates through other much more concrete ideas, such as informed consent, which are usually expressed using the terminology of “rights.”<sup>47</sup> This relationship between human rights and bioethics is very essential for the work of global bioethics and will be furthered examined in 2.3.

### *2.3) Symbiotic Relationship*

The preceding two subsections examined global bioethics and human rights, largely separately. This section seeks to show their relationship. First, a general relationship between global bioethics and human rights will be examined. Second, the symbiotic relationship between global bioethics and human rights will be presented.

Bioethics has not often been thought of in a human rights context and, conversely, human rights has only rarely taken great concern for bioethical issues.<sup>48</sup> However, the boundaries

between human rights and global bioethics are not static, but they are permeable, and the major health issues around the globe are more effectively tackled by harmonizing the disciplines.<sup>49</sup> Further, global bioethics and human rights stand in a symbiotic relationship. Whereas human rights law and cosmopolitan ideals inspired the development of a global bioethics discourse, the converse is similarly true; global bioethics contributes to human rights.<sup>50</sup> However, we should not get the impression that global bioethics can simply be reduced to the application of universal human rights norms to moral issues, for this would be a false view.<sup>51</sup> Rather, human rights form the point of departure and context for global bioethics. Human rights may also function as a constraint and final authority upon bioethical principles.<sup>52</sup> Indeed, when the two fields of human rights and global bioethics are taken together rather than separately then they stand to contribute more and offer greater weight than either alone.<sup>53</sup>

The history of the relationship between bioethics and human rights is quite old, as has already been established earlier in this chapter. The American judges at Nuremberg were comfortable crossing borders between American medical ethics (known today as bioethics) and international human rights law.<sup>54</sup> The Nuremberg Code explicitly links medical ethics and human rights with one another. Since that time, human rights based approaches to bioethics have proliferated. When the formal discipline of bioethics was established in the 1970s, it did not take long for literature on bioethics and human rights to also be published.<sup>55</sup> This field continues to expand and develop, as witnessed in the recent linking of feminist bioethics to both human rights and global ethics.<sup>56</sup>

While the 1947 Nuremberg Code links health and medical ethics to human rights, so does the UDHR. Article 25 of the UDHR specifically connects human rights to health:

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and

necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

(2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.<sup>57</sup>

The centrality of human rights in bioethics, and more specifically the UDHR, is acknowledged internationally.<sup>58</sup> In a 2003 report of the International Bioethics Committee of UNESCO, the authors state that, “modern bioethics is indisputably founded on the pedestal of the values enshrined in the Universal Declaration of Human Rights.” What is more, UNESCO’s 2005 Universal Declaration on Bioethics and Human Rights explicitly adopts the UDHR as its basis. Additionally, the Council of Europe’s 1997 Convention on Human Rights and Biomedicine is another good example of the central role that human rights is beginning to play in the biomedical field. The Preamble refers to the UDHR and notes that the protection and realization of human rights in biomedicine is highly valuable.<sup>59</sup> Although this is a regional rather than a global instrument, its potential impact on a global scale should not be overlooked as it is the only intergovernmental legally binding instrument that comprehensively addresses the linkage between human rights and biomedicine.<sup>60</sup>

The health provisions in the UDHR were echoed in the International Covenant on Economic, Social, and Cultural Rights (ICESCR), adopted by the UN General Assembly in late 1966. This treaty highlights several individual rights, including: right to work, right to fair wages, right to education, and “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>61</sup> Article 12 of the ICESCR guarantees the right to health to all individuals and communities.

As described in section 2.1, the notion of global bioethics is not so much a matter of geography as it is about dealing with phenomena with a global dimension. The issues of today,

due to the globalization of the world, transcend geopolitical boundaries and cultures and are not dependent upon the particularities of a specific society. These issues also make us search for moral views that are said to be shared globally. Because of this, modern bioethics is increasingly connected with international law and, in particular, human rights law. This is due to a similar global vision that is shared between global bioethics and human rights.<sup>62</sup> Indeed, it has been recognized that international human rights law and the ideals of cosmopolitanism inspired the development of global bioethics.<sup>63</sup> By utilizing human rights language, global bioethics expands the circle of moral concern by including a sense of commonality for all humanity and implying that human beings have responsibilities to one another, not only their fellow nation-state citizens, simply by virtue of this common humanity.<sup>64</sup>

One challenge for medicine and health from the latter part of the twentieth century forward is the globalization being experienced. George Annas has argued that medicine and health must develop a global language and global strategy that can be used to improve the health of the world's citizens, particularly those in LMICs.<sup>65</sup> This has been echoed by others such as Elizabeth Fenton and John Arras who have stated that what is needed is a universal language and moral framework that is founded on universally shared, transcultural beliefs. They have held that the human rights framework fulfills this need.<sup>66</sup> The human rights discourse is attractive for global bioethics for a variety of reasons, as will be described in this section.

Individual nation-states are inadequate to address global health issues, and culturally or religiously specific principles are insufficient for addressing the growing issues in global bioethics. Further, bioethics in itself is unable to achieve the universal language and moral framework that is needed. Western-dominated medical ethics has been too closely focused on the individual and has yet to live up to its global aspirations as Potter envisioned. Yet, coupled with

human rights, bioethics attains much more force. Annas has noted that bioethics is not only necessary to make basic human rights a reality, for example by prohibiting physician involvement in torture, but also can advance medicine in a symbiotic manner.<sup>67</sup> In biology, symbiosis is the relationship between two different kinds of living things that live together and depend on each other.<sup>68</sup> For health and human rights, this symbiotic relationship is quite unique: health worsens when human rights are ignored, and human rights abuses impact health.<sup>69</sup>

Generally, human rights are invoked in three bioethics contexts: 1) the protection of humans from being harmed by medicine, 2) the discussion about humans as subjects to medical experiments, and 3) regarding the rights of patients relative to their healthcare services and providers.<sup>70</sup> The language of human rights can be used by individuals and non-governmental organizations (NGOs) to inspire one another towards their goals and in their activities. Several physician groups have been leaders in promoting human rights, such as International Physicians for the Prevention of Nuclear War, Physicians for Human Rights, and Médecins du Monde.<sup>71</sup> The influential and perhaps best-known humanitarian physician's group, Médecins sans Frontières (Doctors without Borders) has officially stated that a defining principle of their organization is the determination to speak in public when faced with mass violations of human rights.<sup>72</sup> However, this is brought into question by recent narratives on the organization.<sup>73</sup> Nonetheless, physicians and healthcare workers interested in promoting human rights have numerous professional organizations they can support.

It has already been discussed above how health is recognized as a fundamental human right in human rights law and obligates states toward the protection and promotion of health for those persons under its governance. This symbiotic relationship between human rights and health has been described by Jonathan Mann, former director of the WHO's AIDS program, as a



relationship of natural allies. That is, the human rights discourse is considered by many to be a formidable tool in advancing health standards in the world.

While the aforementioned has largely focused on the relationship between human rights and global health, we can now reflect on how global bioethics advances human rights. It is argued that these two fields when taken together are often able to offer more than either separately. First, global bioethics is able to reinforce the normative claims of international human rights law. Though there are many aspects of human rights law that are legally binding and have been codified into international treaties and state law, other aspects are less developed and more controversial, making them much more difficult to enforce on an international stage. Such instances highlight the place for ethical arguments to bolster the normative claims of the human rights discourse and stimulate their reception and acceptance into law. As an example, international human rights law is only weakly applicable to corporate actors. The UN has sought to alter this in very recent years with the passage of the UN Guiding Principles on Business and Human Rights and the UN Global Compact, though these are not binding upon states or individual corporations.

Despite this, and as this dissertation in part shows, there is a growing call for greater corporate social responsibilities regarding human rights in many areas, including the area of health. In 2008 the UN Special Rapporteur on the Right to Health issued a report entitled *Human Rights Responsibilities for Pharmaceutical Companies in Relation to Access to Medicine*.<sup>74</sup> Once again, this is an example of non-binding or soft law—actions companies should undertake but are not legally bound to. Lisa Forman and Stephanie Nixon rightly recognize that while these frameworks couch their responsibilities in the language of rights, they are perhaps more appropriately classified as ethical duties rather than legal. Nonetheless, the guidelines offer the

pharmaceutical industry greater precision in regards to their ethical actions, as well as indication of how to measure the ethical actions of the industry. This has the combined effort of strengthening both human rights and bioethical frameworks in this area, as well contributing to a positive view of corporate social responsibility in the public eye, which may aid in recognizing the legal enforceability of certain duties in the future.<sup>75</sup>

Second, global bioethics can also broaden the advocacy framework of human rights. A critical global bioethics seeks to understand dilemmas as having their roots in institutional arrangements, power struggles, and political, social, and economic contexts. Access to power and how power is used is often very near the core of global health disparities. It is clear that global bioethics cannot understand global problems in health without also looking at the multi-faceted causes of these dilemmas. By adding these complementary forms of argumentation to a rights-oriented human dignity argument, the result can be one of strengthening advocacy calls for action.<sup>76</sup>

A third and final way in which global bioethics can advance human rights is in the debate between individual human rights versus public health. These two are often pitted as one against the other, with either individual rights being sacrificed for the sake of the community, or the welfare of the greater community potentially suffering for the sake of maintaining individual human rights.<sup>77</sup> By its nature, the primary objective of public health is the promotion of population benefit, which has a very utilitarian outlook.<sup>78</sup> Forman and Nixon have recognized that while rights are individual entitlements, they also have strong communal elements.<sup>79</sup> For instance, an individual right to health, prescribed in several international documents, cannot be readily realized for the masses without a collective governmental system to ensure this right. The recurrent concern within healthcare systems is how much precedence individual rights may have

over the welfare of the common good, and vice-versa. This was witnessed very publically in the Ebola crisis of 2015 in which a US nurse returned to New Jersey after serving in West Africa and was forced into quarantine.<sup>80</sup> The tension between liberty and public health has been attempted to be solved by a number of different public health theories: libertarian, collectivist, liberal, and paternalistic models have all been suggested by some.<sup>81</sup>

The UK Nuffield Council has proposed a revised liberal model termed the “stewardship model” that attempts at easing the tension between individual human rights and the welfare of the public.<sup>82</sup> In such a model, nation-states have responsibilities towards their citizens that stretch beyond a Lockean natural rights view. The government is regarded as a steward both to individuals, taking into account different needs arising from age, gender, ethnic background or socio-economic status, and to the population as whole. In this stewardship model, the state is obligated to seek to provide conditions that allow people to be healthy, especially in relation to reducing health inequalities. This envisages a more active role of the state than that presented in a typical liberal schema. The government should enact public health policies that promote the health and welfare of its citizens. The government should impose transparent and democratic decision-making so as to safeguard the balancing of individual liberty with public health.<sup>83</sup>

As such, the stewardship model can be highly differentiated from a paternalistic model. Paternalism has a greater likelihood to impose coercive measures on a population to achieve a desired goal, which greatly infringes upon individual liberty and autonomy. Rather, stewardship is sensitive to this tension and seeks the least intrusive manner of achieving a specific policy goal. Further, due to greater levels of transparency and democratic process in the stewardship schema, policies must be adequately justified so that they can achieve consensus. Within a stewardship model, public health policies should be compatible with the views of the public, and

the public should have the opportunity to scrutinize the suitability of proposed policies.<sup>84</sup> The Nuffield Council makes use of ethical arguments throughout their proposal for public health principles. Articulating these principles as ethical norms may have the effect of strengthening their acceptance and application by those who are likely to view human rights as imposing objectionable impediments to public health practice.<sup>85</sup> Hence, this is yet another way in which global bioethics may act to advance public health.

Just as global bioethics advances human rights, the converse is also true, for this is the nature of a symbiotic relationship. Human rights advance global bioethics in at least six ways. First, human rights recognize the duty of states and governments to citizens, yet many HIC governments are reducing expenditures on health due to soaring costs. This reasoning has also been thrust upon LMICs and the result is a refocusing on states' obligations to realize a legal right to health for its citizens. Global bioethics analyses of public policy for health in HICs and LMICs can be informed by human rights doctrine that views health as a chief responsibility of governments.<sup>86</sup> This perspective is poignantly articulated in the Universal Declaration on Bioethics and Human Rights, as well as reflected in global health policy outcomes such as the 2011 Rio Political Declaration on the Social Determinants of Health<sup>87</sup> and the UN Political Declaration on the Prevention and Control of Non-Communicable Diseases.<sup>88</sup>

Second, the social determinants of health are becoming incredibly more prominent in global bioethics and discussions of social responsibility. Human rights contribute to recognizing the protection of rights as itself a determinant of health. One major objective of global bioethics is the identification, analysis, and advancement of ideas about how to improve global health. Yet, as Forman and Nixon have noted, this recognition that the protection of human rights is itself an important determinant of health is largely absent from the discourse on determinants.<sup>89</sup>

Third, a human rights framework is useful for global bioethics because it facilitates the formulation of universal standards due to the fact that international human rights law is based upon the assumption that some basic rights transcend social and cultural diversity. Because bioethics regularly deals with an array of socio-cultural diversity and philosophical and religious pluralism, the usefulness of the universality of the human rights framework is key.<sup>90</sup> Moreover, large numbers of international instruments have been adopted to ensure the respect for individual persons in diverse contexts since the passage of the UDHR. It seems only fitting to make use of this rich normative and institutional system in order to protect persons from harm in the field of biomedicine.<sup>91</sup> Hence, the human rights framework may provide a more useful approach for analyzing and responding to health challenges than any other framework at the disposal of medicine and bioethics.<sup>92</sup>

It has already been stated that individual nation-states are inadequate to address global health issues, and culturally or religiously specific principles are insufficient for addressing the growing issues in global bioethics. What is needed, it is argued, is a *lingua franca*, a universal language and moral framework that is founded on universally shared, transcultural beliefs. It is argued that the human rights framework fulfills such a call.<sup>93</sup> The human rights framework transcends culture, nationality, and religion and presents transcultural normative judgments in a diverse world. Several common characteristics are shared by human rights and bioethics. The modern human rights discourse grew out of the atrocities of World War II, as did medical ethics with the Nuremberg Code, which has been described as the grandmother of modern bioethics.<sup>94</sup> While human rights and bioethics have similar origins they also have similar goals: humans should never again be used as a means to an end. The ideals of equality and human dignity that transcend cultures—an idea that is permeated in the human rights discourse—is very attractive

for global bioethics. Further, if it is accepted that the human rights discourse is an appropriate context within which global bioethics principles can be developed, the advantage to this is that the human rights principles are generally accepted across the globe and adopted by the international community. Human rights can also provide a sort of check or restraint on bioethics by signaling that ethics principles must align with accepted human rights.<sup>95</sup>

A fourth way in which human rights advances global bioethics is through the concept of human dignity. The concept of human dignity is the cornerstone of both human rights and global bioethical norms. The human rights discourse has a long history of utilizing the concept of dignity, yet, by itself, the concept is unable to provide responses to most challenges of bioethics and biomedical advances. The abstract principle of human dignity forms the foundation on which concrete concepts of global bioethics (such as informed consent, non-discrimination, personal integrity) can be built. These concrete concepts are usually formulated using the terminology of “rights”.<sup>96</sup>

Fifthly, Henk ten Have has contended that the international human rights discourse adds to the normative force of bioethical discourse. Human rights are seen as non-negotiable and unable to be compromised because of their root in human dignity. Hence, the weight of human rights is that it presents a framework of principles and norms that are to be upheld and protected without regard for the consequences because of the gravity of what is at stake. Ten Have points out that at times medical research has attempted to apply double standards in its practices, such as a lower standard in a developing country than in a developed one. However, the human rights discourse is aptly able to respond to such practices and counter that ethical principles are universal, not context-specific, and the ends do not justify the means (i.e. gathering health

research data for the improvement of a population does not justify doing so in an ethically dubious manner that may include the exploitation of persons).<sup>97</sup>

Lastly, the human rights discourse is attractive to global bioethics due to its very practical nature. Bioethicists today can be found in all levels of hospital administration and government service, as clinical ethicists, on IRBs and ethics committees, drafting policy for hospitals and federally for the NIH. Human rights can be helpful in matters of public policy due to its practical element that emphasizes the rights people are endowed with simply by being human. Hence, when preparing policy on research guidelines or national healthcare services, the normative and practical edges of human rights provide a universal language for bioethicists to utilize.<sup>98</sup>

The claims above are indicative of the strong relationship between global bioethics and human rights. However, not everyone is enthusiastic about this relationship. Elizabeth Fenton and John Arras have voiced their concern that advocates of a human rights foundation for bioethics are making unreasonable and unsustainable demands on the language and conceptual framework of human rights. Their argument is chiefly that human rights ought to be an important part of our thinking on many bioethical issues, though they ought not exhaust the thinking.<sup>99</sup> Hence, they are not critiquing the relationship between human rights and bioethics but rather those ethicists who would frame all discussions in the human rights discourse. This seems sensible, for a general endorsement of the human rights discourse does not provide unfettered warrant to shove all moral, political, medical, and legal controversies into the human rights linguistic and methodological framework.<sup>100</sup> Rather, we would do well to use the human rights framework only when prudent, or else we run the risk of making nearly all issues human rights topics and diminish what human rights actually mean.

The fields of human rights and global bioethics both have much they can learn from one another. By embracing collaborative efforts then the fields are able to perceptively contribute to one another, create stronger arguments, and have greater influence than either could separately. These points are essential in order to understand rightly how the fields of global bioethics and human rights interplay and are can be utilized in ethics guidelines such as the UNESCO Universal Declaration on Bioethics and Human Rights. As the field of human rights is much more mature than global bioethics, stretching back several centuries, it is able to offer well-established notions of state responsibilities towards health and human flourishing, as well legal frameworks for action, as is evidenced in the UDHR.<sup>101</sup> These ideas are very well developed and engrained in social and political thought. Further, global bioethics offers firm ethical arguments and frameworks for action. These arguments and normative frameworks are needed to address the global health dilemmas of our day. The Universal Declaration on Bioethics and Human Rights prominently brought the two fields together in 2005, which will be further examined in 4.2.

However, further investigation and research into the applications of this intersection should be undertaken for further strengthening. Those within the fields of public health, global bioethics, and human rights are able to gain analytic tools by embracing the largely untapped potential in such collaboration. Further investigation and research may include the intersection of global bioethics and human rights in relation to the restriction of rights in the service of global health interests, responses to new and emerging epidemics and pandemics, and the ethico-legal basis for formulating the obligations of state and non-state actors towards global health.<sup>102</sup>

In summary, this chapter began with an examination of global bioethics. The birth of global bioethics was seen, growing out of medical ethics and bioethics. Van Rensselaer Potter



was tremendously pioneering and influential during this period, coining both the terms “bioethics” and “global bioethics” and attempting to set the agenda for the new fields. Following this, an exploration of human rights was seen. The chapter concluded by analyzing the symbiotic relationship between global bioethics and human rights and how each field is able to contribute to the other.

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## **Chapter 3: Corporate Social Responsibility and the Pharmaceutical and Biotechnology Industry<sup>1</sup>**

For the proposed global bioethics tool that is presented in this dissertation, corporate social responsibility is an integral component. Corporate Social Responsibility (CSR) is an increasingly important issue to stakeholders and the general public. This chapter will first introduce the concept of social responsibility and its relation to global health and bioethics and will then, in the second section, turn to an examination of CSR applied to the pharmaceutical and biotechnology industry.

### *3.1) Social Responsibility in Global Health and Bioethics*

A key concept in global bioethics and global health is the notion of social responsibility and health, which significantly broadens the agenda of bioethics so that the social and basic issues related to the provision of healthcare for populations all over the globe are taken into account.<sup>2</sup> This section examines the concept of social responsibility and how it functions within global health and bioethics.

Social responsibility and health combine two basic ideas: 1) several actors aside from states and governments are responsible for health, and 2) global problems reflect common challenges and, therefore, should be addressed through common action.<sup>3</sup> The notion of social responsibility, as a term, is relatively new, with a majority of the formal writings only being traced back to around the 1950s.<sup>4</sup> The term appeared in the context of the ethics of private companies as a manner of defining the moral duties of companies in society that stretch beyond the limits of legal obligations.<sup>5</sup> While the term may be novel, the concept itself is relatively old, with forms of the idea found in the thirteenth century writings of Thomas Aquinas.<sup>6</sup> Indeed, the world's major religions over the centuries have encouraged extending the notion of responsibility



to others beyond the confines of family to communities and even further.<sup>7</sup> Today, the concept focuses on the responsibility of the broader society, specifically private companies, toward not only property and profits but also to those who are affected by or involved in the activity of a company, which will be explicitly seen how it is applied to the pharmaceutical and biotechnology industry in 3.2. In a broad sense, the term is meant to denote a change or enlargement of perspective in the strategies and aims of, specifically, companies, and calls on them not only to meet their legal duties but also to pledge to improve and advance the welfare of society.<sup>8</sup> This idea has evolved within bioethics and is increasingly recognized. The current section examines the role and concept of social responsibility in bioethics, specifically how a shift from bioethics as committed to an individualistic framework that does not place a high value on the social context to the notion of social responsibility has occurred.

The modern concept of social responsibility and health can be said to address the socio-economic determinants of health.<sup>9</sup> Evidence cited in the World Health Organization's (WHO) 2008 Final Report of the Commission on the Social Determinants of Health demonstrates that the health of both individual and communities is intrinsically tied to social factors.<sup>10</sup> According to the WHO, the social determinants of health—a term that emerged from epidemiology—are the conditions in which people are born, grow, live, work, and age. All of these circumstances are shaped by the ways money, power, and resources are distributed at local, national, and global levels.<sup>11</sup> Similarly, economic determinants, including income and job status, affect health, as higher income and advanced social status have been linked to better health. The WHO reports that as the income gap between the rich and poor increases, so do the differences in health.<sup>12</sup> The principle of social responsibility and health states that innovations in science and technology should address these determinants through access to healthcare and essential medicines, access to

nutrition and potable water, reduction of poverty, and the elimination of the marginalization of certain persons or classes of persons.<sup>13</sup> Because the greatest share of health problems is attributable to the social conditions in which people live and work, tackling major health determinants, through social responsibility, is an important step to improve levels of health.<sup>14</sup>

Social responsibility may be thought of as part of what has been traditionally known as moral or ethical obligations. Such obligations are not legally enforceable by governmental authorities (i.e. they are non-binding). Nonetheless, though such moral obligations are not necessarily legally enforceable does not necessarily render them less important than enforceable regulations. This merely indicates there is no legal precedent or compelling force to fulfill them.<sup>15</sup> As noted above, the notion of social responsibility and health combine the following two basic ideas: 1) Many actors, not just governments, have a responsibility towards health. 2) Global problems reflect common challenges, and thus, should be addressed by common action. Both of these ideas will be explored in turn. The idea that the governments of states are not solely responsible for the health of persons expresses that individuals, as well as private and public organizations such as healthcare sectors, educational services, and private companies, have a personal responsibility towards health as members of the global society.<sup>16</sup> Within global bioethics, the UNESCO Universal Declaration on Bioethics and Human Rights (UDBHR) expressly iterates this perspective in Article 14 of the document, entitled “Social responsibility and health,” which will be further examined in 3.2 and applied to the pharmaceutical and biotechnology industry.

The second basic idea of social responsibility is that global problems reflect common challenges and should be addressed by common action, which presupposes the principles of solidarity and cooperation, which are explored later in this section as a necessary foundation of

social responsibility. Because the protection and promotion of global health involves the cooperation and unity of multiple stakeholders, including private corporations, new frameworks of action may be necessary in order to enhance this type of cooperation at the global level. Further, this accepts that health is a common good and common action should be taken to try to achieve it. While governments should guarantee some adequate level of access to healthcare, healthcare is only one element of health. Other determinants will include environmental concerns, access to potable water and nutrition, and shelter. These common goods should also be protected and, if required, common action taken toward this end.<sup>17</sup>

It is important to note that the notion of social responsibility and health should not detract from responsibility for health on a personal level. Illness, generally, is not something that simply happens to a person. Persons have a greater likelihood of remaining healthy if they take care of themselves and adopt healthier lifestyles. Concern for the personal or individual's role in maintaining health is ancient and can be found in the writings of the Greek physician writing in the second century.<sup>18</sup> Yet, while we cannot discredit that individuals play a large role in their own health, we also must not overlook the social and environmental dimensions of health, which is what the concept of social responsibility for health places before us.<sup>19</sup>

The notion of social responsibility and health cannot be interpreted as an isolated idea. In particular, social responsibility must be viewed in light of the concepts of solidarity and cooperation, as they form foundations for a proper understanding of social responsibility.<sup>20</sup> Solidarity is not a new concept. The usage of the term *solidarité* increased during the French Revolution and found entrance into Napoleon's *Code Civil* in 1804, where it was increasingly extended into the political realm. However, it was the work of August Comte that increased the visibility of solidarity in contexts that were not immediately religious or political. For Comte,

solidarity was a remedy for the increasing individualization and atomization of society, which he viewed as detrimental to social concerns and the wellbeing of the collective. This approach resonates with social contract theorists, such as Thomas Hobbes, John Locke, and Jean-Jacques Rousseau. While these three prominent philosophers differ greatly in their approach of the nature of humanity, a commonality is that they justify the need for governmental authority. Because of their belief that it is impossible for individuals to live safe and fulfilled lives outside of organized social systems, people are implicitly assumed to have agreed to waive their natural freedom to do what they want and to submit themselves to the rule of an authority, which provides them civil freedom in return.<sup>21</sup>

Émile Durkheim was one of the first social theorists to devote significant attention to the notion of solidarity.<sup>22</sup> Durkheim noted that societies are only constructed through social cohesion.<sup>23</sup> Durkheim defined solidarity as a consensus among the individuals of a group, and he demarcated two types of solidarity: mechanical and organic. Mechanical solidarity is the social, physical, and cultural integration of persons in society who have common values, which thus provides motive for persons to unite toward the objective of maintaining equality and perpetuating the group. Organic solidarity is much more established in modern society, which has become increasingly differentiated and interdependent because of the relatively greater division of labor, which requires greater interrelation and cooperation between individuals.<sup>24</sup> Today, organic solidarity predominates, at least in most developed countries, since its pillars are based on social reference points that are determined from norms established through rights. Durkheim stressed that organic solidarity may be developed through mutual interdependence and reliance upon others, with emphasis placed on the individual. Solidarity has been cited by some commentators as essential to addressing common global threats, such as pandemics and

environmental concerns. However, the concept of solidarity may be most useful to global health as a critique to charity-based approaches, which is key for social responsibility.<sup>25</sup>

Hence, the notion of solidarity has been around since ancient times and refers to the social bonds between groups of people that prevent the breakdown of a particular society. Embedded in this concept is the belief that people are connected to one another due to possessing a common goal and identity.<sup>26</sup> According to this group conception of solidarity, generally in most groups there will be some tendency to prefer or to be benevolent towards other members of the group.<sup>27</sup> Massimo Reichlin notes that the idea of solidarity involves, on the one hand, the disposition to care for the defense and promotion of the conditions of social life for which the members of the group are collectively responsible and, on the other hand, the disposition to take particular care of the needs and interests of the weaker members of the group.<sup>28</sup> Indeed the expression of solidarity is presented through mutual actions that occur among people who are within the same environment, in a kind of “social corporatism” in which those persons involved have an interdependent relationship. These interpretations may derive from Aristotle, who placed the foundations of solidarity in a position that is incompatible with individualism.<sup>29</sup>

It has been recognized that if solidarity can be harnessed towards meeting goals such as the promotion of health and social development then it can be a powerful motivating force. Yet, we must think further on why global solidarity is necessary. Two arguments are presented here for the necessity of solidarity. The first is that in addressing global problems such as access to medicine, access to potable water, lack of education, and poverty, more is needed than simple aid and generosity of affluent donors. While the driving motivation behind such aid is goodwill and helping humanity, the recipients are often viewed as helpless victims. Solidarity introduces a mindset that is not synonymous with charity, compassion, fraternity, or philanthropy. While they

convey similar but not identical ideas, there are conceptual clarifications that must be offered to distinguish these terms.<sup>30</sup> The central differing quality is that solidarity signifies that a relationship amongst equals exists. In such a symmetrical relationship then it necessarily means the inclusion of cooperation toward a common goal.<sup>31</sup>

Secondly, global solidarity may be considered a necessity due to the shared, common experience of humanity. If health is considered a common good for all humanity, the health of the world's citizens is a shared concern. While individuals acting alone may be near powerless in the face of ominous global problems, as a unified whole, populations can make a lasting difference. Hence, it has been realized that solidarity is a critical motivating factor for collective action towards a common goal. It is at this point that we can note that solidarity is crucial for the moral discourse of global bioethics because it demonstrates that humans are primarily social beings.<sup>32</sup> Social science has provided evidence that humans flourish best when in community.<sup>33</sup> This idea dates back to at least Aristotelian thought and is essential in order to address the global health concerns of today.<sup>34</sup> Kofi Annan, in his final speech to an American audience as Secretary-General of the United Nations, seemed to have hinted at this idea when he stated that global solidarity is both necessary and possible. Annan proposed that without solidarity, no society can be truly stable, and prosperity cannot truly be secured.<sup>35</sup>

Cooperation is in many respects a similar concept to solidarity. However, it is worth noting how these concepts differ and each form a foundation for social responsibility. An understanding of the significance of cooperation presupposes that there are benefits or mutual advantages in interactions between states, institutions, organizations, groups, or individuals.<sup>36</sup> John Stuart Mill was an early advocate of cooperation in the nineteenth century to solve social troubles. Reacting against the inequality and exploitation of labor he witnessed in his day, Mill

proposed that such ills could be overcome through cooperative processes involving free associations between workers and other workers and between workers and capitalists.<sup>37</sup> Mill was onto the idea that human rights cannot be fully realized without cooperation, and that in order to see true change, joint action and cooperation is required.<sup>38</sup>

While the need for global cooperation is not generally contested, seeing it come to reality is often fraught with political difficulties and can be fragile. This can be explained, at least in part, because two views of cooperation are often in play: cooperation as instrumental and cooperation as an end in itself. Cooperation that is instrumental is based off self-interest, can be short-lived, and goes against the perspective of global bioethics. Humanity, in the perspective of global bioethics and in the concept of social responsibility, cooperates with one another because of their shared interests and experiences, which is cooperation as an end in itself. The moral impetus behind such cooperation is the global concern for humankind and the problems it faces.<sup>39</sup>

Bioethics has not always had a bent towards social responsibility. Bioethics has been charged with focusing too strongly on the individual to the neglect of the social setting and cultural milieu in which medicine exists, as was presented in Chapter 2.1.<sup>40</sup> Since clinical medicine is dedicated to the treatment of the individual, bioethics tended to stake its claim on this part of the moral terrain to the inattention of others.<sup>41</sup> This lack of consideration for the social setting continues to be visible in the wider landscape of mainstream bioethics that generally leans toward a focus on the individual perspective.<sup>42</sup> Albert Jonsen, writing in 2001, was so candid as to say that bioethics lacks a clear and substantial social theory and that as a discipline, bioethics has, in general, failed to integrate social responsibility into its discourse.<sup>43</sup>

The critique of Jonsen and others is that mainstream bioethics may give a head nod to the social context and to theories of justice, yet these considerations are only background questions.

However, the call for bioethics to embrace an ethic that goes beyond an individual orientation has been around for decades on the peripheries, overshadowed by the dominance of individualism.<sup>44</sup> In a 1988 interview, Daniel Callahan was quick to combine medicine and society by noting that societal values, principles, and virtues help to fashion the medical community.<sup>45</sup> Indeed, while bioethics has a history of being staunchly engrained in individualism, exceptions have occurred, even from its inception, such as with the work of the bioethics pioneer Van Rensselaer Potter that was previously presented in chapter two. Another notable example is the 1975 Asilomar Conference. Scientists convened to discuss safety concerns of new recombinant DNA and its implications on broader society. Further, in 1988 the Human Genome Project became the first major scientific undertaking to dedicate significant portions of its budget to associated ethical and social issues. The Human Genome Organization (HUGO) was created to foster this international conversation.<sup>46</sup>

As time has progressed, the scientific community has steadily understood that social responsibilities for health are a fundamental concern for the ethics of professional public health practices. The WHO was among the first to promote social responsibility for health in their “Fourth International Conference on Health Promotion: New Players for a New Era—Leading Health Promotion into the 21<sup>st</sup> Century.” Held in 1997, the conference recommended that both the public (e.g. governments) and private sector (e.g. corporations) should promote health through enacting policies that avoid causing harm to individuals, protect the environment, restrict the production and trade of harmful goods, safeguard the citizen in the marketplace and workplace, and include equity-focused health impact assessments as an integral part of policy



development. This conference was followed in 2000 by the Fifth Global Conference on Health Promotion in which it became clear that social responsibility means different things to different people. Hence, the need for defining what is meant by social responsibility became apparent. Universal consensus on this has still yet to be achieved, as many definitions of social responsibility are in use today.<sup>47</sup>

Though social responsibility has typically not been at the forefront of bioethics, attempts have been made to develop theoretical models that would include the views of social responsibility for health and wellbeing. The discussions on access to healthcare in the 1980s through today have brought social and political philosophy into bioethics.<sup>48</sup> Further, Johanna Ahola-Lanunonen points out that several authors have called for a “bioethics of population health” that would address the difficulties of global and domestic health inequalities, as well as matters of social justice. Such commentators believe that bioethics has a duty to abandon its fixation with the clinical dilemmas of high-tech questions and should further integrate questions of social structure, socioeconomic position, and cultural background more fully into moral analyses.<sup>49</sup>

A major impetus for broadening the scope of bioethics to include a social perspective has primarily come from bioethicists interacting with epidemiological research on social determinants of health and health inequalities.<sup>50</sup> Norman Daniels, a political philosopher and bioethicist, has provided comprehensive commentaries on the concept of social responsibility for health.<sup>51</sup> Daniels claims that society has a duty to protect the opportunities of its members, an argument that he forms by examining multiple theories of justice. He reasons that health holds a special moral importance over other things because maintaining it makes a significant contribution to protecting the range of opportunities open to individuals. Hence, because of its

importance, there is a social obligation to protect the health of the population.<sup>52</sup> Informing his view of health are also the social determinants. Daniels finds that many of these social determinants of health are unequally distributed among ethnicity, gender, and class.<sup>53</sup> It should be noted that there is an abundance of empirical evidence to support the significance of social determinants of health.<sup>54</sup> It may be likely that public health measures based principally on the idea of individual responsibility place the most demanding burden on the most vulnerable groups in the population, as those in more privileged positions are better equipped to pay for the treatments needed. To counter such questionable reasoning, a greater emphasis on social responsibility for health is needed that would seek to counteract the original inequalities.<sup>55</sup>

It has also been realized that the move of bioethics from an individual-oriented perspective to one that has begun to consider the broader social and global context is the consequence of increased globalization across the spheres of political and social life. Bioethics has witnessed rise of global health as a conceptual framework of analysis, due in large part to new and resurgent health threats that cross geo-political borders quickly, such as the Ebola and Zika viruses. This, in turn, has heightened both the recognition of numerous worldwide factors affecting health and of shared global vulnerability.<sup>56</sup> Because of this globalization and the perceived need for moving towards social responsibility in bioethics, Johanna Ahola-Launonen has stated that the recognition of social matters for bioethics is important in order for the social determinants to no longer be of secondary concern and to truly embrace the multidisciplinary and interdisciplinary nature of bioethics. Hence, it can be seen that social responsibility has evolved into more of a prominent position in bioethics, though it has not yet achieved the fully integrated position that many are calling for.<sup>57</sup>

The concept of social responsibility in global health and bioethics plays a major role in the UNESCO UDBHR. This social dimension of bioethics is novel to the UDBHR and was added to subsequent drafts of the document out of a necessity to go beyond the limits of pure medical ethics with the aim of placing bioethics within the context of the political and social world.<sup>58</sup> Article 14 of the UDBHR expressly iterates this perspective in Article 14 of the document, entitled “Social responsibility and health.” The inclusion of Article 14 moves the document beyond the realm of medical ethics and reiterates the need to place bioethics and scientific advances within a larger context of reflection that is open to the corporate, political, and social world.<sup>59</sup> Article 14 reads:

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.
2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:
  - (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;
  - (b) access to adequate nutrition and water;
  - (c) improvement of living conditions and the environment;
  - (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;
  - (e) reduction of poverty and illiteracy.<sup>60</sup>

Article 14 offers a forceful summary both of the social determinants that require addressing and of the “sharing” of responsibility that is essential to perform the task. A list of the main foci of this commitment is clearly bulleted in the second point. However, it is in the wording of the first point that the conceptual link between social responsibility and health is unmistakably stated. The statement implies two things: 1) no actual promotion of health for people is possible without making development of the whole society a pivotal issue, and 2) “all sectors” of society are called upon to share this responsibility that is unquestionably and in the first place a

responsibility of governments, but can in no way be considered a responsibility of governments alone, lest the goal of promoting health be missed.<sup>61</sup> Governments are the first to be addressed by a call for social responsibility in health, as it has been generally agreed that governments have some measure of responsibility towards the promotion of health.<sup>62</sup> Governments have at their disposal both the means to promote health (through legislation) and the resources to fund such endeavors (through taxation).<sup>63</sup> However, while the responsibility towards health may be a responsibility primarily held by governments, it is not solely a responsibility of governments.

The innovation here for healthcare is that the protection and promotion of health is regarded as a shared responsibility. As the policies and practices of multinational companies have the ability of affecting millions of people, the normative argument embedded here is that companies have an obligation to prevent or remediate the negative affects of business for the benefit of the health of others.<sup>64</sup> Article 14 also does not make it possible to regard the geographical boundaries of a society as the limit of obligations. If this were so, governments would merely need to discharge these obligations for their citizens and companies would only be encouraged to look after their shareholders, clients, and employees. The vision behind Article 14, and the concept of social responsibility more generally, is that health can no longer be isolated to pockets of interests and responsibilities dispensed by states. Global trade, international research, and pandemics, for example, clearly involve social relationships that reach well beyond geographic boundaries.<sup>65</sup>

Social Responsibility is also a focal point of UNESCO's International Bioethics Committee (IBC), which in 2010 issued a report *On Social Responsibility and Health*. The report emphasizes the need for new perspectives that go beyond medical ethics and bioethics, and the IBC contends that scientific progress must be located within a context that is open to the social

world.<sup>66</sup> Hence, there is a robust call for a broader, more integrated notion of social responsibility from certain corners of bioethics, especially within international and global bioethics, which is becoming progressively visible in the literature.<sup>67</sup>

Today, social responsibility is oftentimes synonymous with corporate social responsibility, which is, very simply defined, how social responsibility applies to corporate entities. This is largely the subject of 3.2 and, specifically, how CSR applies within the pharmaceutical and biotechnology industry and to the issue of pharmaceutical pricing, which is a perennial problem for the industry.

### *3.2) CSR and the Pharmaceutical and Biotechnology Industry*

After an introduction to the concept of social responsibility in the previous section, this chapter now turns its attention to the specific study of CSR and how it has developed within and applies to the pharmaceutical industry. A key area that has come under fire in recent years in the pharmaceutical and biotechnology industry is the area of pricing. Pharmaceutical pricing is a tremendously important CSR issue and, due to its pervasiveness in the media today, will comprise large portions of this section to try to elucidate how CSR can speak into this issue. Companies that are integrally tied to human health and flourishing, such as the pharmaceutical industry, may be especially addressed by calls for social responsibility in global health. CSR rests upon the premise that most modern companies likely create “bads” as well as goods, and accordingly should conduct activities that deliver social or environmental benefits to offset any adverse consequences of their business. Pharmaceutical companies seem to be special cases because their business decisions directly impact human health and flourishing, making CSR efforts particularly important for them. Further, the UNESCO Universal Declaration on Bioethics and Human Rights can ably address issues of CSR and pricing within the

pharmaceutical and biotechnology industry. Hence, the UDBHR will be invoked in this manner in this section. First, this section will offer an explanation of what CSR is, its origins, and its criticism. Second, CSR will be applied to the pharmaceutical and biotechnology, with the use of the UDBHR, on the persistent issue of drug pricing. Finally, methods for implementing greater CSR within the industry will be examined.

Section 3.1 presented the term “social responsibility” and briefly introduced the expression “corporate social responsibility” or CSR. CSR is a relatively new concept that focuses on a company’s responsibility toward property and profits as well as those who are affected by or involved in the activity of a company. CSR has been defined by the UN, at its broadest, to signify the overall contribution of business to sustainable development.<sup>68</sup> However, a universal consensus on the definition of CSR has not been achieved, as many definitions are in use today.<sup>69</sup> Yet, most view it as more than corporate philanthropy. While companies are bound to legal duties, CSR calls upon companies to meet additional duties that stem from a commitment to improve the welfare of societies, which are more ethical than legal duties. This idea widens the scope of responsibility for corporations from merely stockholders and investors to include also stakeholders—any person or group that can affect or be affected by the achievement of an organization’s objectives.<sup>70</sup>

The concept, practices, and manners of implementing CSR are disputed and rejected by many commentators.<sup>71</sup> The principle is rejected by many on the claim that health is solely the responsibility of governments. Companies that see their sole obligation as to improve the state of their shareholders and fulfill legal obligations see no moral necessity to contribute to the common good of society. This is the argument chiefly advocated by the Nobel economist Milton Friedman. Friedman, a well-respected academic of the time, contended that, “few trends could so

thoroughly undermine the very foundations of our free society as the acceptance by corporate officials of a social responsibility other than to make as much money for their stockholders as possible.”<sup>72</sup> This stance would be broadcast widely in a popular-level *New York Times Magazine* article in 1970, entitled, “The Social Responsibility of Business Is to Increase Its Profits,” which was more easily accessible to masses of people than an academic textbook.<sup>73</sup> For Friedman, a free-market economy meant that the shareholder assumed primacy. Friedman’s position, which is argued persuasively, stands as a quintessential statement of conservative political economists’ rejection of CSR.<sup>74</sup> Yet, one outstanding problem with this narrow view of social responsibility is that it fails to appreciate that corporate decisions often have powerful and far-reaching social impacts. Such firms are social agents, whether they realize it or not.<sup>75</sup>

While there were many writers on CSR in this era, Edward Freeman and Peter Drucker stand out for their contrasting positions to Friedman. Freeman, along with colleague William Evan, in 1988 published their influential article, “A Stakeholder Theory of the Modern Corporation.”<sup>76</sup> This was the beginning of the new stakeholder approach in management that looks not only at the legitimate profit-making ventures of a firm, but also at the many individuals and organizations that are targeted by and/or involved in the activity of a corporation.<sup>77</sup> Similarly, Drucker advocated for the view that successful companies focus on responsibility rather than power, as well as their reputation in society rather than merely piling up short-term results.<sup>78</sup> Drucker furthered the idea that profitability and responsibility are not mutually exclusive for a company; they are compatible. While this was not a novel point, Drucker insisted that businesses ought to convert their social responsibilities into business opportunities.<sup>79</sup> He emphasized, “But the proper ‘social responsibility’ of business is to tame the dragon, that is to turn a social problem into economic opportunity and economic benefit, into productive capacity,

into human competence, into well-paid jobs, and into wealth.”<sup>80</sup> Hence, Drucker believed that social problems could be opportunities for business growth. This vein of reasoning has continued in CSR, as many are now advocating for it as smart business. What is more, Drucker advocated that, “Leaders in every single institution and in every single sector...have two responsibilities. They are responsible and accountable for the performance of their institutions, and that requires them and their institutions to be concentrated, focused, limited. They are responsible also, however, for the community as a whole”.<sup>81</sup> Therefore, Drucker did not see the role of the modern corporation as merely concerned for profits, but rather for profits and people. The modern-day concept of CSR embodies these values.

Certainly not everyone is in agreement with figures like Freeman and Drucker. The notion of CSR may be criticized as simply being opportunistic and as a manner for companies to garner good public relations, not a moral strategy.<sup>82</sup> This seems to be backed by certain empirical evidence that pharmaceutical companies engaged in CSR do so with motives of reputational benefit, employee satisfaction, higher rankings in sustainability indices, entrance into new markets, long-term economic returns, and improved population health.<sup>83</sup> While these motives may not in and of themselves be entirely wrong, it is troubling that any mention of doing so as a moral obligation is noticeably absent. Nonetheless, it might be difficult to make a strong argument that companies must perform social goods out of pure altruism. After all, companies still do need to be concerned with business and profits to stay afloat. John Stuart Mill wrote, “[U]tilitarian moralists have gone beyond almost all others in affirming that the motive has nothing to do with the morality of the action, though much with the worth of the agent. He who saves a fellow-creature from drowning does what is morally right, whether his motive be duty or



the hope of being paid for his trouble.”<sup>84</sup> Consequently, while there may be merit to some of the criticism regarding motivations, this is not enough to dismiss the principle of CSR altogether.

In an article that appeared in *The Wall Street Journal* in mid-2010, Aneel Karnani, Professor at the University of Michigan, avowed that the notion of CSR is an illusion and potentially dangerous. Karnani’s warning is that a focus on social responsibility will either delay or discourage more effective measures to enhance social welfare in those cases where profits and the public good are at odds. Further, as society looks to companies to address these problems, the real solutions may be ignored.<sup>85</sup> Hence, Karnani views social responsibility as merely a temporary fix to address societal concerns. His solution in order to strike a balance between profits and public good is mainly consigned to the government to provide regulation. Karnani, however, does not address the moral dimension of the argument. As this analysis has argued, the decisions of corporations affect myriad peoples. There are vast numbers of stakeholders that are affected by a company’s actions. And because of this, it is argued that a responsible company will seek to both mitigate negative impacts and increase positive effects.

Some argue that if CSR exists and should be exercised by companies then it is best to be handled in a voluntary manner and based upon self-regulation rather than external compulsion. However, voluntariness is not always a very strong motive for change.<sup>86</sup> One benefit of some sort of external mechanism is the accountability that such a structure brings, as well as the transparency it offers to stakeholders. Additionally, others critique CSR from an economic viewpoint, arguing that social responsibility does not aid companies financially in ways that some advocates propose. The business case for CSR and trying to empirically determine what impact it has on the bottom line has tried to be determined for over four decades. Between 1972 and 2002, over 100 studies that empirically examined this relationship were published.<sup>87</sup> To

much dismay, the empirical studies have never been in agreement. Some studies found a positive correlation.<sup>88</sup> Others determined a negative association.<sup>89</sup> Still, others found no correlation at all.<sup>90</sup> Nonetheless, the case for social responsibility in business stretches beyond merely looking at whether or not it is best for the company's bottom line and to the idea that businesses have a moral obligation to look out not only for their profits but also for stakeholders (those affected by the practices of the business) and the environment.

While over 100 studies have examined the link between CSR and financial performance, and the results have been inconclusive, some have taken this to suggest that there is no *a priori* reason for businesses to adopt CSR into their practices. Yet, there are growing calls from society for businesses to adopt a wider range of social and environmental responsibilities. Oftentimes those in the pro-CSR camp attempt to offer a business case for CSR, endeavoring to justify CSR on economic grounds. Surely some kind of business case for CSR is necessary in order to call attention to it and achieve "buy-in" from the business sector, yet the majority of these arguments create too strong a bifurcation between ethical and economic justifications for CSR. This assessment is perpetuated by the view that businesses must meet both social responsibilities and business responsibilities. Yet, we must question whether such a split is actually necessary. The dominant view, espoused by Friedman and others, that businesses must pursue that which is good and valuable and worth pursuing (i.e. profits) is inherently ethically laden. Hence, it can be argued that there is no true separation between ethics and economics. Such a separation between economics and ethics is perpetuated when one attempts to justify positive social behavior in economic terms rather than as a value worth pursuing in and of itself—as an integral element of a healthy capitalist business system.<sup>91</sup>

However, the economic argument for CSR remains highly controversial. Deborah Doane charges that CSR as a concept simplifies some complex economic arguments and fails to acknowledge that trade-offs must be made between the financial health of the company and ethical outcomes. Doane levels several arguments against CSR, though two will be presented here. She states two common myths associated with CSR: 1) It is a myth that there will be a competitive race to the top over ethics amongst businesses, and, 2) It is a myth that in a globalized economy, countries will compete to have the best ethical practices. Doane's critique is that businesses simply hide their irresponsible acts and seek to promote their more ethical ones.<sup>92</sup> Hence, there is no real ethical company, only those who do a better job at cloaking their troubling practices. While transparency is an issue with companies, steps are being taken to address it, especially within the pharmaceutical industry with activities such as the Good Pharma Scorecard project developed by Bioethics International.<sup>93</sup> Doane's critique that there will be a competitive race to the top has not been the experience of the Access to Medicine Index (ATMI). ATMI is a biennial publication that was first published in 2008 and is now well recognized in the pharmaceutical sector for their efforts at social responsibility. This is evidenced by a recent independent, third party evaluation that found that ATMI has made commendable contributions towards advancing the engagement of the industry with the issue of access to medicine. According to the study, ATMI has become a well-regarded authority on access to medicine and has succeeded in building consensus between stakeholders for the industry.<sup>94</sup> The driving idea behind ATMI is that companies will compete, in a sense, for a coveted high ranking on the index. It has been shown that competition can be a catalyst for price reductions, and it is argued that by ranking pharmaceutical companies and publishing the results publicly then competition in regards to access to medicine can be sparked.<sup>95</sup> A recent empirical study that analyzed the

available data on pharmaceutical companies' CSR efforts also studied the role of ATMI and the Dow Jones Sustainability Index (DJSI) in promoting global health. The researchers concluded that there is a need for more attention to be garnered in order for the indexes to meet their potential.<sup>96</sup>

Doane's highly skeptical view of business that purports that companies merely promote good behavior and hide their bad ones simply does not seem to hold up under scrutiny. Organizations today are more controlled by their stakeholders and companies are forced, in a sense, to display greater amounts of transparency in their conduct since stakeholders can freely disseminate information about a firm's behavior. Further, the advent of new forms of technology has also had the effect of increasing transparency now that anybody can readily report on the activities of a company.<sup>97</sup>

Criticism of social responsibility also appears from firms who are established in the field of global health. Pharmaceutical and biotechnology companies are under increasing societal pressure to act responsibly in a globalized world. As a healthcare industry, many have insisted that drug companies cannot merely be concerned for their own profit margins to the neglect of the very people who depend on their medications. An August 2015 poll showed that 74% of the American people believe that drug companies routinely prioritize profits before patients.<sup>98</sup> Many commentators have argued for the responsibility of pharmaceutical companies to address the challenges posed by health crises affecting low- or middle-income countries (LMICs), for, they suggest, a socially responsible company has a moral obligation not only towards shareholders but also to stakeholders.<sup>99</sup> Further, the business decisions of pharmaceutical companies directly impact human health, which makes corporate social responsibility particularly important.<sup>100</sup> Klaus Leisinger, a critical thinker in this area, has suggested that CSR in the pharmaceutical

industry, as in other sectors, encompasses responsibilities with differing degrees of obligation. Leisinger distinguishes between three classes of what is required of business by society, what is expected of business by society, and what is desired of business by society. He argues that companies should do more than the *minima moralia*, especially in view of global social problems. However, noting that such companies have historically been slow to address issues of ethics and access demonstrates, at least implicitly, they have not fully embraced the idea of social responsibility.<sup>101</sup>

While many pharmaceutical companies now have dedicated CSR departments, the industry has not embraced the concept as quickly as some have hoped. The pharmaceutical sector has typically been unwilling to address issues of access to essential medicines through a systematic approach to differential pricing for LMICs. Rather, providing access for costly medicines in LMICs has typically been done through a company's corporate philanthropy unit. Yet, CSR is about more than mere philanthropy, as it challenges companies to rethink their attitudes towards markets in LMICs in order to evaluate and improve the impact their business has on human development and flourishing.<sup>102</sup> Hence, by not addressing such issues then the industry has indirectly criticized, or at least not embraced, the concept of social responsibility. The obligation for pharmaceutical companies to make social responsibility a priority is due to the nature of their business. Simply, the business decisions of pharmaceutical companies directly impact human health and flourishing.<sup>103</sup>

Small or lesser-established pharmaceutical or biotechnology companies may also be more hesitant to deal with ethical issues such as social responsibility. Some have argued that they only need to begin worrying about ethics when their products come to market. However, research verifies that companies miss important opportunities when they assume they only need to

address ethical issue after developing a product. A solid foundation in ethics from the beginning will allow companies to better understand the larger ethical minefields. Further, some companies have also attempted to argue that they are fine as long as they follow FDA guidelines and stay within the law. However, the expectations of society are evolving so that mere legal compliance is not viewed as a sign of necessarily ethical behavior.<sup>104</sup> The pharmaceutical industry has been charged by the media and academia alike with not spending enough resources for the development of new vaccines and drugs to treat issues such as tropical diseases and the ailments of those in LMICs.<sup>105</sup> This lack of interest on the part of the pharmaceutical industry could be explained by the high cost of biomedical research and the small or negative profit margins a company could expect.<sup>106</sup> Ethics bodies such as the International Bioethics Committee of UNESCO have emphasized that the pharmaceutical industry is particularly addressed by social responsibility.<sup>107</sup> Though some have argued that pharmaceutical companies have no special responsibility towards global health, this argument is increasingly seen as implausible for those whose activities clearly have a direct impact on health and human flourishing.

As this section transitions to seeking to understand more thoroughly how CSR is applied to the pharmaceutical and biotechnology industry, it must first be acknowledged that the industry suffers from a CSR and reputation crisis. A major source of this crisis is the numerous pricing scandals that have rocked the industry. In an August 2015 poll completed by the Kaiser Family Foundation, one of the premier healthcare public policy think tanks in the US, it was found that most Americans feel that drug costs are unreasonable (72%) and that drug companies put profits before people (74%).<sup>108</sup> In September 2016 the survey was repeated and found that 77% of Americans felt drug costs were unreasonable.<sup>109</sup> These statistics are not entirely surprising, for an enduring quandary for the pharmaceutical industry has been its aggressive pricing policies. Yet,

one important issue that is not taken into account in this poll is the enormous research and development costs borne by pharmaceutical and biotechnology companies. It is worth considering whether or not the poll would have achieved similar results if the researchers also mentioned these enormous costs and the average 12 years of research and development to produce a new drug.

Nevertheless, there are two paradigm recent examples of the public believing drug costs are unreasonable. The first is the case of Turing Pharmaceuticals and the aftermath that followed in the media and by influential politicians, such as Hillary Clinton, who has called for plans control the “price gouging”.<sup>110</sup> It was revealed in September 2015 that Turing Pharmaceuticals had acquired a 62-year-old drug, Daraprim. In and of itself, this would be unremarkable, but Turing and their CEO Martin Shkreli also announced that they would be raising the price of the anti-protozoal drug from \$13.50 to \$750 per tablet—a 5,000% increase that may be prohibitively expensive for many.<sup>111</sup> Unsurprisingly, this drew national scorn towards the company and the industry in general, as Turing was seen as taking advantage of HIV/AIDS patients who rely on the drug.<sup>112</sup> Similarly, in late August 2016 the American drug company Mylan reached national headlines for the prices of their product EpiPen, which has increased in price 400% since 2009.<sup>113</sup> Similar to the Turing debacle, Mylan drew the attention of U.S. Members of Congress and the scorn of politicians.

These two fresh examples of skyrocketing prices are reminiscent of the late 1990s and early 2000s when the pharmaceutical industry came under fire for not making HIV/AIDS treatments widely available to Sub-Saharan Africa. In 1987, azidothymidine (AZT) became the first anti-HIV drug to be approved by the FDA. Additional antiretroviral drugs soon followed, and by 1997 the number of AIDS deaths had declined significantly in the US. However, by the

end of 2003, fewer than 7% of people in LMICs in need of antiretroviral treatment had access to these medicines, largely due to price. In late 1997, the South African government, under the leadership of Nelson Mandela, took legislative measures to reduce the pharmaceutical prices.<sup>114</sup> The new law included two provisions aimed at bringing down pharmaceutical prices. The first provision sought to take advantage of a gray market by allowing the import of drugs from countries where they may be available for less. The second provision would let the South African government grant licenses to local manufacturers to make their own generic versions. The pharmaceutical companies objected strongly, fearing the erosion of their patent protections.<sup>115</sup> By the end of the controversy, pharmaceutical companies were painted in a very negative light, and South Africa promised to adhere to its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>116</sup> Since then, the industry has made broad accommodations on pricing and access to HIV/AIDS drugs.<sup>117</sup> Yet, from these examples, it is clear that the area of pricing is one that is commonplace and regularly publicized.

To be certain, innovation in the pharmaceutical sector is expensive, and risk must be rewarded. A recent study by the Tufts Center for the Study of Drug Development estimates that developing a new prescription drug that gains marketing approval can cost \$2.6 billion USD and take longer than a decade. This figure takes into account the costs of unsuccessful research and lost investment opportunity.<sup>118</sup> To be sure, these significant costs are a major argument against regulating drug prices, for it is held that putting a cap on drug prices will drive down innovation. Indeed, some commentators have argued that patients definitively will not receive new life-saving medications if prices are capped.<sup>119</sup> Such a strong statement is not easily defensible. Though some novel drugs may be worth paying high prices for, drug prices in the US often have more to do with what the market will bear than anything else.<sup>120</sup> Hence, one reason for the lack



of more reasonable pricing structures for pharmaceuticals may be the result of an American free market run amok. The claim is often made that high prices and profits are nothing short of being exceedingly unwarranted and unethical. The argument is often delivered in terms alleging that pharmaceutical companies could (and ought) easily deliver less expensive products while maintaining a superior quality and not sacrificing research and development. Yet, the task of assessing what constitutes an unethical price or excessive profit proves quite difficult.<sup>121</sup> To be sure, businesses are entitled to a reasonable profit as a reward to investors, itself, and as stability for long-term sustainability. Basic tenets of business dictate that companies, such as those in the pharmaceutical or biotechnology industry, are private corporations that are responsible to shareholders for making profits, and they must produce profits to stay afloat. However, the real problem of research and development is the industry-wide practice of viewing innovation solely from a manufacturing perspective rather than from the perspectives of patients and other stakeholders. Pharmaceutical companies must continue research and development in ways that optimize the medical and economic benefits to shareholders, but they also need to listen to stakeholders and innovate in ways that address real stakeholder needs as opposed to solely industry needs.<sup>122</sup>

The issue of pricing and profit attains much greater significance when the item in question is not a luxury good, such as a BMW or the latest smartphone, or even a non-essential drug such as Viagra, but an indispensable one, such as life-saving or life-prolonging medicine.<sup>123</sup> Hence, normative claims are at stake here. Should free market forces determine the price of essential goods such as pharmaceuticals, or should their pricing be regulated? Is it, in fact, morally wrong for a company to charge high prices if the market can bear it and the consumer can pay it? What are the ethical implications of excessive profit at the expense of human

suffering? A key question that warrants thought is whether or not other viewpoints should be considered. Should companies in the health sector take the needs of the sick into account in light of their considerable stake in these issues?<sup>124</sup> These are questions that only begin to touch the tip of the proverbial iceberg and hope to be examined, to differing degrees, within this analysis.

Though many recognize the high pharmaceutical prices in the US, not all agree that pharmaceutical companies are to blame. Rafi Mohammed, a pricing strategy consultant, has written that pharmaceutical companies are, in fact, not to blame, for they have merely executed well on the rules set by the US government as well as the dictum of “make the most money” set by their shareholders. Mohammed rather sees the onus on the American people for not taking responsibility for deciding how drug prices are set.<sup>125</sup> While there is truth that Congress has not proved keen on enacting regulatory guidelines for pharmaceutical pricing, we also must not gloss over the moral agency of individual actors in the industry and companies. It does not follow that simply because regulatory guidance is lacking that pharmaceutical and biotechnology companies are ethically justified by charging whatever prices the market can bear.

For pharmaceutical and biotechnology companies, caring about their pricing structures and how the public views them should be high on their priority list. Corporate reputation is the sum total of perceptions of a company. These perceptions are largely based on what the company does or neglects to do (Chong 2012). Further, failure to respond to issues, such as access to medicines can quickly lead to reputational harm.<sup>126</sup> Pharmaceutical companies have seen their reputation in the public image eroded over recent decades. The Reputation Institute, a leading consulting and advisory firm on reputation, has noted that the pharmaceutical industry reputation score is 67.6, which is an “average” score. Anything from 70-79 is considered “strong,” and an excellent is a score of 80 or above. However, they also note that the industry reputation is very

polarized, with roughly one-third of respondents viewing the industry as having an excellent reputation, and another third perceiving it as weak or poor.<sup>127</sup> This is not only an American problem, but it is a global phenomenon. The reputational decline coincides with a 2013 PatientView survey of mainly European patients in which only 30% of those surveyed rated pharmaceutical companies as good, a 7 percentage point decline from the previous year. Among the reasons cited for the downward shift in opinion included: offering drugs with only short-term health benefits, not doing enough to discover chemical entities suitable for neglected patient groups, a perceived lack of transparency of pharmaceutical companies, and drug prices that, in some cases, are still unaffordable to many patients or their payers.<sup>128</sup>

While the pharmaceutical sector struggles to regain a positive public image, it must be stressed that a company's reputation is vital. A recent study estimates that it is the intangible assets of a company, including reputation, that currently represent as much as 40-60% of a company's market capitalization, leading to the conclusion that a company's reputation is among its most valuable assets.<sup>129</sup> Pharmaceutical and biotechnology research needs the cooperation and participation of large segments of society, and citizens need confidence that researchers are working for the benefit of the population. When the public reads of issues of scientific misconduct or what they perceive to be "greed" and working adversely for the population's benefit, societal trust in research is undermined. Greed is simply a bad way of doing business, especially when it makes people oblivious to the suffering of others. Indeed, such behavior is at odds with civic virtue. A society or business that seeks to press for maximum advantage and exploit their neighbors in order to make windfall profits is not praiseworthy.<sup>130</sup> Indeed, science and technology cannot flourish without societal trust, which is one of the reasons global bioethics is expanding.<sup>131</sup>

Generally, public confidence in business is low, and the public's scrutiny of business is high.<sup>132</sup> This may be even more so for the pharmaceutical industry that has been tied to dubious marketing practices, excessive policies, and the flaunting of regulations and law. Corporate reputation depends on the past experience that persons have had with a company and the extent or nature of their communication with it through the media and conversation. For companies in the pharmaceutical and biotechnology sector, how stakeholders view companies is influenced largely by the lay professional media (print, TV, radio, online) and the internet (blogs and social media).<sup>133</sup> Hence, the pharmaceutical industry reputation appears to be an amalgam of perception by its different stakeholders, including investors and patients, as well as the reality of its policies, practices, systems, and performance.<sup>134</sup> Yet, reputation is at the very heart of a business, especially one that is so closely aligned with personal welfare of the public, such as the pharmaceutical industry. The reputation problem facing the pharmaceutical industry is currently too sizeable for any one company to address alone. The industry must work together to rebuild trust.<sup>135</sup> This restoration will not be an easy task. Some research indicates that it takes an average of 3.5 years for a company to restore a declining reputation.<sup>136</sup> For an industry like the pharmaceuticals business, the timeline may be greatly protracted. Transparency, as has already been advocated, will need to be high on the priority list in order to accomplish this. This will be explored in further in the subsequent subsection in which manners of restoration are explored in detail.

Up to this point it has been shown that pharmaceutical and biotechnology companies suffer from a CSR and reputation crisis that is largely a result of pricing troubles. Many commentators have made the case that the industry cannot merely be concerned for their own profit margins to the neglect of the very people who depend on their medications. That is, the

business decisions of pharmaceutical companies directly impact human health, which makes CSR particularly important.<sup>137</sup> Prominent NGOs and international groups such as UNESCO, Oxfam, Save the Children, and Voluntary Service Overseas, have challenged the pharmaceutical industry to adopt a broader scope of responsibility and improve its efforts to tackle the health crisis affecting LMICs.<sup>138</sup>

Global bioethics, and a tool such as the UNESCO Universal Declaration on Bioethics and Human Rights is a powerful instrument to involve multiple stakeholders in shared concerns and approaches. The availability of a global ethical framework that takes into consideration viewpoints from all UNESCO member states presents an excellent opportunity to rebuild trust and a positive reputation for pharmaceutical and biotechnology companies. Particularly, private companies need to rebuild the trust of society because of issues of accessibility of healthcare and affordability of medical treatment. There is generally no qualm from society that the pharmaceutical industry be concerned for profits, for they are not charities.<sup>139</sup> There is concern that they also have regard for social issues. Transparency will be a first step, but to increase reputation and regain societal trust, more will be required.

As presented in section 3.1, Article 14 of the UNESCO UDBHR directly addresses social responsibility. Responsibility in Article 14 does not refer to the personal responsibility of individuals, but rather to the responsibility of an individual as a member of society. Such a view entails that many actors are responsible for promoting health, not only governments.<sup>140</sup> It is similarly the responsibility of private enterprises such as pharmaceutical and biotechnology companies. Indeed, every industry activity implies social responsibility. Businesses must manage working conditions, interface with how they affect the environment, set pricing for drugs that either make the drug accessible or not, and so forth. The globalization of the healthcare industry

has made these responsibilities more evident.<sup>141</sup> The policies and practices enacted by multinational corporations have the potential to affect millions of people, and the normative argument that companies have the onus of preventing or remediating negative effects of their activities for health places emphasis on the notion of corporate social responsibility.<sup>142</sup> Hence, the notion of social responsibility does not let companies operate under the belief that their decisions do not have impacts on countless individuals. Rather, social responsibility stresses that all sectors—public and private—are to view the protection and promotion of health as a shared societal responsibility.

Pharmaceutical and biotechnology companies have utilized programs of CSR for a variety of causes.<sup>143</sup> However, these companies have been critiqued by some for only attempting to repair compromised public beliefs about their perceived unethical commercial endeavors.<sup>144</sup> That is, if a major pharmaceutical company were to offer free vaccines for the children of a specific developing country, and to do so as the pivotal message of an advertising strategy, then an unavoidable conclusion might be that in many circumstances, the protection and promotion of health are merely the means a company uses to obtain something else (approval, loyalty, trust, readiness to buy) much more than a goal as such. While there may be merit to some of the criticism regarding motivations, this is not enough to dismiss the principle of CSR. Even the most instrumental application of the practices stemming from the principle of social responsibility is not a justification to reject the principle for, quite the reverse, it underlines its importance and the potential extensiveness of its effects.<sup>145</sup> Hence, whether a company performs responsible acts to enhance their prestige or out of undiluted altruism, this matters little as long as the responsible decision is made and the act realized.<sup>146</sup>

As a healthcare industry, many have insisted that drug companies cannot merely be concerned for their own profit margins to the neglect of the very people who depend on their medications. That is, the business decisions of pharmaceutical companies directly impact human health, which makes corporate social responsibility particularly important.<sup>147</sup> UNESCO, agreeing with the assessments made by the non-governmental organizations (NGOs) Oxfam, Save the Children, and Voluntary Service Overseas, challenges the pharmaceutical industry to adopt a broader scope of responsibility and improve its efforts to tackle the health crisis affecting LMICs.<sup>148</sup> A socially responsible company, so the reasoning goes, ought to have policies in place on access to treatment for LMICs which include the following five priorities: 1) pricing, 2) patent, 3) joint public private initiatives, 4) research and development, and 5) the appropriate use of drugs.<sup>149</sup>

An obligation for CSR rests upon certain claims about businesses having moral responsibilities. It is argued that all businesses are shaped by and depend upon social values, such as honesty, integrity, fidelity, and fairness. Values play a pivotal role in creating a climate within and among companies for conducting business, and without these values in place, corruption, theft, fraud, and various other ethical problems would make it impossible to do business. Hence, businesses recognize the importance of ethical conduct. Many people would accept the premise that moral values play an important role within business, but they might argue that they do not play a role in the interaction between businesses and the larger society in which they operate. However, David Resnik have argued that businesses have societal responsibilities because they exist within societies where people care about the environment, public safety, public health, and other goods. Resnik contends there are at least two reasons why businesses have social responsibilities: 1) Businesses that ignore their social responsibilities may face the

public's wrath. For example, a company that recklessly pollutes a river will have to face the backlash for it. Therefore, social responsibility makes good business sense. 2) Corporations are like moral agents in that they make decisions that have important effects on human beings. If corporations are like moral agents, then they have some of the same duties that apply to other moral agents. In particular, corporations have obligations to avoid causing harm and to promote social welfare and justice.<sup>150</sup>

Applied to the pharmaceutical industry, Resnik asserts that large, global pharmaceutical companies have social responsibilities to LMICs based upon the principles of beneficence and justice. Regarding beneficence, pharmaceutical companies should seek to promote the greatest balance of benefits and harms for society. Concerning justice, pharmaceutical companies should distribute benefits and burdens equitably. One way that pharmaceutical companies, Resnik claims, may exercise these responsibilities to LMICs is by investing in research and development related to diseases that affect LMICs, offering discounted drug prices, and initiating drug giveaways.<sup>151</sup>

However, Resnik's analysis is certainly not without its critics. Norman Daniels has taken issue with Resnik's formulations, and he posits that social moral responsibilities do not derive from what society cares about, as Resnik believes, but rather they are the result of a kind of social contract that establishes them. Further, Daniels takes issue with Resnik's claim that businesses have social responsibilities because they are like moral agents. However, Daniels' principal assertion is the skepticism he expresses regarding a reliance upon appeals to moral social responsibilities as a solution to the problem of affordable drugs. To make his case, Daniels points to the fact that developing countries have regularly ignored intellectual property rights and taken drug production into their own hands because global pharmaceutical companies have



rarely exercised their social responsibilities. Daniels concludes that the solution to affordable drugs for developing countries lies in domestic and international regulatory action to regularize the contributions of pharmaceutical companies towards meeting the needs of those developing countries.<sup>152</sup> While regulation may be an appropriate action, Daniels does not elaborate at all on how such action would be accomplished.

In a 2004 article in the prominent newsmagazine *The Economist*, the author raises many doubts about CSR. Subscribing to a classic view that the proper role of businesses is to only show concern for the profits of shareholders, the article emphasizes, “From an ethical point of view, the problem with conscientious (as opposed to fake) CSR is obvious: it is philanthropy at other people’s expense.” While the author acknowledges that CSR may be good for profits, it is also much too quick to label CSR as unethical.<sup>153</sup> Rather than engaging in a serious conversation about the merits and snags of CSR, the author ends up sounding dismissive. We must be cognizant that business practices not only affect investors and employees but also persons in numerous sectors of society. Nevertheless, this classic reasoning about businesses only showing regard for their direct shareholders is commonplace, and it is a view that Freeman, Drucker, and others, such as the UNESCO UDBHR, have sought to counter.

Thus far in this analysis the CSR and reputation problems experienced by the pharmaceutical and biotechnology sector have been analyzed. It has been argued that much of the woes of the industry stem from the public viewing these companies as simply concerned with profits and not people. This is a major issue for pharmaceutical and biotechnology companies, and if companies are to engage CSR seriously, implementation mechanisms must be thoughtfully considered. In the below, the possibility of using price differentiation for pharmaceuticals will be analyzed and then the use of social pressure as a way to instill change will be assessed.

One manner of combating prohibitive prices would be to reach agreements with the pharmaceutical industry on a voluntary price differentiation between HICs and LMICs, allowing the latter to pay only production costs and not the hefty research and development costs.<sup>154</sup> Price differentiation (also called differential pricing, equity pricing, or preferential pricing) is a promising approach for access to expensive medications in LMICs. In such a schema, HICs would pay more for drugs, while LMICs would only pay production costs and not the cost of research and development. Hence, prices are set in such a way that reflects a country's ability to pay, as measured by level of income.<sup>155</sup> To put an example in real terms, the Danish company Novo Nordisk, for instance, sells their products for 20% of the price they charge developed countries in the least-developed countries of the world. The principle behind this is to keep the value of the drug. If they were purely to give it away, they claim, it makes the drug valueless, and it also would not respect the hard work of the employees of Novo Nordisk who developed these products.<sup>156</sup> Differential pricing allows pharmaceutical companies to signal that their pricing policies are socially responsible and consistent with their obligations to society and not merely geared towards maximizing their profit.<sup>157</sup>

It may be surprising to learn that there is considerable variation in the retail price of a drug, not only among countries, but even within a country. Factors such as import tariffs, taxes, and various mark-ups depending if the drug is sold retail or wholesale also contribute to these differences. Organizations such as the WHO have called for differential pricing to become standard operating procedure for pharmaceutical and biotechnology companies.<sup>158</sup> The aim of such a program is quite clear: to enable LMICs to access essential drugs that would normally be at too high a price point for their population to access. Further, one of the factors that the Access to Medicine Index scores is the area of "Pricing, manufacturing, and distribution". More

companies are now using a tiered pricing structure, yet the overall effect on affordability of drugs remains unclear. Hence, transparent data about just how affordable a company's products are in a LMIC is needed.<sup>159</sup>

However, it is not surprising that the pharmaceutical industry has historically been, in general, opposed to such widespread appeals, for it would remove the pricing of drugs from the free market. As recently as 2002, the US pharmaceutical industry trade association, known as PhRMA, robustly defended free-market economics for pharmaceuticals. Yet, one need not even be a vehement critic of capitalism to doubt the assertion that every marketable good has a price, and the price is set by a free-market economic system.<sup>160</sup> However, pharmaceutical business models are gradually changing to incorporate aspects of social responsibility that include affordable pricing. This is not a short-term outcome but is a long-term schema. Nonetheless, some businesses are realizing that the public and shareholders no longer see improving access to essential medicines for LMICs as simple philanthropy but rather as another sustainable way to do profitable business.<sup>161</sup>

Many pharmaceutical companies have adopted price differentiation policies, and the 2014 Access to Medicine Index notes that, compared to 2012, more companies have committed to or newly engage in equitable pricing, tailoring their prices to different population segments. However, the Index also brings words of admonishment to the pharmaceutical industry for lacking universal pricing guidelines for their sales agents. The majority of companies, as the Index notes, have yet to set clear, universal pricing guidelines for their sales agents in countries, and most do not monitor mark-ups. Further, even where guidelines are in place, no company trains its agents on their implementation, and no company has guidelines that universally apply to third-party distributors, wholesalers and retailers.<sup>162</sup> Hence, as can be seen, price

differentiation is an area in need of additional work. For companies to take the moral duty of social responsibility and health sincerely they must address these concerns.

Critics of these proposals will surely form an argument based upon economics. While this is primarily an ethics analysis, the economics of this situation are hard to evade. To emphasize, the concern for CSR presented in this analysis does not imply that pharmaceutical companies should simply become charities that distribute their products at a loss or for meager profits. Long-term stability of the pharmaceutical industry does depend heavily upon substantial profits. Yet, this paper has argued that the industry as a whole must seek to more appropriately balance their concern for profit with an equal consideration of the importance of social responsibility and justice.

Indeed it must be noted that there may be negative side effects of interfering in the pricing structures of pharmaceuticals. The classic critique is that a decrease in profits will inevitably lead to a decrease in research and development spending, which will, in turn, decrease innovation. George Scangos, CEO of American biotechnology company Biogen, has flatly stated that interfering in drug prices will slow the development of pharmaceuticals and biotechnology products.<sup>163</sup> Further, shareholders will not go for such a course of action. Admittedly, it is difficult to define what a reasonable level of profitability would be for a drug. However, one has only to look at the pricing scandals discussed in the introductory sections of this analysis to note that there are issues that need addressing systematically. Klaus Leisinger has been prominent in the area of pharmaceutical social responsibility by balancing it with realistic forethought about pricing and intellectual property rights. While not getting into specific economic recommendations, he does argue that private enterprises, such as pharmaceutical firms, have neither the societal mandate nor the capabilities to provide healthcare to the sick throughout the

world. Nevertheless, private enterprises do have some responsibilities to society if they are to be good corporate citizens.<sup>164</sup> Those with expertise in pharmacoeconomics and finance will need to determine the financial viability of enhanced CSR, for this is largely outside the scope of this ethics analysis.

For a global solution of pharmaceutical social responsibility in regards to pricing to become reality, an emphasis on social pressure may be the most beneficial means of achieving the desired end. Social pressure on companies to change their practices has certainly worked before. John Ruggie, professor at the Harvard Kennedy School and chief drafter of the UN Guiding Principles on Business and Human Rights, has noted that businesses require not only a legal license to operate but also a social license. Nike is a case example of this when they came under harsh social pressure in the 1990s due to low wages and abusive working conditions in their overseas production facilities. After initially denying their responsibility, Nike accepted its obligation to their offshore workers and eventually became a founding member of the UN Global Compact.<sup>165</sup> Social pressure has also been effective on the pharmaceutical industry itself. Oxfam and Médecins Sans Frontières (MSF) joined forces at the turn of the millennium to cut drug prices for LMICs.<sup>166</sup> MSF has witnessed particular success in its campaign, which has involved monitoring the patent barriers, prices, and availability of antiretroviral medication, as well as pushing for the adoption of policies that promote access to affordable drugs. Due to their pressure and generic competition, the price of antiretroviral drugs has dropped by more than 99% over the last decade.<sup>167</sup> These experiences could be repeated for a more systematic reduction of pricing in both HICs and LMICs. A compelling campaign for responsible pricing by a similar NGO may prove persuasive to raise societal awareness and sway companies into concrete action.

A less likely example of social pressure might take the form of a pharmaceutical or biotechnology company taking the lead on CSR to be a pioneer in their sector. Such a company might have a particularly high commitment to the principles found in research ethics guidelines or they simply may desire the positive public relations that they would reap. Media interest would assuredly be piqued if a pharmaceutical company decided to routinely campaign for and enact internal policies on responsible pricing. Regardless of the motive, the company would have a high degree of transparency and display how they are attempting to be socially responsible, and they would endeavor to hold similar companies accountable. Such a scenario coming from within the industry would be a unique contribution to the field of social responsibility, as most reporting mechanisms come from external sources. Indeed, highlighting this method is the chief purpose of this dissertation. A pharmaceutical or biotechnology firm could take the UNESCO UDBHR as a starting document and create measurable indicators and benchmarks from it to ascertain both qualitatively and quantitatively how they are doing in fulfilling the principles. This will be much further examined in chapters five and six.

CSR on a large scale has been promoted by the UN in the Global Compact, an initiative launched in 2000 to encourage companies towards doing business in a responsible manner and taking actions to advance broader societal goals that brings together over 12,000 signatories in 170 countries. Through its ten principles on human rights, labor, the environment, and anti-corruption, the Global Compact aims at committing companies to a non-binding agreement with the objective of corporate sustainability and taking actions that advance societal goals. The Global Compact is a unique initiative for the breadth and volume of companies who have become signatories to it. Through encouraging its partnering companies to operate responsibly and take actions that support society, the Global Compact works to ensure that business activity

adds value not only to the bottom-line, but also to people, communities, and the planet. In fact, creating measureable benchmarks to ascertain how a particular firm is doing in regards to fulfilling the principles of a global document is not so far-fetched, as such a project has already been undertaken on the Global Compact.<sup>168</sup> Signatories to the Global Compact must submit an annual Communication on Progress to disclose how they are attempting to implant the ten principles into their practices. Indeed, in the area of global health, many pharmaceutical companies now have designated units for incorporating corporate social responsibility, such as the UN Global Compact principles, into their business policies and practices.<sup>169</sup>

We must remember that the Global Compact is voluntary, non-binding, and is primarily driven through peer or social pressure, social norms, and potential benefits to the company through positive public relations.<sup>170</sup> While the majority of the foremost pharmaceutical and biotechnology companies have committed to Global Compact and its ten principles, there are certainly differing levels of compliance. Additionally, the Global Compact was not specifically designed for the pharmaceutical or biotechnology sector; it is much too broad. Therefore, while Global Compact has proven effective at getting companies to sign on to broad corporate sustainability principles, a more specific compact for those companies involved in the healthcare sector, and the social pressure for companies to join it, might be an appropriate step towards responsible pricing. Creating such a platform based upon the UDBHR from within the industry with a way to measure and self-assess how different firms are doing in fulfilling the principles may be a good step for the industry. While this is no guarantee of reaping reputational benefits as a result, it does seem that such a step would be looked upon favorably by outsiders.

Social or peer pressure can also come from external sources, such as the Access to Medicine Index, Dow Jones Sustainability Index, or Bioethics International. An underlying

notion of these indexes is that sustainability and social responsibility practices constitute a potential component for long-term value creation from which shareholders will benefit.<sup>171</sup> Further, such external bodies aim to publish publicly accessible reports on how pharmaceutical companies are doing in specific areas. For example, the Access to Medicine Index, published every two years, ranks pharmaceutical companies' efforts to improve access to medicine in developing countries. The Index is built upon an interesting supposition: simply 'naming and shaming' companies in the pharmaceutical industry does not encourage change. Instead, good practice needs to be recognized within the pharmaceutical industry that shows which companies do the most to improve access to medicine and how. The biennial reports of ATMI seem to indicate that pharmaceutical companies do change their practices when under this type of scrutiny. Similarly, DJSI, launched in 1999, was the first global sustainability benchmark. DJSI tracks the stock performance of the world's leading companies in terms of economic, environmental, and social criteria. According to DJSI, the data they provide serve as benchmarks for investors who integrate sustainability considerations into their portfolios, as well as providing an effective engagement platform for companies who want to adopt sustainable best practices.<sup>172</sup> Hence, social or peer pressure may include such external bodies taking a more robust role in helping to change the pricing policies of pharmaceutical and biotechnology companies.

This analysis has examined the notion of social responsibility and health and has kept the issue at the forefront for pharmaceutical and biotechnology companies as a way to repair society's trust and restore a positive reputation. Reputation is key for a company, and what may matter more than anything is the specific acts of a company. Ian Read, CEO of Pfizer, has remarked, "Making reputation and respect all the more important to us is knowing that we gain it in drops, but lose it in gallons".<sup>173</sup> Read, and surely others in the industry, understands that their



reputation is at stake by what they do. Hence, for the pharmaceutical and biotechnology sector to regain societal trust and restore a positive reputation, steps need to be taken. Though there are many areas in which the industry can improve upon in order to act responsibly and take seriously a call to social responsibility and health, this section will focus on issues of transparency and the need for companies to be very vocal about what the company is doing to act responsibly.

Transparency has been focused on at various points in this analysis because of its importance. Transparency is a vital ingredient for building merited trust in the pharmaceutical sector and their work. The public must feel that they can trust a company and how they price their products. As complaints grow about astronomical drug prices, pharmaceutical and biotechnology companies are coming under pressure to disclose the research and development costs and profits of those drugs, as well as the rationale for charging what they do.

Pharmaceutical cost transparency bills were introduced in at least six state legislatures in 2015, aimed at making drug companies justify their prices, which the industry often attributes to high research and development costs.<sup>174</sup> Such legislation, if enacted, may prove successful at forcing the hand of pharmaceutical companies to reveal such data about pricing. Yet, this is not likely to help the reputation of the pharmaceutical sector, for what would be more desirable would be pharmaceutical and biotechnology companies freely offering this information rather than doing so involuntarily.

In practical terms, transparency may also involve more information about what a company is doing in regards to CSR. Most major pharmaceutical and biotechnology companies have some form of CSR department. Yet, to demonstrate that CSR is more than an exercise in merely public relations, companies will need a clear, comprehensive policy on the subject, which include measurable targets that are implemented and reported on by a board.<sup>175</sup> Many companies

have signed onto a document such as the UN Global Compact and include a report on their progress to implement the ten principles, which is a matter of public record and readily accessible on the Compact's website. However, many of these reports are not highly detailed and lack depth and clarity of what a company is practically doing to implement human rights and social responsibility into their company ethos.

Business transparency will also include data transparency. For years, drug companies have been accused by the public of reckless disregard for patient safety.<sup>176</sup> The antidepressant Paxil (paroxetine) was introduced by GlaxoSmithKline (GSK) in 1992 and soon became a blockbuster drug for the company. Yet, it was found in the years since that GSK had performed outcome switching in the clinical trials for Paxil, a procedure in which the questions that a scientific study was initially set up to answer are swapped part way through for a different lot. Very little data showed that Paxil was any better than the placebo, yet it was marketed as a breakthrough in depression medication. In 2012 the company was fined \$3 billion USD by American authorities for misrepresenting data on a variety of drugs, one of which was Paxil.<sup>177</sup> Such misrepresentation of data is commonplace.<sup>178</sup> While some attempts have been made for greater sharing of data, the industry as a whole has not embraced data sharing with open arms. In 2013, drug company AbbVie filed a lawsuit (which has subsequently been dropped) to halt the European Medicines Agency from releasing clinical trial data for its chemotherapy and immunosuppressant drug Humira (adalimumab). The pharmaceutical industry argues that proprietary business information needs to be protected; yet withholding safety data that could affect clinical decision-making is inexcusable. The sustained lack of data transparency gives volumes of credence to critics and the public that drug companies have lost their ethical compass.<sup>179</sup>

A second area for pharmaceutical and biotechnology companies to focus on in order to restore their reputation is to be very vocal about the good they are trying to do. History is littered with examples of companies that addressed social issues and, in turn, received reputational benefits. The case of Nike, already presented above, is an example of this.<sup>180</sup> The pharmaceutical industry needs to effectively communicate how it has reformed unethical practices so that the public is assured that past underhanded practices will not be repeated.<sup>181</sup> Further, if a company finds an ethical remedy to a problem that works, these best practices should be shared so that other players in the industry can be involved as well. Being more vocal about altruistic activities, such as philanthropic drug or vaccine access programs, benefit sharing, the embrace of environmentally friendly technologies, or other forms of assistance may go far in countering the public's image of the greedy pharmaceutical company.<sup>182</sup>

International solidarity and cooperation may also be a necessary component of attaining the vision of social responsibility. The challenge of a global social responsibility for health may entail a willingness to improve the sharing of resources, standards of education, and policies oriented to ameliorating the negative social determinants of health. Stefano Semplici has written that this may entail attempting to reverse the brain drain of skilled health and research professionals from LMICs to high-income countries.<sup>183</sup> While a difficult undertaking, the populations of LMICs are served well by highly skilled professionals, so it would be prudent for governments to seek to retain these specialists. Such retention may not be cheap, but it would be prudent and in the best interest of the people. While none of these recommended courses of action are foolproof systems to ensuring social responsibility in global health, further research into enacting these via policy or other means may be sound guidance. Surely the majority of this

is not novel, but some of these courses of action may need to be enhanced to see social responsibility for global health to come to fruition.

For pharmaceutical and biotechnology firms that are regularly involved in research and development, a manner that should be considered, as mentioned above, is using the UNESCO UDBHR as a standard-setting tool in research ethics. The UDBHR, as a global ethics document with the adoption of some 190 UNESCO Member States, is well positioned to aid the pharmaceutical industry in ethics. Again, such an initiative would have the most force if it were begun from inside the industry rather than from an external agency. Further, as a global document operating at the global level, the UDBHR attempts to take into account the perspectives of Western and non-Western states, HICs and LMICs, alike. Surely this is no guarantee that the industry's or a specific firm's reputation would increase as the result of such a platform. However, this does seem like a sensible way to attempt a resolution.

In conclusion, this chapter has presented corporate social responsibility in the pharmaceutical and biotechnology industry. Section 3.1 discussed the topic of social responsibility in global health and bioethics. It was argued that the notion of social responsibility and health combine the following two basic ideas: 1) Many actors, not just governments, have a responsibility towards health. 2) Global problems reflect common challenges, and thus, should be addressed by common action. Further, the principles of solidarity and cooperation were examined as crucial for social responsibility and health. Finally, the role of social responsibility in the UNESCO UDBHR was examined in 3.1. In section 3.2, corporate social responsibility specifically applied to the pharmaceutical and biotechnology industry was analyzed. This section began by noting several major pharmaceutical pricing scandals and the resulting impact this has had upon the reputation of the industry. The major positions on CSR were examined, and several

critiques of CSR were offered. The section concluded by offering the possibility of using price differentiation for pharmaceuticals and the use of social pressure upon companies as manners of instilling change.

Social pressure is a very promising idea to combat high pharmaceutical prices and to embed CSR further within the pharmaceutical and biotechnology industry. Social pressure has worked before, such as the case of Nike presented above. However, while external social pressure is certainly of value, having this type of pressure come from within the industry itself would be ideal. For pressure to come from within the industry rather than externally may be superior because it would send a strong message to the public and stakeholders that the industry has heard their cries for change, understands its problems, and has sought to remedy its issues. The global bioethics tool, presented further in this dissertation in chapters 5 and 6, aims to achieve such a goal by creating a collaboration of pharmaceutical and biotechnology companies that wish make a change within the industry and position themselves as leaders of pharmaceutical and biotechnology CSR. As the UNESCO UDBHR includes a principle on social responsibility, and as it was approved the governments of the world, it is well positioned to be the ethics document from which to build consensus on bioethical CSR issues for the pharmaceutical and biotechnology industry.

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## Endnotes

<sup>1</sup> Significant portions from section 3.2 were originally published as: Daniel J. Hurst, “Restoring a reputation: invoking the UNESCO Universal Declaration on Bioethics and Human Rights to bear on pharmaceutical pricing,” *Medicine, Health Care, and Philosophy* 20, no. 1 (March 2017): 105-17. Springer has graciously granted permission to use the text within the context of this dissertation.

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<sup>6</sup> Thomas Aquinas, *Summa Theologiae*, II-II, 66, “Of Theft and Robbery,” Question 7, accessed August 9, 2016, available at: [http://www.ccel.org/ccel/aquinas/summa.SS\\_Q66\\_A7.html](http://www.ccel.org/ccel/aquinas/summa.SS_Q66_A7.html)

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[http://www.who.int/social\\_determinants/sdh\\_definition/en/](http://www.who.int/social_determinants/sdh_definition/en/)

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## Chapter 4: Analysis of Current Bioethics Guidelines and Governance

Chapter four examines the bioethics guidelines that have been produced since the end of World War II and the role of governance in bioethics. The purpose of such an undertaking is to analyze the evolution of bioethics guidelines, note where there are areas of convergence and divergence between documents, and to introduce the UNESCO Universal Declaration on Bioethics and Human Rights as well situated to be the foundation of the global bioethics tool. While no guideline is perfect, and changes occur within medicine, technology, and society to prompt changes to guidelines, the UDBHR, based upon a moral human rights framework and broad enough to cover many social dimensions of bioethics, is appropriate for the task of creating a global bioethics tool to unite pharmaceutical and biotechnology companies around ethical principles. Section 1 attempts to move chronologically through the major ethics guidelines of the twentieth and early twenty-first century. Section 4.2 then introduces the UDBHR in detail and makes an argument for why it is used as the foundation of the proposed global bioethics tool. Finally, section 4.3 examines the role of governance in bioethics, examining the various forms of accreditation, certification, and rating.

### *4.1) Ethics Guidelines: 1947—Present*

Since World War II, a number of prominent bioethics guidelines have been produced, almost exclusively by a Western commission, leading to the conclusion by some that modern bioethics predominantly reflects the traditions of Western moral philosophy and political and social theory.<sup>1</sup> Many guidelines for the ethical conduct of research with human have been produced as the result of misconduct and scandal.<sup>2</sup> Some of these guidelines address a narrow aspect of bioethics, some have a degree of governmental authority, some are issued by non-governmental organizations, and others are advisory.<sup>3</sup> Much regulatory guidance tends also to

have a specific purpose, such as the International Conference on Harmonisation, which has the purpose of generating shared policies across HICs for the “registration of pharmaceuticals for human use.”<sup>4</sup> The following table depicts the selected guidelines that will be discussed within section 4.1. These guidelines have been selected as they represent monumental landmarks in the field of research ethics.

<b>Guideline</b>	<b>Issuing Body</b>	<b>Year Issued, Revised, and/or Amended</b>
Nuremberg Code	Nuremberg Military Tribunal decision in <i>United States v. Brandt et. Al</i>	1947
Declaration of Geneva	World Medical Association	1948; revised: 1968, 1983, 1994, 2005, 2006
Declaration of Helsinki	World Medical Association	1964; revised: 1975, 1983, 1989, 1996, 2000, 2008, 2013; notes of clarification: 2002 and 2004
Belmont Report	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	1978/79
45 CFR 46 (Common Rule)	US Department of Health and Human Services (DHHS) and 16 other US federal agencies	DHHS guidelines: 1981 Common Rule: 1991
International Ethical Guidelines for Biomedical Research Involving Human Subjects	Council for International Organizations of Medical Sciences	1982; revised: 1993, 2002, 2016
Good Clinical Practice	International Conference on Harmonisation	1996
Resolution 196/96: Rules on Research Involving Human Subjects— Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention)	Council of Europe	1997

In this section, in order to make a concise and well-analyzed argument for the utilization of the UNESCO Universal Declaration on Bioethics and Human Rights as the grounding for the global bioethics tool, these aforementioned bioethics guidelines will need to be systematically analyzed, their strengths and weaknesses analyzed, and conclusions drawn as to why they are less suited for the task of a global bioethics tool than the UNESCO Universal Declaration on Bioethics and Human Rights.

The Nuremberg Code, as has already been presented earlier, was a product of the aftermath of World War II and the Nuremberg Military Tribunal decision in *United States v. Brandt et. Al*. The Nuremberg Code has been a staple of research ethics since its inception. However, it has often exerted more rhetorical invocation, owing in part to its historical significance, rather than actual practice. This may be due to its blanket prohibition of any research that is not voluntary or for its lack of interpretive or enforcement mechanism.<sup>5</sup> To be sure, the Nuremberg Code was a reaction against the grave violations committed against humankind in the name of “science”, yet to insist “the voluntary consent of the human subject is absolutely essential” seems too far.<sup>6</sup> This would prohibit much pediatric research, research on dementia patients, and would totally exclude any sort of proxy consent. Nonetheless, the Nuremberg Code was a very fine guideline for its day and age, though it may have overly reacted due to the atrocities of WWII. While the Nuremberg Code was in many ways the beginning of medical ethics guidelines, many would follow.

The World Medical Association (WMA), also in response to the crimes committed by the physicians and scientists during WWII, issued a code of medical ethics in September 1948 that was known as the Declaration of Geneva. It was envisioned as a modern update to the Hippocratic Oath and intended to be sworn by physicians upon admission to the medical

profession.<sup>7</sup> The Declaration of Geneva is still in use today and has been revised five times, in 1968, 1983, 1994, 2005, and 2006.<sup>8</sup> From its genesis, the Declaration of Geneva code proved very ambiguous and difficult to interpret.<sup>9</sup> The extent to which the declaration is disseminated and utilized as an oath by physicians entering into the medical profession varies greatly by country, and its total usage by new doctors entering the profession is not adequately known. In many regions of the world, the declaration is not recognized as a contemporary successor to the Hippocratic Oath.<sup>10</sup>

The more prominent and well-respected ethics guideline produced by the WMA is the Declaration of Helsinki (DoH). Originally adopted in June 1964, it has since undergone seven revisions, tripling its original size, with the most recent version being approved in 2013.<sup>11</sup> The DoH is very prominent in the field of research ethics, arguably the most widely known and influential in the field. Indeed, perhaps the largest strength of the DoH is its current standing as the most well known guideline on medical research ethics. The DoH has enjoyed international status placing it over and above national legal and policy issues in certain cases. Other notable strengths of the declaration include the importance it places on balancing risk and benefit, attempting to define the moral status of clinical research, and its considerations of justice for patients, subjects, and entire populations.<sup>12</sup>

While there are certainly numerous strengths to the DoH, a number of weaknesses exist and reasons for why it is less suitable than the UNESCO UDBHR to be used as the foundational guideline for the global bioethics tool. Richard Ashcroft has noted that every version of the DoH has contained contradictions, vague formulations, and controversial elements.<sup>13</sup> Physician-bioethicist Ezekiel Emanuel takes the criticism of the 2013 DoH even further by charging that there are at least nine distinct problems with the current version: 1) it has an incoherent structure,



2) it confuses medical care and research, 3) it addresses the wrong audience, 4) it makes extraneous ethical provisions, 5) it includes contradictions, 6) it contains unnecessary repetitions, 7) it uses multiple and poor phrasings, 8) it includes excessive details, 9) and it makes unjustified, unethical recommendations.<sup>14</sup> Emanuel also takes issue with the frequency with which the DoH is revised, approximately every six years, as he sees this as fostering sloppiness in the drafting process and undermining the legitimacy and goals of the declaration. Such glaring revisions include putting forward certain ethical requirements such as the use of placebos and post-trial access—and then later revising and minimizing their reach, which seems to be an admission that the original claims were erroneous.<sup>15</sup>

Furthermore, certain human rights groups have accused the DoH of diluting universal ethical standards of care by permitting placebos to be used on research subjects in LMICs rather than the best-proven treatment, which is a tremendous cost savings to the trial sponsor. Critics accuse that such dilution is tantamount to a double standard, purely based on economics, convenience, and efficiency. Nonetheless, Aurora Plomer has defended the use of the DoH above the UDBHR on two questionable grounds: 1) the uncertain status of the UNESCO UDBHR as a source of international law; and 2) professional codes of practice, particularly the DoH, play an essential role in ensuring that fundamental human rights are respected.<sup>16</sup> In response to Plomer, it is uncertain as to why she questions the status of the UDBHR as a source of international law. First, the UDBHR does not itself anywhere claim to be binding law. Further, it has been adopted by all UNESCO Member States and each state is then free to create from it their own national laws. In the UN system, declarations act like recommendations but are named as such due to their importance. Declarations are adopted during the General Conference of a specialized UN agency, such as UNESCO, and governments who adopt them agree (at least in principle) to

implement them in their own countries. While they are part of the body of what is known as “soft law” (body of laws that is intended over the long run to produce binding rules), they contribute to the expansion of positive law and provide the public with a tool to drive their governments to act.<sup>17</sup>

Yet, Plomer writes, “The UDBHR does not as yet have the status and authority of a legally binding document in international law.”<sup>18</sup> This is a true statement and neither UNESCO nor anyone else to my knowledge has made such an argument. Further, while a true statement, the very same could be said of the DoH—that it does not yet have the status nor the authority of legally binding international law. Countries may enshrine the DoH into its legal codex, but the document itself, and perhaps more specifically the WMA, have no power to produce international law. Hence, this is not a valid argument. Contrary to Plomer’s criticism, UNESCO has been successful in creating several national bioethics committees in a number of countries, promulgating core bioethics curriculum in universities around the globe, and helping to enact ethically relevant legislation in various Member States.<sup>19</sup> To date, ethics committees have been put in place and continue to be supported by UNESCO in 17 countries, and several other countries from various regions of the world have approached UNESCO to create similar institutions.<sup>20</sup>

Plomer’s second contention for why the UDBHR should not supersede the position of the DoH is that professional codes of practice, particularly the DoH in her view, play an essential role in ensuring that fundamental human rights are respected. There is no argument here. From the very origins of bioethics guidelines, beginning with the Nuremberg Code, human rights has been intertwined with bioethics. Indeed, the chief purpose of the Nuremberg Code was to protect the fundamental human rights of patients and research participants. Hence, the argument that

professional codes of conduct play an important role in ensuring the respect of fundamental human rights does not place the DoH on any greater footing than the UDBHR, because the UDBHR similarly plays an essential role in ensuring that fundamental human rights are respected. Therefore, under close scrutiny, the arguments Plomer uses for why the DoH should not be abandoned in favor of the UDBHR do not seem to hold up.

Future versions of the DoH need to offer justification for why previous editions are being revised. Further, the DoH should establish universal, minimum standards without which research is unethical and cannot be conducted. National laws, regulations, and other guidelines should decide on the specification and application of these broad principles, not the DoH itself. Hence, the universal document could then be tailored to local circumstances by specification in the laws of individual countries. Emanuel has stated correctly that in order for the DoH to be a truly authoritative document then it must aspire to “tentative immortality”. That is, while revisions of the text may be necessary as biomedical research changes, the document should be meticulously crafted with the objective of enduring for decades rather than merely six-year intervals.<sup>21</sup>

Perhaps the most compelling reason for why the DoH is less suited for the task of creating a global bioethics tool is due to the nature of its creation. The DoH was created by a small handful of people and then has been imposed upon states without their adequate input. In the 2000 version of the DoH it places itself above national legislation and legal norms, which suggests that where legal norms conflict with anything with the DoH, the DoH should take precedence. Article 9 of the 2000 DoH reads, in part, “No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.”<sup>22</sup> Such a statement leaves no room for national legislation to question the prescriptions of the DoH and places the DoH on a paramount moral standing

equivalent to such enduring documents as the Universal Declaration of Human Rights. The problem with such a claim is twofold. First, the DoH is not as enduring as it might believe, as is evidenced by its numerous revisions and clarifications, some of which backtrack on earlier pronouncements. Second, the DoH was not adopted by national governments, as UN declarations are, but rather by the World Medical Association's General Assembly with a very limited membership. In fact, at the time of this writing, only 111 countries were constituent members of the WMA, representing just over half of the world's nations, which leaves out considerable opinions and viewpoints. Indeed, the drafting of the DoH has generally been done by an even smaller group of physicians, usually three or four. Such small numbers raise a number of questions about the drafting process and whether viewpoints from various cultural contexts are adequately respected and taken into account.<sup>23</sup> Having such small numbers of persons involved in creating such a significant document is also troubling because it may lend itself to pushing particular viewpoints and stifling others. Yet, ethics must rise above individual or group interests to advocate for and present what is universally true and binding upon humankind.<sup>24</sup> Henk ten Have has suggested that UNESCO be present in consultative and deliberative processes for the revisions of the DoH.<sup>25</sup> Such an idea is good, as a large international organization such as UNESCO would greatly aid the drafting process of the DoH and add valuable perspectives. However, it is difficult to foresee such a proposal coming to light and the WMA inviting UNESCO into that process.

Therefore, though there are numerous strengths of the DoH and it has been widely used by the international biomedical research community, problems continue to plague it. Section 4.2 will present in greater detail the UNESCO Universal Declaration on Bioethics and Human Rights and provide further justification for why it is more suitable than the Declaration of

Helsinki to serve as the foundational document for the proposed global bioethics tool that seeks to unite pharmaceutical and biotechnology companies.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78) produced a report that proved very significant for the direction of healthcare ethics,<sup>26</sup> largely as a response to the scandal of the Tuskegee Syphilis Study.<sup>27</sup> The National Commission selected seven principles that should underlie biomedical human research. These seven would be reduced to three in the *Belmont Report*: respect for persons, beneficence, and justice.<sup>28</sup> The *Belmont Report* was issued in its final form in late September 1978 and then published into the *Federal Register* on April 18, 1979. While the *Belmont Report* is not very extensive, it articulates a basic core framework of ethical precepts and has become greatly influential for guiding the direction of research ethics in the US. In the area of academic bioethics, the *Belmont Report* has also proved very significant. Much of the influence of the *Belmont Report* is attributed to being the first official biomedical ethics account to identify three fundamental principles.<sup>29</sup> Soon after its release, Tom Beauchamp and James Childress published their seminal tome in 1979: *Principles of Biomedical Ethics*. Within it they promoted the principles of autonomy (respect for persons), beneficence, non-maleficence, and justice, very similar to the principles laid out within the *Belmont Report*, and their method would become known as principlism. Beauchamp and Childress' four principles, inspired in large part by the *Belmont Report*, would largely shape the agenda of normative bioethics for the decades afterward.<sup>30</sup>

While continuing to be widely prominent, the principlism view is not without its due criticism. Principlism has been critiqued for a number of reasons, including that it gives insufficient attention to the practical context one is analyzing and the lived experiences of the

people in that situation. Rather, principlism merely attempts to fit all ethical questions into its four-principle mold. A second criticism is that the approach is overly Western. While no one seriously argues the fact that bioethics has grown out of a Western milieu, leaving it there without expanding and taking into consideration differing viewpoints and experiences would be insular and not helpful in the long run. Critical reflections upon the Western sociocultural context within which bioethics developed is a rare phenomenon. Hence, the four pillars of principlism have at times led to the position that these pillars are unquestionable, and any sociocultural perspective that deviates from these tenets is presumed to be erroneous.<sup>31</sup>

While the *Belmont Report* (and the principlism approach) has formed the groundwork for much of the national legislation on medical research ethics in the US, such as the Common Rule (45 CFR 46),<sup>32</sup> it is also very limited in its scope and does not address the breadth of biomedical topics of today. Though the *Belmont Report* has been highly influential within a US context, outside the US, though it is still widely known, its reach and authority on national bodies is not as well accepted. Indeed, the *Belmont Report* was primarily meant for a US audience, as is recognized by its team of American-only drafters and its lack of an international perspective. Therefore, while the *Belmont Report* is fundamental for biomedical research ethics, it is judged not to be well suited to act as the foundational document for the proposed global bioethics tool.

In the US, Title 45, Part 46 of the Code of Federal Regulations (generally stylized as 45 CFR 46) concerns the protection of human participants in research. These regulations are put in place by the Office for Human Research Protection of the Department of Health and Human Services. The legally binding regulations found in 45 CFR 46 are based in large part on the *Belmont Report* and other work completed by the US National Commission. The Department of Health and Human Services revised and expanded these regulations in the late 1970s and early

1980s in order to offer basic protections to human subjects involved in both biomedical and behavioral research.<sup>33</sup> 45 CFR 46 is divided into four subparts: Subpart A is typically referred to as the “Common Rule” and contains the uniform set of guidelines in US federal policy for the protection of human research participants. Subpart B provides additional protections for pregnant women, in vitro fertilization, and fetuses. Subpart C contains additional protections for prisoners. Subpart D contains additional protections for children. Subpart A, or the Common Rule, primarily includes requirements for assuring compliance by research institutions, requirements for researchers’ obtaining and documenting informed consent, and requirements for Institutional Review Board membership, function, operations, review of research, use of federal funds, and record keeping.

The governance process of 45 CFR 46 to ensure the compliance process for human subject protection is quite simple. The Department of Health and Human Services requires that any institution that is engaged in non-exempt human research must submit a written letter of compliance to the Office for Human Research Protection. Through the assurance of compliance, an institution commits to the Department of Health and Human Services that it is and will comply with the requirements set forth in 45 CFR 46.<sup>34</sup>

The US 45 CFR 46, while fine as a national code, is inadequate for a global or universal guideline. First, 45 CFR 46 is binding legislation in the US that is not specifically designed for an international audience. It was designed to function within the US as binding protections for human research subjects rather, and has proved effective in that task, yet its international exposure is limited. Second, and most importantly, if 45 CFR 46 were used as the foundational document for the global bioethics tool then it would be exceedingly difficult to have any pharmaceutical and/or biotechnology company that is based outside the United States participate.

The global bioethics tool would be viewed upon as an act of Western ethical imperialism if 45 CFR 46 were recommended as the foundational guideline. Hence, this makes it not useful for the proposed global bioethics tool.

The Council for International Organizations of Medical Sciences (CIOMS) was formally constituted by both the World Health Organization (WHO) and the United Nations Educational, Scientific, and Cultural Organization (UNESCO) in 1949, and continues to remain under the sponsorship of these two UN organizations.<sup>35</sup> CIOMS first issued guidelines on human experimentation and medical ethics in 1982. The fourth and current version was released in December 2016 and is now the fourth installment of CIOMS guidelines, superseding the 2002, 1993 and 1982 guidelines. The present version consists of 25 guidelines with commentaries on each of the guidelines that aid in explaining it.<sup>36</sup> The membership of CIOMS consists of 44 member organizations, representing, according to the organization itself, many of the biomedical disciplines.

CIOMS has sought to unite itself intimately to the DoH. In the 2002 version it explicitly states the nature of their relationship:

CIOMS set out, in cooperation with WHO, to prepare guidelines to indicate how the ethical principles that should guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be effectively applied, particularly in developing countries, given their socioeconomic circumstances, laws and regulations, and executive and administrative arrangements.<sup>37</sup>

Hence, CIOMS envisions their guidelines as complementing the DoH by elaborating how the very general, succinct principles in the DoH can be applied, with particular regard given to LMICs. Indeed, the 2002 revision of the CIOMS guidelines was prompted in part by new issues and questions that have arisen in regards to multinational research. The revision attempted to respond to these pressing questions of science. Strong support for the revision was elicited by the



WHO and the Joint UN Programme on HIV/AIDS (UNAIDS) and also included support and expertise from both HICs and LMICs. The 2002 revision took nearly four years to complete and consensus was reported as difficult to achieve.<sup>38</sup> For the 2016 revision, preparations began as early as 2009, with the Executive Committee of CIOMS seeing it as valuable to craft a new version that would coincide with the 2008 version of the DoH and respond to several developments in the field of biomedical research. In 2011 the Executive Committee elected to establish a group to revise the CIOMS guidelines. This group consisted of ten members, one chair (president of CIOMS), four advisers (from WHO, UNESCO, COHRED and WMA) and one scientific secretary. While CIOMS has stated that the composition of the group ensured that different cultural perspectives were present, there is reason to question such an assertion and if research saturation could truly be achieved due to the small group of consultants.<sup>39</sup> This revision process resulted in the release of the new CIOMS guidelines in December 2016.

Though CIOMS was established in the very infancy stages of bioethics, its membership, as of late 2016, is still very limited, including 44 international, national, and associate member organizations, which, CIOMS asserts, represent many of the biomedical disciplines, national academies of sciences, and medical research councils.<sup>40</sup> Twelve countries are National Members, and of these, nine are HICs and 3 LMICs.<sup>41</sup> Though CIOMS has thoughtfully considered how to apply many of the principles of the DoH, it is questionable whether or not it is truly a global guideline and has sincerely attempted to consider the sociocultural viewpoints of large varieties of persons and groups. With only three National Members being from LMICs, it is worrisome that the views of the developing world may not be completely represented in the guidelines. Hence, while the CIOMS guidelines have done much good work in further specifying the DoH,

its practicality to be used as the foundation for the proposed global bioethics tool is problematic due to its small membership and seemingly limited consultative process.

Good Clinical Practice is an international quality standard for designing, conducting, recording, and reporting trials that involve human participants. Good Clinical Practice is provided by the International Conference on Harmonisation (ICH), an international body that defines standards.<sup>42</sup> ICH states, “Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.”<sup>43</sup> Governments can use these standards by transposing them into regulations for clinical trials involving human subjects, such as what the US Food and Drug Administration (FDA) has now done.<sup>44</sup> The objective of the Good Clinical Practice (GCP) guidelines is “to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.”<sup>45</sup> These standards for clinical trials are oftentimes referred to as ICH-GCP.

The stated purpose of ICH, the body that created GCP, is to create common rules across developed countries for the registration of pharmaceuticals for human use. The mission of the ICH is stated as:

ICH’s mission is to make recommendations towards achieving greater  
153subsidized153n153 in the interpretation and application of technical guidelines and  
requirements for pharmaceutical product registration, thereby reducing or obviating  
duplication of testing carried out during the research and development of new human  
medicines.<sup>46</sup>

Hence, the aim of ICH is more along the lines of increasing the efficiency of pharmaceutical drug approval rather than the protection of those persons participating in research, as is demonstrated in its deferring to the Declaration of Helsinki in these matters.<sup>47</sup> Indeed, there are

essentially thirteen principles of the ICH-GCP and the first principle states that clinical trials should adhere to the DoH.<sup>48</sup> The remainder of the document can essentially be divided into two parts. The first part, including from Guideline 3 to Guideline 5, sets out the detailed duties and responsibilities of ethics committees/IRBs, investigators, and research sponsors that are relevant to human subject protection. The second part, from Guideline 6 through Guideline 8, provides guidance on the documentation of the clinical trial process and the pertinent information that must be documented at each stage of the clinical trial.<sup>49</sup>

The US Food and Drug Administration (FDA) recognizes the GCP guidelines for its international clinical trials. In 2008 the FDA amended its regulations on acceptance of foreign clinical studies not conducted under an investigational new drug application. The amendment replaces the requirement that these studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki (specifically the 1989 version), with a requirement that the studies be conducted in accordance with GCP.<sup>50</sup> It was widely believed that the FDA made this decision due to less stringent guidelines of the GCP. The ICH-GCP guidelines do not address certain ethical requirements that are stipulated in the DoH, such as the use of placebos versus standard therapy, post-trial access to treatment and other benefits for participants (benefit sharing) the public disclosure of trial design, the publication of trial results, and the disclosure of conflicts of interest by researchers.<sup>51</sup> The FDA, feeling that the WMA overstepped its mandate with revisions of the DoH that increasingly required more and more from researchers and sponsors opted to simply abandon the DoH.<sup>52</sup>

Hence, ICH-GCP has been criticized by some commentators for lacking the breadth, depth, and moral authority of the Declaration of Helsinki.<sup>53</sup> Further, Sharon Kaur and Choony Yeow Choy raise an astute observation, stating that at the heart of the ICH, which heavily

impacts the GCP, is two main activities: first, ensuring that wherever drug development and manufacturing takes place, drugs are developed, tested, registered, and monitored in a fashion that ensures both quality and safety; and second, making the development of new drugs more efficient and less expensive. Hence, with this in mind, Kaur and Choy conclude that it is no surprise that the ICH-GCP guideline is to a large extent made up of administrative duties.<sup>54</sup> As such, the ICH guidelines are insufficient to be used as the guiding document from which to build the global bioethics tool, as a chief purpose in creating the tool is enhancing the ethical conduct of pharmaceutical and biotechnology companies in how they conduct clinical trials and in their dealings in LMICs. The ICH-GCP is largely concerned with the administrative duties of IRBs and defers to the DoH for much other human research protection.

By this point it is evident that there have been numerous bioethics guidance documents created. The past two decades have witnessed an upsurge of interest in international declarations on bioethics and, specifically, global bioethics and the governance of bioethics.<sup>55</sup> The 1997 Council of Europe “Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine”, often simply termed the Oviedo Convention in reference to the location of the convention in Oviedo, Spain, is a notable example.<sup>56</sup> As this document preceded the Universal Declaration on Bioethics and Human Rights by nearly a decade, it is sometimes lauded as “the first international treaty in this field,” yet it is limited only to Europe.<sup>57</sup> The Council of Europe, founded in 1949, is an intergovernmental organization that is mandated with fostering political, legal, and cultural cooperation between its 47 member states. The Council of Europe has the ability of passing legally binding treaties for its members on a wide variety of topics at the international level.<sup>58</sup> The Council of Europe has passed a number of relevant treaties for

bioethics, such as Treaty No. 168 on the “Prohibition of Cloning Human Beings,”<sup>59</sup> Treaty No. 203 on “Genetic Testing for Health Purposes,”<sup>60</sup> Treaty No. 216 “Against Trafficking in Human Organs,”<sup>61</sup>

The Oviedo Convention contains 38 articles that seek to affirm that progress in biology, medicine, and technology should be used for the benefit of present and future generations, stress the need for international cooperation, recognize the importance of promoting a public debate on the questions posed by the application of biology and medicine, and resolve to take the necessary measures to safeguard human dignity and the fundamental rights and freedoms of individual persons with regard to the application of biology and medicine.<sup>62</sup> At the time of its ratification, the Oviedo Convention was praised by Roberto Andorno as “the best current example of how to promote the protection of human rights in the biomedical field at a transnational level.”<sup>63</sup>

Andorno, even after the adoption of the UDBHR by UNESCO Member States and having been a member of the International Bioethics Committee from 1998-2005 has written that though the Oviedo Convention is a regional rather than a global instrument, “its potential impact on a global scale should not be overlooked as it is the only intergovernmental legally binding instrument that comprehensively addresses the linkage between human rights and biomedicine.”<sup>64</sup> A great strength of the Oviedo Convention, as Andorno points out, is that it is legally binding upon fellow Council of Europe states. Further, human dignity acts as the bedrock of the guidelines, with the primacy of the individual person seen as paramount.<sup>65</sup>

Additionally, the Oviedo Convention, much like the UDBHR which would follow eight years later, takes a comprehensive approach to bioethics. In 1997 when ratified, up to that point other international instruments in bioethics had attempted to unite human rights and bioethics, yet they focused on narrow aspects. For instance, UNESCO’s Declaration on the Human

Genome and Human Rights (1997) concentrated exclusively on genetics. Yet, the Oviedo Convention aimed at covering the whole domain of bioethics, linking it with human rights, and creating a truly unique document.<sup>66</sup> The linking of bioethics to human rights was not novel to Oviedo, as it was done in the Nuremberg Code. However, the scale of it, how explicit it is, and the fact that Oviedo is a binding document is novel. Several reasons justify why the Oviedo Convention, and later the UDBHR, appeal so strongly to human rights. First, there is an obvious link between health issues and fundamental human rights. Second, the claim of human rights is universalistic, which greatly facilitates the creation of transcultural, transnational standards. Third, key concepts in the biomedical field are already formulated using the language of rights (informed consent, right to health, access to health care and medicines, etc.). Fourth, there is a lack of any conceptual and institutional instrument other than the human rights framework to produce an international framework of norms relating to biomedicine, as the human rights framework is able to function as a *lingua franca*.<sup>67</sup>

We should not get the image that the Oviedo Convention is without flaws, though. Despite its binding nature, the European Court of Human Rights cannot enforce the Oviedo Convention, whose only task in this matter is to state opinions regarding the interpretation of its norms (Article 29), without mention to any specific pending court case. Further, there are no sanctions provided should a member state violate the norms of the Convention. Additionally, the Oviedo Convention has also been critiqued for its silence on the topic of abortion and having very little to say about the permissibility of certain reproductive techniques, euthanasia, and end-of-life decisions. The obvious conclusion that is drawn from this is that the drafters considered these topics too controversial to approach comprehensively out of fear of not gaining consensus and the Convention not being ratified. However, if this is in fact the reason for the omission of

contentious topics, one commentator has noted that the Convention then cannot be considered a wide-ranging basic document on biomedical ethics.<sup>68</sup> Further, numerous other bioethics guidelines have omitted these provocative issues as well, so similar critiques could be made about them.

Yet, such a judgment may be hasty, for the Oviedo Convention is wide-ranging on the basic elements of biomedical ethics that can could be agreed upon at an international level, and it leaves open the possibility for national legislatures to craft more stringent policy if they choose to do so. An example of this would be the legal position of abortion in Poland. Poland, a Member State of the Council of Europe, has much tougher abortion laws than the rest of Europe, permitting abortion only in cases of severe and irreversible damage to the fetus, a serious threat to the mother's health, or if the pregnancy is the result of rape or incest.<sup>69</sup> The only two European states with more strict abortion laws are Malta and Vatican City, the latter not being a Member State of the Council of Europe. Hence, Poland has adopted the Oviedo Convention like other Member States and because the Convention does not cover abortion, the national legislature has upheld and continually enforced its more stringent regulation, which they are free to do. They have even at various points attempted to completely outlaw abortion, but these attempts have failed. However, if this had been attempted within the Oviedo Convention itself then the vast majority of Council of Europe Member States, who do not hold the viewpoint of Poland on this issue, would never have been in harmony.

In summary, despite its criticism, the Oviedo Convention has many pronounced strengths and was very pioneering for its time. While it is a binding document, it is also, strictly speaking, a regional document, as having only been ratified by the 47 European Council Member States. While this is a great feat for Europe, this will not be suitable for a global audience. One

weakness of the Oviedo Convention versus the UDBHR is that the UDBHR was crafted with global input—HICs and LMICs—rather than solely regional input. If the Oviedo Convention were used as the foundational document for the proposed global bioethics tool then there would be numerous states that would feel as though they were merely being subjected to a European-imposed imperialism. Hence, the strength of the UDBHR over the Oviedo Convention is that the UDBHR was developed with global participation and achieved global, rather than regional, consensus.

As this section has now examined eight bioethics documents that have been produced from 1947 forward, before moving forward to section 4.2 where the UNESCO UDBHR will be examined then some concluding remarks are offered. Ezekiel Emanuel, David Wendler, and Christine Grady have charged that existing biomedical ethics guidance is neither comprehensive nor systematic. In their view, current guidelines lack justifications for their claims, leading to the conclusion that their principles are either thought to be *prima facie*, self evident, or beyond debate. They state that there is a great need for a broader, systematic, and comprehensive framework that includes both an ethical justification for ethics principles and includes how to apply and fulfill each principle in practical terms.<sup>70</sup> Indeed, bioethics declarations generally are not very lengthy, and their principles are typically not justified very well within the text. Additional commentaries have, however, been produced on certain documents, which are helpful. Further, one goal of the proposed global bioethics tool is to include how to apply the principles to the pharmaceutical and biotechnology industry. With the use of sharing best practices then this has the possibility of being very helpful for the industry and enhance their bioethical performance.



Therefore, in conclusion, section 4.1 presented eight of the most prominent bioethics guidelines that have been created since the end of World War II. It was seen that there are many notable strengths to these guidelines, yet none of them are suitable to be the foundation of the proposed global bioethics tool. The weaknesses of each guideline were examined, with particular attention given to the WMA Declaration of Helsinki, as it arguably the most well-known and utilized bioethics guideline today. While immensely popular, the revision and drafting process of the DoH was called into question for not adequately taking into account the viewpoints of sufficient numbers of people. In the following section, the UNESCO Universal Declaration on Bioethics and Human Rights is examined. Reasons for why the UDBHR is more suitable than other guidelines to act as the foundation document for the proposed global bioethics tool will be assessed.

#### *4.2) UNESCO Universal Declaration on Bioethics and Human Rights*

In order to solve global problems, global solutions and the commitment of the global community are necessary.<sup>71</sup> Further, not only are there global health problems, but education, insights, and fresh solutions to these problems flow in all directions.<sup>72</sup> Ergo, the need for global solutions will need to be collective and collaborative, and these solutions will affect countless persons. For bioethics, the proposition to develop a universal declaration to work at solving some of these global problems was suggested in 1999 by science ministers at the World Conference on Science in Budapest, Hungary. The ministers of science, concerned by the rapid progression of science and technology and the importance of sharing knowledge with LMICs, decided that it was necessary begin dialoging on the subject.<sup>73</sup> In 2001, the UNESCO Director-General was asked to look into the possibility of developing a universal bioethics instrument. On the basis of the International Bioethics Committee's subsequent report, the 2003 General Conference

declared the setting of universal bioethical standards to be “imperative and desirable.” An extensive drafting and consultation period then ensued, involving member states and other stakeholders.<sup>74</sup> Because of the need to incorporate international and universal perspectives, the UDBHR is by necessity the result of compromise. Indeed, it is this compromise and internationality that provides strength to the declaration and its normative ethical standards. The declaration represents the viewpoints of the governments of UNESCO Member States rather than scientists and biomedical ethics experts.<sup>75</sup>

UNESCO was well suited for the task of crafting universal, normative bioethics guidelines. First, from its founding, UNESCO has emphasized its role as a moral conscience. This was expressed by the first Director-General, Julian Huxley, when he stated that science and values must be married in order to contribute to peace and human flourishing. UNESCO acting as a moral conscience is also reflected in it creating an International Bioethics Committee in 1992 because of the need to have these sensitive and important biomedical conversations at the global level. Second, UNESCO has the unique position, as an intergovernmental organization, not merely to explain or clarify bioethics principles but to seek their application in state policies. While the organization certainly has its flaws, no other global entity combines the standard-setting work and practical implementation activities in the field of bioethics at the same level of UNESCO, which makes it unique. Third, UNESCO has acted as a bridging agency, not only between science and values, as was envisioned by Potter, but between countries as well. Moral perspectives from all Member States are brought together into one organization and each are given fair treatment. Those who might critique bioethics guidelines as the result of Western imperialism have no such argument for the work of UNESCO. LMICs and even some HICs, such as Saudi Arabia, are reported to very sensitive to such accusation of Western imperialism,

and this is exemplified in their scrutiny of proposals from Western nations. Lastly, UNESCO has a crucial ideological role that has aided it in making global pronouncements. As ten Have has recognized, “UNESCO is driven by certain values that are utterly relevant for global bioethics.”<sup>76</sup> Particularly, UNESCO places an emphasis on the common heritage of humankind—the idea that certain elements/resources are part of humanity’s shared inheritance and should be protected for future generations. This directs attention both to human flourishing and the common good of humankind. Seeing the common heritage of humankind enacted, though, can only be accomplished through pragmatic acts of global solidarity, cooperation, and authentic respect for diversity.<sup>77</sup>

In mid-2016 the author received a grant from the bioethics division of Novo Nordisk to work on the creation of a voluntary industry-based and industry-originated global bioethics tool. During the fall of 2016 the author had numerous conversations with representatives from major pharmaceutical and biotechnology companies to attempt at generating support for creating a global bioethics tool to be used by the pharmaceutical and biotechnology industry that is based upon the UNESCO Universal Declaration on Bioethics and Human Rights. One question the author received on at least two occasions was the rationale for the using the UDBHR rather than the better-known DoH. The UDBHR is better positioned than any other biomedical ethics framework, including the DoH, to be the framework upon which the global bioethics tool is built for at least the following four reasons: 1) it is the first and only bioethics declaration to gain the approval of international governments (all UNESCO Member States), with the input of bioethics experts, rather than solely a group of individuals with bioethics or scientific expertise, 2) it efforts to incorporate major principles in bioethics, such as those included in the Declaration of Helsinki and ICH-GCP, 3) the Declaration reaches beyond individual orientations to bioethics to

a global perspective, focusing on issues such as the environment, respect for cultural diversity, capacity building, and future generations, and 4) the Declaration is very useful for countries that lack an infrastructure in bioethics. The need for worldwide standard-setting in bioethics has been strongly expressed by LMICs who want to share the benefits of the developments of science and technology and not only be the providers of data and resources for the world.<sup>78</sup> Each of these four reasons will be explicated below.

First, the UDBHR is very unique among research ethics guidelines as it is the first and only bioethics declaration to gain the approval of all international governments with the input of international experts in bioethics. The UDBHR was unanimously adopted on October 19, 2005 at the 33<sup>rd</sup> General Conference of UNESCO by all Member States.<sup>79</sup> As an international organization, UNESCO is charged with taking into account all perspectives that are relevant to all Member States so that one nation or context is not improperly favored over another and to ensure that the cultural diversity of the world is respected. The UDBHR was primarily drafted by UNESCO's International Bioethics Committee (IBC)—the only ethics committee with a truly global scope, composed of 36 experts in different disciplines: genetics, medicine, law, philosophy, ethics, history, and social sciences.<sup>80</sup>

The UDBHR was not crafted by a small group of persons. Rather, UNESCO Member States had considerable input. In January 2004, nearly two years before its formal adoption, a written consultation with Member States was launched; 191 Member States,<sup>81</sup> Associate Member States and Permanent Observer Missions received a simple, concise questionnaire inviting responses concerning (1) aims and scope, (2) the structure, and (3) the content of the declaration. While only 67 official replies were received, representing only approximately one-third of

Member States, the replies were helpful in determining the scope of the declaration and what would be included within it.<sup>82</sup>

Second, the UDBHR efforts to incorporate the major principles in bioethics into one universal document. Having the declaration consist of general principles that could be the object of a large, worldwide consensus and which could be applied to new scientific advances in the future was thought to be advantageous and the best route to pursue.<sup>83</sup> In one sense, the UDBHR presents a related network of principles. The UDBHR principles themselves are associated with other principles that have been adopted in the UN system and principles that have been used for many decades in the international governance of medical research. Because of this historical and pragmatic background, many UDBHR principles are not new, but are in fact practical “translations” for their use in global bioethics governance. Therefore, it can be said that the UDBHR focuses, to a large extent, on basic principles of bioethics that are intended to withstand the test of time, and that it has incorporated many principles from other existing bioethics guidelines, making it truly a universal document in its scope.<sup>84</sup> While this is true, the UDBHR still has incorporated more innovative principles into its guidelines as well, such as the requirement of benefit sharing, the connections of bioethics with the larger environment, and giving consideration to future generations.

Third, the UDBHR reaches beyond individual orientations to bioethics to a global perspective, focusing on issues such as the environment (Article 17), respect for cultural diversity (Article 12), capacity building (Article 24), and future generations (Article 18). Saying that these are global, universal issues that affect the entire planet and every nation on it is not hyperbole. The universality of the UDBHR is not merely a matter of crossing borders or continents; it concerns the planet as a whole and, hence, embraces the vision of Potter in the early

days of bioethics.<sup>85</sup> Justice Michael Kirby, chair of the UDBHR drafting committee, addressed this very point by stating that the UDBHR “lifts the eyes of bioethicists from the patient’s bedside and the hospital ward to a new insistence on the relevance to the bioethics discipline for society, the community, humanity, all living beings and the biosphere”.<sup>86</sup>

Henk ten Have and Bert Gordijn have argued that the establishment of a global bioethical framework such as the UNESCO UDBHR signifies the genesis of a “global moral community”. This is recognized in global bioethics principles such as protecting future generations, as cited above, but also through the principle of benefit sharing (Article 15) that seeks to counteract the injustices of biopiracy.<sup>87</sup> This brings into the forefront conversation on the common heritage of humankind—that the earth is not the sole possession of one people group or generation, but is inherited with each passing generation and entrusted to the current generation for safekeeping. This is also quintessential Potter, who viewed ethics as a tool to extend the idea of human community broader to include the soil, water, plants, and vertebrate and invertebrate life forms.<sup>88</sup>

Fourth, the UDBHR is very useful for countries that lack an infrastructure in bioethics. UNESCO has had ethics standard-setting activities for several decades now. Considering that many Member States have only a limited infrastructure in bioethics, such as LMICs, they lack expertise, educational and training programs, research committees, legal frameworks, and public debate.<sup>89</sup> The common principles and shared values that are focused on in the UDBHR create the space for the global standards of the UDBHR to be used by both HICs and LMICs. This attempts to address a large gap that was present in bioethics.<sup>90</sup> This highlights the usefulness of not only UNESCO as a universal, standard-setting organization, but also of the UDBHR.

To attempt to further answer the question of why the UNESCO UDBHR should be the guideline of choice for the global bioethics tool rather than the more prominent DoH is the task

of the remainder of this section. As has been stated elsewhere, the UDBHR is the first international effort for a global approach to bioethics, involving governmental and non-governmental actors, and eventually being unanimously adopted by all UNESCO Member States. This was quite the feat, considering the countless religious and sociocultural backgrounds that were represented. However, this demonstrated that UNESCO had the ability to locate common ground between nations in order to set a minimum universally accepted standard for bioethics.<sup>91</sup>

While human rights and bioethics have had an intertwined relationship since the development of the Nuremberg Code, the UDBHR is the first international instrument to comprehensively integrate international human rights law into biomedicine. Richard Magnus has pointed out that, “By broadening the scope of the respect principle from personal autonomy to human dignity, the UDBHR overcomes a shortcoming of previous bioethics documents, which seemed to accord respect only to autonomous persons.”<sup>92</sup> Magnus’ argument is that the UDBHR includes protections for those who are not yet (future persons and generations) as well as those who are no longer morally autonomous, such as infants, those with mental disorders, and those suffering with dementia. Future persons are to be respected and protected as well, for human dignity requires that new technologies and procedures, like germ-line interventions, do not result in a compromise of the integrity of humankind. Further, integrating the human rights framework into bioethics is a meaningful task because these most fundamental rights and freedoms are desirable to all persons, irrespective of characteristics such as ethnicity and gender, as well as intellectual and physical abilities. Hence, the UDBHR recognizes and affirms that science and technology cannot be advanced without thoughtful reflection on the impact of humanity’s actions on both the environment and the rest of humankind. Due to the fact that the UDBHR encourages

such consideration and recognizes the need to give due regard to other human beings that we share this common planet with, the UDBHR can truly be considered a universal bioethics guideline. Hence, the UDBHR, unlike much bioethical discourse that focuses heavily on the individual person, places great emphasis on both the larger society and even the global community.<sup>93</sup>

Further, one significant contribution of the UDBHR is that it provides guidance for transnational health research (Article 21), stating that research should go before ethical review of the host state and the state in which the sponsor is located, transnational health research should be responsive to the needs of the host country, terms for benefit sharing should be reached when negotiating a research agreement, and, very specifically, states should take appropriate measures to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources, and genetic-related materials. Therefore, UNESCO has tried to implement strategies to ensure that science is not unjustifiably impeded and research participants in all corners of the globe are duly protected. There are hints of the principle of global justice in this Article and throughout the UDBHR.<sup>94</sup>

Finally, the UDBHR has sought to focus on basic principles that are intended to withstand the test of time. Many principles have been derived from other existing guidelines and some are unique to the UDBHR. By focusing on common principles and values that are shared by humankind, the UDBHR was able to establish global normative standards that were acceptable and could be used by both HICs and LMICs. The comprehensive approach of integrating human dignity and human rights into bioethics was a first in the field for the UDBHR.<sup>95</sup>



The UDBHR is not a perfect bioethics document, just as a UNESCO is not a perfect organization, if there is even such a thing. Further work needs to be done in elaborating the principles articulated in the UDBHR and, specifically, how they are and have been applied in real-world scenarios, such as in governments, research universities, and even individual companies. This will take further dialog between countries, industries, and individual companies, as well as a greater depth of understanding the religious and sociocultural divisions of the world. Indeed, it would be useful for UNESCO to publish detailed accounts of exactly how a developing world country, with little capacity in research ethics, has sought to implement the UDBHR. Such a work would not only be fascinating from a policy and governance standpoint, it would conceivably be of great value and benefit to other LMICs in similar situations who are looking to implement the UDBHR.

Further empirical research on the ground, dealing with the lived experiences of actual people, will need to be conducted to find out what works and what does not. The compilation and publication of best practices would be very helpful for countries, organizations, universities, and companies trying to implement the UDBHR into its operations. The IBC has done some of this work, elaborating on certain principles through the use of reports on the principles of consent (Article 6), respect for human vulnerability and personal integrity (Article 8), and social responsibility and health (Article 14).<sup>96</sup> Further the 2009 commentary on the UDBHR also discusses the work of application in some detail.<sup>97</sup> Yet, such work needs to increase in order for the application of the UDBHR to continue growing. Indeed, a great strength of the proposed global bioethics tool is its use of best practices as a way to encourage companies to adopt similar practices.

To conclude this section, we must recognize that certainly UNESCO's resources are not inexhaustible and must be prudently utilized. However, in order for the UDBHR to achieve greater acclaim and wider recognition in the world, these may need to be priorities. Further, as has been asserted above, one task of UNESCO is to be a standard-setting organization for bioethics. In order to fulfill this agenda in a more comprehensive manner, UNESCO must also look to the application of standards and not merely to the setting of them. Such work will undoubtedly be opposed by some, as there will be varying opinions on the application of principles. This is why extensive dialogue between relevant stakeholders is immensely important. Yet, the application of principles and even sharing best practices between countries, industries, and individual companies seems to be the next step in the process of ensuring that essential principles of bioethics and human rights are being adhered to. The following section provides analysis of the topic of bioethics governance and different models of accreditation, certification, and rating that have been created in order to send a signal to the public about the activities of a company.

#### *4.3) Bioethics Governance and the Differing Models of Accreditation, Certification, and Rating*

The previous two sections described the various biomedical ethics guidelines that have been developed in the aftermath of WWII onwards and argued for the role of the UNESCO UDBHR as being most well suited for the task of creating a global bioethics tool from which to unite pharmaceutical and biotechnology companies. This section begins by elaborating on what is meant by "governance" and elaborates its role in global bioethics. This section then moves into the differing models of accreditation, certification, and rating, and makes some recommendations for their use in the global bioethics tool.

To determine the principles of bioethics, enshrined in different guidelines and declarations as presented in the previous two sections, is one thing. Yet, the application of principles is different, and this is the work of governance. Broadly, governance can be defined as the actions and means that are adopted by a society to promote cooperative action and deliver collective solutions toward a desired, common goal.<sup>98</sup> Global governance is this type of cooperative action between actors, primarily states, on a global scale. Within a specific country or locale, bioethical problems are addressed with the common mechanisms of government. Henk ten Have has recognized that these common mechanisms, such as legislation and political decision-making, do not always work in such a globalized world. Indeed, this is one of a number of challenges that globalization has created. On a global scale, no authority exists that is responsible for the application of principles, and the global nature of the problems that are encountered today make national approaches insufficient. Practices that are rejected in one country on ethical grounds, sometimes with the backing of legislation (such as the case of abortion in Poland presented in 4.1), are permitted in another country. This highlights the grave challenge, if not impossibility, of simply applying an ethical position within one country at a global level to all countries. For global health, states have recognized that they are not effective in regulating health, which has highlighted the need for a governance system that encompasses both state and non-state actors.<sup>99</sup> This is the problem of governance.<sup>100</sup>

Indeed, governance has developed alongside globalization and is no longer sufficient to be applied merely within states. By the mid-nineteenth century, globalization in the form of increased trade and travel between states precipitated the need for governments to initiate dialogue on health threats that were considered to be of international significance, such as the plague, yellow fever, and cholera. This would evolve to collective action between states on other

issues such as pollution, humanitarian law during wartime, and labor agreements.<sup>101</sup> Hence, the need for cooperation on global health matters is apparent.

Similarly, cooperation towards the oversight and implementation of global bioethics principles cannot be considered the work of a particular state, but must be the activity of a coalition of partners, which may necessarily involve those who are regularly affected by bioethics, such as the pharmaceutical industry. There are many problems for global bioethics governance both at the international state level (between governments) and at the level of commerce (between companies) that will need to be discussed.<sup>102</sup> The need for greater cooperation at the state level and the level of commerce will be explained in this section. For pharmaceutical and biotechnology companies, the problem of globalization and the issue of governance are particularly salient. These companies are bound legally to the rules in which they operate, yet these can differ significantly from one country to another. A HIC may have strict legislation in place to protect research subjects from harm, yet a LMIC may not have similar protections in place. This emphasizes the problem caused by the globalization of multinational corporations, the relevance of governance, and the need for a mechanism such as the global bioethics tool that will be presented in the subsequent chapters.

Understanding the role of governance in bioethics requires the historical consideration of how bioethics became institutionalized into the specific forms of committees, regulatory bodies, and commissions.<sup>103</sup> First introduced by the World Bank and later receiving academic dignity in James Rosenau and Ernst-Otto Czempiel's influential essay collection on *Governance without Government* in 1992, the concept of governance has become a highly utilized term in both political and scientific debate.<sup>104</sup> The concept of global governance became more widespread

after its use in the 1995 report of the Commission on Global Governance, which met to report on the future of the UN and has defined governance as follows:<sup>105</sup>

Governance is the sum of the many ways individuals and institutions, public and private, manage their common affairs. It is a continuing process through which conflicting or diverse interests may be accommodated and co-operative action may be taken. It includes formal institutions and regimes empowered to enforce compliance, as well as informal arrangements that people and institutions either have agreed to or perceive to be in their interest.<sup>106</sup>

Hence, governance was thought of by the Commission as an output of the international system that is aimed at addressing issues that have the potential to affect everyone, irrespective of national borders.<sup>107</sup> While governance is often thought of in terms of states and governments, it is also applicable to companies, foundations, and institutions. In the realm of bioethics, declarations and, specifically the applications of the principles, at local levels such as companies and research universities, as well as at national levels, is the idea of governance.<sup>108</sup> It is this type of governance that is most applicable for the proposed global bioethics tool that is presented in chapter five.

There are at least two notable challenges for global governance. First, the question is often posed of how the globalized world can be successfully governed. Two premises are embedded in this question. First, globalization has entailed that some processes, services, and challenges are not met by either local institutions (public or private) or by traditional policy-making means. The distinction between domestic and international, that was once more marked, has become more obsolete in a sense. A second premise is that a government-like, hierarchical management style to solve the world's problems is simply not possible in the absence of a world government.<sup>109</sup> Hence, some have criticized the notion of global governance as being overly utopian and claiming it can only work in the presence of a unified world government.

Nevertheless, cooperation between states and global solidarity towards a common goal is not a utopian ideal, but is an attainable goal.

Ten Have has pointed out that such pressing issues of our day, such as ever-present pandemics, migration spurred by conflicts, and climate change, cannot be adequately addressed by states and interstate cooperation alone. He has identified at least five facets of global governance: 1) a focus on global problems, 2) necessity of collective action, 3) a variety of actors, including not only state governments but intergovernmental organizations and NGOs, 4) various levels of activity, and 5) diverging objectives.<sup>110</sup> Health has been an objective of global governance for many years, as evidenced by the UN's Millennium Development Goals, established in 2000, three of which are specific to health and others indirectly involve health as a stepping stone to the fulfillment of another goal and to a better standard of living.<sup>111</sup> Surely individual governments bear the brunt of responsibility for the health of their citizens, as was argued in chapter three. However, in the absence of a global government, global health problems must be addressed, managed, and coordinated in a different manner, making global cooperation and solidarity a necessity.<sup>112</sup>

John Ruggie, the chief architect of the UN Guiding Principles on Business and Human Rights, has contended that, "The root cause of the business and human rights predicament today lies in the governance gaps created by globalization—between the scope and impact of economic forces and actors, and the capacity of societies to manage their adverse consequences. These governance gaps provide the permissive environment for wrongful acts by companies of all kinds without adequate sanctioning or reparation. How to narrow and ultimately bridge the gaps in relation to human rights is our fundamental challenge."<sup>113</sup> Thomas Weiss and Ramesh Thakur have attempted to define what these governance gaps actually are, and each will be briefly

explained: knowledge gaps, normative gaps, policy gaps, institutional gaps, and compliance gaps.<sup>114</sup> First, a gap in knowledge signals that little or no consensus exists about the nature, origins, seriousness, and magnitude of a problem. Second, a gap in norms is present due, in large part, to the enormously difficult task of achieving a consensus on universally accepted norms. Third, policy gaps showcase that there is disagreement on the formulation of norms, who should be involved in the formulation, and how to implement policies. Fourth, institutional gaps often limit governance due to lack financial resources and adequate authority. Fifth, compliance gaps indicate that the monitoring and enforcement that is needed to ensure compliance to an agreed upon norm or standard is deficient. Indeed, the challenge of filling global governance gaps is exhibited by the tremendous difficulty in ensuring compliance.<sup>115</sup>

Governance gaps in global health become even more evident when applied to real-life scenarios. The first cases of the recent Ebola virus epidemic were reported in the West African nation of Guinea in December 2013. The disease would later spread to neighboring Sierra Leone and Liberia. In hindsight, the WHO has recounted that in Guinea, the origin of the outbreak, it took nearly three months for health officials and their international partners to identify the causative agent as the Ebola virus. However, by that time, the virus was firmly entrenched in society, and its spread was primed to explode.<sup>116</sup> After more than six months into the Ebola outbreak there was no strong sense of who was leading the international response, how funds were being collected and distributed, which organizations were providing medical equipment and personnel, and when any of these efforts would make a noteworthy difference in slowing the epidemic in West Africa.<sup>117</sup>

What contributed to this protracted length of time to target the specific disease and to coordinate a response? West African countries had never before experienced an Ebola outbreak,

and they were poorly prepared for this unfamiliar and unexpected disease at every level, including early detection of the first cases to orchestrating an appropriate response. Healthcare providers and clinicians in these countries had never managed Ebola cases, and laboratories in the countries had never diagnosed a patient specimen.<sup>118</sup> This could be considered a gap in knowledge. However, gaps in knowledge were not the only contributory factor. The WHO has reported that certain high-risk behaviors among those in the countries were also heavily present during the epidemic. Adherence to ancestral funeral and burial rites were singled out as 175subsidi large explosions of new Ebola cases. Data available in August 2014, as reported by Guinea's Ministry of Health, indicated that 60% of cases in that country could be linked to traditional burial and funeral practices. This is comparable to an estimate in November 2014 by WHO staff stationed in Sierra Leone who estimated that 80% of cases in that country were linked to these practices. In Liberia and Sierra Leone, some mourners have been known to bathe in or anoint others with rinse water from the washing of corpses and to sleep in close proximity to an infectious corpse for several nights. Several experts have noted that when technical interventions to treat diseases cross purposes with entrenched cultural practices, such as what was seen in West Africa, culture always wins.<sup>119</sup> This is evident of a knowledge gap, but it also goes beyond that. Knowledge is often not the decisive problem. In the Ebola outbreak, eventually the virus had been identified, diagnostic tests were available, and the mechanisms of contagion and prophylactic measures were known. However, knowledge can be ignored, and this was observed in West Africa.<sup>120</sup> Hence, this may more closely be described as a gap in compliance on the part of many people in the affected West African states.

“Good” global governance as defined by Weiss and Thakur implies not that an organization, such as the UN, holds exclusive policy jurisdiction, but rather an optimal



partnership between the state, intergovernmental, and non-governmental actors are cooperating at national, regional, and global levels.<sup>121</sup> This seems to imply not only greater cooperation than what is present currently, as illustrated in the scenario of the recent Ebola epidemic of West Africa, but also that governance is not exclusively directed towards states, as it is often defined. For global health governance, the WHO remains at the center, but it increasingly shares responsibility and agenda-setting activities with other organizations. The current system is highly fragmented, involving the contributions and activities of many actors, such as multinational, national, and private organizations with missions and responsibilities that intersect at various points, a diverse set of fundraising and fund distribution, and an assortment of monitoring and evaluation standards.<sup>122</sup>

Global health governance has been critiqued for many reasons, including, first, for its fragmented nature, as discussed above. Second, it has also been criticized for a lack of participation and/or cooperation by certain actors, which also contributes to the fragmented nature of global health governance. Till Bärnighausen, David E. Bloom, and Salal Humair of the Harvard School of Public Health have stated that this problem, in part, arises because certain key global health institutions are established and funded by individual donors or private firms who are not obligated to invite any particular group of people to participate in their decision-making. Affluent donors have the ability to skew public health and medical programs towards the issues of greatest concern to them, though not necessarily of the most urgent need.<sup>123</sup> Third, a lack of transparency is yet another reason for criticism leveled against the current form of global health governance. Lack of transparency extends to matters of decision-making, political moves, and how finances are expended. Connected to this is a fourth reason for criticism: lack of accountability. There is a need for institutions and individuals to account for their decision-

making and hold responsibility for the consequences of their decisions. Transparency is a first and necessary step, but in and of itself it is insufficient for comprehensive accountability. Fifth, a final reason that global health governance is often criticized has already been alluded to: effectiveness and efficiency. The effectiveness and efficiency of global health governance is often called into question especially in times of pandemic or epidemic when coordination of healthcare and resources is necessary, yet, as has been seen in both the Ebola and more recent Zika response, is not always a reality. The consequences of poor coordination and multiple, and include duplication of efforts, breakdowns in communication, lost opportunities to learn from one another, and inadequate patient care.<sup>124</sup>

A number of methods and proposals have been offered for how to improve upon global health governance.<sup>125</sup> Spicer et al have proposed that mechanisms focused on partnership and collaboration between entities, as well as coordination between them, could aid participation in global health and the transparency of these entities.<sup>126</sup> Sridhar has stated that the principal responsibility for global health lies with the WHO. Nonetheless, there are various other actors, primarily private donors, such as the Bill and Melinda Gates Foundation, who pour enormous sums of money into global health. While this funding is positive, an unintended consequence is the great competition for that money amongst organizations, leading some to question whether the actual needs of developing countries are being met or is the agenda of the donor being accomplished. Hence, some sort of monitoring mechanism could benefit this process.<sup>127</sup> In this dissertation, the global bioethics tool is offered as a mechanism to aid global health governance in regards to ethical issues surrounding pharmaceutical and biotechnology companies.

Just as global health governance in the realm of the WHO and other non-profit entities whose chief aim is to improve human health and enhance the conditions through which human

beings flourish is oftentimes in a state of disarray due to competing interests, lack of coordination, and inadequate amounts of transparency with the public and even with similar organizations, the same is true of for-profit corporations who have a similar aim of eradicating disease and improving human health. For-profit pharmaceutical and biotechnology companies are, by their very nature, involved in global health. Their governance mechanisms include the laws in their particular country or region, such as the FDA in the US and legislation passed by the EU or Council of Europe in Europe. Yet, companies within this industry rarely communicate with one another. As has been seen in previous chapters, the concept of corporate social responsibility is increasing within the pharmaceutical and biotechnology industry, and individual companies have responded to the public's outcry on matters of CSR. Yet, these efforts are largely done company-by-company apart from the coordination of the industry. In the field of pharmaceutical bioethics more generally, very little cooperation between companies exists. Yet, as this dissertation demonstrates, cooperation between for-profit companies on global bioethics is not only hypothetically possible, it is achievable.

Bioethics plays an important role in global health governance because governance is not merely a technical or managerial approach based on facts and scientific expertise. Rather, governance also involves the values, norms, and ideas of persons and collective societies, which is a particular strength of bioethics. The field of bioethics has a wealth of reflective resources at its disposal that can make intellectual contributions to the clarification of normative perspectives that guide policies and institutions in specific directions. Today, bioethics is increasingly becoming a mechanism of governance itself.<sup>128</sup> Not only are individual nation-states utilizing bioethics in their crafting of public policy, such as the notable 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that produced the

Belmont Report, but such bioethics governance is happening on a global scale as well. The methodology of bioethics governance is typically similar, whether done at the local or global level. First is the creation of an ethics committee, and second is the development of an ethical framework.<sup>129</sup>

Ten Have has recognized that nowadays governance is often accomplished through bioethics. This approach is based on four functions of global bioethics: regulation, oversight, deliberation, and interaction. Regulation in regards to bioethics is the process of developing normative instruments to be used by countries and organizations. These were examined in 4.1 and 4.2. Oversight refers to the ethics committees that have proliferated in countries to provide assurance that regulations are being fulfilled. Deliberation is an important step in order for making bioethics be representative of large swaths of people. Developments in science, technology, and medicine must be publicly discussed and debated. Finally, the function of interaction refers to the values and ethics that must be engaged with in global bioethics.<sup>130</sup>

For global bioethics, if there are global ethical frameworks, how can they be applied at a global level in order to address problems on a global scale?<sup>131</sup> This is a question that the proposed global bioethics tool seeks to answer. Using ten Have's four functions of global bioethics above, the instrument of regulation for the global bioethics tool is the UDBHR. The mechanism of oversight is the self-reporting and transparency embedded in the global bioethics tool. The process of deliberation would take place between pharmaceutical and biotechnology companies on a number of bioethics topics in trying to discern best practices and how best to apply the principles of the UDBHR within the industry.

For the functions of regulation and oversight, some have proposed a system of accreditation, certification, or rating to validate how pharmaceutical companies are doing in

regards to certain indicators. Companies, and even entire industries, have participated in systems of accreditation or certification due to public distrust. When the voices of public distrust become louder and directed at a single industry, then there is an increased risk of government regulation. For example, a national, independent accrediting body, the Association for the Accreditation of Human Research Protection Programs, originated in large part to assist institutional review boards do the work of self-regulating in order to keep government regulators at bay.<sup>132</sup>

In the literature and in practice there are differing models of accreditation, certification, and rating for companies in regards to implementation of ethical principles. Accreditation systems date back around a century. During the early 20<sup>th</sup> century accreditation agencies were established in both education and healthcare. For education, accreditation was used to establish a common basis from which to admit students to different institutions.<sup>133</sup> In healthcare, the precursor to the Joint Commission would propose establishing a system of hospital standardization circa 1910.<sup>134</sup> In 1917-1918 the American College of Surgeons developed a one-page *Minimum Standards for Hospitals*.<sup>135</sup> Today, scores of accreditation agencies exist covering industries such as education and healthcare to agencies that monitor and assess greenhouse gas emissions and nutraceuticals. Accreditation systems can serve as indicators of a product's or company's environmental impact, as well as, in the case of nutraceuticals, whether the product actually contains what it specifies to and is made with certain stringent standards.

Such a system is also possible for the pharmaceutical and biotechnology industry, as has been demonstrated recently by Jennifer Miller and her colleagues at Bioethics International.<sup>136</sup> Bioethics International has created a rating index called the "Good Pharma Scorecard" that ranks the twenty largest pharmaceutical companies and every new FDA approved drug on clinical trial transparency and legal compliance. Key criteria such as design of clinical trials, how

clinical trials are conducted, clinical trial transparency and data sharing, medical marketing concerns, accessibility of medicine and vaccines are examined in order to come up with a ranking list for the different companies.

Voluntary codes of conduct have also sprung up to try to regulate and govern aspects of business. A lack of effective legal responses from national governments and other international, regional, and multilateral institutions to restrain the conduct of multinational corporations that is considered socially undesirable has given rise to them being challenged by NGOs in the international economic and sociopolitical arena. These NGOs have been quite effective in pressuring multinational corporations to be accountable for their business activities and the negative side effects of their business practices in such areas as environmental protection, fair treatment of workers, human rights abuses, and bribery and corruption. The recognition of increasingly hostile sociopolitical environments on the part of individual multinational corporations and industry groups has prompted these organizations to take action in the form of voluntary codes of conduct that would pledge certain standards of conduct and outline corporate and industry responses to societal concerns. It has been recognized that the primary focus of these codes of conduct is twofold: 1) assuage public concerns and build further trust/repair reputation in multinational corporations; and 2) take actions that would improve their current state of affairs without unduly restricting the company in the conduct of their business or imposing burdensome regulatory oversight and heavy financial liabilities upon them.<sup>137</sup> It is worth noting that voluntary codes of conduct differ from CSR principles. In direct contrast to conventional codes developed by individual companies or an industry, CSR-related codes of conduct call on companies and entire industries to voluntarily assume the costs associated with the industry's negative externalities.<sup>138</sup>

Voluntary certification systems are a rather recent invention and achieved popularity in the late 1980s largely in response to activists who viewed the logging industry and population growth as threats to forests and the environment. Activist groups and NGOs created incentives for the logging industry to address societal concerns by participating in the SmartWood Rainforest Alliance certification program.<sup>139</sup> The Rainforest Alliance was a multi-stakeholder group with independent, third-party certification, which assures consumers that the wood products they purchase come from well-managed forest.<sup>140</sup>

Rating systems date back to around the turn of the twentieth century and have been notably used by the Access to Medicine Foundation in their biennial publication.<sup>141</sup> One of the first was produced by John Moody in 1909, who saw the need for such a tool after the stock market crashed in 1907. Moody's company published a book, known as *Moody's Manual*, that offered investors an analysis of security values. *Moody's Manual* analyzed the railroads and their outstanding securities and offered concise conclusions about their relative investment quality. Moody expressed his conclusions using letter rating symbols and with this endeavor he became the first to rate public market securities.<sup>142</sup> Today, rating systems are prolific—available in numerous industries to aid stakeholders in comparing companies and identifying industry best practices. Such systems do not require industry support, as many are based on information that is publicly available via other publications and reports.<sup>143</sup> In the pharmaceutical sector, the Access to Medicine Index (ATMI), published by the Access to Medicine Foundation, rates the top 20 research-based pharmaceutical and biotechnology companies on how they make medicines, vaccines, and diagnostics more accessible in LMICs. Along with a numerical ranking system, ATMI also includes examples of what each company is doing well, incorporating best practices, and areas in which they could improve.

The benefits of an accreditation, certification, or rating system for the pharmaceutical industry, according to Miller, are at least fourfold: 1) it would allow stakeholders better understand and define what it looks like for pharmaceutical companies not to act well and, contrasting, 2) it would help them also to understand and define what it looks like for the industry to act well; 3) it would motivate companies to move from bad practices to good practices, and 4) it would identify and communicate when the good has been implemented in ways that are trustworthy. Further, Miller includes steps for how such a system would be created. First, the concerns of stakeholders or the perceived problem areas are identified and prioritized for addressing initially. Second, standards or benchmarks are set to address the concerns. Third, measurement instruments are developed in order to evaluate the degree to which individual firms have or have not implemented these standards. Follow-up to ensure how particular firms are doing would consist of a self-assessment questionnaire, completed by the company, on how it senses its own performance in relation to the specified standards. This process might entail companies submitting certain types of evidence demonstrating how it attempts to comply with the standards throughout their organization. The second follow-up step in Miller's proposed process would involve the certification body dispatching a team to interview a selection of the company's employees who are responsible for implementing the standard in order to determine the veracity of the company's implementation claims. Finally, companies that receive a satisfactory score are accredited or certified and would be free to use a seal or label attesting to that for a defined period.<sup>144</sup>

These different models each have their own merits and need to be considered for the proposed global bioethics tool. While some sort of rating system is certainly promising for the proposed global bioethics tool, a system of certification or accreditation is outside the bounds of



the project at this time. As it currently stands, the global bioethics tool is not designed to be a statement or verification that participating companies have eliminated harmful bioethics practices and are certified as being upstanding bioethics citizens, which is what accreditation and certification mechanisms, such as the proposal by Miller, in large part, attempt to do. Rather, the proposed tool enhances the transparency of the industry and is a measure of how well companies are doing in regards to applying and implementing certain principles. While it is envisioned that stakeholders and the general public will be able to compare how and what Company X is doing in comparison to Company Y, a system of certification or accreditation would be asking too much of the global bioethics tool at this germinal stage.

A model that is more promising at this very infantile stage of the proposed global bioethics tool is rating, which is very similar to the process of the ATMI. While there have been shown to be many positive benefits of a rating system, such as stimulating companies towards competition within the industry and thus greater social responsibility,<sup>145</sup> rating does not typically inspire collaboration between competing companies, as the very nature of a rating system is to perform your best so as to be better than others. Yet, the proposed global bioethics tool is based around the idea of generating best practices for the industry and spurring greater transparency rather than rating companies. The global bioethics tool seeks to form a collaborative partnership between firms in the pharmaceutical and biotechnology industry. Hence, even a rating system is not overly promising for the global bioethics tool at this stage. Rather, as will become apparent in the subsequent chapters, the proposed global bioethics tool seeks to be an industry-initiated bioethics governance tool, which would be novel for the pharmaceutical and biotechnology industry.

In conclusion, this chapter began by first exploring eight bioethics declarations and guidelines that have been created over the past seven decades. The Nuremberg Code, Declaration of Geneva, Declaration of Helsinki, Belmont Report, 45 CFR 46 (US Common Rule), CIOMS guidelines, Good Clinical Practice, and a resolution from the Council of Europe (Oviedo Convention) were all examined. It became evident during this process that while there are undoubtedly many merits to all these biomedical ethics guidelines, they are not well suited for the task of creating a global bioethics tool that could be used to unite pharmaceutical and biotechnology companies.

Section 4.2 then presented the UNESCO Universal Declaration on Bioethics and Human Rights in detail and provided justification for why UNESCO is a suitable organization to aid in this task and why the UDBHR is appropriate for the foundation of the proposed global bioethics tool. It was seen that the UDBHR is the first and only bioethics declaration to gain the approval of international governments, its efforts to incorporate major principles in bioethics, it reaches beyond individual orientations to bioethics to a global perspective, and it is useful for countries that lack an infrastructure in bioethics. As a universal document, grounded in human rights and having been adopted by the global community, the UDBHR is currently the premier bioethics guideline for this project.

Finally, section 4.3 discussed the issue of bioethics governance and the differing models of accreditation, certification, and rating that have been created. An analysis of each was completed. This is useful in order to explore how these might apply to the proposed global bioethics tool. The proposal of Jennifer Miller for how a pharmaceutical accreditation or certification program might look was also reviewed. It was determined that at this stage in the global bioethics tool, such a mechanism would not be advised.

Now that the groundwork for the proposed global bioethics tool has been laid, chapter five presents the methodology for the creation of the tool and the development of indicators. Chapter five also introduces the benchmarking process and how the tool is envisioned working in practice. Chapter six then applies the tool to specific pharmaceutical and biotechnology companies. Chapter seven is then a concluding chapter that discusses further research that needs to be completed and offers next steps on developing the global bioethics tool.

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## **Chapter 5: Global Bioethics Tool: Methodology and the Development of Indicators**

The proposed global bioethics tool involves four main steps: First, a preliminary phase, consisting primarily of desk research, is conducted to develop indicators, research the viability of the project, and determine the interest level of UNESCO. Second, an exploratory phase seeks to gather interest from 4-5 top pharmaceutical and biotechnology companies so that a partnership can be formed. The exploratory phase also involves reaching out to the UN Global Compact to discover if there are partnership opportunities with them. The third phase commences once there is a commitment from 4-5 companies. This phase is also the longest and consists of refining the indicators, interviewing the companies, generating best practices, producing a functioning self-reporting website, and other activities in order to make the global bioethics tool eventually reach the point of sustainability. Finally, the fourth phase forms a non-profit foundation to house the global bioethics tool. To make the foundation financially sustainable, member organizations would pay into the foundation with a dues structure based upon the annual revenue of the organization. Such a system has been set up before, as similar dues structures are used by Business for Social Responsibility<sup>1</sup> and other industries have also set up similar foundations, such as IPIECA, the global oil and gas industry association for environmental and social issues.<sup>2</sup>

Section 5.1 begins by presenting the rationale behind the creation of the proposed global bioethics tool. This then transitions into an analysis of determining best practices and benchmarking. Section 5.2 then presents the indicators that have been developed for the principles of the Universal Declaration on Bioethics and Human Rights. Each of the principles within the UDBHR has been translated into specific questions, termed indicators, so that individual pharmaceutical and biotechnology companies can ascertain qualitatively how they are doing in implementing the principles.

### *5.1) Rationale, Methodology, and Benchmarking*

In order to justify that the proposed global bioethics tool is needed, we must provide evidence that there is sufficient demand for this type of evaluation from stakeholders in order to convince pharmaceutical and biotechnology companies to participate. In other words, is there a strong business case for firms in the pharmaceutical to divulge aspects of bioethics and human rights implementation and assist the industry in developing best practices? Jennifer Miller has described the case for accreditation, certification, or rating within the pharmaceutical industry based upon consumer interest, which was discussed in the previous chapter.<sup>3</sup> Similarly, this rationale is significant for the proposed global bioethics tool. We must remember that prescription sales, vaccines, and immunizations are not the only products produced by pharmaceutical companies. Many firms offer a vast array of over-the-counter (OTC) medicines or home health products. For instance, Bayer is known for their aspirin and their “One A Day®” line of vitamins, and Johnson & Johnson is known for numerous OTC medicines like Tylenol® as well as medical supply products like Band-Aid®. Hence, even persons who do not regularly take prescription medication are likely to use at least some of the non-prescription products from a pharmaceutical company.

The benefits of a voluntary, industry-initiated, transparent global bioethics tool reach beyond restoring reputation and positive public image for the pharmaceutical industry. Such a tool would aid the industry in better understanding and defining what good ethical practices look like in practical terms, motivate companies to incorporate better ethical processes into their operations, and send a clear message to their multiple stakeholders that they are serious about implementing bioethics into their business. Miller has written that the concerns of stakeholders around the business practices of the pharmaceutical industry fall into four interrelated categories:

(a) the design and management of clinical trials, (b) the dissemination of trial results, (c) corporate marketing strategies, and (d) the accessibility of medicines.<sup>4</sup> Recent headlines that have painted the industry in a bad light have primarily revolved around the accessibility of medicines and, more specifically, the pricing of these medicines. This was detailed in chapter three and will not be reiterated here. Yet, as Miller recognizes, the pricing of products may be a primary category of concern, but it is not the sole category.

Many concerns persist around the design and management of clinical trials and the dissemination of results. In particular, industry sponsorship of trials and the conflict of interest it poses is great. In a 2005 study that analyzed 397 psychiatric clinical trials, the authors concluded that industry sponsorship of a clinical trial was associated with a greater likelihood of reporting a drug to be superior than a placebo.<sup>5</sup> That industry-funded trials are more likely to produce a positive result than independently funded trials has been reported both in scientific, peer-reviewed literature and in more popular media.<sup>6</sup> Critics have charged that pharmaceutical and biotechnology companies regularly suppress unfavorable study findings and/or disseminate them in ways that are misleading and have a likelihood of biasing the body of evidence about drug efficacy and safety.<sup>7</sup> Further, industry critics argue that companies substitute alternate endpoints for genuine clinical endpoints to make a novel drug in the clinical trial process look more successful. Critics also believe that pharmaceutical and biotechnology companies cherry-pick research participants who make drugs appear more effective than they actually will be if released in their intended markets. The obtaining of genuine informed consent in clinical trials from participants in LMICs is another area of worry that has been persistent for decades.<sup>8</sup> Hence, problems surrounding the design and management of clinical trials seem ubiquitous.

What is more, as Miller has noted, corporate marketing strategies have also been a category of attention. Only two countries in the world allow pharmaceutical direct-to-consumer advertising of prescription drugs: New Zealand and the US.<sup>9</sup> In the US, this type of advertising is under fire. At the November 2015 Interim Meeting of the American Medical Association, physicians adopted new policy to ban pharmaceutical advertising.<sup>10</sup> Researchers have linked direct-to-consumer advertising with unnecessary increased utilization of prescriptions, diminished time evaluating a patient by a physician, and misinformation.<sup>11</sup> The promotion of off-label drugs and the utilization of financial incentives, grants, lavish gifts, and large honorariums for consulting or speaking for physicians and researchers has also been criticized.<sup>12</sup> The four categories of concern that Miller has highlighted aid in showcasing the rationale for the proposed global bioethics tool. The public's perception of the pharmaceutical and biotechnology industry is not flattering, and the proposed tool may be part of the solution.

The global bioethics tool began taking shape in the summer of 2015 when Dr. Henk ten Have contacted the bioethics division at Novo Nordisk to ascertain if there might be an opportunity for this author to gain experience in corporate bioethics. This was warmly welcomed by Novo Nordisk and resulted in a meeting in November 2015 at Duquesne University between the author, Dr. ten Have, and Dr. Lise Holst of Novo Nordisk to discuss a project proposal for the global bioethics tool. In January 2016 the bioethics division of Novo Nordisk awarded a 6-month grant to Duquesne University to work on developing a global bioethics tool for use by the pharmaceutical and biotechnology industry and to see if such a tool is viable for the industry. The Principal Investigators (Pis) on the study were Lise Holst, MD, PhD, Director of Global Bioethics Management at Novo Nordisk and Henk ten Have, MD, PhD, Director of the Center for Healthcare Ethics at Duquesne University and former Director of the Division of Ethics of

Science and Technology at UNESCO (2003-2010). As chief researcher on this project, the author was deeply invested in this project from its origin. The following will describe the process that took place in beginning the project and the different phases, including trying to collaborate with multiple stakeholders, comprising major pharmaceutical and biotechnology companies and UNESCO.

After the November 2015 meeting between Holst, ten Have, and myself, a grant to begin work on the project was drafted and submitted by Duquesne University to Novo Nordisk. The grant was approved, and the initial preliminary phase of the project commenced in January 2016. The first step involved identifying possible indicators for assessing the implementation of the UDBHR principles. These indicators will be discussed in much greater detail in 5.2. The second step of the preliminary phase examined existing reporting methods for the implementation of human rights principles and CSR. In the third step, the development of a “Global Compact for Bioethics,” patterned off the UN Global Compact, was explored. Such a tool would ideally be connected to a UN organization, and since UNESCO was the body in charge of the UDBHR, they were contacted regarding their interest in being connected to this project. In May 2016, the author and the two Pis traveled to UNESCO headquarters in Paris, France in order to meet with Dafna Feinholz, PhD, Chief of Section – Bioethics and Ethics of Science. Feinholz expressed pronounced interest in the global bioethics tool and creating some level of partnership between the bioethics division of UNESCO and the formation of this tool. Lastly, benchmarking and examining best practices comprised the fourth step of the preliminary phase, which will be explained later in this section.

In July 2016 the grant was extended for an additional 6-month period as an “exploratory study” to investigate the feasibility of engaging primarily pharmaceutical and biotechnology

companies in setting up this initiative. A number of major, top-20, pharmaceutical and biotechnology companies were contacted to ascertain their interest in collaborating on this project. The entire methodology describing the process of how the project unfolded will be presented in detail in this subsection.

A primary goal of the global bioethics tool is to create a platform through which companies can discuss and develop industry best practices. To achieve this, a process of determining best practices through benchmarking will need to occur. The concept of benchmarking began in the late 1970s by the Xerox Corporation as a way to position itself more competitively in the market. Definitions of benchmarking vary considerably, but key themes include measurement, comparison, identification of best practices, implementation, and improvement. Numerous definitions are available in the literature, with one article citing at least 49 unique definitions for benchmarking.<sup>13</sup>

Essentially, benchmarking is the process of identifying the highest standards of excellence for products, services, or processes, and then making the improvements necessary to achieve those standards, which are commonly termed “best practices”.<sup>14</sup> Another way to describe benchmarking is simply as the systematic search for best practices that leads to superior performance.<sup>15</sup> Hence, no matter how benchmarking is defined, it is always best-practice-oriented. In the late 19<sup>th</sup> century, the management science work done by Frederick Taylor encouraged work processes to be compared through the scientific method. Taylor believed there was a single “best way” for work to be performed, which could be discovered via scientific study, and should then be applied as the standard for performance.<sup>16</sup>

The concept of benchmarking also draws from the Japanese industrial practice *dantotsu*, referring to a method for finding the best practice that consistently yields the best results in that

industry.<sup>17</sup> From its inception, benchmarking has been utilized to identify aspects of an organization's activity that could be more efficient/effective by comparison with the performance of other relevant organizations. The data regarding the other relevant organizations and their key processes are used to identify and implement changes.<sup>18</sup>

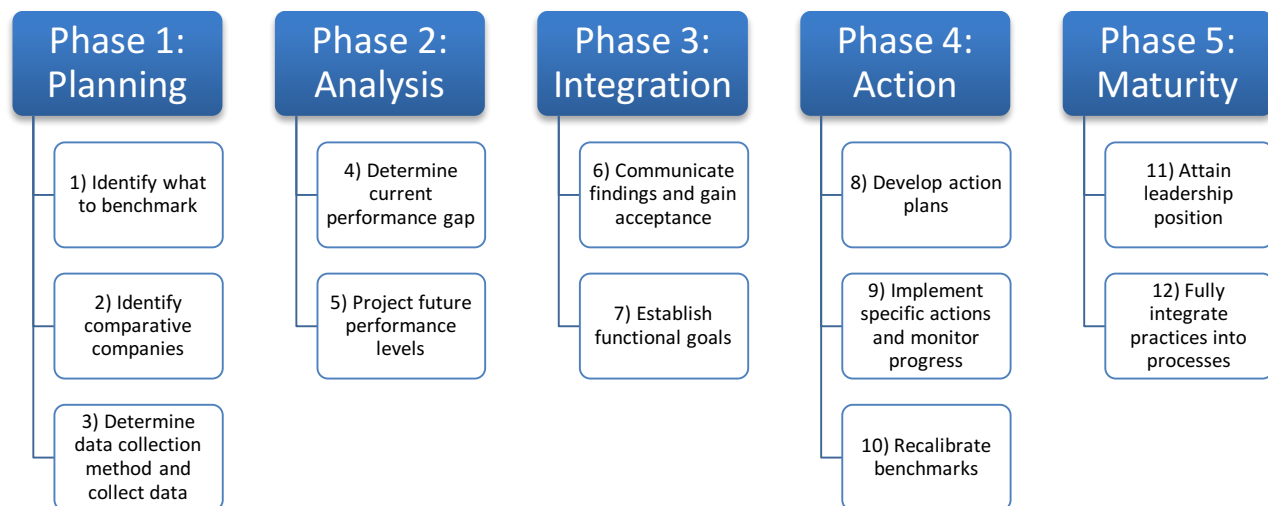
The benefits of benchmarking are substantial. First, benchmarking is able to enhance transparency. There is a push from society for companies to be more transparent about their processes. The UN Guiding Principles on Business and Human Rights desire for companies to both know and show that they are respecting human rights. This type of thinking can be applied to all issues of bioethics; companies should know what they are doing and should show it. Hence, the hope of benchmarking and the global bioethics tool is to be an effort that drives transparency in regards to a company's actions on human rights and bioethics, which is certainly very relevant for the investors, employees, local communities, customers, and other stakeholders of a company, not to mention government regulators and the general public.<sup>19</sup> Companies, through the use of benchmarking are able to know and show their actions and achievements, which allows stakeholders to evaluate the company. This opens the door to multi-stakeholder contribution to open dialogue, and this transparency has the ability to benefit not only stakeholders and the general public, but also the company itself. Benchmarking and the transparency that may go along with it is a signal to stakeholders that the company has nothing to hide and truly does attempt to operate in a responsible manner.

Second, accountability is increased with benchmarking. With benchmarking it is much easier for stakeholders and for others inside the industry to hold the company accountable for its actions. The hope with the global bioethics tool is that benchmarking would spur companies to greater ethical responsibility. Third, benchmarking allows companies to more readily compare



their actions to one another. For the individual company, benchmarking allows for internal comparison, as the company is able to gauge progress over a specific time period, such as from year to year. Benchmarking can also allow for competition between companies, which has been witnessed by the Access to Medicine Index.<sup>20</sup>

The history of modern-day benchmarking is not very old. Robert C. Camp, a logistical engineer for Xerox, would head up the now-famous study on benchmarking at Xerox and would also coin the term in late 1980.<sup>21</sup> Benchmarking was perceived to be a strategic tool to increase productivity, enhance learning, assess performance, and continuously improve upon an operation.<sup>22</sup> While there is no single accepted method for making benchmark analyses, a frequently used model is proposed by Camp. Camp divides benchmarking into two main parts: practices and measures.<sup>23</sup> He delineates a twelve-step process on benchmarking that is split into five phases. The process starts with deciding what to benchmark and whom to involve, following up with planning and conducting investigations to collect data, determining performance gaps and projecting future performance levels, and communicating findings. The final steps are focused on revising and improving performance goals, developing an action plan, and finally implementing action plans, monitoring results, refining benchmarks when necessary, attaining leadership position, and fully integrating the practices into the processes.<sup>24</sup> This is depicted as a chart below:



To demonstrate how this can be applicable for pharmaceutical and biotechnology companies, as a succinct example to show how benchmarking might be applied, let us use a case study for illustrative purposes:

Company X is a major pharmaceutical company who has vast experience working with clinical trial participants from various cultures. Lately, though, they have become concerned that their normal processes of consent have not been adequate to convey the information about the proposed study to a particular people group in South America on whom they would like to perform a research trial for a neglected tropical disease (NTD). Company X has decided to use a new strategy for consent amongst this people group in South America, which will consist of having one of their researchers live in the community for up to 6 months in order to learn more about their customs. Though this is time consuming and will delay the start of their clinical trial, they see value in measuring whether the group fully understands the clinical trial. Company X wants to know if their new strategy for consent in this group (who are very communal and their culture is much different than the trial's sponsoring country) has the following outcomes: 1) whether it actually helps to convey the information they need to the persons in an understandable way, and 2) whether it is efficient in terms of time and resources compared to what they have been doing in the past and what other companies are doing.

So, to use Camp's model of benchmarking to assess Company X's new mode of consent in comparison to the mode used by other companies in a very succinct, elementary manner might look something like the following:

**Step 1: Identify what to benchmark**—The new consent process/strategy among a people group in South America on whom Company X wants to begin a trial for a NTD. Outcomes to measure include 1) whether the new consent strategy actually helps to convey the information they need to the persons in an understandable way, and 2) whether it is an efficient use of resources compared to what they have been doing in the past and what other companies are doing. Camp recommends for the company to prepare a project description describing the rationale for wanting to benchmark a specific process.<sup>25</sup>

**Step 2: Identify comparative companies**—There are surely other companies who have performed trials on people groups that are more communally oriented. Company X needs to identify these companies. One tremendous benefit of the global bioethics tool is that many pharmaceutical and biotechnology companies would be gathered together around a common goal of increasing bioethical performance and, thus, it would be simpler for Company X to identify companies to whom they can compare their processes.

**Step 3: Determine data collection method and collect data**—Company X will need to devise a method for determining whether the persons they are seeking consent from truly understand what they are potentially agreeing to. Further, Company X also wants to measure the resources utilized for this new strategy of consent, so they will need to keep track of this. They will also need their comparative companies to be transparent about their strategies and results.

**Step 4: Determine current performance gap**—This step moves into the analysis phase and Company X would then determine how their new strategy for consent measures up to their comparative companies. There very well may be a performance gap where another company has received better results on something they are doing or their resource utilization is lower. This is termed the performance gap.

**Step 5: Project future performance levels**—Once the current performance gaps have been defined in the previous step, the future performance levels need to be projected. Camp defines this as the difference between expected future performance and the best in the industry.<sup>26</sup> Continuing with our example, Company X will need to evaluate if the gap between where they currently are and where they want to be is widening or closing.

**Step 6: Communicate findings and gain acceptance**—Once the performance gap has been discovered and Company X has projected future performance levels, it is time to communicate those findings. For the global bioethics tool, this is envisioned as a multi-stakeholder process. That is, Company X will communicate their findings on their new informed consent process and how it compares to other companies. The opportunities that have been identified by the benchmarking process will also have to be communicated internally within Company X, and it will need to be accepted that change needs to occur in order to better their informed consent process.

**Step 7: Establish functional goals**—To establish functional goals, Camp recommends stating important benchmark findings into statements of operating principles.<sup>27</sup> For company X, let us postulate that another company was shown to receive greater levels of understanding among their research population and they spent less time doing so. Hence, for Company X, functional goals might be twofold: 1) Obtain greater level of understanding of the proposed clinical trial by the research population, while 2) reducing the time it takes to obtain consent and thereby reducing personnel costs.

**Step 8: Develop action plans**—Step 8 begins the action phase of the benchmarking process. Now that the company knows that there is a gap in performance between where they are and where other competitors in the industry stand, in this step Company X will begin to plan and

plot how they are going to work towards their functional goals. Not only must Company X develop plans for how they will reach their functional goals, but they also must plan how they will attain the support of their organization for the implementation of their new goals.<sup>28</sup>

**Step 9: Implement specific actions plans and monitor progress**—Implementation depends largely on understanding the new practices and the differences that are being made in the processes. The roles and responsibilities of individuals must also be understood. Monitoring progress includes standard approaches of monitoring that all business undertake with their processes of evaluation: comparing progress against predefined milestones, determining causes for variance, taking corrective action where variance is significant, and reviewing results with stakeholders and management.<sup>29</sup> Periodic review of progress would then be based on the new functional goals.<sup>30</sup> Hence, for our example, Company X will now implement the action plans they developed in the previous step.

**Step 10: Recalibrate benchmarks**—Benchmarks and best practices are rarely, if ever, static. They are more often fluid and because of the fluidity, recalibration needs to occur in order to stay current with evolving conditions and be able to maintain superior performance. Benchmarking recalibration will not just happen. Rather, it must be deliberate and planned.<sup>31</sup> For the global bioethics tool, recalibrating benchmarks will be a continuous process in which pharmaceutical and biotechnology companies are transparent with others in the industry and with the public about what they are doing in regards to implementing bioethics and human rights. The process for recalibration, according to Camp, is simply a matter of re-implementing steps 1-10 of the benchmarking process.

**Step 11: Attain leadership position**—Step 11 moves into the maturity phase of benchmarking. The benchmarking process will need to be continually evaluated and given

attention by company management and by partners of the global bioethics tool. Camp notes that once a company attains leadership position in a specific area over competitors, the company must continually refine and improve, lest they lose their leadership.<sup>32</sup>

**Step 12: Fully integrate practices into processes**—The final step in the process is to fully integrate the new practices into processes. At this step, all levels of the company should have buy-in on the new practices and procedures. For Company X, not only are researchers and field scientists now fully trained on their new process of consent, but managers have integrated it into their operational policies, data analysts and those who write up the consent documents and IRB proposals are intimately aware of the changes.

There are two broad types of benchmarking: internal and external. Within these broad categories there can be numerous sub-types. Camp delineates four types of benchmarking: internal, competitive, functional, and generic. Each type has its specified outcomes and benefits depending on what the organization wants to achieve, and each will be discussed.<sup>33</sup> Internal benchmarking is the most straightforward of the four types, and it should be viewed as a starting point for businesses. In internal benchmarking, as well as the other types, the same process is undertaken as described in the above graphic, yet the target of the benchmark differs. For internal benchmarking, one is looking at processes within the company and comparing them to other similar processes. Indeed, a prerequisite for effective benchmarking is a focus on the work process, which is why internal benchmarking is oftentimes a more straightforward and streamlined process.<sup>34</sup> In the second type of benchmarking—competitive benchmarking—one is looking to compare a process within their company to a leading competitor in their industry. Camp notes that at some stage, the gaps between the competitor company and one's own company must be known in order to assess the strengths and weaknesses of the company.<sup>35</sup> This

is a very similar process to what is hoped to be achieved with the global bioethics tool in order to discover best practices.

Functional benchmarking is a third type of benchmarking, and is the process of comparing a business function to that of a functional leader, which is often not in the same industry. As the pharmaceutical and biotechnology industry is such a specialized industry, and as the global bioethics tool is concentrated on the area of biomedicine and clinical research, this type of benchmarking may not prove as beneficial. Finally, a fourth type of benchmarking is known as generic process benchmarking. In this type of benchmarking, a key business process that the company wants to benchmark is identified, such as product shipping. Once the process to be benchmarked is identified, benchmarking is pursued to find the best practices in product shipping, wherever they may be. This type of benchmarking also typically occurs across various industries and, one again, this usefulness of this type of benchmarking for the global bioethics tool seems limited.<sup>36</sup>

Camp's model of benchmarking is not the only model. Others have been proposed by Spendolini,<sup>37</sup> Watson,<sup>38</sup> Zairi,<sup>39</sup> and Iacobucci.<sup>40</sup> Michael Spendolini attempts to simplify the benchmarking process by benchmarking the benchmarking processes that were in use in leading companies of the early 1990s, such as Xerox, AT&T, and DuPont. From this analysis he offers a five-stage process for benchmarking: Step 1) Determine what to benchmark; Step 2) Form a benchmarking team; Step 3) Identify benchmarking partners; Step 4) Collect and analyze benchmarking information; Step 5) Take action.

Gregory Watson reportedly surveyed nearly 70 models of benchmarking for his research on the subject.<sup>41</sup> He utilizes a four-phase approach, with numerous steps comprising each phase. The four phases are: 1) planning the benchmark project, 2) collecting the necessary data, 3)

analyzing the data for performance gaps and enablers, and 4) improving by adapting process enablers. Watson goes into a fair amount of depth in describing the steps that accompany each phase.<sup>42</sup> Nonetheless, Camp's model still appears to be more in-depth. This is not to say that there are not aspects of benchmarking to be learned from Watson, for his process is not markedly different than others, it is merely to suggest that Camp's model may prove more useful in the beginning stages of the global bioethics tool. What is more, the global bioethics tool seeks to attract major pharmaceutical and biotechnology companies to participate. These companies surely have their own wealth of experience in benchmarking, which should be harvested and gleaned.

Mohamed Zairi outlines a 16-step process for implementing benchmarking. Steps 1-7 comprise the effectiveness stage, and steps 8-16 comprise the competitiveness stage. Zairi's steps will be briefly detailed here: 1) Understand internal processes; 2) Evaluate current processes, 3) Identify process limitations/opportunities for improvement; 4) Improve processes; 5) Measure and evaluate; 6) Set internal standards; 7) Control and manage processes; 8) Select process suitable for benchmarking; 9) Identify suitable partners; 10) Agree on measurement strategy; 11) Compare standards; 12) Understand why difference in performance; 13) Change relevant practices for improving performance; 14) Compare standards; 15) Repeat experience with same/new partners on regular basis; 16) Apply benchmarking to all processes.<sup>43</sup> A strength of Zairi's work is that it documents the European view and application of benchmarking, rather than the American viewpoint where benchmarking originated.<sup>44</sup> Yet, Zairi does not provide the detailed commentary on each of the steps in his process as Camp does. Hence, his model might prove difficult for a novice to follow and implement.



Dawn Iacobucci and Christie Nordhielm have proposed that benchmarking begin by starting from the customer's point of view. They write,

To begin the process, list each step of your customers' buying experience, from the initial recognition of need to the final follow-up after the purchase. Next, determine which factors most influence customers' perception of value at each step. Finally, identify companies that excel at each factor—no matter what industry they're in. By breaking down the value delivery system into detailed, customer-focused steps, this process helps managers identify relevant companies to study.<sup>45</sup>

This approach is novel and has potential for positive outcomes, yet it would need to be significantly tailored for the use of benchmarking human rights and ethics activities, as the global bioethics tool seeks to do.

At this point at least six different processes of benchmarking have been briefly analyzed and it seems that the process of benchmarking and determining best practices as proposed by Camp is most suited for the proposed global bioethics tool. This is not to say that his model may not need additional tweaking for the purposes of the global bioethics tool, but at this juncture it seems well suited for this task.

Benchmarking is far from being free of criticism, and it is most often criticized on three fronts: information, implementation, and theory. In regards to information-oriented criticism, Andrew Campbell has asserted that businesses spend considerable effort in benchmarking while attempting to gather data describing advantages, often covertly, and they may fail to focus on their own unique situation. This may make the company prone to distraction and misdirection. Campbell also argues that benchmarking is always a retrospective process, as you are looking to what your competitors have done in the past, which may not yield considerable advantage in fast-moving markets.<sup>46</sup> This is a fair criticism that companies must keep in mind when deciding to start a benchmarking process. What is more, Metin Kozak and Kevin Nield claim that the information required to implement benchmarking properly inherently reduces heterogeneity

within industries and escalates the risks of uncompetitive homogeneity if product differentiation declines.<sup>47</sup> Surely this is a risk, yet this risk within the pharmaceutical and biotechnology industry does not seem plausible, for their industry thrives on innovation of products and competition. Benchmarking human rights and ethical issues would not seemingly reduce heterogeneity of products in terms of pharmaceuticals.

In regards to implementation-oriented criticism, Gregory Watson, whom we have discussed above, in his 1993 book cited two major difficulties that he perceived in implementing a rigorous benchmarking study: 1) deciding what process for the company to focus the benchmarking resources on, and 2) agreeing on what organizations to solicit as partners in order to compare processes.<sup>48</sup>

There are many theory-oriented critiques of benchmarking.<sup>49</sup> Robert Pederson has questioned the ability of benchmarking to provide anything aside from marginal improvements in processes.<sup>50</sup> Yet, the experiences of Xerox and others like it would show otherwise. Michael Hammer and James Champy argued that benchmarking has the potential to produce a restrictive framework for innovation by only focusing on those business processes that are already occurring within one's industry. They further argued that benchmarking sets a ceiling on ambition by seeking to be only equal to the best and not surpassing it.<sup>51</sup> However, in Camp's benchmarking model he is very keen to discuss not only trying to equal the best in the industry, but to attain the leadership position by continuing to improve. Further, in regards to theory-oriented critiques, as early as 1979, Julie Wolfram Cox and colleagues lamented the absence of a sufficiently developed theory that would explain the differences between effective and ineffective efforts of implementing benchmarking.<sup>52</sup> K.W. Wöber has also stated that benchmarking lacked a rigorous foundation in management science and added that a generally

accepted methodology for selecting suitable benchmarking partners was only addressed in the year 2000.<sup>53</sup> Indeed, this is a fair criticism, as the majority of the literature on benchmarking is overwhelmingly more pragmatic than deeply theoretical. The literature is largely process-driven and oriented around case studies of benchmarking success stories.

Benchmarking companies on areas of human rights and/or ethics is a fairly novel project, but it has been done before. Currently, the Corporate Human Rights Benchmark (CHRB), a collaboration between Aviva Investors, Business & Human Rights Resource Centre, Calvert Investments, Institute for Human Rights and Business, VBDO, and Vigeo Eiris, is attempting to do just that. The CHRB touts itself as the “first-ever ranking of the world’s largest publicly listed companies on their human rights performance.”<sup>54</sup> It aims to rank the top 100 companies across the agricultural, apparel, and extractives sectors on their human rights related policies, procedures, processes, practices, and responses in order to try to incentivize companies to greater performance.

The CHRB is based on publicly available information, such as from the company’s website or other public documents, for example CSR reports or newspaper articles. This approach differs from the methodology of the proposed global bioethics tool, as the global bioethics tool expects for companies to self-disclose this information and share it with others as a mechanism for learning and spurring one another to best practices. Nonetheless, the CHRB is grounded primarily in the UN Guiding Principles on Business and Human Rights.

The CHRB has created indicators to score companies on human rights. For each indicator a company can score zero, one, or two points based upon the sufficiency of the company’s response for the indicator. A complete methodology has been released by the CHRB that

demonstrates companies can indeed be benchmarked on their approach to human rights. The pilot CHRB benchmark was released in mid-March 2017.

As this section concludes, it is important to bear in mind that benchmarking will not be an easy, quick process, for it will take substantial time and commitment from all participating companies. Further, companies will have to guard against becoming complacent once easily attainable goals have been accomplished. In the late 1990s, the toy manufacturer Mattel announced that it was implementing a new global code of conduct, including such items as legal and ethical business practices, for all its production facilities and manufacturers. In the initial phases of the new code of conduct, processes for improving upon its business practices were swift and effective, and the code was seen as successful. However, as time went by, it became apparent that all of the easily attainable goals had been achieved and that further progress would be incremental and accommodated in normal business operations. Mattel eventually decided to discard public disclosure of its code compliance activities.<sup>55</sup> The lesson to be learned from the Mattel case study is that at the beginning of the life of the global bioethics tool, there will, presumably, be some easily achievable goals that will not take much effort. Yet, the work of improving the implementation of human rights and bioethics does not stop once the simple items are complete. This highlights the need for companies that are involved in the global bioethics tool to continually push one another on towards advancing human rights and bioethics within their own companies and not to grow complacent.

### *5.2) Development of Indicators*

Performance measurement is a fundamental principle of good management. The measurement of performance is significant because it identifies performance gaps between current and desired performance and provides indication of progress towards closing the gaps.

The use of key performance indicators may identify precisely where to take action to improve performance. Key performance indicators represent a set of measures focusing on those aspects of organizational performance that are the most critical for the current and future success of the organization.<sup>56</sup>

A key performance indicator can be defined as an item of information collected at regular intervals in order to track or measure the performance of a particular system.<sup>57</sup> Qualitative and quantitative key performance indicators are used as a means of measuring and monitoring the progress towards particular goals and objectives.<sup>58</sup> In the UNESCO Universal Declaration on Bioethics and Human Rights, the core of the declaration is found in fifteen principles (Articles 3-17).<sup>59</sup> Indicators, in the form of questions, are developed based upon each of these principles so that one can qualitatively assess how a particular company is doing in implementing the international standards. In developing these indicators, the UNESCO UDBHR was first compared to the other prominent bioethics guidelines, such as those presented in 4.1. As an example of this process, Article 15 of the UDBHR concerns benefit sharing and states the following:

Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms: (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research; (b) access to quality health care; (c) provision of new diagnostic and therapeutic modalities or products stemming from research; (d) support for health services; (e) access to scientific and technological knowledge; (f) capacity-building facilities for research purposes; (g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.<sup>60</sup>

As the Declaration of Helsinki also discusses sharing of benefits in Articles 22 and 34, the two documents were compared for similarities and to see the general requirements of benefit sharing in each document. Additionally, prominent, current literature on each of the principles was

examined and will continue to be investigated during this process to better understand how each principle could be implemented by the pharmaceutical and biotechnology industry. For the principle of benefit sharing, the following three indicators have been developed based upon the principle of benefit sharing:

- 1) How does the company ensure that the benefits resulting from its scientific research are shared with society as a whole?
- 2) When conducting clinical trials, does the company ensure that in advance of the trial, provisions are made for post-trial access for all participants who still need an intervention identified as beneficial in the trial (DoH, Article 34, 2013)
- 3) How does the company ensure against improper inducements to participate in research?

Therefore, other prominent bioethics guidelines were consulted while forming these indicators, as well as the two PIs on this study, one of which is an expert in corporate social responsibility, pharmaceutical bioethics, and animal welfare, and the other an authority in global bioethics. Moreover, the author is under no illusion of the importance of substantial stakeholder engagement to further refine these indicators, which cannot be overstated. Nonetheless, as the first expedition into such a global bioethics tool to instrumentalize the UNESCO UDBHR for the pharmaceutical and biotechnology industry, the developed indicators provide a good starting ground for the global bioethics tool. In the explanatory memorandum of April 2005 the IBC stated that, “Principles always require further interpretation since the norms implicit in principles have to be translated into concrete laws, policies, guidelines and practices.”<sup>61</sup> This is exactly what the global bioethics tool has sought to do for the pharmaceutical and biotechnology industry.

The following tables showcase the indicators that have been developed for each of the principles (Articles 3-17) of the UNESCO UDBHR. Following each of the tables is an explanation of how the indicators were arrived at and further steps that might be taken.

Article 3 – Human dignity and human rights	
<b>UNESCO UDBHR</b>	<p>1. Human dignity, human rights and fundamental freedoms are to be fully respected.</p> <p>2. The interests and welfare of the individual should have priority over the sole interest of science or society.</p>
<b>Indicators:</b>	<p><b>General:</b></p> <ul style="list-style-type: none"> <li>• How does the company avoid infringing on the human rights of others? (cf UN Guiding Principles on Business and Human Rights (UNGPBHR) Principle 11)</li> <li>• How does the company ensure the welfare of its employees by providing safe and suitable working conditions?</li> <li>• How does the company implement standards of working hours for its employees, such as those put forth by the International Labour Organization?</li> <li>• How does the company ensure fair living wages in relation to the context of their employees such as to meet the basic needs of employees and dependents?</li> <li>• How does the company ensure the elimination of all forms of forced or compulsory labor in its employees and suppliers? (cf UN Global Compact (UNGC) Principle 4)</li> <li>• How does the company ensure the effective abolition of child labor of its employees and its suppliers? (UNGC Principle 5)</li> <li>• How does the company ensure that a system is in place so that employees may voice concerns regarding aspects of human dignity and human rights? (UNGPBHR Principle 18)</li> <li>• Does the company have in place a human rights due diligence process to identify, prevent, mitigate and account for how they address their impacts on human rights? (UNGPBHR Principle 15b)</li> </ul> <p><b>Human Research:</b></p> <ul style="list-style-type: none"> <li>• How does the company promote and safeguard the health, wellbeing, and rights of human research participants?</li> <li>• Does the company place the goal of generating new knowledge in clinical trials above the rights and interests of the individual research participant?</li> <li>• How is the priority of patients’ safety respected during a trial, and after market marketing of a new product?</li> </ul>

	<p><b>Safety:</b></p> <ul style="list-style-type: none"> <li>• How do investigators ensure the research is acceptable within the community it takes place? How does a company ensure it complies with good scientific principles that would lead to best science and greatest benefit?</li> <li>• How is it ensured that participants during a trial obtain new information that might affect their decision to continue in the trial?</li> </ul>
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Article 3 is standard fare for the protection of human dignity and human rights in the context of medical research on human participants. In international law, human dignity is a foundational principle connoting equal respect for every human being, and human rights are the concrete, tangible norms that are needed to flesh out the principle of human dignity in social life.<sup>62</sup> To become functional for the pharmaceutical and biotechnology industry, human dignity and human rights must take on tangible form. That is, concrete actions need to be specified.<sup>63</sup> Notably, the principle makes use of the familiar Kantian formula that persons should not be treated as a means only, but rather always as an end in themselves.<sup>64</sup> Hence, persons should not be instrumentalized, and the interests and welfare of the individual should have priority over the interest of science and society. From this, certain specifications for companies, specifically the pharmaceutical and biotechnology industry, can begin to be formulated. Specifications may include the following: 1) certain requirements on the welfare and safety of the employees and research trial participant, 2) fairness in regards to hours (ILO), wages, and leave, 3) non-discrimination policies, and 4) fair treatment of employees. To create the indicators for this Article, the principles of both the UN Global Compact and UN Guiding Principles of Business and Human Rights were examined to see what could be learned and borrowed from them. As the UNESCO Declaration is very unique in its explicit connection of bioethics to human rights, other bioethics guidelines were not as useful for this Article. This Article, as well as Article 4, contains the most indicators of any. To make this tool functional and easy to use, succinct and minimal



indicators have attempted to be created. This dissertation presents merely an initial version of this tool that has undergone a simple peer-review process. To make the tool even better and more usable, more stakeholders will need to be involved in this process.

	<b>Article 4 – Benefit and harm</b>
<b>UNESCO UDBHR</b>	In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.
<b>Indicators:</b>	<p><b>General:</b></p> <ul style="list-style-type: none"> <li>• How is any possible harm minimized?</li> <li>• How is direct and indirect benefit maximized?</li> <li>• How does a company ensure that investigators and staff are trained and scientifically qualified</li> <li>• How is the cont. evaluation of a marketed product through research of safety, efficacy, accessibility and quality ensured?</li> <li>• If a clinical trial participant is harmed, how is harm assessed and who determines/assesses if compensation is appropriate?</li> </ul> <p><b>Review:</b></p> <ul style="list-style-type: none"> <li>• Are qualified research ethics committees (institutional review board/ethical review board) present and reviewing research protocols to ensure benefit is maximized and harm minimized?</li> <li>• Who and how is it decided if the non-clinical and clinical knowledge is adequate to support a clinical trial?</li> </ul> <p><b>Conflicts of Interest:</b></p> <ul style="list-style-type: none"> <li>• How are conflicts of interest amongst research ethics committee members and affiliated researchers stated and mitigated?</li> </ul> <p><b>Risk Monitoring:</b></p> <ul style="list-style-type: none"> <li>• How is harm/benefit ratio determined by the company?</li> <li>• What is the procedure for stopping a research study if the risks of proceeding are shown to outweigh the potential benefits? (WMA Declaration of Helsinki Article 20, 2008)</li> <li>• How does the company respond to a situation in which a research participant has an apparent research-related harm occur?</li> </ul>

Article 4 states a very basic principle of human research: benefits should be maximized and risks/harms should be minimized. There are several methods currently in use to discern how

benefits can best be balanced against harms, and this will not need to be specified by the company. Methods for evaluating the ratios of harm and benefit are usually qualitative, probabilistic value judgments made by patients, health professionals, investigators, or policymakers, such as the “QALYs” method (quality adjusted life years).<sup>65</sup> The proposed indicators do not currently go into this level of detail, yet this is an area of further consideration in the future.

This Article, similar to Article 3, dates back to the Nuremberg Code. The indicators were initially created very broad, simply inquiring about how harms are minimized and benefit maximized, generally. The indicators then move into questions about ethics review of a proposed study. The express purpose of such a committee as an institutional review board (IRB) is to ensure the rights and welfare of humans participating in research.<sup>66</sup> Conflicts of interest must also be managed accordingly, which is typically the role of the IRB. A simple working definition states that a conflict of interest is a situation in which financial and/or other personal considerations have the *potential* to compromise or bias professional judgment and objectivity. A person need not have to act on a conflict in order for there to be one present; there merely has to be the potential for one. Not only may a conflict of interest lead to injury or serious harm to study participants, but also, on a larger scale, a conflict of interest has the ability to damage an entire research enterprise by reducing the trust and confidence that people may have in research.<sup>67</sup>

Risk monitoring is the next category of indicators in Article 4. These questions, similar to the other indicators, would require companies to qualitatively provide answers. To streamline this process, these indicators may be able to be combined with others, but this would need to be accomplished with other stakeholders in order to further dialogue. Finally, the category of animal

research is often overlooked in biomedical ethics, which mainly focuses on humans rather than non-human animals. However, for pharmaceutical and biotechnology companies, the use of animals in scientific research is imperative. Animal research has played a vital role in many scientific and medical advances of the past and continues to aid our understanding of various diseases and how drugs work. Yet, the use of animals in scientific research has been hotly debated.<sup>68</sup> Pharmaceutical and biotechnology companies often contract the brunt of criticism from lobbying and special interest groups, such as PETA (People for the Ethical Treatment of Animals).<sup>69</sup> Because we must recognize that the ethical treatment of animals is important to many stakeholders, four indicators were created to help the company analyze how they utilize animals in their research.

	<b>Article 5 – Autonomy and individual responsibility</b>
<b>UNESCO UDBHR</b>	The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.
<b>Indicators:</b>	<p><b>Research Participants:</b></p> <ul style="list-style-type: none"> <li>• How does the company ensure the autonomy (freedom, liberty, self-determination) of human research participants?</li> <li>• How is the right to withdraw at any time without repercussions for the participant ensured?</li> </ul> <p><b>Employees:</b></p> <ul style="list-style-type: none"> <li>• How does the company uphold the freedom of association and the effective recognition of the right to collective bargaining? (UNGC Principle 3)</li> </ul>

The right of personal autonomy is greatly important in medical research and while there are limits to the right to exercise one’s autonomy, these limits are restricted, typically enshrined in law, and usually deal with protecting the autonomy of other persons.<sup>70</sup> Therefore, the importance of the right to personal autonomy is why it also imperative that research participants are allowed to continue to exercise that right within the confines of a clinical study, which

includes the right to withdraw from the study at any time and for any reason without fear of retribution or reprisal.

While autonomy is certainly greatly important, it is not the sole paradigm for bioethics or even the chief paradigm, as some have attempted to make it out to be. The inadequacy of autonomy as the singular normative paradigm for bioethics is visible when one considers the profound vulnerability of patients or research participants in the clinical and/or research setting. Patients seeking care surely desire information and the opportunity to give consent to treatment. Similarly, many clinical trial research participants desire information about a potential therapy for their disease or ailment. Yet, first and foremost, they are asking for help.<sup>71</sup> The right of autonomy and individual responsibility is also important for employees of pharmaceutical and biotechnology companies, as the UNGC and International Labour Organization (ILO) recognize the freedoms to associate and to bargain collectively as fundamental rights<sup>72</sup>

	<b>Article 6 – Consent</b>
<b>UNESCO UDBHR</b>	<p>1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.</p> <p>2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.</p> <p>3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual’s informed consent.</p>

<b>Indicators:</b>	<p><b>Information:</b></p> <ul style="list-style-type: none"> <li>• How does the company ensure that consent of human research participants is informed?</li> <li>• What is included in this information component?</li> <li>• Are participants provided informed consent in a language and manner that is appropriate?</li> </ul> <p><b>Voluntariness:</b></p> <ul style="list-style-type: none"> <li>• How does the company ensure that consent of human research participants is voluntary and in no way coerced?</li> <li>• How does the company provide measures against undue inducement?</li> </ul> <p><b>Competence:</b></p> <ul style="list-style-type: none"> <li>• How does the company ensure that the research participant is competent to give consent?</li> </ul> <p><b>Training of Researchers:</b></p> <ul style="list-style-type: none"> <li>• How are researchers or investigators trained in the process of obtaining informed consent, including providing information in an appropriate manner that is understandable for the participant?</li> <li>• When is it appropriate to consult family members and community leaders in the consent process?</li> <li>• Is the participant given the option of being informed about general outcomes and results of the study?</li> <li>• How is it ensured that emerging new information is promptly given to trial participants in a long-term study that may affect their desire to stay in the study?</li> <li>• When is it appropriate to ask for re-consent during a trial?</li> </ul> <p><b>Research Participants:</b></p> <ul style="list-style-type: none"> <li>• How is the right to withdraw at any time ensured?</li> <li>• Who determines if a person is competent to give consent and how is it determined?</li> </ul> <p><b>Compensation:</b> Who and how is it determined?</p> <p><b>Human Biosamples:</b></p> <ul style="list-style-type: none"> <li>• What is the company's course of action in regards to biosamples used in research that are collected by researchers after prior informed consent for collection, storage and use/reuse? If consent of the participant is not possible, has an ethics committee approved?</li> </ul>
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Consent is one of the ways in which human dignity and autonomy take on a tangible form, and it is one of the most well known elements of modern-day bioethics. Though it is well

known and generally accepted, there is oftentimes a lack of clarity when it comes to the question of implementing the principle in various contexts.<sup>73</sup> Valid informed consent is typically understood to be comprised of at least four elements: 1) disclosure of information, 2) understanding of information, 3) voluntariness of decision and competence, and 4) formal consent.<sup>74</sup>

Problems with obtaining genuine informed consent linger. Ingrid Klingmann, chairman of the European Forum for Good Clinical Practice, recently specified that the organization had “clearly identified there is an urgent need to do informed consent better... The pressure is really huge on all those involved to better enable patients to understand the implications of their study participation, their benefits, risks and obligations.”<sup>75</sup> It is simple for the process of informed consent to merely become and exercise in box-ticking focused on offering legal protection to a trial’s organizer rather than actually protecting participants. Indeed, there is data showing that the median length of consent forms has tripled in the 15 year time frame between 1995 and 2009.<sup>76</sup> In a study conducted on the understanding of informed consent on a small number of oncology research participants in the US (n=207), 63% were unaware of the additional risk associated with participating in the research study, and 70% did not realize that the treatments being offered were unproven.<sup>77</sup> While the study was small, which limits generalizability, it certainly raises questions about the quality of informed consent on a larger scale.

Solutions to fix the perceived problems with the current informed consent process have been proposed. One solution that has been proposed is to model informed consent forms on those used in Norway, where a brief summary of the main aspects of a trial precedes more detailed information. Yet, it is uncertain how much better the Norwegian forms are, if any, at increasing understanding of a proposed study by participants. Further, others have offered that the greater

use of graphics and charts might help patients better understand the proposed study.<sup>78</sup>

Nonetheless, ideas exist for improving the consent process, and some pharmaceutical and biotechnology companies are, presumably, doing well at this. Hence, the global bioethics tool and the dialogue it would create between companies would help to stimulate the sharing of best practices so that a larger cohort of companies can implement these.

Application of consent may also be shaped by the cultural context in which it is applied. This is especially important for pharmaceutical and biotechnology companies who regularly conduct clinical trials in contexts that are foreign to them, oftentimes in LMICs. Further, as clinical trials only continue to become more global, it is essential for study sponsors to understand any cultural differences that may impact care and know how to appropriately address them. While it is increasingly recognized that different strategies of application of informed consent are needed in various cultural and social contexts, there is little agreement about what processes and documentation are appropriate in these contexts. Once this is recognized, the true challenge for pharmaceutical and biotechnology firms is to establish procedures and protocols that are both ethically sound and culturally sensitive. It has been suggested that one manner of resolving such situations is through careful and sustained community involvement in research, which will be time, manpower, and resource consuming for firms, though it may be a necessary step.<sup>79</sup>

	<b>Article 7 – Persons without the capacity to consent</b>
<b>UNESCO UDBHR</b>	In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent: (a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent; (b) research should only be carried out for his or her direct health

	<p>benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.</p>
<p><b>Indicators:</b></p>	<p><b>General:</b></p> <ul style="list-style-type: none"> <li>• Has authorization for research been obtained in accordance with the best interest of the person concerned and in accordance with domestic law?</li> <li>• Has the research participant been involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent?</li> <li>• Do the results of the research have the potential to produce real and direct benefit to the health of the incapable research participant?</li> <li>• Can research of comparable effectiveness be carried out on individuals capable of giving consent?</li> </ul> <p><b>Training of Researchers:</b></p> <ul style="list-style-type: none"> <li>• How are researchers/investigators trained in dealing with and protecting persons with diminished capacity to consent?</li> </ul> <p><b>Determination of Capacity:</b></p> <ul style="list-style-type: none"> <li>• How it is determined who is not capable of providing consent?</li> <li>• How is capacity determined in the protocol review process and by the investigator(s) performing research?</li> <li>• How do researchers obtain proxy or surrogate consent?</li> </ul> <p><b>Exception:</b></p> <p>If it is not possible to comply with the above, the UDBHR does formulate as an exception for research that does not have the potential to produce results of direct benefit to the health of the individual concerned. The following conditions must be met to permit such research:</p> <ul style="list-style-type: none"> <li>• The research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease, or disorder, to the person concerned or to other persons in the same category of disease or disorder.</li> <li>• The research must only entail minimal risk and minimal burden for the individual concerned.</li> </ul>



Article 7 addresses persons without the capacity to offer formal consent, such as the demented, pediatric, or those in an unconscious state. Generally, capacity is assumed in adults and incapacity has to be demonstrated.<sup>80</sup> Conducting research activities on participants who do not have the capacity to understand and consent to research activities is regarded as one of the most complex and controversial areas of research ethics, especially when taking into account the sordid history of research on vulnerable persons.<sup>81</sup>

Applying this principle within the pharmaceutical and biotechnology industry mainly concerns clinical trials. For instance, it is plausible that a company would develop a new therapy or drug for the treatment of Alzheimer's and be ready for clinical trials in human participants. However, the decision-making abilities of a person affected with Alzheimer's, particularly further along in the course of the disease, is seriously questionable. Hence, the goal of these indicators for Article 7 is to provide some clarification on the ethical issues surrounding persons who do not have the capacity to consent.

Part B of Article 7 provides guidance for how to implement this principle within the medical research context. First, the research must have the real potential of producing direct health benefit. Second, the research can only be conducted if no alternative research of comparable effectiveness with research participants who are able to consent is possible. Third, if research does not have the potential for direct health benefit, it should only be undertaken by way of exception and not as a matter of principle. This should be undertaken with the utmost restraint, with the aim of exposing the person only to a minimal risk and burden and if the research is expected to contribute to the health benefit of other persons in the same category. Fourth, if such persons, or their legally appointed guardian, do refuse to take part in research, this should be respected. Having policies in place at the corporate level for such scenarios is a first,

basic step for pharmaceutical and biotechnology companies. Additional steps, including how the policies are actually implemented in the real world by researchers, need to be assessed.

	<b>Article 8 – Respect for human vulnerability and personal integrity</b>
<b>UNESCO UDBHR</b>	In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.
<b>Indicators:</b>	<p><b>Vulnerability &amp; Marginalization:</b></p> <ul style="list-style-type: none"> <li>• How does the company define “vulnerable” persons and population?</li> <li>• How does the company specify who needs specific consideration? (UNGPBHR: Women, children, people with disabilities, indigenous people, migrants, elders, prisoners, pregnant women, economically and educationally disadvantaged are considered vulnerable)</li> <li>• How are the vulnerable additionally safeguarded against undue influence or coercion?</li> <li>• Are the knowledge and products from the clinical trial made reasonably available to benefit that group?</li> </ul> <p><b>Identification:</b></p> <ul style="list-style-type: none"> <li>• How does the company identify vulnerable individuals or groups?</li> </ul> <p><b>Alternatives:</b></p> <ul style="list-style-type: none"> <li>• Can the research be carried out in a non-vulnerable group? (Helsinki, 2013)</li> </ul> <p><b>Protection:</b></p> <ul style="list-style-type: none"> <li>• What guidelines has the company established to protect vulnerable persons?</li> <li>• Does the company comply with the laws concerning research with vulnerable persons? If no such legislation exists in the context where the research is being conducted (host community), what does the company do?</li> </ul> <p><b>Benefits:</b></p> <ul style="list-style-type: none"> <li>• Does the vulnerable group stand to benefit from the knowledge, practices or interventions that result from the research? (Helsinki, 2013)</li> <li>• Is the medical research with a vulnerable group responsive to the health needs or priorities of this group? (Helsinki, 2013)</li> </ul>

Article 8, “Respect for human vulnerability and personal integrity,” connects seamlessly to the previous Article due to the issue of vulnerability. The etymology of “vulnerability” is

Latin, coming from the word *vulnus*, which means “wound”. Hence, “vulnerability” is defined as the ability or susceptibility of being wounded.<sup>82</sup> Everyone at one time or another is in a vulnerable state, such as infants, and vulnerability is the general predicament of humans, while autonomy is the exception.<sup>83</sup> It could be argued that a chief aim of the Nuremberg Code was to protect vulnerable persons from the harms of scientific research. One enduring quandary is how to define a vulnerable person. The US Department of Health and Human Services provides extra protections in its federal research guidelines for vulnerable persons, which it defines as children, pregnant women, fetuses, and prisoners.<sup>84</sup> However, is this encompassing enough? How the company defines vulnerable persons, and the protections they have in place to ensure they are safeguarded, is a necessary initial step to implement this principle.

The notion of personal integrity refers to the state of keeping one intact or not affecting a person physically or psychologically. At the biomedical level it means that persons are entitled to a negative right (a right of non-interference) that demands respect and reverence from others.<sup>85</sup>

Maria Patrão Neves has astutely recognized that,

The principle of vulnerability requires the recognition that the exercising of autonomy and the giving of consent do not eliminate vulnerability which, subtly and surreptitiously, is still susceptible to exploitation, for example through optimistic presentation of clinical trials, for whom volunteers are needed, or the compensation offered to them, such as free medical examinations and clinical assistance, or by the exaggeration of biomedical successes in the media.<sup>86</sup>

Pharmaceutical and biotechnology companies must not only be aware of this, but must actively work to combat such assaults on personal integrity and abuses of vulnerable persons. Therefore, describing how the company seeks to define vulnerability and ensure that vulnerable persons are protected and their personal integrity kept intact is vital for the indicators of this Article.

Article 9 – Privacy and Confidentiality	
<b>UNESCO UDBHR</b>	The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.
<b>Indicators:</b>	<p><b>Risk:</b></p> <ul style="list-style-type: none"> <li>• What are the risks of the infringement of privacy?</li> <li>• What is the risk of infringement of personal data?</li> </ul> <p><b>Measures:</b></p> <ul style="list-style-type: none"> <li>• What measures does the company take in order to maintain the right to privacy of participants in human research?</li> <li>• How is it ensured that information is only shared or disclosed as it has been specified in the consent?</li> </ul>

Article 9 states that the privacy and confidentiality of persons should be respected and protected. Confidentiality in the realm of bioethics refers to the unique and oftentimes fiduciary relationship between researcher/subject and doctor/patient, and specifies that the personal information of the participant or patient shall remain undisclosed unless a strictly defined, compelling interest justifies disclosure.<sup>87</sup> Any aspect of the proposed research study that touches on the privacy of the participant must be carefully explained, and any invasion of privacy must be fully agreed upon by the participant and limited only to the needs of the study.<sup>88</sup>

Research into pharmacogenomics illustrates a current application of Article 9. Pharmacogenomics is relatively novel field that investigates how genes affect a person’s response to drugs.<sup>89</sup> The goal of pharmacogenomics is to tailor treatments to the genetic makeup of the individual, which allows for personalized care with maximized therapeutic drug response and minimized adverse reactions. Pharmacogenomics aims to study the complete spectrum of genes that are involved in determining a person’s response to a medication. Hence, studies into pharmacogenomics require large databases of genomic profiles, which present new privacy

challenges in the years ahead due to the scale of having comprehensive genetic makeups on file.<sup>90</sup> Companies will have to learn how best to navigate these challenges without compromising the privacy of individuals. In dialogue with numerous companies, specific questions could be crafted to more precisely aim at tackling these challenges.

<b>Article 10 – Equality, justice and equity</b>	
<b>UNESCO UDBHR</b>	The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.
<b>Indicators:</b>	<ul style="list-style-type: none"> <li>• How does the company manage scarce resources in order to guarantee a just and equitable healthcare system?</li> <li>• How does the company ensure certain groups are not under- or over-represented in research?</li> <li>• How does the company ensure that groups and communities are invited to participate in a way that the burden and benefits are equitably distributed?</li> <li>• Will the participants, to the best of the company’s knowledge, be able to afford the product when marketed without it being of significant burden?</li> <li>• How do the investigators ensure the research is fair to the subject?</li> </ul>

One of the hallmarks of modern-day clinical trials is that they are often conducted in LMICs. This brings to the forefront questions of equality, justice, and equity. These three terms are often used interchangeably. Though they are closely related, they should not be confused and simply amalgamated. Justice is a complex term that has been described in different ways. Justice has received much attention in contemporary philosophical thought, due in no small part to the work of John Rawls.<sup>91</sup> Justice as fairness is the central motif of Rawls’ conception of justice, which is a political conception and not intended as the application of a general moral conception to the structure of society.<sup>92</sup> Aristotle has at least two meanings for the word “just”. In its first meaning, “just” is used to describe a conduct in agreement with the law. Hence, it is a conduct that conforms to an established, authoritative rule of human conduct. In its second meaning, “justice” signifies equality or a fair mean.<sup>93</sup> Aristotle also espoused what has been known as a

principle of formal justice (or formal equality): equals must be treated equally, and unequals must be treated unequally.<sup>94</sup> Hence, all persons must be treated in accordance with their merits, which forms the idea of distributive justice. Gabriel d'Empaire notes that this concept of distributive justice dominated until the modern era when it began to change. Today, distributive justice, in pragmatic terms, is largely based on how a society ought to allocate its resources among individuals who have competing needs but without taking into account their merits. It is commonly accepted today that basic needs have to be awarded to everybody, not as a charity, but as a right based on justice.<sup>95</sup>

In bioethics, and of importance for the pharmaceutical and biotechnology industry, distributive justice becomes more significant under conditions of scarcity. In today's world there is rapid development of technology with the possibility for serious limitations on its fair use. As d'Empaire recognizes, "This contrast becomes more evident when a serious intention of achieving equality, equity, and justice is made in a time in which biotechnology should be taken into account in a scenario of scarce resources."<sup>96</sup> Hence, distributive justice is a greatly important concept in bioethics and for the pharmaceutical and biotechnology industry and should be thoughtfully considered in dialogue with various stakeholders.

Aristotle generally equated justice to equity:

What is just, then, and what is equitable are generally the same, and both are good, though what is equitable is better (Aristotle, 2004: 121).<sup>97</sup>

For Rawls, equity is a basic and necessary requirement in terms of justice. Equity is said to exist when all participants freely define and accept the rules, benefits, and charges. Equality is a more recent principle, though it has become fundamental in the context of human rights. No two human beings are precisely physically, mentally, psychologically, or genetically equal. Nor is humankind equal in terms of values or principles they hold. Nonetheless, it is generally accepted

and desirable that all humanity, regardless of merit or opportunity, be considered equals in terms of dignity, justice, and rights.<sup>98</sup>

New technologies, therapies, and drugs are constantly in various stages of development by the pharmaceutical and biotechnology industry. This new reality needs a new way of addressing the equality, justice, and equity issues that will naturally arise. This points to the importance of both the indicators and the process of relevant stakeholders dialoguing on these issues.

<b>Article 11 – Non-discrimination and non-stigmatization</b>	
<b>UNESCO UDBHR</b>	No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.
<b>Indicators:</b>	<ul style="list-style-type: none"> <li>• How does the company take care to avoid the systematic development of medicines for one group within a population to the neglect of others?</li> <li>• When conducting clinical trials, does the company discriminate or stigmatize certain populations or genders so that they are under-represented in research?</li> <li>• Does the company have a grievance procedure for handling allegations of discrimination and stigmatization?</li> </ul>

Article 11 prohibits the discrimination and stigmatization of individuals and groups that would violate human dignity, rights, and freedoms. Discrimination is a legal concept that has longstanding tradition within human rights law, and stigmatization is a more recent construct in the field of human rights law.<sup>99</sup> Non-discrimination and non-stigmatization is also found in the UNESCO International Declaration on Human Genetic Data (2003). Article 7 stipulates:

- (a) Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities.
- (b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.<sup>100</sup>

Hence, this Article addresses discrimination and stigmatization resulting from developments in behavioral genetic studies, which is certainly appropriate for the pharmaceutical and biotechnology industry.

However, the UDBHR Article can also be applied more broadly. There is of course no definitive, exhaustive list of discriminatory or stigmatizing practices that can be listed in order for companies to avoid. Nonetheless, some particular practices stand out and should be addressed. In the context of biomedical research, the selection of research subjects should not be influenced by a belief that members of a given group are less deserving of protection from the risks associated with research than others. Additionally, this Article is applicable to aspects of gender bias or ethnic prejudice.<sup>101</sup> In UNESCO’s *Report of the IBC on the Principle of Non-discrimination and Non-stigmatization*, the IBC states that there are several persistent problem areas for non-discrimination and non-stigmatization. These include neglected tropical diseases, HIV/AIDS, and organ donation, transplantation, and trafficking. Further, emerging problems include biobanks, nanotechnology, and developments in the field of neuroscience.<sup>102</sup> This list is not exhaustive, but it provides pharmaceutical and biotechnology companies with areas for reflection. Finally, a system of due diligence for reporting and handling allegations of discrimination and stigmatization should be present.

<b>Article 12 – Respect for cultural diversity and pluralism</b>	
<b>UNESCO UDBHR</b>	The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.
<b>Indicators:</b>	<ul style="list-style-type: none"> <li>• In clinical trials with human research participants, how does the company handle cultural differences regarding informed consent?</li> <li>• When doing business in an unfamiliar cultural milieu, how does the company approach these cultural differences?</li> <li>• Does the company provide training for its employees on issues of cultural diversity and pluralism?</li> </ul>



Article 12 of the UDBHR concerns the respect of cultural diversity and pluralism. In an era where clinical trials have gone global, often sponsored by Western HICs and carried out on populations in LMICs, this principle is of heightened importance. Reasons to conduct studies in LMICs rather than in the sponsor’s home country include reduced expense, faster recruitment of participants, less strict regulations, and simply because it has often been in LMICs that certain disease outbreaks have occurred that as of yet have no treatment and companies want to test their products.<sup>103</sup> It is against this backdrop that pharmaceutical and biotechnology companies regularly operate, and respect for cultural diversity and pluralism must be on their radar.

To instrumentalize this Article, indicators inquiring about what the company does in regards to performing clinical trials in different cultures were created. Those who are involved in the business aspects of the company in a different cultural context, including those tasked with carrying out clinical trials (such as consenting people) should be trained on what is appropriate for that setting, and some sort of education process should be ongoing, for cultures are not static. There is no “one-size-fits-all” approach to this type of training, for each culture will differ and have different nuances. Yet, a company should be striving to respect the culture in which they work, and a first step of this is to understand that culture.

<b>Article 13 – Solidarity and cooperation</b>	
<b>UNESCO UDBHR</b>	Solidarity among human beings and international cooperation towards that end are to be encouraged.
<b>Indicators:</b>	<ul style="list-style-type: none"> <li>• How is the company working towards capacity-building in the area of public and global health?</li> <li>• How is the company contributing to the UN Sustainable Development Goals?</li> </ul>

This proposed global bioethics tool rests in part upon the premise that pharmaceutical and biotechnology companies ought to work together, in solidarity and cooperation, on bioethics

matters in order to have a greater impact. Solidarity and cooperation work on numerous levels. There is the obvious level of work done between companies, as just mentioned, but there is also partnership between a company and a particular geographical context or towards an area of public concern. The work of capacity-building in public and global health is one area that is ripe for the aid of the pharmaceutical industry. Further, the UN has 17 Sustainable Development Goals that they want to see accomplished by the year 2030.<sup>104</sup> Companies may consider how they are contributing to these goals for the betterment of the entire world.

Solidarity can also be applied in the area of access to drugs. At the September 2010 Belgian EU presidency conference on “Innovation and Solidarity in Pharmaceuticals” held in Brussels, the conference concluded with a call to make valuable innovative medicines accessible in the EU, which also contained recommendations for coordinated action to stimulate, measure and valorize pharmaceutical innovation.<sup>105</sup> There are calls from the political sphere for greater cooperation between states on achieving access to certain medicines.<sup>106</sup> The pharmaceutical industry would be prudent to take further steps on access to medicines and be seen as working towards solidarity and cooperation, rather than have more regulations forced upon them externally.

Article 14 – Social responsibility and health	
<b>UNESCO UDBHR</b>	<p>1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.</p> <p>2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:</p> <p>(a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;</p> <p>(b) access to adequate nutrition and water;</p> <p>(c) improvement of living conditions and the environment;</p> <p>(d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;</p> <p>(e) reduction of poverty and illiteracy.</p>
<b>Indicators:</b>	<p><b>Promotion of Health and Social Development:</b></p> <ul style="list-style-type: none"> <li>• How does the company aim to promote health and social development?</li> <li>• Article 14 states that “all sectors of society share” in the promotion of social responsibility and health. How does the company seek to address: 1) access to quality health care and essential medicines, 2) access to adequate nutrition and water, 3) the improvement of living conditions and the environment, 4) the elimination of the marginalization and the exclusion of persons on the basis of any grounds, and 5) the reduction of poverty and illiteracy?</li> </ul> <p><b>Relationship to Developing Countries:</b></p> <ul style="list-style-type: none"> <li>• Does the company have differential pricing policies so that lower income countries pay lower prices for essential medicines than higher income countries?</li> <li>• Does the company invest in research and development for diseases that primarily affect lower income countries?</li> <li>• Does the company have policies on access to treatment for developing countries, including the five priorities of pricing, patent, joint public private initiatives, R&amp;D, and the appropriate use of drugs?</li> </ul>

Social responsibility and the public perception of the pharmaceutical industry has already been discussed at length earlier in this dissertation. Much has been written on incorporating corporate social responsibility into pharmaceutical and biotechnology companies, and we must bear in mind that these are primarily *moral* rather than *legal* obligations. One of the main contexts for the concept of social responsibility to be applied is undoubtedly in the healthcare

context, with the protection and promotion of human health.<sup>107</sup> The IBC released a report on Article 14 in 2010 detailing a number of ways in which the Article can be applied to the pharmaceutical industry. Ways that the Article may apply to the industry, according to the IBC, include in tackling global health crises, drug patents, and pricing.<sup>108</sup>

The indicators that have been developed for this Article aim at discerning how the company is promoting health and social development, as well as the dealings of the company in developing countries. Stefano Semplici has asserted that within Article 14 it is implicit that no actual promotion of health for humankind is possible without also making development of the whole society a pivotal issue.<sup>109</sup> Hence, capacity building is an important feature of social responsibility in this view, just as it was important in the preceding Article. This is an area that will need increased attention, as capacity building is currently lacking. What is more, another area that merits increased attention is that of research into diseases that are not likely to be highly profitable for the pharmaceutical and biotechnology industry. Both the private and public sector carry out research on diseases with the aim of curative therapies. The majority of scientific development is driven by interest in potential financial reward rather than potential social benefits or an inclination towards social responsibility.<sup>110</sup> Yet, if the vision of social responsibility in the UDBHR is to be instrumentalized, greater dialogue on research into less profitable diseases, such as tropical diseases or so-called “orphan diseases”, will need to be carried out.

Article 15 – Sharing of benefits	
<b>UNESCO UDBHR</b>	<p>1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms: (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research; (b) access to quality health care; (c) provision of new diagnostic and therapeutic modalities or products stemming from research; (d) support for health services; (e) access to scientific and technological knowledge; (f) capacity-building facilities for research purposes; (g) other forms of benefit consistent with the principles set out in this Declaration.</p> <p>2. Benefits should not constitute improper inducements to participate in research.</p>
<b>Indicators:</b>	<p><b>Sharing of Benefits:</b></p> <ul style="list-style-type: none"> <li>• How does the company ensure that the benefits resulting from its scientific research are shared with society as a whole?</li> <li>• When conducting clinical trials, does the company ensure that in advance of the trial, provisions are made for post-trial access for all participants who still need an intervention identified as beneficial in the trial? (DoH, Article 34, 2013)</li> <li>• If the company is involved in bioprospecting, how does it ensure that indigenous knowledge and resources have been respected?</li> </ul> <p><b>Undue Inducement:</b></p> <ul style="list-style-type: none"> <li>• How does the company ensure against improper inducements to participate in research?</li> </ul>

Article 15 concerns the principle of sharing of benefits. Sharing of benefits, which has alternatively been called benefit sharing, has been described in numerous manners and has received greater attention in the past several years. The Convention on Biological Diversity, adopted in 1992 at the UN Conference on Environment and Development, is a multilateral treaty with three major aims: 1) the conservation of biodiversity, 2) the sustainable use of the components of biodiversity; and 3) the fair and equitable sharing of benefits arising from genetic resources. A supplementary agreement, the Nagoya Protocol, was adopted in 2010 and specifically addressed genetic resources and the sharing of benefits arising from their utilization.<sup>111</sup> Since this time, much has been written on benefit sharing. A very simple definition

of benefit sharing that has been proposed by Doris Schroeder states that, as a matter of justice, those who contribute to scientific research ought to share in its benefits.<sup>112</sup> This definition slightly differs from Article 15, which indicates that scientific advances should not only benefit a select group, but all humanity should benefit.

For this Article, indicators on benefit sharing and undue inducement were created that tried to encapsulate both the UDBHR definition and more recent definitions, such as the one of Schroeder. There are many applications of Article 15 to pharmaceutical and biotechnology companies. Perhaps one of the most well known cases surrounding the type of benefit sharing that Schroeder describes is that of the San people of Southern Africa and the traditional knowledge they possessed about the *Hoodia* plant—a plant they had used for centuries to quench thirst that also possibly had appetite suppression qualities. *Hoodia* and the plight of the San peoples became a showcase of the challenges encountered by indigenous communities when faced with bioprospecting of a major pharmaceutical company trying to bring *Hoodia* to market.<sup>113</sup> Hence, the indicators for Article 15 have been created with both the description of sharing of benefits provided by the UDBHR and the usage that is more common today in mind.

Finally, benefit sharing is not often discussed without also discussing undue inducement, which is also known as undue influence. The *Belmont Report* states,

Undue influence...occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.<sup>114</sup>

Undue influence could potentially arise in a clinical trial situation when a company offers participants excessive rewards for their participation, or when persons view the company or its representatives as persons in a position of authority or commanding influence over them. It is important to note that not all incentives to participate in research are viewed as unethical.

UNESCO's International Bioethics Committee (IBC) in its Report on the Principle of Benefit Sharing has suggested,

[W]hat characterizes inducement as improper is that the offer has the potential to undermine a person's ability to make a free choice and causes her or him to accept certain risks imposed by participation against her or his better judgment. What is of relevance is not the attractiveness of an offer but the potential of the offer to undermine the subjects' ability to evaluate the situation as well as the risks that it could entail.<sup>115</sup>

According to this understanding, three elements must then be taken into account when determining whether an inducement is proper or improper. The first element is the nature and seriousness of the risks that have the potential of impacting the participant. Physical or bodily harms are only one aspect for consideration. Risks to privacy or moral integrity may be just as important as physical harm, and therefore must also be considered. The second element to be considered is the impact of an offer on the decision-making process of the research participant. What may appear as an autonomous decision of the participant on the surface may in fact be caused by the circumstances that they face, such as a need or desire for healthcare. The third element of consideration, according to the IBC, is veracity on the possible benefits of participating. Inappropriate or misleading information provided to research participants on any possible benefits can lead to improper inducement, for it may make the participant more willing to consent. Hence, this is why the IBC states, "It is important to ensure that patients participating in research are not victims of a therapeutic misconception or mis-estimation, where they over-estimate the benefits they might gain from the research or under-estimate possible harms."<sup>116</sup> To conclude this Article, benefit sharing and the avoidance of undue inducement are ethical obligations that may, to some, be difficult to align. Though this belief is held by some, other commentators have concluded that the fear of undue inducement must not lead to neglecting

benefit sharing.<sup>117</sup> Hence, companies must look for ways to fulfill the moral obligation of benefit sharing while also avoiding undue inducement.

Article 16 – Protecting future generations	
<b>UNESCO UDBHR</b>	The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.
<b>Indicators:</b>	<ul style="list-style-type: none"> <li>• In bioethical decision-making, does the company take into account the impact on the present generation and also try to evaluate the impacts on future generations?</li> <li>• If the company is involved in research on human genomic information, how does the company ensure that such new technology will not result in undesired outcomes for future generations?</li> <li>• How does the company evaluate any possible influence a test compound can have on genes or germ cells?</li> </ul>

Article 16 is a very unique principle that the drafters of the UDBHR felt was imperative to include.<sup>118</sup> The Article broadly claims that due regard in the advancement of the life sciences should be given to future generations, and specific regard is given to issues of genetics. Recently, the content of this Article has come to the forefront with CRISPR-Cas9 technology. This technology provides the potential for treating myriad diseases and also editing genes of human embryos.<sup>119</sup> Such edits would then be passed down to any progeny, having lasting effects, and creating the potential for undesirable consequences. The bioethical decision-making process, therefore, should not merely take into account the bearing on the present generation, but also try, to the best of its abilities, to evaluate impacts on future generations. In the context of rapidly developing medical technologies that have the potential to alter gene lines, scientists coming from the healthcare milieu should not be the only ones involved in the decision-making process. With the potential for mammoth implications on future generations, broad spectrums of stakeholders should be involved in the process to contribute to the decisions, including social scientists and even the general public. The necessity to examine thoughtfully the implications of such monumental advances in biomedical technology should not be taken lightly.



This concept is very similar to that of the “common heritage of mankind”—the juridical notion that there are “common space areas” which no one can own though are hypothetically managed by all.<sup>120</sup> In the concept of common heritage, no single company or country owns the rights to certain areas, but rather they are entrusted to the current age of humanity and to be passed on to future generations, hopefully in an unaltered state. Hence, there is a forward-looking aspect to common heritage, just as this Article is very much forward-looking. As medical technology constantly advances, this Article may prove to be of immense importance in guiding companies on their conduct and research in the decades to follow.

	<b>Article 17 – Protection of the environment, the biosphere and biodiversity</b>
<b>UNESCO UDBHR</b>	Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

<b>Indicators:</b>	<p><b>Impact on Environment:</b></p> <ul style="list-style-type: none"> <li>• As it has been recognized that the company has a responsibility to protect the environment, how does the company prevent advances in molecular biology, recombinant technology, genetics, biotechnology, and other advances from negatively impacting the environment?</li> <li>• Does the company participate in the development of new technologies that pose risk of irreversible damage to the environment?</li> <li>• Does the company have in place emergency guidelines in the event of an accident affecting the environment?</li> <li>• Does the company minimize the use of chemicals and other dangerous substances, as well as ensuring their safe handling and storage?</li> <li>• If applicable to the business, does the company encourage the development and use of environmentally friendly technologies?</li> </ul> <p><b>Biosphere:</b></p> <ul style="list-style-type: none"> <li>• How does the company seek the protection of experimental animals? (cf Article 4)</li> <li>• How does the company seek to eliminate the need for using animals in research?</li> <li>• How does the company seek to protect and promote the welfare on the animals used in research?</li> </ul> <p><b>Impact on Biodiversity:</b></p> <ul style="list-style-type: none"> <li>• Does the company prevent, minimize and remedy impacts on biodiversity?</li> </ul>
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Potter’s envision for global bioethics was of a discipline that married the biological sciences with the rest of the created world. The inclusion of Article 17 on the protection of the environment, biosphere, and diversity moves us closer to that vision. It is indisputable that there are linkages between human activity and environmental issues. Global environmental concerns require the cooperation of many actors and necessitate local action steps to be taken.<sup>121</sup> For example, the UN’s 2015 Paris Climate Change Conference brought together representatives from 195 countries to agree on steps to deal with greenhouse gas emissions.<sup>122</sup> This large cohort of the world’s countries has to take local action steps in order to see cumulative and lasting change. Hence, having the pharmaceutical and biotechnology industry work in tandem to create lasting change on areas where their business intersects with the environment seems advantageous.

Prakash Tandon has asserted that it is essential that safeguarding the capacity of ecosystems go hand in hand with the improvement of living standards and the promotion of human flourishing and development, which includes the introduction of any advances of science and technology for this purpose.<sup>123</sup> The indicators that were created for this final principle attempted to address the environment, biosphere, and biodiversity. As humanity learns more about how we impact the world around us, these indicators will surely need to be revisited and revised. Nonetheless, this principle showcases that when assessing the ethical implications of any biological research or biotechnology, it is imperative to take into account not only its utility for human welfare, but also its overall impact on the ecosystem.<sup>124</sup>

To conclude this chapter, it is worth recapping what chapter five has covered and consider further the future direction of the global bioethics tool. Section 5.1 initially began by looking at the history and development of the proposed global bioethics tool. This then moved into a discussion of benchmarking. Prominent persons in the field of benchmarking, including their theories, were presented and examined. A brief case study utilizing Camp's model of benchmarking and how this could be applied within the global bioethics tool was demonstrated. It was established that Camp's model of benchmarking is very instructive and could very well be utilized to benchmark both companies and processes on their implementation of human rights and bioethics. This is not to say that Camp's model may not need tweaking, rather we should view the model of Camp as an initial starting point from which the cohort of companies comprising the global bioethics tool can then adjust as is best. The criticism of benchmarking was also presented in 5.1, and rebuttals to the critiques were provided.

Finally, the Corporate Human Rights Benchmark (CHRB) was briefly discussed as a way of demonstrating that it is possible to benchmark companies on their human rights approach. The

CHRB is a very interesting endeavor that is just now getting off the ground and becoming established. It will be curious in the years to come to see the results of this endeavor. As there are many potential points of intersection between the CHRB and the global bioethics tool, it would be worth exploring in the future areas of partnership and collaboration between the two organizations.

Section 5.2 presented the global bioethics tool, including the indicators in the form of questions that have been created for each of the fifteen principles (Articles 3-17) of the UNESCO Universal Declaration on Bioethics and Human Rights. A section of commentary was also provided for each of the Articles detailing how the indicators were created and why they are important for the pharmaceutical and biotechnology industry. It is worth noting again that these indicators will continue to be a work in progress. In the field of software development, a piece of software is said to be in the “beta” phase when it has all of its primary features yet is likely to contain a number of known and/or unknown flaws. The global bioethics tool is in such a stage of its lifespan development. The indicators need to be tried and tested, deliberated on with additional stakeholders, and further refined. Further, new indicators will surely need to be created in the years to come. The future of medicine and technology is uncertain, as new discoveries are constantly somewhere in the process of taking place. Bioethics must rise to meet the new challenges presented by innovations in medicine and technology, and the global bioethics tool must also arise to this challenge. In this way, the global bioethics tool is a living tool; it is not static, but dynamic. Nonetheless, the indicators in their extant state present a snapshot of how the UDBHR could be utilized to enhance the human rights and bioethics interests of the pharmaceutical and biotechnology industry. In the following chapter we will

apply these indicators to real-world companies to show the feasibility of the global bioethics tool.

There are several steps that would have to be completed in order to see the proposed global bioethics tool actually be put into practice for the pharmaceutical and biotechnology industry. First, a smaller cohort of pharmaceutical and biotechnology companies would need to partner together and resolve to further develop and implement the global bioethics tool. UNESCO's bioethics unit would also be involved if they would so choose to be. This smaller cohort of companies would take the lead in initially overseeing the tool. Second, a pilot run of the tool with this small cohort of companies would seem advisable. The cohort of companies would need to each answer the indicators and then perform the benchmarking process on smaller scale. Representative from each company would then all meet together in order to discuss the outcomes of the pilot run. This pilot run would demonstrate to stakeholders the viability of the tool and seek to remedy any apparent issues that may arise. Third, the cohort would then seek expansion by inviting additional companies to join. All along this process then publicity around the global bioethics tool would seek to be generated. This would involve giving interviews for news outlets and publishing articles for academic journals and scholarly conferences on the proposed tool.

These are merely preliminary steps that would need to take place in order to witness the global bioethics tool be implemented in the pharmaceutical and biotechnology industry. These steps may seem insurmountable, yet it would only take a handful of large companies in the beginning to initiate this process and demonstrate to the rest of the industry the value of such a tool.

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## **Chapter 6: Global Bioethics Tool: Application**

Chapter six develops the reporting framework for the global bioethics tool and applies the indicators that were presented in the previous chapter to two pharmaceutical and/or biotechnology companies. As the implementation of human rights and bioethics principles is an ongoing process, it is envisioned that the indicators discussed in the previous chapter will need revising on a continuous basis in consultation with various stakeholders and as technology and healthcare advances. Nonetheless, this first step of application is necessary in order to establish a baseline of where certain companies are at in implementing the principles of the Universal Declaration on Bioethics and Human Rights. In order to accomplish this, publicly accessible information has been first utilized, specifically from the company's website, past reports submitted to the UN Global Compact, and corporate social responsibility documents put forth by the company. Additionally, select persons from each company are to be contacted for further information in gathering this information if needed.

Section 6.1 first examines a number of reporting frameworks that have been developed over approximately the last decade to report on how companies are implementing the human rights and corporate social responsibility principles from specific guidelines. Advantages and disadvantages of each reporting framework will be studied. From this analysis a proposal will be prepared for how to setup a reporting structure for the proposed global bioethics tool. Section 6.2 then applies the indicators that were developed in chapter five to specific companies and utilizes the developed reporting framework from 6.1 to accomplish this task. GlaxoSmithKline, a very large multinational pharmaceutical company based in London and Sun Pharmaceuticals, headquartered in Mumbai, India, have been chosen as the two companies to be examined in section 6.2.

### *6.1) The Reporting Framework*

Methods for the implementation of human rights principles are predominantly split into reporting systems and petition systems, with the vast majority of human rights treaties relying on some sort of reporting and/or monitoring system as the sole method of compelling compliance. For UN treaties with this type of reporting mechanisms, a formal review by a neutral inspector, termed a Special Rapporteur, might also occur. Increasingly, reporting is being combined with some level of monitoring, making reporting more rigorous.<sup>1</sup> Troubles with reporting in the international human rights system are numerous, including bureaucratic redundancy and overlapping jurisdiction. The UN has adopted nine core human rights treaties, and there is bound to be redundancy in them, and yet, nonetheless, reporting for each has to be completed in order to remain in good standing with the organization, which places a heavy administrative burden on countries.<sup>2</sup> This is a genuine concern for the proposed global bioethics tool and is an area in which later revisions of this tool will need to take into account. While this tool is very unique in its aim, there will certainly be some level of overlap with areas of human rights and corporate social responsibility reporting.

A second manner of implementing human rights is a petition system. In a petition system (also known as a complaints system), a state, organization, or individual makes a petition or complaint against another state or organization to a central body. In the UN system, this can take the form of states complaining about other states, individuals complaining about states, and inquiries initiated by the treaty bodies in response to accusations of abuse.<sup>3</sup> In reality, the petition system has been underused by the UN system and often classified as ineffective. Historically, the state-to-state complaints system has never been used in the UN. It has been utilized a few dozen

times in Europe, and minimally in the Americas and Africa. Part of the ineffectiveness stems from the hesitation of states to lodge complaints against fellow states.<sup>4</sup>

A third mode of implementation is a combination system that combines both self-reporting and petitions. For example, the Inter-American Convention on the Prevention, Punishment and Eradication of Violence Against Women (1994) utilized reporting procedures, advisory opinions (in which the States parties and the Inter-American Commission of Women may request of the Inter-American Court of Human Rights *advisory opinions* on the interpretation of the Convention), and petitions.<sup>5</sup>

However, implementing human rights and other principles, such as actions of corporate social responsibility, may also take form through pressure from external bodies, which may include social pressure. By joining an initiative such as the UN Global Compact or the UN Guiding Principles Reporting Framework, companies assume certain responsibilities (implementation of principles) and they also accept that they will report and be monitored for their work and transparency by external bodies (such as the UNGC, Access to Medicine Foundation, or similar NGO) and the general public. The below chart summarizes these implementation mechanisms succinctly:

<b>Implementation Mechanism</b>	<b>Advantages</b>	<b>Disadvantages</b>
Self-Reporting (e.g. UN Global Compact)	-Straightforward implementation	-Reporting can be laborious and redundant -No incentives for increased activities as it is very difficult to get an overview, to compare performance and identify best practices. - No clear advantage or gain by being a good or the best performer
Petition (complaints) System	-Some type of petition or complaints is advantageous so that individuals or other companies who learn about	- This model is reactive and not proactive, as misconduct has already taken place. -Many persons who might suffer abuse

	abusive practices have a way to voice their concerns.	from a company may not have the resources or knowledge to access the complaints system (whether it be because they do not have access to the internet or simply because they are unaware that such a system is in place) and effectively file a complaint. -Complaints can sit in backlog for months, as persons must investigate -Consequences for violation are uncertain
Combination System: Self reporting and petition	-A model of implementation could include elements of both self-reporting and petition (such as a whistleblower). Advantage of this would be it still includes self-reporting and also leaves possible a mechanism for persons or companies to file complaints against another company	-Combining the two systems do not eliminate the weaknesses of any of the systems. -Such a system would still need to account for the main disadvantage of a petition system, which is the backlog that can be created by numerous complaints if sufficient resources are not allocated to meet demand. Further, the cost of such a system might be an obstacle to implementation.
External Body	-An external body may help to hold companies accountable for various aspects of how they conduct business. -External body may be useful for spurring social action and garnering attention of media -The constitutions and operations of the external bodies might provide additional trustworthiness to information, indexes and ranking.	-This model is selective and depends on the focus of the external body. Hence, one might not get a broad idea about a company's performance. -Consequences for violations of a requirement or high/low ranking on an index are uncertain, aside from social consequences, such as the report of the external body being publicized and investors, media, public, etc. reacting in a manner that may be undesirable.

For the global bioethics tool, a complaints or petition system is not the aim. The aim is collaboration between companies. Yet, the advantages of the external body model, as described in the chart, must not be overlooked. Hence, in regards to reporting, the global bioethics tool is envisioned as a set of questions, with a self-reporting framework, and an overarching central body that seeks to hold companies accountable for their reporting and their conduct. It is

envisioned that this centralized body would be a non-profit that “houses” the tool is responsible administratively for it.

One problem with reporting frameworks in general is that they can become overly cumbersome and laborious, as briefly mentioned above. Every reporting framework that a company joins will require a separate report, which could result in numerous reports being filed annually with much manpower utilized.<sup>6</sup> The overabundance of reporting in the human rights realm by state actors has been shown to spread a government’s available resources thinly rather than investing in high-quality reporting.<sup>7</sup> Global Reporting Initiative, an international independent standards organization that helps businesses and governments understand and communicate their impacts on issues such as climate change, human rights, and corruption, estimates that the cost for a company to report issues of sustainability can vary from as little as €2,000 to over €100,000. The majority of this cost stems from the time it takes to prepare the report, including time for senior management and other staff to discuss the report, time for gathering and inputting data, time to implement new processes, including staff training, data collection, time for checking information, and time for preparation of the report itself.<sup>8</sup> Indeed, such reporting may even require a full-time employee to complete these tasks, not to mention the smaller portions of time committed from other persons. For small and medium-sized businesses, such reporting may be especially onerous, as economies of scale understandably limit their personnel and resources.<sup>9</sup> Hence, in order for an implementation mechanism such as the global bioethics tool to be maximally effective, and for companies not to view the global bioethics tool in a negative light, a self-reporting framework that seeks to minimize the burden placed upon companies seems advantageous.

The reporting frameworks of several organizations in the industry will be examined in this section for their strengths and weaknesses in order to make a recommendation for the proposed global bioethics tool. The first reporting framework to be discussed here is the one used by the UN Global Compact (UNGC), known as the “communication on progress” (COP). COPs have three minimum requirements: 1) There must be a statement by the CEO expressing continued support for the UN Global Compact and renewing the participant’s ongoing commitment to the initiative, 2) a description of practical actions the organization has taken or plans to take to implement the Ten Principles of the UNGC in each of the four areas (human rights, labor, environment, anti-corruption), and 3) there must be a measurement of outcomes. Signatories are required to submit this report annually.<sup>10</sup> Aside from these basic requirements, there is little in regards to style or format requirements of the COP provided, leaving every company to create their own process.

Therefore, there is often great variance between COPs. After reading the most recent COPs compiled by several top pharmaceutical companies the impression received was that most were very lengthy and not user-friendly. Of the nine COPs examined, page length varied significantly, as displayed in the chart below.

<b>Company (Year of COP)</b>	<b>Page Length of COP</b>
AstraZeneca (2015)	80
Eli Lilly (2015)	134
GlaxoSmithKline (2015)	58
Johnson & Johnson (2015)	122
Merck & Co. (2015/2016)	392
Novartis (2016)	98
Novo Nordisk (2015)	35
Pfizer (2016)	137



The majority of COPs seemed to be prepared as a general document put out by the company's Corporate Social Responsibility (CSR) department rather than as a streamlined document specifically for the UNGC outlining how the company efforts to implement the ten principles of the UNGC. Further, of all the reports examined, each utilizes different styles for their COP and lacked any uniformity. This is disadvantageous, for there is no systematic reporting style, which leads to confusion, much difficulty when trying to ascertain how one company may compare to another, and a general lack of user-friendliness. Lastly, the overall specificity in what a company is actually doing on the ground to implement the principles of UNGC is not clear enough from the majority of COPs as to provide evidence on progress or to be helpful to stakeholders. Such knowledge should not be considered confidential, as one company attested in their COP, as this seems to go against the spirit of implementing corporate sustainability. This does not allow for a learning process to take place in which companies who are doing well at implementing aspects of human rights and sustainability can share their expertise with companies who are not yet as advanced.

While there are weaknesses to the UNGC's COP system, strengths are also present. One of the most pronounced strengths is the transparency that the UNGC COP system prompts and promotes from companies. While this transparency could certainly be strengthened by further prompting companies to divulge more real-world evidences of what they are doing to implement the principles, the COPs are, nonetheless, openly published online and available to anyone with Internet access. This level of transparency is unrivaled in the area of corporate sustainability initiatives, particularly with the volume of organizations who have become signatories. It is the ambition of the global bioethics tool to also emulate the transparency of the UNGC, and to

surpass it, so that various stakeholders can freely ascertain what specific companies are doing in regards to bioethics and human rights. Additionally, the three minimum requirements that the UNGC requires of all its submitted COPs are also strengths. However, they could be made considerably stronger. The second requirement of the COP is that it must contain, “A description of practical actions the company has taken or plans to take to implement the Ten Principles in each of the four areas (human rights, labour, environment, anti-corruption).”<sup>11</sup> By requiring more examples of practical ways companies have implemented the UNGC principles, as has been stated, would significantly strengthen the COP. Further the third requirement of the COP is that it must contain, “A measurement of outcomes.” By requiring that the COPs be arranged in a systematic, easy-to-follow manner, might have the effect of further increasing their visibility due to more people using them. Finally, an interesting feature of UNGC that is developed directly from the COPs is that UNGC provides a Global Opportunity Report to inform companies on ideas for future action.<sup>12</sup> This is yet another way of inspiring companies to take sustainable action towards key goals. For the global bioethics tool, in the future it should be considered how creating a similar report that could accompany an account on best practices would be beneficial for companies.

The second reporting framework to be discussed is a collaboration between The Danish Institute for Human Rights, the Confederation of Danish Industry, the Ministry of Economic and Business Affairs, and the Danish Investment Fund for Developing Countries has created a Global Compact Self Assessment Tool that is designed to help a company evaluate how they are doing in integrating and implementing the UNGC in their company. The tool is aimed at both small and large companies and touts itself as being able to identify specific needs of companies, regardless of sector or their context. This tool was briefly discussed in an earlier chapter, but the

reporting framework will be scrutinized more closely here. The Global Compact Self Assessment Tool contains indicators that are set up in the form of questions so that companies can see how well they are doing in implementing the ten principles of the UNGC.<sup>13</sup> This is very similar to the setup followed by the proposed global bioethics tool, presented in the preceding chapter.

The Global Compact Self Assessment Tool can be downloaded directly from their website as a Microsoft Excel spreadsheet. It is composed of 45 questions with indicators for each question. The indicators are close-ended—i.e. they are meant to be answered either “yes” or “no”. While this is streamlined and presumably reduces the time a company utilizes in completing the assessment, it is also limiting. There is surely variability in the answers to questions that a simple “yes” or “no” response does not capture. For example, the initial question in the human rights section of the self-assessment asks, “Does the company ensure that its workers are provided safe, suitable and sanitary work facilities?” There are then eight indicators listed beneath that question that are to be answered either “yes” or “no” to gauge how well the company is doing in ensuring the workers’ facilities. This is similar to the proposed global bioethics tool, yet there are weaknesses to this system. For example, one of the indicators for this question states, “The company routinely monitors its production processes, machinery and equipment to ensure that they are safe and in good working order.” A simple “yes” or “no” is not specific enough to answer this adequately. For example, the machinery in question could be examined routinely on an annual basis, but it is supposed to be examined monthly. However, the indicator is not specific enough with simply a “yes” or “no” to ascertain this depth of information. Hence, this is one weakness of the Global Compact Self Assessment Tool that the proposed global bioethics tool has sought to remedy through the use of qualitative, open-ended

responses. Nonetheless, much can still be emulated from the Global Compact Self Assessment Tool regarding the user-friendly layout.

The third reporting framework to be examined has been developed by the Human Rights Reporting and Assurance Frameworks Initiative (RAFI), which is funded by the governments of Norway, Sweden, and the United Kingdom. RAFI is co-facilitated by Shift, a non-profit organization founded directly after the endorsement of the UN Guiding Principle on Business and Human Rights, and Mazars, an international organization specializing in audit, advisory, accounting, and tax services. In 2015 they launched a UN Guiding Principles Reporting Framework that seeks to help companies self-report on their activities implementing the UN Guiding Principles on Business and Human Rights.<sup>14</sup> The Reporting Framework takes the form of a questionnaire (12 main questions and 23 supporting questions) for companies to answer as they strive to meet their human rights responsibilities. This framework was developed over a period of two years the RAFI team led an open, global, consultative process involving individuals from over 200 companies, investor groups, civil society organizations, governments, assurance providers and other expert organizations from all regions of the world.

The questions in the framework are open-ended—i.e. they are not meant to be answered with a simple “yes” or “no”. The guidelines state that companies claiming to use the UN Guiding Principles Reporting Framework should, at a minimum, provide substantive response to the main questions, which they state is designed in such a manner so as to be attainable by a company that actually does seek to address aspects of human rights within its business conduct. Over time, reporting companies should work towards answering the supporting questions as well, and, in addition, improving the quality of their responses to all questions over time. A reporting database is also available. The database does not judge how well a company is implementing the UN

Guiding Principles, nor does it rate or rank corporate performance or disclosure. Instead, the database enables companies and their stakeholders to draw their own conclusions about how meaningfully a company is reporting on its progress towards implementation of the UN Guiding Principles. The database draws only from information companies publish in their own websites and reports, in order to support integrated approaches to how companies think and talk about human rights in their core business. The database's catalogue of corporate disclosure can be used widely to support analysis, ranking or benchmarking of corporate reporting on human rights by other initiatives.<sup>15</sup>

With these three reporting frameworks in mind, recommendations can be made for how to setup the reporting of the proposed global bioethics tool. Admirable qualities from the above frameworks are to be included in the proposed framework. These include making it user friendly, stressing the need for uniformity, and making the process as streamlined as possible. Because it is the hope that companies will self-report this information rather than a team of independent researchers having to search for the data, companies will need to devote significant time to answering the questions. Hence, making it as streamlined as possible is advantageous, but this will have to occur with latter revisions of the global bioethics tool once it is in further stages of stakeholder dialogue.

Items to consider in future revisions of the global bioethics tool would be whether to amend any of the questions to include a Likert scale. Likert scales are a type of rating system that is widely used in research, specifically questionnaires. They are commonly used to quantify attitudes and behaviors. These types of scales provide respondents with a list of statements and requests that they select the response that best represent the rank or degree of their answer.<sup>16</sup> A sample of how this would be used for the global bioethics tool would be to ask a question such

as, “How well is the Company doing in ensuring that persons in LMICs on whom research is conducted have recourse to share in the benefits of the research?” In a Likert scale model, answers could be:

- a) Excellent
- b) Good
- c) Average
- d) Needs Improvement
- e) Poor

The company would then pick one of the choices and perhaps provide some supporting data or narrative to support their choice. There are advantages and disadvantages to using Likert scales. Advantages include their ease to create and, generally, to answer. They are also very flexible and versatile, having the ability to be tailored to specific questions. On the other hand, disadvantages include uncertainty in answers, which can skew results. For instance, what does “average” in regards to benefit sharing really look like? Additionally, Likert scales assume a normal distribution, generally. For instance, there is not room to answer somewhere between “average” and “good”. Hence, there are both advantages and disadvantages to using a Likert scale in the reporting framework, and this will need to be discussed with more stakeholders.

### *6.2) Application to the Industry*

This section will seek to apply the global bioethics tool, with the list of indicators developed in section 5.2 and the reporting framework developed in section 6.1, to two pharmaceutical companies—one of which is a major Western company and the second a mid-sized firm based in a LMIC. The purpose of choosing a company both from a HIC and a LMIC is to demonstrate that the global bioethics tool is a useful instrument for any pharmaceutical or biotechnology company that is involved in research and development, not only large Western entities. In the exploratory phase of this study (July-December 2016), conducted in conjunction

with Novo Nordisk, companies were initially screened for whether they were signatories to the UN Global Compact, if they were included in the 2014 Access to Medicine Index, Dow Jones Sustainability Indices, and whether they were a member of Business for Social Responsibility. If a company was found in multiple of these then they were viewed as having interests in the area of CSR. Hence, this formed the initial criterion for contacting companies to ascertain their interest in a bioethics tool. At the time of this writing, the following companies have been contacted to ascertain their interest in forming a collaborative partnership to develop the global bioethics tool: Merck, Genentech (biotechnology subsidiary of Roche), Novartis, Pfizer, Johnson & Johnson, Takeda, Bristol-Myers Squibb, GlaxoSmithKline, and Sanofi.

As of this writing, the funding for the global bioethics by the industry has not continued. Hence, this section is largely hypothetical, though it does use real-world, publically accessible data to apply the indicators to specific companies. Public information found on the company's websites, available in academic literature, and reported through alternative mechanisms such as the UN Global Compact COP has been scoured. Additionally, representatives from each company have been contacted for further information on an as needed basis. While this section is largely hypothetical, as the global bioethics tool is still in a state of some flux, the purpose of applying the tool in this section is to demonstrate its viability. Hence, the global bioethics tool is not merely a curious academic exercise, but it is a practical way to more fully implement bioethical principles into the business practices of the pharmaceutical and biotechnology industry. Applying the tool to specific companies will also showcase areas where the tool is in need of refinement. However, refinement will best come through engagement with multiple stakeholders and having intimate knowledge of the workings and practices of specific companies, which is difficult to accomplish by an outsider.

If the funding of the global bioethics tool by industry were to begin in the future, the tool, its development, and its refinement will primarily be driven by a cooperation of several pharmaceutical and biotechnology companies. Hence, the engagement and commitment of others in this industry is the first key step to seeing the global bioethics tool take on a meaningful role for the industry. Nonetheless, seeing that the global bioethics tool has not continue to be funded by industry, reasons for not implementing the tool will be studied in the concluding chapter. Further options for seeing the tool adopted by the pharmaceutical and biotechnology industry, such as alternate ways of promotion or seeking support from others in the industry, will be assessed.

The companies that have been chosen to assess for this section include: 1) GlaxoSmithKline and 2) Sun Pharmaceuticals. The reason GlaxoSmithKline (GSK) was selected is multifaceted. First, GSK is a large multinational corporation that is based in a HIC, the UK. Second, GSK has topped the Access to Medicine Index since the ranking was first published in 2008. For this reason, there is ample data available about what GSK is doing in regards to corporate social responsibility. Because of the ample public data available, GSK serves as a good indicator to see how much of the data requested by the global bioethics tool is publically available. The second company, Sun Pharmaceuticals, was chosen for two reasons. First, the global bioethics tool is envisioned as not only a tool for companies based in HICs, but also those in LMICs. Sun is headquartered in Mumbai, India and is a sizable company with over 52,000 employees and \$4 billion USD in revenue. Nonetheless, though Sun is a sizable company, it is still much smaller than other major Western pharmaceutical companies, is not a signatory to UNGC, and lags behind other companies in terms of what bioethics information is publically available. Hence, this is a second reason Sun was chosen, in order to showcase that pulling



publically available data is simply not enough to answer the indicators of the global bioethics tool. For the vision of the global bioethics tool to be fully realized, and for stakeholders to gain an honest and transparent look at what companies are doing to fulfill their responsibilities, an insider perspective must be achieved.

In what follows, the global bioethics tool is first applied to GSK. Some concluding notes on that application process directly follows. Then, the application will be mimicked for Sun Pharmaceuticals, along with some concluding thoughts on that process and how it could improve.

<b>Global Bioethics Tool for Pharmaceutical and Biotechnology Companies</b>
<i>Instructions: Please answer the following questions about your company as truthfully and succinctly as possible.</i>
<b>Company Name:</b> GlaxoSmithKline
<b>1) Article 3: Human dignity and human rights</b>
<p><i>1.1: How does the company avoid infringing on the human rights of others? (cf UN Guiding Principles on Business and Human Rights (UNGPHR) Principle 11)</i></p> <p>In 2012, GSK undertook an independent third-party assessment to help them understand potential human rights impacts associated with their business practices. Seven priority areas were identified from this: access to health care, air quality impact relating to propellants, clinical trial standards, employment practices, patient safety, product counterfeiting and use of third-party suppliers.<sup>17</sup></p> <p>GSK also has a human rights statement which states their commitment to the Universal Declaration of Human Rights and the UN Guiding Principles on Business and Human Rights. They state their commitment to providing fair wages and safe working conditions. GSK also reserves the right to enter into their third party supplier's premises to monitor compliance of their human rights statement.<sup>18</sup></p>
<p><i>1.2: How does the company ensure the welfare of its employees by providing safe and suitable working conditions?</i></p> <p>As stated in 1.1, the company has policies in place that state it does ensure employees have safe and suitable working conditions. Further, GSK states that they focus on incident prevention and risk assessment through trainings and communications on key risks.<sup>19</sup></p>
<p><i>1.3: How does the company implement standards of working hours for its employees, such as those put forth by the International Labour Organization?</i></p>

No information could be located.

*1.4: How does the company ensure fair living wages in relation to the context of their employees such as to meet the basic needs of employees and dependents?*

GSK states that they are “committed to providing a fair salary and good conditions of employment,” yet it is unclear how “fair salary” is determined.

*1.5: How does the company ensure the elimination of all forms of forced or compulsory labor in its employees and suppliers? (cf UN Global Compact (UNGC) Principle 4)*

In its human rights statement, GSK states that their contracts with suppliers and business partners contain a labor rights clause that requires the supplier to warrant, “It does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work.”<sup>20</sup> GSK reserves the right to monitor compliance with this, though it is uncertain how, or if, this is done.

*1.6: How does the company ensure the effective abolition of child labor of its employees and its suppliers? (UNGC Principle 5)*

In its human rights statement, GSK states it is, “opposed to all forms of slavery and exploitative child labour and will work with appropriate partners to address this problem responsibly wherever we encounter it.” Further, GSK requires their suppliers to assure, “It does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child.”<sup>21</sup>

The indicator, however, asks how the company “ensures” that child labor has effectively been abolished in its company and suppliers rather than merely stating opposition to it. It is unclear how this is guaranteed.

*1.7: How does the company ensure that a system is in place so that employees may voice concerns regarding aspects of human dignity and human rights? (UNGPBHR Principle 18)*

GSK states that its suppliers shall “ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies.”<sup>22</sup> Further, GSK has a system for expressing concerns regarding breaches of its code of conduct or other corporate policies.<sup>23</sup> The company states that concerns will be handled promptly, discreetly, and professionally. Complaints may be lodged by speaking to local management, HR, or legal services, via telephone, letter, or filling out an online report.

*1.8: Does the company have in place a human rights due diligence process to identify, prevent, mitigate and account for how they address their impacts on human rights? (UNGPBHR Principle 15b)*

GSK states that after a complaint about a possible breach of their code of conduct, company policies, or procedures is lodged, the steps that happen afterward are:

- Your report will be forwarded to appropriate GSK management for follow-up
- Members of management will review and address your concern; they may include representatives from the Global Ethics and Compliance function, Human Resources, and/or Legal
- Your concern will be handled promptly, discreetly, and professionally. Discussions and enquiries will be kept in confidence to the extent appropriate and permitted by law
- On request, you may obtain certain follow-up information about how your concern was addressed.<sup>24</sup>

*1.9: How does the company promote and safeguard the health, wellbeing, and rights of human research participants?*

In their policy statement entitled, “Clinical Trials in the Developing World,” GSK follows the ICH-GCP guidelines and the Declaration of Helsinki (DoH), only performs clinical trials in countries where the medicines are likely to be suitable for the wider community in the country, and, when necessary, reaches agreement before the start of the trial, on issues such as responsibilities for the standard of care and post-trial treatment (type of benefit sharing).<sup>25</sup>

*1.10: Does the company place the goal of generating new knowledge in clinical trials above the rights and interests of the individual research participant?*

From the policy statement, “Clinical Trials in the Developing World,” it does not appear so.

*1.11: How is the priority of patient safety respected during a trial, and after market marketing of a new product?*

Trials are conducted in accordance with ICH-GCP guidelines and the DoH. After a product comes to market, monitoring is overseen by GSK’s Global Safety Board, which is chaired by the chief medical officer. The board reviews safety reports of its products.<sup>26</sup>

*1.12: How do investigators ensure the research is acceptable within the community it takes place? How does a company ensure it complies with good scientific principles that would lead to best science and greatest benefit?*

GSK states, “GSK follows ICH methodologies as a minimum standard and works, where appropriate, with community leaders, charities, religious figures and Health Authorities, in compliance with local laws and practices, to ensure that the risks and benefits for trial participants are effectively evaluated and appropriate measures put in place.”<sup>27</sup>

*1.13: How is it ensured that participants during a trial obtain new information that might affect their decision to continue in the trial?*

No information could be found publically available on this.
<b>2) Article 4: Benefit and harm</b>
<p><i>2.1: How is any possible harm minimized?</i></p> <p>GSK states that it follows ICH-GCP guidelines “to ensure that the risks and benefits for trial participants are effectively evaluated and appropriate measures put in place.”<sup>28</sup> Further, all clinical trials are evaluated for harms and risks by an IRB, and they must demonstrate that the anticipated benefits justify the risks.</p>
<p><i>2.2: How is direct and indirect benefit maximized?</i></p> <p>As 2.1 states, clinical trials must be approved by an IRB and demonstrate that benefits justify any risks. It is not clear from the published materials how direct and indirect benefit is maximized specifically.</p>
<p><i>2.3: How does a company ensure that investigators and staff are trained and scientifically qualified?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.4: How is the continued evaluation of a marketed product through research of safety, efficacy, accessibility and quality ensured?</i></p> <p>After a product comes to market, monitoring is overseen by GSK’s Global Safety Board, which is chaired by the chief medical officer. The board reviews safety reports of its products.<sup>29</sup></p>
<p><i>2.5: If a clinical trial participant is harmed, how is harm assessed and who determines/assesses if compensation is appropriate?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.6: Are qualified research ethics committees (institutional review board/ethical review board) present and reviewing research protocols to ensure benefit is maximized and harm minimized?</i></p> <p>Yes. As GSK follows ICH-GCP guidelines, an IRB is in place to review research protocols.</p>
<p><i>2.7: Who and how is it decided if the non-clinical and clinical knowledge is adequate to support a clinical trial?</i></p> <p>The GSK public policy position on “Pharmacovigilance” states, “Before evaluation of a potential new medicine in humans can begin, extensive preclinical (or laboratory research) must be conducted. This research typically involves years of experiments including animals and human cells. If this stage of testing is successful, these data are provided to regulatory authorities, requesting approval to begin evaluating the potential new medicine in humans. This evaluation is done through clinical trials and is usually conducted in three main phases. Each phase addresses different questions that determine if the testing of the “Investigational Medicinal Product” (IMP)</p>

can proceed to the next phase.” Further, GSK states that the “benefit/risk profile of a GSK medicine is assessed throughout its lifecycle using a benefit/risk framework and appropriate analyses.”<sup>30</sup> However, it is uncertain that exactly how this benefit/risk profile is assessed and what are the steps of remediation if it is found that risks are too high.

*2.8: How are conflicts of interest amongst research ethics committee members and affiliated researchers stated and mitigated?*

GSK, in a public policy statement, says that it “expects all staff to be free from actual or potential conflicts of interest.”<sup>31</sup> In its public policy position on performing clinical trials in the developing world, GSK asserts: “GSK will always seek formal approval for trials from independent ethics committees. In some developing countries independent ethics committees do not exist or their membership is not in line with international regulatory requirements. If a local ethics committee does not exist, GSK will not conduct the trial.” Hence, it appears that the company uses independent ethics committees to approve its clinical trials, which would have their own sets of rules for conflict mitigation. Additionally, within the company, GSK has stopped paying doctors to promote its products and ended the practice of tying compensation of sales representatives to the number of prescriptions doctors write.<sup>32</sup>

*2.9: How is harm/benefit ratio determined by the company?*

This is uncertain. From 2.7, GSK has a system to determine this, and notes that, “When information is found that changes the benefit/risk balance in a negative direction, action is taken to characterise, communicate and minimise the risk. Proposed actions are discussed with regulatory authorities and can include modifying the prescribing information (which includes the patient information leaflet), communications to physicians and other healthcare providers and sometimes carrying out further clinical trials. In certain cases it may be appropriate to stop clinical trials or to withdraw the medicine from the market.”<sup>33</sup> However, it is still uncertain how harm/benefit ratio is exactly determined.

*2.10: What is the procedure for stopping a research study if the risks of proceeding are shown to outweigh the potential benefits? (WMA Declaration of Helsinki Article 20, 2008)*

This is not known. GSK does states that, in certain cases, it may appropriate to halt a trial due to the risk/benefit ratio, though actual procedures do not appear to be public knowledge.

*2.11: How does the company respond to a situation in which a research participant has an apparent research-related harm occur?*

No information could be found publically available on this.

### **3) Article 5: Autonomy and individual responsibility**

*3.1: How does the company ensure the autonomy (freedom, liberty, self-determination) of human research participants?*

<p>GSK states that they follow ICH-GCP guidelines, which has inclusion for the autonomy of persons in clinical trials. No other information could be located on this.</p>
<p><i>3.2: How is the right to withdraw at any time without repercussions for the participant ensured?</i></p> <p>GSK states that they follow ICH-GCP guidelines, which has inclusion for a participant’s right to withdraw from clinical trials. No other information could be located on this.</p>
<p><i>3.3: How does the company uphold the freedom of association and the effective recognition of the right to collective bargaining? (UNGC Principle 3)</i></p> <p>In its Human Rights Statement, GSK states that they are, “respectful of the right of employees to join an independent trade union, the right to collectively bargain, and of freedom of association.”<sup>34</sup></p>
<p><b>4) Article 6: Consent</b></p>
<p><b>Information</b></p>
<p><i>4.1: How does the company ensure that consent of human research participants is informed?</i></p> <p>GSK follows ICH-GCP guidelines, which requires the voluntary and informed consent of research participants. The company states, “In cultures other than those in Western society, additional measures may often be needed to ensure the objectives of informed consent are met. While still complying with ethical and legal requirements, additional steps are therefore taken to match the objectives of informed consent to local culture. For example, local leaders and/or family members may need to be involved. Where formal <i>written</i> informed consent from the participant is not possible in a GSK sponsored trial (due, for example, to poor literacy) investigators will work with independent witnesses to document a verbal consent process. They will formally verify that the purpose of the trial has been explained to the participant and he/she has understood what is proposed and involved.”<sup>35</sup></p>
<p><i>4.2: What is included in this information component?</i></p> <p>No information could be found publically available on this.</p>
<p><i>4.3: Are participants provided informed consent in a language and manner that is appropriate?</i></p> <p>Yes, see 4.1. However, examples on how this has been accomplished successfully in the past would be appropriate in this section.</p>
<p><b>Voluntariness</b></p>
<p><i>4.4: How does the company ensure that consent of human research participants is voluntary and in no way coerced?</i></p> <p>As GSK follows ICH-GCP guidelines, it does try to ensure that participation in human research is completely voluntary. This is addressed by the company, in particular, in regards to payments and other recompense to participants:</p>

<p>“At the individual level, reimbursement for costs incurred by the participant is reasonable, and in poorer societies it is particularly important that the individuals do not incur loss as a result of involvement in a trial. Also, the reverse is a concern as in some societies it is important that individuals do not benefit from study involvement to an extent that it sets them apart in that society. In all circumstances, problems can be avoided by involving the local ethics committee (disclosure of payment plans has been an obligatory part of the ethical review process since the mid-1990s) and ensuring that any payments are appropriate to the local setting. The standard continues to be that participation in clinical trials is voluntary. Care must therefore be taken to avoid undue financial influence on participants’ decisions.”<sup>36</sup></p>
<p><i>4.5: How does the company provide measures against undue inducement?</i></p> <p>See 4.4. GSK seeks to make any recompense available to participants appropriate to the local economy so as not to unduly influence persons.</p>
<p><b>Competence</b></p>
<p><i>4.6: How does the company ensure that the research participant is competent to give consent?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Training of Researchers</b></p>
<p><i>4.7: How are researchers or investigators trained in the process of obtaining informed consent, including providing information in an appropriate manner that is understandable for the participant?</i></p> <p>No information could be found publically available on this.</p>
<p><i>4.8: When is it appropriate to consult family members and community leaders in the consent process?</i></p> <p>GSK states, “In cultures other than those in Western society, additional measures may often be needed to ensure the objectives of informed consent are met. While still complying with ethical and legal requirements, additional steps are therefore taken to match the objectives of informed consent to local culture. For example, local leaders and/or family members may need to be involved.”<sup>37</sup></p>
<p><i>4.9: Is the participant given the option of being informed about general outcomes and results of the study?</i></p> <p>No information could be found publically available on this.</p>
<p><i>4.10: How is it ensured that emerging new information is promptly given to trial participants in a long-term study that may affect their desire to stay in the study?</i></p> <p>No information could be found publically available on this.</p>
<p><i>4.11: When is it appropriate to ask for re-consent during a trial?</i></p>

No information could be found publically available on this.
<b>Research Participants</b>
<i>4.12: How is the right to withdraw at any time ensured?</i>
No information could be found publically available on this.
<i>4.13: Who determines if a person is competent to give consent and how is it determined?</i>
No information could be found publically available on this.
<b>Compensation</b>
<i>4.14: Who and how is it determined?</i>
GSK attempts to make compensation appropriate to the local economy. Their proposal is then submitted to an independent ethics committee for consideration. Since the mid-1990s, GSK has made the disclosure of payment plans to the local ethics committee an obligatory part of its ethics review process. <sup>38</sup>
<b>Human Biosamples</b>
<i>4.15: What is the company's course of action in regards to biosamples used in research that are collected by researchers after prior informed consent for collection, storage and use/reuse? If consent of the participant is not possible, has an ethics committee approved?</i>
No information could be found publically available on this.
<b>5) Article 7: Persons without the capacity to consent</b>
<b>General</b>
<i>5.1: Has authorization for research been obtained in accordance with the best interest of the person concerned and in accordance with domestic law?</i>
GSK follows ICH-GCP guidelines in its clinical trials. Each clinical trial must be approved by an IRB and states that it works within local laws and practices. <sup>39</sup>
<i>5.2: Has the research participant been involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent?</i>
As GSK states that they follow ICH-GCP, Guideline 4.3.4 of ICH-GCP states that a research participant may withdraw from a study at any time for any reason. Specific details of how potential participants are involved in the consent process and ensured that they are able to withdraw at any time is uncertain.
<i>5.3: Do the results of the research have the potential to produce real and direct benefit to the health of the incapable research participant?</i>
No information could be found publically available on this.



<p>5.4: <i>Can research of comparable effectiveness be carried out on individuals capable of giving consent?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Training of Researchers</b></p>
<p>5.5: <i>How are researchers/investigators trained in dealing with and protecting persons with diminished capacity to consent?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Determination of Capacity</b></p>
<p>5.6: <i>How it is determined who is not capable of providing consent?</i></p> <p>No information could be found publically available on this.</p>
<p>5.7: <i>How is capacity determined in the protocol review process and by the investigator(s) performing research?</i></p> <p>No information could be found publically available on this.</p>
<p>5.8: <i>How do researchers obtain proxy or surrogate consent?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Exception</b></p> <p><i>If it is not possible to comply with the above, the UDBHR does formulate as an exception for research that does not have the potential to produce results of direct benefit to the health of the individual concerned. The following conditions must be met to permit such research:</i></p> <p>1) <i>The research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease, or disorder, to the person concerned or to other persons in the same category of disease or disorder.</i></p> <p>2) <i>The research must only entail minimal risk and minimal burden for the individual concerned.</i></p>
<p><b>6) Article 8: Respect for human vulnerability and personal integrity</b></p>
<p><b>Vulnerability &amp; Marginalization</b></p>
<p>6.1) <i>How does the company define "vulnerable" persons and population?</i></p> <p>As GSK follows ICH-GCP, vulnerable persons are defined as ICH defines them. Guideline 1.61 of ICH-GCP defines vulnerable subjects in research.<sup>40</sup> No information could be found publically available on this.</p>
<p>6.2) <i>How does the company specify who needs specific consideration? (UNGPBHR: Women, children, people with disabilities, indigenous people, migrants, elders, prisoners, pregnant women, economically and educationally disadvantaged are considered vulnerable)</i></p> <p>See 6.1. No other publicly available information could be found on this.</p>

<p>6.3) <i>How are the vulnerable additionally safeguarded against undue influence or coercion?</i></p> <p>In clinical trials in the developing world, which could be considered a vulnerable population, local ethics committees are involved to ensure that any payments participants receive are appropriate to the context.<sup>41</sup> No additional information could be found publically available on this.</p>
<p>6.4) <i>Are the knowledge and products from the clinical trial made reasonably available to benefit that group?</i></p> <p>GSK has the following policy statement on the post-trial availability of medicines: “GSK strongly supports the goal of improving access to medicines and we recognise our responsibility for helping to improve access to our products worldwide. Where appropriate, working with host country governments and researchers, GSK will endeavour to make provisions for post-trial access to any interventions identified as beneficial in the trial, notifying participants of any such provisions made through the informed consent process in advance of the trial.”<sup>42</sup></p>
<p><b>Identification</b></p>
<p>6.5) <i>How does the company identify vulnerable individuals or groups?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Alternatives</b></p>
<p>6.6) <i>Can the research be carried out in a non-vulnerable group? (Helsinki, 2013)</i></p> <p>No information could be found publically available on this.</p>
<p><b>Protection</b></p>
<p>6.7) <i>What guidelines has the company established to protect vulnerable persons?</i></p> <p>GSK follows ICH-GCP guidelines and tries to seek input from local community members and leaders prior to beginning a research trial in a developing country. No other information on performing research on vulnerable persons could be located.</p>
<p>6.8) <i>Does the company comply with the laws concerning research with vulnerable persons? If no such legislation exists in the context where the research is being conducted (host community), what does the company do?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Benefits</b></p>
<p>6.9) <i>Does the vulnerable group stand to benefit from the knowledge, practices or interventions that result from the research? (Helsinki, 2013)</i></p> <p>GSK states, “GSK-sponsored clinical trials are only conducted in countries where the medicines</p>

are likely to be suitable for the country's wider community. Furthermore, clinical trials of investigational medicines are not conducted in countries when it is known at the outset that there is no intent to pursue registration and make the medicine available for use in that country.”<sup>43</sup>

*6.10) Is the medical research with a vulnerable group responsive to the health needs or priorities of this group? (Helsinki, 2013)*

GSK states, “GSK-sponsored clinical trials are only conducted in countries where the medicines are likely to be suitable for the country's wider community. Furthermore, clinical trials of investigational medicines are not conducted in countries when it is known at the outset that there is no intent to pursue registration and make the medicine available for use in that country.”<sup>44</sup>

## **7) Article 9: Privacy and confidentiality**

### **Risk**

*7.1) What are the risks of the infringement of privacy?*

The exact risks of the infringement of privacy are not known. However, “GSK is committed to exercising high standards of integrity in dealing with personally identifiable information, and takes several measures to protect the PII of employees, researchers and clinical trial participants.”<sup>45</sup>

*7.2) What is the risk of infringement of personal data?*

The exact risks of infringement of personal data are not known. See 7.1.

### **Measures**

*7.3) What measures does the company take in order to maintain the right to privacy of participants in human research?*

GSK does take measures to protect the privacy of research participants. However, in their public policy position paper, “Safeguarding Personally Identifiable Information A Summary of GSK's Binding Corporate Rules,” it is not quite clear exactly what methods they use to protect the privacy of research participants and how/if this differs from protecting the personally identifiable information of employees.<sup>46</sup>

*7.4) How is it ensured that information is only shared or disclosed as it has been specified in the consent?*

No information could be found publically available on this.

## **8) Article 10: Equality, justice, and equity**

*8.1) How does the company manage scarce resources in order to guarantee a just and equitable healthcare system?*

GSK is a signatory of the United Nations CEO Water Mandate. The company has a policy statement asserting how they steward water, which is a scarce resource.<sup>47</sup> It is not certain how the

<p>company manages scarce healthcare resources, specifically scarce pharmaceuticals, in a just and equitable manner.</p>
<p><i>8.2) How does the company ensure certain groups are not under- or over-represented in research?</i></p> <p>No information could be found publically available on this.</p>
<p><i>8.3) How does the company ensure that groups and communities are invited to participate in a way that the burden and benefits are equitably distributed?</i></p> <p>No information could be found publically available on this.</p>
<p><i>8.4) Will the participants, to the best of the company’s knowledge, be able to afford the product when marketed without it being of significant burden?</i></p> <p>In its policy position on clinical trials in the developing world, GSK states, “Where appropriate, working with host country governments and researchers, GSK will endeavour to make provisions for post-trial access to any interventions identified as beneficial in the trial, notifying participants of any such provisions made through the informed consent process in advance of the trial.” The company also states, “GSK is not, in general, responsible for the provision of nationally licensed medicines after a trial. This responsibility lies with governments as part of national healthcare programmes. For this reason, GSK-sponsored clinical trials in chronic conditions will not be carried out unless we are assured at the outset by the investigator that subjects will receive or be referred for any necessary continued healthcare and that the healthcare system is able to provide for the continued care of study subjects.”<sup>48</sup></p>
<p><i>8.5) How do the investigators ensure the research is fair to the subject?</i></p> <p>Aside from following ICH-GCP guidelines and the Declaration of Helsinki, no other specific information could be found.</p>
<p><b>9) Article 11: Non-discrimination and non-stigmatization</b></p>
<p><i>9.1) How does the company take care to avoid the systematic development of medicines for one group within a population to the neglect of others?</i></p> <p>In their policy statement on clinical trials in the developing world, GSK states:  “GSK has a long-standing commitment to research and development into diseases of the developing world (DDW). Our R&amp;D portfolio includes projects for a number of diseases of particular relevance to developing countries including: bacterial meningitis, Chagas disease, Chlamydia, dengue fever, HIV/AIDS, human African trypanosomiasis, leishmaniasis, malaria, pandemic flu, pneumococcal disease and TB.</p> <p>We are keen to do more but we recognise that the challenges are too complex to be addressed by any one organisation alone. Partnership is essential and that is why we are pursuing an ‘open</p>

innovation' approach to DDW research, working together with industry, academia, NGOs and governments.

Open innovation at GSK includes:

- Sharing our expertise and resources with scientists from around the world through our Tres Cantos Open Lab.
- Sharing our intellectual property and know-how through the Pool for Open Innovation against Neglected Tropical Diseases.
- Being more open with our data and DDW research to help stimulate research outside GSK.”<sup>49</sup>

In particular, these are the areas GSK is currently working in to meet the needs of the developing world:

“In 2016, we committed to working with governments, multinational organisations and NGOs to enhance preparedness against potential future outbreaks of diseases such as Ebola and Zika. We are supporting the Coalition for Epidemic Preparedness Innovation and are proposing to create a permanent ‘biopreparedness organisation’ at our Rockville, Maryland Vaccines site.

In 2016, our gel to help prevent umbilical cord infections in newborns received a positive scientific opinion from the European Medicines Agency (EMA). Three million babies die each year from infection, often when the newly-cut umbilical cord attracts bacteria – a particular issue in developing countries. If approved by local regulators, we will make the gel available at a not-for-profit price and share manufacturing knowledge so it can be widely made.

Our *Mosquirix* vaccine targets a significant health threat – malaria. Phase III trials of the vaccine, which received a positive opinion from the EMA in 2015, have shown the vaccine could have a considerable public health impact when used in combination with malaria control measures.

In 2016, the World Health Organization confirmed that full funding has been committed to enable the pilot implementation of *Mosquirix* in three settings in sub-Saharan Africa due to begin in early 2018.”<sup>50</sup>

*9.2) When conducting clinical trials, does the company discriminate or stigmatize certain populations or genders so that they are under-represented in research?*

No information could be found publically available on this.

*9.3) Does the company have a grievance procedure for handling allegations of discrimination and stigmatization?*

GSK has a procedure for handling allegations of discrimination and stigmatization amongst its employees,<sup>51</sup> but it a policy on research participants could not be located.

## **10) Article 12: Respect for cultural diversity and pluralism**

*10.1) In clinical trials with human research participants, how does the company handle cultural differences regarding informed consent?*

In their public policy statement, “Clinical Trials in the Developing World,” GSK states, “In cultures other than those in Western society, additional measures may often be needed to ensure the objectives of informed consent are met. While still complying with ethical and legal requirements, additional steps are therefore taken to match the objectives of informed consent to local culture. For example, local leaders and/or family members may need to be involved. Where formal written informed consent from the participant is not possible in a GSK sponsored trial (due, for example, to poor literacy) investigators will work with independent witnesses to document a verbal consent process. They will formally verify that the purpose of the trial has been explained to the participant and he/she has understood what is proposed and involved.”<sup>52</sup>

*10.2) When doing business in an unfamiliar cultural milieu, how does the company approach these cultural differences?*

As stated in 10.1, GSK has “additional measures” in place for cultures that differ from Western society. They state that involving cultural leaders and/or family members may be appropriate, but no other measures are specified.

*10.3) Does the company provide training for its employees on issues of cultural diversity and pluralism?*

No information could be found publically available on this.

## **11) Article 13: Solidarity and Cooperation**

*11.1) How is the company working towards capacity-building in the area of public and global health?*

In March 2014 GSK announced strategic investments in Africa to increase access to medicines, build capacity, and deliver sustainable growth. They are working towards increasing self-sufficiency in Africa.<sup>53</sup> This is only one example of the capacity-building GSK is involved with.<sup>54</sup>

*11.2) How is the company contributing to the UN Sustainable Development Goals?*

GSK has a policy position statement on the UN Sustainable Development Goals stating that they are fully committed to the SDGs.<sup>55</sup> The position statement includes many ways GSK has tried to implement the SDGs in their business conduct, including delivering over 690 million vaccine doses, research into diseases of the developing world, setting environmental emission limits for its manufacturing sites, support of the Paris Agreement on climate change, and working with the organization Save the Children to widen immunization coverage, address nutritional needs of children, and train researchers in the poorest communities.

## **12) Article 14: Social responsibility and health**

<b>Promotion of Health and Social Development</b>
12.1) How does the company aim to promote health and social development?
12.2) Article 14 states that “all sectors of society share” in the promotion of social responsibility and health. How does the company seek to address: 1) access to quality health care and essential medicines, 2) access to adequate nutrition and water, 3) the improvement of living conditions and the environment, 4) the elimination of the marginalization and the exclusion of persons on the basis of any grounds, and 5) the reduction of poverty and illiteracy?
<b>Relationship to Developing Countries:</b>
12.3) <i>Does the company have differential pricing policies so that lower income countries pay lower prices for essential medicines than higher income countries?</i>
GSK leads the Access to Medicine Index in equitable pricing. “All of its products with equitable pricing are priced with consideration for socio-economic factors in at least some countries in scope; it uses equitable pricing for more products than any other company in scope; and has the most marketed products with equitable pricing strategies that target countries with a particular need for access to the products in question.” <sup>56</sup>
12.4) <i>Does the company invest in research and development for diseases that primarily affect lower income countries?</i>
GSK does invest in such research and development. In early 2014 GSK announced that they would “invest £25 million to create the world’s first R&D Open Lab for non-communicable diseases (NCDs) in Africa.” The company also works on developing “new products designed to meet the specific needs of Africa, for example through its ongoing work with partners to develop the world’s first vaccine against malaria and to create new nutritional products fortified with micro-nutrients to tackle childhood malnourishment.” <sup>57</sup>
12.5) <i>Does the company have policies on access to treatment for developing countries, including the five priorities of pricing, patent, joint public private initiatives, R&amp;D, and the appropriate use of drugs?</i>
In the 2016 Access to Medicine Index (ATMI) report, ATMI reported that “GSK has more products with equitable pricing strategies than in 2014, covering a broad range of diseases, including HIV/AIDS, lower respiratory infections, asthma, pertussis and hypertensive heart disease. Some (38%) of GSK’s products have equitable pricing strategies that target priority countries (disease-specific sub-sets of countries with a particular need for access to the product in question).” Further, has stated that GSK is a leader in intellectual property management and consistently engages in voluntary licensing. <sup>58</sup>
<b>13) Article 15: Sharing of benefits</b>
<b>Sharing of Benefits</b>
13.1) <i>How does the company ensure that the benefits resulting from its scientific research are shared with society as a whole?</i>

In regards to post-trial provisions of drugs, GSK states: “Where appropriate, working with host country governments and researchers, GSK will endeavour to make provisions for post-trial access to any interventions identified as beneficial in the trial, notifying participants of any such provisions made through the informed consent process in advance of the trial.”<sup>59</sup>

*13.2) When conducting clinical trials, does the company ensure that in advance of the trial, provisions are made for post-trial access for all participants who still need an intervention identified as beneficial in the trial? (DoH, Article 34, 2013)*

Yes. See 13.1.

*13.3) If the company is involved in bioprospecting, how does it ensure that indigenous knowledge and resources have been respected?*

“GSK is not directly involved in any bioprospecting,” and they uphold the Nagoya Protocol.<sup>60</sup>

#### **Undue Inducement**

*13.4) How does the company ensure against improper inducements to participate in research?*

GSK states that they attempt to ensure that post-trial access to medicines and healthcare, as well as capacity-building, does not constitute undue inducement. Specificity on how this is accomplished is not stated.<sup>61</sup>

#### **14) Article 16: Protecting future generations**

*14.1) In bioethical decision-making, does the company take into account the impact on the present generation and also try to evaluate the impacts on future generations?*

No information could be found publically available on this.

*14.2) If the company is involved in research on human genomic information, how does the company ensure that such new technology will not result in undesired outcomes for future generations?*

No information could be found publically available on this.

*14.3) How does the company evaluate any possible influence a test compound can have on genes or germ cells?*

No information could be found publically available on this.

#### **15) Article 17: Protection of the environment, the biosphere and biodiversity**

##### **Impact on Environment**

*15.1) As it has been recognized that the company has a responsibility to protect the environment, how does the company prevent advances in molecular biology, recombinant technology, genetics, biotechnology, and other advances from negatively impacting the environment?*

No information could be found publically available on this.



*15.2) Does the company participate in the development of new technologies that pose risk of irreversible damage to the environment?*

It does not appear so. GSK has environmental policies and procedures in place to reduce carbon emissions, waste, and water usage.<sup>62</sup>

*15.3) Does the company have in place emergency guidelines in the event of an accident affecting the environment?*

No information could be found publically available on this.

*15.4) Does the company minimize the use of chemicals and other dangerous substances, as well as ensuring their safe handling and storage?*

No information could be found publically available on this.

*15.5) If applicable to the business, does the company encourage the development and use of environmentally friendly technologies?*

GSK has invested in sustainable buildings that use less energy, including the use of solar panels. Their Philadelphia operations hub was awarded LEEDS Platinum certification.<sup>63</sup> Hence, GSK encourages the use of environmentally friendly technologies.

### **Biosphere**

*15.6) How does the company seek the protection of experimental animals? (cf Article 4)*

GSK follows the three Rs of animal welfare: replace, reduce, refine.

- Replace animal research with other methods where/when possible
- Reduce the quantity of animals used in a study while still providing information of a given amount and precision
- Refine techniques to minimize pain and distress and improve the welfare of animals

GSK scientists make attempts to design studies that do not require animals. All proposed animal research is reviewed by an ethics panel, which is independent of the scientific group commissioning the study.<sup>64</sup>

*15.7) How does the company seek to eliminate the need for using animals in research?*

GSK has made strides in their application of the 3Rs. GSK researchers have:

- replaced some research in animals with computer simulations and ‘in vitro’ techniques, where tests are done on individual cells, cultures or tissues
- applied statistical methods to our work, so that we can be confident in results obtained using many fewer animals
- introduced the use of imaging that can track physical and chemical changes caused by treatment over time, removing the need to compare treated animals with non-treated animals<sup>65</sup>

*15.8) How does the company seek to protect and promote the welfare on the animals used in research?*

In addition to the above, GSK shares their practices with other scientists and regulatory authorities and publish the results of our research in scientific journals. They are also involved with other organizations that aim to reduce the need for animal testing and promote animal welfare including:

- UK National Centre for the 3Rs (NC3Rs)
- European Centre for the Validation of Alternative Methods (ECVAM)
- European Partnership for Alternative Approaches to Animal Testing (EPAA)
- Center on Alternatives for Animal Testing (CAAT)
- Scientist Center for Animal Welfare (SCAW)
- Institute for Laboratory Animal Research (ILAR)<sup>66</sup>

**Impact on Biodiversity**

*15.9) Does the company prevent, minimize and remedy impacts on biodiversity?*

GSK has sought to reduce its water and waste expenditures. They have cut operational carbon emissions by 18% since 2010.<sup>67</sup>

As is evident from the above application of the global bioethics tool to GlaxoSmithKline, there is a lack of knowledge, from a standpoint of what is publically available, in what the company is substantively doing in regards to the indicators of the global bioethics tool. Some specificity is present, though there is not enough to gain best practices and to be able to benchmark companies well. This is one of the limitations with this hypothetical application in which an external researcher (the author) attempts to respond to the indicators rather than have a more knowledgeable person from inside the company complete the global bioethics tool questionnaire.

In regards to human rights aspects, accountability is a central feature of human rights, for absent of accountability, human rights can develop into little more than window-dressing. Accountability is an essential, and achievable, goal of the global bioethics tool. Accountability provides individuals and communities with an opportunity to understand how those with human

rights responsibilities have discharged their duties. Equally, it provides those with human rights responsibilities the opportunity to explain what they have done and why.<sup>68</sup> GSK has a stand-alone human rights and has also been responsive to in-depth questions posed to them by the Business & Human Rights Resource Centre, a London-based charity existing to advance human rights in the business sector.<sup>69</sup> Hence, it would be optimal if an insider from GSK would answer the indicator questions of the global bioethics tool as well in order to gain insight into their bioethics processes.

While much information could be located on GSK's bioethics, human rights, and CSR actions, some details are still lacking. The following inquiry was sent to GSK's Senior Vice President of Global Ethics and Compliance regarding several of the items that could not be publically located:

Greetings,

I am a PhD student in bioethics in the United States at Duquesne University and am writing my dissertation on bioethics, human rights, and corporate social responsibility as it relates to the pharmaceutical industry. Particularly, my dissertation takes the 15 principles from the 2005 UNESCO Universal Declaration on Bioethics and Human Rights and attempts to turn these principles into measurable indicators and benchmarks.

I have been scouring your website, reports from the UN Global Compact, and the Access to Medicine Foundation for more information about GSK's actions in regards to bioethics, human rights and CSR.

In particular, it would be helpful to know how clinical researchers who are performing research trials are trained by the company on informed consent, how capacity to participate in a trial is determined, how researchers go about obtaining proxy or surrogate consent, if/how GSK provides training for its employees on issues of cultural diversity and pluralism, and if/how the company seeks to protect future generations which may be effected by GSK's work. Any information on the above would be greatly appreciated. Thank you.

As of the time of this writing, GSK had not yet responded to the email.

## Global Bioethics Tool for Pharmaceutical and Biotechnology Companies

*Instructions: Please answer the following questions about your company as truthfully and succinctly as possible.*

**Company Name:** Sun Pharmaceutical Industries Limited

### 1) Article 3: Human dignity and human rights

*1.1: How does the company avoid infringing on the human rights of others? (cf UN Guiding Principles on Business and Human Rights (UNGPHR) Principle 11)*

Sun Pharmaceuticals states in its 2015-16 Business Responsibility Report that they have an “all-encompassing Human Rights Policy covering various principles ranging from freedom of association to freedom from harassment.”<sup>70</sup> However, this policy could not be located publically.

*1.2: How does the company ensure the welfare of its employees by providing safe and suitable working conditions?*

In regards to the health and safety of its employees, Sun states, “Wellness of the workforce is given pivotal importance at Sun Pharma. Our robust Environment, Health and Safety (EHS) policy and operating guidelines ensure a safe and healthy environment. Compliance to ISO/OHSAS 18001 standards and to the laws of the land is non-negotiable... We encourage reporting of accidents, injuries and near- misses, which enables us to be better prepared in the future. Safe work practices are endorsed and the usage of unsafe equipment is disallowed.”<sup>71</sup> However, the EHS policy referenced could not be located publically.

*1.3: How does the company implement standards of working hours for its employees, such as those put forth by the International Labour Organization?*

No information could be found publically available on this.

*1.4: How does the company ensure fair living wages in relation to the context of their employees such as to meet the basic needs of employees and dependents?*

No information could be found publically available on this.

*1.5: How does the company ensure the elimination of all forms of forced or compulsory labor in its employees and suppliers? (cf UN Global Compact (UNGC) Principle 4)*

Sun states, “Our actions emanating from these policies [Human Rights policies] speak louder than our intentions. Not only are we compliant with all the statutory laws and regulations, we have grievance redressal mechanisms in place for violations, if any. In the reporting year, there were no human rights violation complaints, relating either to child, forced and involuntary labour or sexual harassment / discriminatory employment, against the Company.”<sup>72</sup> However, no other information could be found about the actions they speak of.

*1.6: How does the company ensure the effective abolition of child labor of its employees and its suppliers? (UNGC Principle 5)*

See 1.5. Sun merely states they are compliant with laws and does not make any mention of how they ensure this.
<i>1.7: How does the company ensure that a system is in place so that employees may voice concerns regarding aspects of human dignity and human rights? (UNGPBHR Principle 18)</i>
It is uncertain how or if Sun Pharmaceuticals ensures this.
<i>1.8: Does the company have in place a human rights due diligence process to identify, prevent, mitigate and account for how they address their impacts on human rights? (UNGPBHR Principle 15b)</i>
Sun Pharmaceuticals states, “we have grievance redressal mechanisms in place for violations” of human rights. <sup>73</sup> Yet, it is unclear what these mechanisms entail.
<i>1.9: How does the company promote and safeguard the health, wellbeing, and rights of human research participants?</i>
No information could be found publically available on this.
<i>1.10: Does the company place the goal of generating new knowledge in clinical trials above the rights and interests of the individual research participant?</i>
No information could be found publically available on this.
<i>1.11: How is the priority of patient safety respected during a trial, and after market marketing of a new product?</i>
No information could be found publically available on this.
<i>1.12: How do investigators ensure the research is acceptable within the community it takes place? How does a company ensure it complies with good scientific principles that would lead to best science and greatest benefit?</i>
No information could be found publically available on this.
<i>1.13: How is it ensured that participants during a trial obtain new information that might affect their decision to continue in the trial?</i>
No information could be found publically available on this.
<b>2) Article 4: Benefit and harm</b>
<i>2.1: How is any possible harm minimized?</i>
No information could be found publically available on this.
<i>2.2: How is direct and indirect benefit maximized?</i>
No information could be found publically available on this.

<p><i>2.3: How does a company ensure that investigators and staff are trained and scientifically qualified?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.4: How is the continued evaluation of a marketed product through research of safety, efficacy, accessibility and quality ensured?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.5: If a clinical trial participant is harmed, how is harm assessed and who determines/assesses if compensation is appropriate?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.6: Are qualified research ethics committees (institutional review board/ethical review board) present and reviewing research protocols to ensure benefit is maximized and harm minimized?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.7: Who and how is it decided if the non-clinical and clinical knowledge is adequate to support a clinical trial?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.8: How are conflicts of interest amongst research ethics committee members and affiliated researchers stated and mitigated?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.9: How is harm/benefit ratio determined by the company?</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.10: What is the procedure for stopping a research study if the risks of proceeding are shown to outweigh the potential benefits? (WMA Declaration of Helsinki Article 20, 2008)</i></p> <p>No information could be found publically available on this.</p>
<p><i>2.11: How does the company respond to a situation in which a research participant has an apparent research-related harm occur?</i></p> <p>No information could be found publically available on this.</p>
<p><b>3) Article 5: Autonomy and individual responsibility</b></p>
<p><i>3.1: How does the company ensure the autonomy (freedom, liberty, self-determination) of human research participants?</i></p> <p>No information could be found publically available on this.</p>

<p>3.2: <i>How is the right to withdraw at any time without repercussions for the participant ensured?</i></p> <p>No information could be found publically available on this.</p>
<p>3.3: <i>How does the company uphold the freedom of association and the effective recognition of the right to collective bargaining? (UNGC Principle 3)</i></p> <p>Sun states that their Human Rights Policy covers freedom of association, yet that policy could not be found publically.<sup>74</sup></p>
<p><b>4) Article 6: Consent</b></p>
<p><b>Information</b></p>
<p>4.1: <i>How does the company ensure that consent of human research participants is informed?</i></p> <p>No information could be found publically available on this.</p>
<p>4.2: <i>What is included in this information component?</i></p> <p>No information could be found publically available on this.</p>
<p>4.3: <i>Are participants provided informed consent in a language and manner that is appropriate?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Voluntariness</b></p>
<p>4.4: <i>How does the company ensure that consent of human research participants is voluntary and in no way coerced?</i></p> <p>No information could be found publically available on this.</p>
<p>4.5: <i>How does the company provide measures against undue inducement?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Competence</b></p>
<p>4.6: <i>How does the company ensure that the research participant is competent to give consent?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Training of Researchers</b></p>
<p>4.7: <i>How are researchers or investigators trained in the process of obtaining informed consent, including providing information in an appropriate manner that is understandable for the participant?</i></p> <p>No information could be found publically available on this.</p>
<p>4.8: <i>When is it appropriate to consult family members and community leaders in the consent process?</i></p>

No information could be found publically available on this.
<i>4.9: Is the participant given the option of being informed about general outcomes and results of the study?</i>
No information could be found publically available on this.
<i>4.10: How is it ensured that emerging new information is promptly given to trial participants in a long-term study that may affect their desire to stay in the study?</i>
No information could be found publically available on this.
<i>4.11: When is it appropriate to ask for re-consent during a trial?</i>
No information could be found publically available on this.
<b>Research Participants</b>
<i>4.12: How is the right to withdraw at any time ensured?</i>
No information could be found publically available on this.
<i>4.13: Who determines if a person is competent to give consent and how is it determined?</i>
No information could be found publically available on this.
<b>Compensation</b>
<i>4.14: Who and how is it determined?</i>
No information could be found publically available on this.
<b>Human Biosamples</b>
<i>4.15: What is the company's course of action in regards to biosamples used in research that are collected by researchers after prior informed consent for collection, storage and use/reuse? If consent of the participant is not possible, has an ethics committee approved?</i>
No information could be found publically available on this.
<b>5) Article 7: Persons without the capacity to consent</b>
<b>General</b>
<i>5.1: Has authorization for research been obtained in accordance with the best interest of the person concerned and in accordance with domestic law?</i>
No information could be found publically available on this.
<i>5.2: Has the research participant been involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent?</i>
No information could be found publically available on this.
<i>5.3: Do the results of the research have the potential to produce real and direct benefit to the</i>



<i>health of the incapable research participant?</i>
No information could be found publically available on this.
<i>5.4: Can research of comparable effectiveness be carried out on individuals capable of giving consent?</i>
No information could be found publically available on this.
<b>Training of Researchers</b>
<i>5.5: How are researchers/investigators trained in dealing with and protecting persons with diminished capacity to consent?</i>
No information could be found publically available on this.
<b>Determination of Capacity</b>
<i>5.6: How it is determined who is not capable of providing consent?</i>
No information could be found publically available on this.
<i>5.7: How is capacity determined in the protocol review process and by the investigator(s) performing research?</i>
No information could be found publically available on this.
<i>5.8: How do researchers obtain proxy or surrogate consent?</i>
No information could be found publically available on this.
<b>Exception</b>
<i>If it is not possible to comply with the above, the UDBHR does formulate as an exception for research that does not have the potential to produce results of direct benefit to the health of the individual concerned. The following conditions must be met to permit such research:</i>
<i>1) The research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease, or disorder, to the person concerned or to other persons in the same category of disease or disorder.</i>
<i>2) The research must only entail minimal risk and minimal burden for the individual concerned.</i>
<b>6) Article 8: Respect for human vulnerability and personal integrity</b>
<b>Vulnerability &amp; Marginalization</b>
<i>6.1) How does the company define "vulnerable" persons and population?</i>
No information could be found publically available on this.
<i>6.2) How does the company specify who needs specific consideration? (UNGPBHR: Women, children, people with disabilities, indigenous people, migrants, elders, prisoners, pregnant women, economically and educationally disadvantaged are considered vulnerable)</i>

No information could be found publically available on this.
6.3) <i>How are the vulnerable additionally safeguarded against undue influence or coercion?</i>
No information could be found publically available on this.
6.4) <i>Are the knowledge and products from the clinical trial made reasonably available to benefit that group?</i>
No information could be found publically available on this.
<b>Identification</b>
6.5) <i>How does the company identify vulnerable individuals or groups?</i>
No information could be found publically available on this.
<b>Alternatives</b>
6.6) <i>Can the research be carried out in a non-vulnerable group? (Helsinki, 2013)</i>
No information could be found publically available on this.
<b>Protection</b>
6.7) <i>What guidelines has the company established to protect vulnerable persons?</i>
No information could be found publically available on this.
6.8) <i>Does the company comply with the laws concerning research with vulnerable persons? If no such legislation exists in the context where the research is being conducted (host community), what does the company do?</i>
The guidelines that Sun Pharmaceuticals follows in regards to clinical trials is uncertain. Sun states on their website under their “Research & Development section that, “Our 408-bed clinical pharmacology unit with expert staff works on bioequivalence/bioavailability studies in compliance with GCP. Facilities include a full-fledged site for Phase I clinical studies. Our CPU has been audited by US FDA, ANVISA, MHRA, and DCGI among others.” <sup>75</sup> However, this statement is not entirely clear at all.
<b>Benefits</b>
6.9) <i>Does the vulnerable group stand to benefit from the knowledge, practices or interventions that result from the research? (Helsinki, 2013)</i>
No information could be found publically available on this.
6.10) <i>Is the medical research with a vulnerable group responsive to the health needs or priorities of this group? (Helsinki, 2013)</i>
No information could be found publically available on this.
<b>7) Article 9: Privacy and confidentiality</b>

<b>Risk</b>
7.1) <i>What are the risks of the infringement of privacy?</i>
No information could be found publically available on this.
7.2) <i>What is the risk of infringement of personal data?</i>
No information could be found publically available on this.
<b>Measures</b>
7.3) <i>What measures does the company take in order to maintain the right to privacy of participants in human research?</i>
No information could be found publically available on this.
7.4) <i>How is it ensured that information is only shared or disclosed as it has been specified in the consent?</i>
No information could be found publically available on this.
<b>8) Article 10: Equality, justice, and equity</b>
8.1) <i>How does the company manage scarce resources in order to guarantee a just and equitable healthcare system?</i>
No information could be found publically available on this.
8.2) <i>How does the company ensure certain groups are not under- or over-represented in research?</i>
No information could be found publically available on this.
8.3) <i>How does the company ensure that groups and communities are invited to participate in a way that the burden and benefits are equitably distributed?</i>
No information could be found publically available on this.
8.4) <i>Will the participants, to the best of the company's knowledge, be able to afford the product when marketed without it being of significant burden?</i>
No information could be found publically available on this.
8.5) <i>How do the investigators ensure the research is fair to the subject?</i>
No information could be found publically available on this.
<b>9) Article 11: Non-discrimination and non-stigmatization</b>
9.1) <i>How does the company take care to avoid the systematic development of medicines for one group within a population to the neglect of others?</i>

<p>Sun states, in its Business Responsibility Report from 2015-16, the following:          “We leverage the intrinsic nature of our business to further the cause of healthcare and care for patients across the economic strata. While making medicines which are more accessible and affordable is our role, we also up the ante by offering certain medicines free of cost to the socially challenged.”<sup>76</sup> However, this does not specifically address the precise question of non-discrimination and non-stigmatization. No other information could be found.</p>
<p><i>9.2) When conducting clinical trials, does the company discriminate or stigmatize certain populations or genders so that they are under-represented in research?</i></p> <p>No information could be found publically available on this.</p>
<p><i>9.3) Does the company have a grievance procedure for handling allegations of discrimination and stigmatization?</i></p> <p>In its Code of Conduct, Sun has a policy in place on non-discrimination and encourages employees to report any violations. The Code of Conduct states that any concern will be handled confidentially and without fear of retribution.<sup>77</sup></p>
<p><b>10) Article 12: Respect for cultural diversity and pluralism</b></p>
<p><i>10.1) In clinical trials with human research participants, how does the company handle cultural differences regarding informed consent?</i></p> <p>No information could be found publically available on this.</p>
<p><i>10.2) When doing business in an unfamiliar cultural milieu, how does the company approach these cultural differences?</i></p> <p>No information could be found publically available on this.</p>
<p><i>10.3) Does the company provide training for its employees on issues of cultural diversity and pluralism?</i></p> <p>No information could be found publically available on this.</p>
<p><b>11) Article 13: Solidarity and Cooperation</b></p>
<p><i>11.1) How is the company working towards capacity-building in the area of public and global health?</i></p> <p>Sun Pharmaceuticals, in its 2015-16 Business Responsibility Report, stated a number of capacity-building projects they have completed:</p> <ul style="list-style-type: none"> <li>• The provision of drinking water supply to 4 hamlets of Malaipalayam village in Madurantakam Taluka of Kanchipuram District was completed, providing 960 households with potable water.</li> <li>• Education: Upgrading infrastructure of surrounding schools and enhancing the standard of education, impacting 3,859 students.</li> </ul>

- Organization of a festival to promote local art and culture, with a broader aim of promoting tourism for the economic enhancement of the area surrounding the UNESCO World Heritage Site of Champaner-Pavagadh at Halol Taluka – Panchmahal District.<sup>78</sup>

*11.2) How is the company contributing to the UN Sustainable Development Goals?*

No information could be found publically available on this.

## **12) Article 14: Social responsibility and health**

### **Promotion of Health and Social Development**

*12.1) How does the company aim to promote health and social development?*

Sun is involved in a number of projects aimed to promote health and social development. The following are listed in their 2015-16 Business Responsibility Report:

- Distribution of medicines to monasteries
- Financial support of a 450-bed cancer hospital
- Providing access to potable water and sanitation
- Assisting in disaster relief
- Medical mobile units
- Upgrading infrastructure of primary schools<sup>79</sup>

*12.2) Article 14 states that “all sectors of society share” in the promotion of social responsibility and health. How does the company seek to address: 1) access to quality health care and essential medicines, 2) access to adequate nutrition and water, 3) the improvement of living conditions and the environment, 4) the elimination of the marginalization and the exclusion of persons on the basis of any grounds, and 5) the reduction of poverty and illiteracy?*

Sun has attempted to address several of these areas:

- 1) The company aids financially-challenged persons with free medicines. Sun also distributes medicines to monasteries.
- 2) Sun has a large sanitation program in several villages, installing toilets and providing potable water.
- 3) Sun has taken steps to be environmentally-friendly, which are detailed in section 15.
- 4) No information could be found publically available on this.
- 5) No information could be found publically available on this.

### **Relationship to Developing Countries:**

*12.3) Does the company have differential pricing policies so that lower income countries pay lower prices for essential medicines than higher income countries?*

This is not fully known. However, Sun states, “We directly support the socio-economically challenged sections of the society by providing medicines at no or subsidised costs to the patients in need.”<sup>80</sup>

<p><i>12.4) Does the company invest in research and development for diseases that primarily affect lower income countries?</i></p> <p>This is not altogether clear from Sun’s publically available information. The company itself is headquartered in a LMIC (India) and does have a robust R&amp;D department, yet the extent to which it targets diseases that primarily affect lower income countries is not known.</p>
<p><i>12.5) Does the company have policies on access to treatment for developing countries, including the five priorities of pricing, patent, joint public private initiatives, R&amp;D, and the appropriate use of drugs?</i></p> <p>No information could be found publically available on this.</p>
<p><b>13) Article 15: Sharing of benefits</b></p>
<p><b>Sharing of Benefits</b></p>
<p><i>13.1) How does the company ensure that the benefits resulting from its scientific research are shared with society as a whole?</i></p> <p>In their 2015-16 annual report, Sun states, “We directly support the socio-economically challenged sections of the society by providing medicines at no or subsidised costs to the patients in need. Financially challenged patients continue to gain our assistance in the form of free-of-cost medicines. In the reporting period, we continued to dispense free Riluzole which is used in the treatment of Amyotrophic Lateral Sclerosis (a life-threatening disease) to all patients. We have also been regularly distributing medicines to monasteries in Sikkim.”<sup>81</sup></p>
<p><i>13.2) When conducting clinical trials, does the company ensure that in advance of the trial, provisions are made for post-trial access for all participants who still need an intervention identified as beneficial in the trial? (DoH, Article 34, 2013)</i></p> <p>No information could be found publically available on this.</p>
<p><i>13.3) If the company is involved in bioprospecting, how does it ensure that indigenous knowledge and resources have been respected?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Undue Inducement</b></p>
<p><i>13.4) How does the company ensure against improper inducements to participate in research?</i></p> <p>No information could be found publically available on this.</p>
<p><b>14) Article 16: Protecting future generations</b></p>
<p><i>14.1) In bioethical decision-making, does the company take into account the impact on the present generation and also try to evaluate the impacts on future generations?</i></p> <p>No information could be found publically available on this.</p>
<p><i>14.2) If the company is involved in research on human genomic information, how does the company ensure that such new technology will not result in undesired outcomes for future</i></p>

<p><i>generations?</i></p> <p>No information could be found publically available on this.</p>
<p><i>14.3) How does the company evaluate any possible influence a test compound can have on genes or germ cells?</i></p> <p>No information could be found publically available on this.</p>
<p><b>15) Article 17: Protection of the environment, the biosphere and biodiversity</b></p>
<p><b>Impact on Environment</b></p>
<p><i>15.1) As it has been recognized that the company has a responsibility to protect the environment, how does the company prevent advances in molecular biology, recombinant technology, genetics, biotechnology, and other advances from negatively impacting the environment?</i></p> <p>No information could be found publically available on this.</p>
<p><i>15.2) Does the company participate in the development of new technologies that pose risk of irreversible damage to the environment?</i></p> <p>Sun states on their website that they have had a policy on the environment, health &amp; safety (EHS), yet it could not be located. Nonetheless, the company does state that care for the environment is a core value. They state, “Our EHS policy provides for the creation of a safe and healthy workplace and a clean environment for employees and the community. It aims for the highest international standards in plant design, equipment selection, maintenance and operations. The policy is a commitment that we will manufacture products safely and in an environmentally responsible manner.”<sup>82</sup></p>
<p><i>15.3) Does the company have in place emergency guidelines in the event of an accident affecting the environment?</i></p> <p>No information could be found publically available on this.</p>
<p><i>15.4) Does the company minimize the use of chemicals and other dangerous substances, as well as ensuring their safe handling and storage?</i></p> <p>No information could be found publically available on this.</p>
<p><i>15.5) If applicable to the business, does the company encourage the development and use of environmentally friendly technologies?</i></p> <p>Sun states, “Investments have been made in process improvements as well as upgradation of effluent treatment plants, using membrane based technologies, multi-effect thermal evaporators, agitated thin film dryers and hazardous waste incinerators. These measures have helped to reduce the environmental burden. With these equipment installed at all our major facilities for recycling of the treated effluent, we have achieved the status of “zero liquid discharge”.<sup>83</sup></p>

<p>Further, Sun states specifically that, “We have invested significantly in green energy, principal amongst which is our investment in wind energy. One of our facilities is dedicated towards harnessing the power of wind to generate energy. In FY16, we generated around 1,145,560 kWh of clean energy.”<sup>84</sup></p>
<p><b>Biosphere</b></p>
<p><i>15.6) How does the company seek the protection of experimental animals? (cf Article 4)</i></p> <p>No information could be found publically available on this.</p>
<p><i>15.7) How does the company seek to eliminate the need for using animals in research?</i></p> <p>No information could be found publically available on this.</p>
<p><i>15.8) How does the company seek to protect and promote the welfare on the animals used in research?</i></p> <p>No information could be found publically available on this.</p>
<p><b>Impact on Biodiversity</b></p>
<p><i>15.9) Does the company prevent, minimize and remedy impacts on biodiversity?</i></p> <p>Sun has put in place a number of projects to reduce their impact upon the environment and biodiversity, including reducing the reduction of waster, recycling materials when able, and reusing materials when possible. Further, Sun has six functional facilities equipped the biomass-fuelled boilers.<sup>85</sup></p>

Very little information could be located publically regarding the bioethics, corporate social responsibility, and human rights performance and activities of Sun Pharmaceuticals. The company is not a member of the UN Global Compact and nearly the only information that could be located publically about their activities in the areas of human rights and bioethics comes from their website. The author contacted the research and development department of Sun Pharmaceuticals through their website with the following message:

Greetings,

I am a PhD student in bioethics in the United States and am writing my dissertation on bioethics, human rights, and corporate social responsibility as it relates to the pharmaceutical industry. I have been scouring your website for more information about what Sun does in regards to bioethics. In particular, it would be helpful to know which, if any, international bioethics guidelines the company adheres to (such as Helsinki, ICH-



GCP) and where the company's Human Rights Policy can be located. Additionally, any information you could provide on clinical trials, how participants are chosen, and information about how their protection is ensured would be greatly appreciated. Thank you.

As of the time of this writing, Sun had yet to respond to this message.

From the above application, this is an example of how the global bioethics tool would positively serve a pharmaceutical or biotechnology company, aiding the company in disclosing publically what they are doing in areas of bioethics, human rights, and corporate social responsibility. We should not get the picture that Sun Pharmaceuticals is simply not involved in the indicators that could not be answered. Rather, it is assumed that they are simply not reported via their public website. However, stakeholders, shareholders, and the general public want this type of information to be accessible to them. Hence, a company such as Sun may greatly benefit by utilizing the global bioethics tool.

As this final body chapter concludes, it is necessary to review the contents of this chapter. The first section examined several reporting systems and recommended a reporting framework for the global bioethics tool. Reporting and petition systems were first examined and the merits and weaknesses of each were discussed. The reporting style of the UN Global Compact, known as the Communication on Progress, was then analyzed in detail. There are many positive aspects of the UNGC's COP, such as the transparency it promotes. However, several limitations also exist in order for the COP to be more functional as a way to compare companies in a manner that is user-friendly.

As has been argued throughout this dissertation, the global bioethics tool aims to promote the transparency of the pharmaceutical and biotechnology industry and to do so in a manner that stakeholders can easily compare how Company X is doing in comparison to Company Y. This is not currently easily accessible with the present COP system. Further, another principal goal of

the global bioethics tool is to promote industry best practices in areas of bioethics, human rights, and corporate social responsibility. Again, this is not presently a chief concern of the COP system. Hence, these are major ways in which the reporting and management style of the global bioethics tool would differ from the UNGC COP. To be certain, the reporting style is important, but what is of equal importance is what an organization does with the information they collect. The global bioethics tool would like to publically disseminate the reports on its website for free of charge (similar to what the UNGC does) but would also like to organize either an annual or biennial forum in which representatives from participant pharmaceutical and biotechnology companies would gather together and be able to discuss best practices and how to move forward in the area of bioethics. This would also be an opportunity for collaboration on how to improve the global bioethics tool.

The second section then sought to apply the global bioethics tool to two pharmaceutical companies: GlaxoSmithKline and Sun Pharmaceuticals. These two specific companies were chosen for different reasons, as was detailed above. This lengthy application section was a necessary component of this chapter in order to practically demonstrate that the global bioethics tool is much more than merely a curious exercise. Rather, the global bioethics tool, as is demonstrated by this application section, is a feasible mechanism to measure qualitatively how well pharmaceutical and biotechnology companies are doing in disclosing these important aspects of bioethics, human rights, and CSR.

As was seen in section 2, there is great contrast between GlaxoSmithKline and Sun Pharmaceuticals. First, GSK is based in a high-income country (UK), while Sun is headquartered in a developing country (India). Second, their philosophies in regards to what they publically disseminate in regards to bioethics, human rights, and corporate social responsibility differs

considerably. Showcasing this contrast is advantageous for the purposes of the global bioethics tool because it highlights the benefit of the global bioethics tool for companies such as Sun that have not seemingly previously placed considerable emphasis on publically broadcasting such information. As was seen in section 2, there were numerous areas in Sun's report in which responses to the questions could not be located publically, and it was recorded as such. This demonstrates that a company such as Sun would, assumedly, benefit greatly by utilizing such a system as the global bioethics tool in order to make its bioethics activities more prominent as well as public. What is more, by participating in the global bioethics tool, a company such as Sun could learn from larger companies with more robust bioethics activities (such as GSK) on how best to begin more work in that area.

The following, concluding chapter offers final thoughts on this dissertation. Included in this will be ways to see the global bioethics tool achieve implementation within the pharmaceutical and biotechnology industry. Limitations to this current study and manners of overcoming them in the future if the global bioethics tool gains greater traction will also be discussed. This concluding chapter will also offer a grand vision of what the author would like to see done with the global bioethics tool in the future and reiterate both the usefulness and necessity of such a system for the pharmaceutical and biotechnology industry to take its bioethics, human rights, and corporate social responsibility obligations more sincerely and make it an emphasis to stakeholders.

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## **Chapter 7: Conclusion**

The purpose of this dissertation has been to highlight the need of creating and implementing a global bioethics tool for the pharmaceutical and biotechnology industry. It is the author's desire to see the pharmaceutical and biotechnology industry firmly implant systems to measure, report, and enhance issues of bioethics, human rights, and corporate social responsibility. To this end, the global bioethics tool that has been presented and argued for would be helpful in creating this culture of bioethical responsibility.

Chapter 2 examined the relationship between global bioethics and human rights. This relationship is fundamental to this dissertation, and it was seen that a symbiotic relationship exists. Global bioethics has grown out of the older, more traditional field of healthcare ethics or bioethics. Van Rensselaer Potter was instrumental in the formation of bioethics as a separate discipline with the aim of bridging science and values, nature and culture, and man and nature. Almost two decades after coining the term "bioethics" he would also coin the phrase "global bioethics," which focused largely on environmental and conservational issues in the stream of Aldo Leopold. Yet, Potter also envisioned this field as addressing the crucial questions of the day, such as poverty, war, politics, and population growth—all of which were not being addressed by the more mainstream version of bioethics coming out of academic centers such as Georgetown University.

The symbiotic relationship between global bioethics and human rights was showcased in this chapter in order to solidify further the foundational principles of this dissertation. Global bioethics contributes to human rights, and human rights contribute to global bioethics. It was described how global bioethics is able to reinforce the normative claims of international human rights law, how it can broaden the advocacy framework of human rights, and how it can aid in



the debate between individual human rights versus public health. Further, human rights contribute to and advances global bioethics in at least six ways that were each described in this chapter.

Chapter 3 examined the growing importance of corporate social responsibility within the pharmaceutical and biotechnology industry. The initial section presented the topic of social responsibility and its role in health. It was argued that social responsibility and health combines two basic ideas: 1) several actors aside from states and governments are responsible for health, and 2) global problems reflect common challenges and, therefore, should be addressed through common action. Social responsibility as presented within the UNESCO Universal Declaration on Bioethics and Human Rights was introduced, and it was seen that placing the principle of social responsibility into a bioethics guideline reiterates the need for bioethics to be able to reflect on meta-issues within science, including issues that touch the corporate, political, and social world.

The second section of this chapter applied corporate social responsibility to the pharmaceutical and biotechnology industry. The central thesis in this section was that companies that are integrally tied to human health and flourishing, such as the pharmaceutical industry, may be especially addressed by calls for social responsibility in global health. The area of pricing has been on center stage for the pharmaceutical industry and, because of the pressing nature of this issue, was heavily utilized in this section. The chapter concluded by considering ways of further infusing corporate social responsibility into the pharmaceutical industry. Social pressure and some sort of mechanism to measure how well the industry is doing were seen as practical and viable solutions.

The fourth chapter opened by analyzing the bioethics guidelines that have been produced since the end of World War II. A number of documents were compared and it was seen how

bioethics has evolved over the decades. The second section then concentrated on the UNESCO Universal Declaration on Bioethics and Human Rights. UNESCO was well-situated for the task of creating universal ethical norms due to its work in science and values, its unique position as an intergovernmental agency, and the way it acts as a bridge between science and values.

Further, the uniqueness of the Universal Declaration on Bioethics and Human Rights and its ability to be translated into a global bioethics tool for the pharmaceutical and biotechnology industry was examined. Indeed, it was argued that the UDBHR is better positioned than any other biomedical ethics framework, including the Declaration of Helsinki, to be the framework upon which the global bioethics tool is built for the following reasons: 1) it is the first and only bioethics declaration to gain the approval of international governments with the input of bioethics experts, rather than solely a group of individuals with bioethics or scientific expertise, 2) it efforts to incorporate major principles in bioethics, such as those included in the Declaration of Helsinki and ICH-GCP, 3) the Declaration reaches beyond individual orientations to bioethics to a global perspective, focusing on issues such as the environment, respect for cultural diversity, capacity building, and future generations, and 4) the Declaration is very useful for countries that lack an infrastructure in bioethics. The need for worldwide standard-setting in bioethics has been strongly expressed by LMICs who want to share the benefits of the developments of science and technology and not only be the providers of data and resources for the world.

Chapter 5 presented the global bioethics tool. The first section offered greater detail on the rationale, methodology, and benchmarking process that is envisioned for the tool. Benchmarking was not completed within the space of this dissertation, but the process was described, and it is hoped that in the future this will lead to the promotion of best practices. The second section developed the indicators that comprise the global bioethics tool. Justification was

provided for why the particular indicators were created. It is worth noting that these indicators are not set in stone. While a type of peer-review process was undertaken with them, as experts in global bioethics and CSR were consulted, more discussion and consultation needs to take place.

Chapter 6 first set up the reporting framework of the global bioethics tool. Several reporting frameworks were discussed and analyzed for their effectiveness and usefulness for the proposed global bioethics tool. In particular, the reporting framework of the UN Global Compact, known as the Communication on Progress, was assessed. Strengths and weaknesses of the Communication on Progress were evaluated, and suggestions for the global bioethics tool reporting framework were presented. In the second section the indicators of the global bioethics tool were applied to GlaxoSmithKline and Sun Pharmaceuticals.

In order to achieve implementation of the proposed global bioethics tool presented in this dissertation within the pharmaceutical and biotechnology industry, several steps are necessary. It is currently envisioned that the pharmaceutical and biotechnology industry would internally create and support this initiative. This seems advantageous versus having regulators or an NGO impose this on the industry externally. For this to happen, a company or coalition of companies would need to adopt this tool and publicize it to other companies. This small cohort of companies would showcase how the tool works and promote the reasons they feel it is needed. This is going to take substantial effort as well as resources. However, one full-time employee working on behalf of a small cohort of companies could be enough in the beginning phases of this project in order to get the project running. Costs spread over a small cohort of companies would be minimal.

If this vision of the pharmaceutical and biotechnology industry adopting the global bioethics tool were to become a reality, embraced by a larger cohort of companies, then it would

be advisable for a non-profit to be created that houses the tool and handles the administrative duties. This would be supported financially by the industry. Realistically, this would be years away. However, the issue of bioethics, human rights, and corporate social responsibility within the pharmaceutical and biotechnology industry is pressing and ever-present; it is not going away. Hence, one must have a long-term goal in view and not be shortsighted or discouraged by small gains and advancements.

This study also has some limitations that must be considered. As has been previously discussed, more input from various stakeholders should be accumulated. The input and data from this will need to be used to re-assess the indicators that were created for the proposed global bioethics tool. What is more, other stakeholders also need to be consulted in order to reach some level of research saturation in order to ensure that adequate and quality data on the indicators have been collected.

Nonetheless, while some limitations exist in this study due to the nature of its design as primarily a hypothetical exercise, this does not negate the viability of the global bioethics tool and its usefulness for the pharmaceutical and biotechnology. The global bioethics tool is a practical way of holding the industry further accountable for certain actions within bioethics, human rights, and corporate social responsibility. However, it also more than this. The global bioethics tool is a very innovative tool for the pharmaceutical and biotechnology industry, because at the heart of the tool is the idea of determining and sharing best practices. When the author was seeking to gather support for the tool then many stakeholders expressed their enthusiasm regarding it and saw the potential for its usefulness within the industry. Representatives from the bioethics section at UNESCO were encouraging and offered their assistance. A small number of pharmaceutical and biotechnology companies also expressed their

interest in collaborating on the project, demonstrating that there is support for such a tool from those within the industry.

To move forward with this project with the hopes of seeing the global bioethics tool adopted by the pharmaceutical and biotechnology industry, the next phase would require soliciting a greater level of industry support. Greater numbers of stakeholders and experts in pharmaceutical, global, and research ethics would need to be consulted regarding the indicators. Indeed, with the public's general mistrust of specific pharmaceutical companies and the industry in general, and with the excessive number of pricing scandals, charges of clinical trial data manipulation, and other acts of misconduct that have rocked the industry, the moment is prime for a tool such as this to impact the industry immensely. Undeniably this is an area that needs focused attention by the pharmaceutical and biotechnology industry. This dissertation has made the case for a global bioethics tool to act as one piece of the puzzle to aid the pharmaceutical and biotechnology industry in its reputation and see their obligations towards bioethics, human rights, and corporate social responsibility take center stage.

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