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Research and Reality: Towards Responsible Medical Research for Catholic Universities

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LOYOLA UNIVERSITY CHICAGO

RESEARCH AND REALITY:
TOWARDS RESPONSIBLE MEDICAL RESEARCH
FOR CATHOLIC UNIVERSITIES

A DISSERTATION SUBMITTED TO
THE FACULTY OF THE GRADUATE SCHOOL
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PROGRAM IN INTEGRATIVE STUDIES IN ETHICS AND THEOLOGY

BY

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CHAPTER ONE

A BRIEF HISTORY OF THE DEVELOPMENT OF MEDICAL RESEARCH

Introduction

The rapid development of medical research over the past 150 years has resulted in scientific innovations with greater capabilities of addressing catastrophic and population-based health events, treating acute health needs, developing new drugs, and utilizing cutting-edge technology to improve medical care. Describing the details of these advances in medicine would require several dissertations; therefore, this chapter modestly aims to provide a brief sketch of the way medical research develops over the past century and a half. I will focus on the ways in which medical research contributes to bettering the health of individuals and populations and the effect of these innovations on society at large. However, this dissertation is not simply about the development of medical research, but also about how the trajectory of these developments has led to a socio-economic and global imbalance with respect to the beneficiaries of medical research.

In order to understand the unequal distribution of the developments within medical research, a first step requires understanding what constitutes medical research, as well as the implications for individuals and for communities. Medical research in the late nineteenth century, begins by taking-up local concerns. However, larger political and economic contexts shape local health concerns. While the Second Chapter takes up the ethical norms aiming to protect research subjects, this First Chapter describes the various contexts in which medical
This chapter begins with a brief description of what constitutes medical research. The remaining three sections describe the progress made in medical research beginning from the mid-nineteenth century, by turning to exemplary case studies to describe the variety of research being conducted and the contextual problems to which it responds. The first of these periods focuses on the research from the cholera epidemic of 1850s London and the acute and population-based health responses. The work of John Snow, Robert Koch, and the international hygiene movements exemplify the research of this period. The practices of the hygiene movements within this period mark an important development in research translation and the dissemination of new knowledge. Dissemination of knowledge plays an essential role in the second period I consider in this chapter—research during the pre and post-World War era.

Research during and after the World Wars centers on the health of particular classes or groups of people, chief among them workers and soldiers. Yellow fever research, emerging surgical techniques, and eugenic research all play key roles in advancing scientific knowledge in the hope of developing a stronger and “more fit” society. While this second period is characterized by a focus on particular groups of people, the examples in the third period demonstrate an interest on broader global health concerns that target disease eradication and new ways of improving the lives of those suffering from chronic and infectious disease.

In this final section, the eradication of smallpox, the necessity of medicating hypertension, and the possibilities of research in synthetic biology demonstrate the potential of research that targets the treatment or prevention of particular diseases. The focus on smallpox, and its eradication, represents a targeted approach to research that allows for more
intentional focus on populations who disproportionately bear the burden of particular diseases. The importance of concentrating on diseases that affect the global poor, as smallpox did, is a practice that I will emphasize throughout my argument. However, as the cost of research rises, so too has the importance of earning an economic return on investments in research—explored most fully in Chapter Four. While economics now plays an important role in deciding which medical research options to pursue, judging from the definitions of medical research from international research institutes, the emphasis placed on financial gain as an explicit goal of the practice of medical research varies.

What is Medical Research?

Henry Sigerist, a medical historian from Switzerland, describes medicine as a practice motivated by bettering the health of individuals. He describes medicine’s task “under the following four headings: 1. Promotion of health; 2. Prevention of illness; 3. Restoration of health; and 4. Rehabilitation.” Following Sigerist, medicine concerns itself about positive health outcomes. Medical research, then, participates in this mission by combining the focus on disease prevention and restoration of health with scientific investigation. Thus, one of the many motivations in the development of a medical research, as related to the goals of medicine, requires a genuine interest in improving the lives and health of people.

International Definitions of Medical Research

Highlighting different international definitions of medical research contributes to a broader understanding of what constitutes medical research, and, additionally, the diversity in motivations for its pursuit. France’s Institut national de la santé et la recherche médicale (Inserm) articulates its mission as the only public institute in France focusing “entirely on human

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health.” Its definition emphasizes the humanistic element present in medical research and also highlights the public and private partnerships necessary in making research possible. University hospitals and research centers serve as two of Inserm’s primary collaborators. In the U.K., the Medical Research Council (MRC) more broadly states their intention to support research in order to “produce skilled researchers, advance and disseminate knowledge and technology to improve the quality of life and economic competitiveness of the U.K.; and promote dialogue with the public about medical research.” Here the MRC’s definition begins to point to the role medical research can play economically in promoting research. The U.S.’s National Institute of Health (NIH) takes a slightly different tone by describing it as “fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.” The NIH emphasizes the importance of increasing and disseminating the discoveries of medical research in the hope of enabling longer and healthier lives. Offering a different perspective, and at least a non-western perspective, is that of the Indian Council of Medical Research (ICMR). The ICMR describes the types of projects that fall within the purview of medical research as:

control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and

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3 Institut national de la santé et de la recherche médicale, “The Institute Mission.”


hematological disorders; mental health research and drug research (including traditional remedies). All these efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population.\(^6\)

The ICMR does not include economic interests or pursuit of new knowledge in its mission statement, and instead lists specific types of research concerning the importance of the population’s overall health. The wide-ranging mission statements from leading international medical research organizations give strong indications, not only as to the type of initiatives that constitute medical research, but also the intellectual, economic, and health-based commitment of the various research institutes.

While high-income countries focus on economics and technological innovation as a component of medical research, India’s ICMR, a low-middle income country, does not mention either of these aspects, focusing instead on research that impacts population health. Population health is not only concerned with outcomes, but also with the underlying factors—environmental, social, political, economic, etc.—that contribute to the health challenges of particular communities and how they can be overcome.\(^7\) The ICMR values medical research pertaining to the health of individuals within the context of the health of the community as a whole. Any allusion to community or public health, which is a constitutive dynamic of improving or maintaining health, remains absent from the descriptions from Inserm, NIH, or the MRC. The inattention to the health concerns of community in framing the goals of medical research creates a tension that contributes to health disparities and disparate medical research priorities between lower and higher income countries, a topic I address in Chapter Four and Five. For the purposes of this chapter,


however, it is important to note who has established the priorities for research historically and overseen its progress, as well as who stands to benefit from the basic science, clinical, and epidemiologic research being conducted.

Basic, Epidemiologic, and Clinical Research

Basic science research is driven by a desire to discover and/or to understand some biological phenomena. The NIH describes basic science research broadly as an area that leads to a deeper understanding of the “biological rules of life.”

While basic research provides the building blocks, clinical research sets out to apply the fruits of basic research in an effort to understand more fully their efficacy in the clinical setting.

Clinical research is broken down into three sub-categories: epidemiologic-based, patient-oriented, or outcome/delivery-based. In some instances clinical research can be difficult to distinguish from good clinical practice, which can operate as a research-like process. However, arriving at the best approach to patient care transcends the latest

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9 While epidemiological research is a form of medical research in its own right, it also functions as a sub-category of clinical research. An example of this type of study might be a clinical trial that sets to study the effects of a particular drug on a certain group of people in a particular area.

10 Robert J. Levine, *Ethics and Regulation of Clinical Research* (New Haven, Conn: Yale University Press, 1988); Ruth R. Faden et al., “An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics,” *Hastings Center Report* 43, no. s1 (2013): s16. An example of this can be seen when a patient is being treated for pain management or when treating a psychological disorder. In both instances, the concern of the physician is to try a variety of treatments aimed at curing or managing symptoms. The treatment is therapeutic in nature, specifically focusing on the care of the patient’s health, but could also be considered a form of research because it is not immediately clear what the best course of treatment for the patient is. Those responsible for the care of the patient inevitably enter into a process of trial and error in an effort to discover the possible treatment. Many of the ethical issues in research stem from clinical trials, particularly ensuring that patient’s understand they are participating in an experiment and may not receive any therapeutic benefit from their participation. Questions of research ethics will be taken up in more detail in the next chapter.
scientific advances in order to consider how these advances affect or fail to affect change in the health of the population—a practice often left to epidemiologic research.

Epidemiologic research works within the discipline of epidemiology to apply knowledge related to a population’s health and the spread of disease by drawing on both basic science and clinical research, with the goal of improving the health of particular persons or groups of people. Leon Gordis defines epidemiology as the “study of how disease is distributed in populations and of the factors that influence or determine this distribution.”

Epidemiologic-based medical research, then, begins with a focus on the particular health-related needs of the community and considers other factors that contribute to this particular distribution of health. Epidemiologic-based medical research proves important when identifying health challenges faced by particular communities. Both epidemiologic and basic science research prove crucial in the first phase of research development that discovered the relationship between bacteria and hygiene and its effects on particular communities during the cholera epidemics of the latter half of the Nineteenth Century.

**Bacteria and Hygiene**

The developments in medical research from 1850 to the early parts of the twentieth century focus largely on controlling widespread and population-based health problems. At that time, one of the more rampant health problems stemmed from frequent cholera epidemics. Cholera is a bacterial disease that spreads by drinking water or eating food that has been contaminated by fecal matter. While the transmission of the disease is now

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12 Gordis defines five objectives for epidemiology: 1) identify etiology cause of disease, and risk factors; 2) determine extent of disease in a given community; 3) study natural history and prognosis of disease; 4) evaluate existing and new preventative and therapeutic measures; 5) provide foundation for developing public policy and regulatory decisions related to environmental problems. See Gordis, *Epidemiology*, 4.
commonly understood, it remained a mystery until late into the nineteenth century. At that time, it was thought to have spread through air that smelled, i.e. “bad air.”

The epidemiologic research of John Snow and the basic science efforts of Robert Koch, some 20 years after Snow’s epidemiologic research, contradicted the miasma (“bad-air”) theory. Koch’s scientific proof of Snow’s epidemiologic-based hypothesis leads to the mobilization of global campaigns to promote hygiene and prevent the spread of disease. These hygiene campaigns, largely funded by the U.S.-based Rockefeller Foundation, serve as catalysts for an array of international efforts to improve hygiene practices. What proves distinctive about the development of medical research in this period is the importance placed on public health strategies by various stakeholders within the research community, including public and private investors.

**John Snow**

English physician John Snow’s anesthesia research provided him necessary physiologic data that offered an alternative to the miasma theory. The miasma theory posited that cholera was spread through the inhalation of noxious fumes. If this were valid, Snow concluded the same physiologic process that took place in aestheticizing a patient would hold true for the inhalation of cholera. It was his anesthesia research, focused on understanding the physiological interaction between the respiratory and circulatory systems,

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14 Michael Ramsay, “John Snow, MD: Anesthetist to the Queen of England and Pioneer Epidemiologist,” *Baylor University Medical Center Proceedings* 19, no. 1 (2006): 24. Snow’s understanding of the beginnings of his investigations took place, unbeknownst to him, as a medical student. During his time as a student, he and others participated in the examination of patients after death, a process which made many students become sick. He then set up a series of experiments in which he traced the cause of his colleagues’ nausea to the inhalation of the arsenic vapors from the embalmed bodies. Not only was arsenic a common source for embalming, it was also used in candles in order for them to burn longer and brighter. Snow’s research also paved the way for a halt in the sale of candles that used arsenic.
that played a crucial role in his ability to offer an alternative theory.\textsuperscript{15} Armed with the knowledge that the breathing in of oxygen led to its circulation throughout the body, Snow hypothesized that he would find a high percentage of cholera deaths within the same household. When this proved not to be the case, he took up a more diligent study of the weekly notifications of deaths in London to determine if a common location or pattern existed between the various deaths.

Snow’s physiologic understanding of the airborne transmission of disease, combined with the \textit{Weekly Return’s} reports of births and deaths in London, provided him with the necessary information to theorize how cholera spread. The \textit{Weekly Returns}, published by London’s primary demographer, William Farr, proved essential to Snow’s project. If cholera spread because of an airborne disease, then those living in the same neighborhood and the same home were significantly more likely to have contracted the disease.\textsuperscript{16} After reviewing the \textit{Weekly Returns}, Snow traveled door-to-door to investigate the households of those who suspected to have died of cholera in an effort to determine if anyone still living was symptomatic. Though he could not definitively prove that other family members did not have the disease, his respiratory and circulatory background led him to believe that if the miasma theory were true they should display symptoms of cholera. Given the absence of these factors, Snow believed the disease was not airborne.

Snow’s research during the cholera epidemic functioned as epidemiologic research through its focus on the health of a particular population and studying the factors that contributed to the disproportionate distribution of cholera in certain areas. The uneven

\textsuperscript{15} Ramsay, “John Snow, MD,” 24.

distribution of cholera led him to focus his research on various companies that provided water to some 300,000 persons. Snow’s study included:

people of both sexes, of every age and occupation, and of every rank and station, from gentlefolks down to the very poor, were divided into two groups without their choice, and in most cases, without their knowledge; one group being supplied with water containing sewage of London, and, amongst it, whatever might have come from the cholera patients, the other group having water quite free from impurity.\(^{17}\)

His study represented a wide segment of the population and focused tested a very specific outcome related to water consumption. Snow’s had to test the water supply from two companies: Southwark and Vauxhall Company and the Lambeth Company. In one of the sub-districts that drew Snow’s attention, 44 deaths had occurred due to cholera. Of those 44 deaths, 38 had their water supplied by Southwark and Vauxhall, four from Lambeth, and two from personal pumps.\(^{18}\) Yet, the most compelling aspect of his study came from the research undertaken near his own home. Snow began canvassing his own neighborhood, and discovered the most frequently used water source was the Broad Street pump. The pump did emit noxious fumes, contributing to the miasma theory, but the source of the fumes came from London’s raw sewage leaking into the city’s water supply underneath the pump and the source of contagion.\(^{19}\) Though Snow had discovered the contamination source, he could not corroborate it as the culprit of the epidemic due to the infant stage of bacteriological studies. The slow acceptance of his conclusions signaled the necessity of complementary research to affect health outcomes. The research of Robert Koch proved to be the missing link in understanding the spread of cholera.


\(^{19}\) Johnson, 178-179.
Robert Koch

Robert Koch’s discovery of the cholera causing bacteria validated both Snow’s research outcomes and Louis Pasteur’s “germ theory.” Pasteur’s germ theory evolved through his work in the 1860s that demonstrated certain diseases developed from microscopic bacteria that infect the body. Koch built on the groundwork laid by Pasteur by devising a scientific process capable of isolating, reproducing, and establishing particular bacteria as the root cause of certain diseases, cholera being one of them. In an address at the 1890 International Medical Conference in Berlin, Koch described the method for determining the pathology for a bacteriological disease.

If, however, it can be proved: First that the parasite is met with in each individual case of the particular disease and under the conditions which correspond to the pathological changes and the clinical course of the disease; secondly that in no other disease is it found as an accidental non-pathogenic guest; and thirdly, that if completely isolated from the body and cultivated in pure cultures with sufficient frequency it can reproduce the disease—then it can no longer be considered an accidental accompaniment to the disease, but in that case no other relation between the parasite and the disease can be admitted than that the parasite is the cause of the disease.\(^\text{20}\)

The talk at Berlin proved essential in describing to the scientific community the fundamentals of bacteriology, and in particular how it applied to cholera. The cholera bacteria consistently manifested itself when isolated and cultivated in an uncontaminated host. By proving that certain bacteria existed as the root cause of the disease, Koch’s presentation became a high point the conference, and led to his appointment on the German Cholera Commission.\(^\text{21}\)


\(^{21}\) Koch’s presentation was able to articulate how to reproduce bacterial cultures of several micro-organisms including: anthrax, which commonly resulted in the death of farm animals in Germany, and tuberculosis in 1882. Koch attempted, but ultimately failed, at developing a vaccine for tuberculosis, tuberculin, which
Koch’s role allowed him to continue his research and work with those in both Europe and Northern Africa to prevent the further transmission of bacterial disease. In his capacity as a member of the German Cholera Commission, Koch discovered that the bacteria developed from a foodborne infection. This discovery, ultimately led Koch’s to translate his findings from the scientific discovery to the implementation of public health practices that proved crucial for the success of international hygiene commissions.

The scientific research of Koch paved the way for further developments of the international hygiene movement. By the mid 1860s, the International Sanitary Conference (ISC) had built on the work of Koch and Snow and concentrated its efforts on cholera as the disease that Europe needed to prevent from returning. In an effort to stop its spread, a more coordinated international effort centered on effective communication of the necessary preventive measures needed to take hold. The purpose of the ISC was to serve as a type of clearinghouse for communicating and developing strategies aimed at disease prevention. Among the practices implemented were quarantining of those who had contracted communicable diseases and simple education about disease transmission. The ISC, however, was not the only organization that would take this as its mission.

**International Hygiene Movements**

The ISC was the first in a number of international organizations aimed at establishing and implementing hygiene standards and practices. As a direct result of the ISC, the International Sanitary Bureau (ISB) was established in 1902 to implement the strategies somewhat tainted his legacy as a researcher, see Christoph Gradmann, “Robert Koch and the Pressures of Scientific Research: Tuberculosis and Tuberculin.” *Medical History* 45, no. 1 (2001).


of the ISC in the Americas. In 1907, *L’Office International d’Hygiène Publique* was established to focus on regional European concerns facing the shipyards of European ports. The shipyards represented potential sources for importing or exporting cholera and/or other epidemic-causing diseases. As the growth of the shipping and trade industry continued throughout the early part of the twentieth century, so too did the development of hygiene commissions. In addition to the multiple hygiene commissions already established, in 1923, the League of Nations Health Organization (LNHO) added to the growing list of organizations charged with preventing the spread of disease. These various international sanitary commissions assumed the tasks of studying epidemic diseases, revising and administering preventive guidelines, and preparing international conferences at which important epidemiologic and public health information could be exchanged. By implementing new preventive strategies and communicating best practices, these institutions became laboratories for studying public health and hygiene, but, like most research endeavors, funding proved essential.

The institutionalization of the sanitary and hygiene movement ushered in an era of public institutes of health that required significant financial and intellectual investments in order to perform the research necessary to prevent the spread of disease. The New York-based Rockefeller Health Commission (RHC) provided funding for research investigating the cause of disease and its prevention. The Rockefeller Foundation made substantial contributions to implement the protocols developed by the sanitation movement by establishing its own health commission in 1913. In its 1914 annual report, the Rockefeller Foundation reflected on its commitment to “the advancement of public health through

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medical research and education, including the demonstration of known methods of treating and preventing disease, afforded the surest prospect of such usefulness.” The RHC, unlike the other hygiene commissions, supported medical research that could lead to new information aimed at prevention or treatment. In the foundation’s efforts to demonstrate their successful methods, the RHC centered its U.S. efforts on hookworm disease.

The Rockefeller Health Commission and Hookworm

At the turn of the century, the southern U.S. states were a particularly agrarian society, and given the nature of the work in the fields, those living in the south had a higher risk of contracting the disease. While cholera contaminated water, the hookworm bacteria contaminated the soil. Hookworm caused “vast suffering, partial arrest of physical, mental and normal growth, great loss of life, and noticeable decrease in economic efficiency over vast regions…” The U.S.-based program had been able to treat some 500,000 persons by establishing agencies focused on promoting “public sanitation and the spread of the knowledge of scientist medicine.” These efforts included a focus on personal hygiene, but also testing the possibilities of “scientist medicine” to gauge dosing amount and frequency. A.G. Fort reported at the 1914 meeting of the American Public Health Association on collaborative clinical research between the state of Georgia and the RHC that demonstrated the effectiveness of particular drugs over others, which resulted in differing mortality rates


27 Hookworm is a disease that has not been eradicated and remains a problem in 2/3rds of the world.


30 Ibid.
amongst those who were compliant versus non-compliant with recommended treatments.31

The RHC wanted to take the collaborative works on hookworm, however, beyond the southern U.S. states and beyond hookworm.

In their 1913-14 annual report, the RHC described their efforts to combat the spread of disease through a variety of “military-sanitary campaigns” in collaboration with the U.S. government. These campaigns extended beyond the U.S. and included work with Britain’s territories, British Honduras (Belize), Federated Malay States (Malaysia), Fiji, and Australia.32

By 1922, the Rockefeller Foundation was a key contributor to the League of Nations and was essentially the sole funder of the Epidemiological Intelligence Service of the League of Nations. In other words, without the Rockefeller Foundation, health-based research in both the U.S. and abroad would have been quite limited. Furthermore, the targeted and disease-focused approach of the Rockefeller Foundation played an essential role in influencing the practice medical research. The RHC’s international and targeted approach to research shifted from the general sanitary and hygiene practices of the international commissions concerned with public health. They now took a disease-based approach to medical research that targeted the treatment of individuals, once treatments regimens were verified through clinical trials.

From the middle of the nineteenth century through the 1920s, medical research developed significantly in three impactful ways: understanding of disease, the importance of public health/hygiene practices, and the necessity of investment in clinical research. John Snow and Robert Koch distinguished themselves as examples of how diseases came to be understood and how the spread of disease could be controlled. Building on the work of


32 Bashford, Global Biopolitics and the History of World Health, 71.
Snow and Koch, public health measures proved important as a key development to prevent the spread of disease and to improve health outcomes. This was one of the key tasks of the hygiene commissions that served as clearinghouses for best preventive practices. These practices placed a priority on the needs of the community above those of individuals. Examples of this can be seen in the practice of quarantine in which one individual was isolated in order to prevent others from contracting the disease. Yet, prevention does not always happen, and, therefore, it proved necessary to develop methods for targeted treatments. Within this initial phase, tension began to develop between disease prevention, promoted by the public health and hygiene commissions, and disease control, focused on research for developing curative treatments. The Rockefeller Foundation found itself as one of the key players in emphasizing research both for prevention and treatment of particular diseases.

The RHC’s hookworm strategy demonstrated the confluence of the contributions of epidemiologic and basic science to developing targeted clinical trials aimed at controlling the spread of disease by treating it and ultimately eliminating it. Their targeted approach to research and generous financial investments, set the stage for how the Rockefeller Foundation would shaped development of research during the second phase of research described in this chapter. This second phase of research was influenced heavily by the two World Wars, which provided the catalyst for countless developments in medical research aimed at responding to the acute injuries of soldiers and the importance of health in the rebuilding of society during the aftermath of war.

**Disease, Wars, and the Pursuit of Perfection**

The two World Wars provided the catalyst for many technological and scientific innovations that advanced medical research by focusing on the health of individuals and
their ability to contribute to the rebuilding of a post-war society. With countless economic and human resources being poured into the Wars and the expansion of international trade through the Panama Canal, there was heightened concern about preventing the potential global spread of a disease. The first example of research in this period highlights a disease-based approach focused on disease prevention through vaccine development. Research on disease prevention research addressed directly the concern about transporting the contagious yellow fever disease through trade routes, while also allowing for the vaccination of soldiers fighting abroad. Yet, diseases were not the only threat soldiers faced, the nature of combat had changed to the degree that wounds sustained in battle had never before been seen.

The second example described below details the improvements in surgical innovations for those suffering facial wounds in battle. Utilizing a surgical team comprised of dentists, surgeons, nurses, and artists to treat persons was an experiment in and of itself, but also proved significant for enabling soldiers to return from war and function in society after the war. Being able to contribute to society was crucial following the World Wars. The importance placed on working in society, and limiting the roles of those who were not judged to be adequately contributing, was of central importance in the global efforts in eugenics research.

The final example from this section focuses on the international development of eugenics programs that reached a crescendo with the Nazi eugenics experiments. While the Nazi eugenic experiments were the most ethically egregious in their practice, centers for eugenics were widespread. Eugenics research, in many ways, reduced the measure of prevention and promotion of health to a genetic level, compared to vaccines that had the potential to benefit all. Moreover, the differences in eugenics and vaccine research highlight
tensions in priorities of research that had the potential to benefit a select few versus the majority. The tensions between health benefit for a few or the many, seem to be fueled during this period of war and economic expansion as the world became increasingly interconnected. The beginnings of this interdependence can be seen in the Rockefeller-sponsored yellow fever research.

Yellow Fever

William Gorgas served as the U.S. Surgeon General in 1914, leading the first of three Rockefeller-funded yellow fever research teams throughout South America. The first commission ran from 1914 until 1916, but was halted by the shifting of U.S. resources after their entrance into World War I in 1917. While the war caused the delay in research, it was the presence of increased trade routes via the Panama Canal that served as a significant source of concern for Gorgas. Gorgas, and others, feared that the frequent merchant travel would add to the prospect of disease spread to the U.S. and beyond. “Yellow fever could be carried directly to South Africa and India, and through the Panama Canal, to Hawaii, the Philippines, Australia, and China.” 33 Given the increased risk of the spread of disease, the importance of developing a treatment, or at the least an etiological understanding of the disease, became the focus of the work of the next commission in 1918. The second commission made significant strides toward understanding yellow fever and paved the way for vaccine development.

Hideyo Noguchi played a key role in the work of the RHC’s second yellow fever commission in Ecuador. Noguchi believed the cause of yellow fever originated from a

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bacterium similar to jaundice. Noguchi reproduced the suspected bacterium by taking blood from those who had died from yellow fever and experimenting with potential cures. By the fall of 1918 he was confident he had discovered a vaccination.

That fall, Noguchi and his team vaccinated 325 military members and their families, for a total of 427 non-immune individuals. Of those vaccinated, only five developed yellow fever, compared with 386 reported cases in the unvaccinated population. Out of the 386 cases, 217 victims died. Given the success of these initial trials, inoculation efforts were made to expand beyond Ecuador and into Brazil, Mexico, and Peru. After this expansion, over 20,000 individuals were vaccinated in the region. Though widespread research efforts had begun in Central and South America, the West African arm of the RHC began to discover results that differed from those of Noguchi.

By the mid 1920’s the West African RHC group had begun to conduct corollary experimentation following-up on Noguchi’s findings. Their research with monkeys, mosquitos, and human victims of yellow fever resulted in strikingly different results. In one such experiment the team drew blood from a human victim and injected it into a host monkey. Upon showing symptoms, a swath of mosquitos fed upon the monkey. “By December, the Asisbi strain of ‘virus’ had been passed by mosquitoes through 26 monkeys,”

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34 Center for Disease Control and Prevention, “Yellow Fever,” Center for Disease Control and Prevention, http://www.cdc.gov/yellowfever/ (accessed January 15, 2015). Jaundice causes yellow discoloration of the skin that is frequently linked to liver disease, particularly in forms of hepatitis or gastrointestinal cancers. The initial symptoms of yellow fever include: sudden onset of fever, chills, severe headache, back pain, general body aches, nausea, and vomiting, fatigue, and weakness.

35 Farley, To Cast Out Disease a History of the International Health Division of the Rockefeller Foundation (1913-1951), 93.


37 Here some real ethical questions emerge, particularly with respect to informed consent, i.e. did the research subjects people want to be inoculated? Was the vaccination sufficiently tested? The ethical implications of this research and the development of bioethics and research ethics in particular will be taken up in Chapter Two.
all but two of which developed a high fever and died.”38 This led the West African research team to conclude that Noguchi mistook jaundice for yellow fever. Upon hearing these results, a disbelieving Noguchi came to work with the West African research team in 1928. After several weeks of experimentation he concluded that he had made a serious error and had not developed an effective vaccine for yellow fever. This insight proved crucial to the continued work of the yellow fever commission in its third phase, a phase marked by an increased sense of urgency with the looming possibility of biological warfare during World War II.

Fred Soper served as the regional director during the third commission of the RHC’s International Health Division in South America. With the disproven results of Noguchi’s experiments, a greater urgency existed to study the disease more closely. While this included focusing on vaccine development, it also meant taking measures to control the disease. During this third phase, Soper and his researchers began the practice of taking liver cultures from victims to develop vaccines. The preferred method of study was through viscerotomy, a procedure through which the pieces of liver would be resected from the victims in order to be cultured and studied. The procedure was performed on persons who died from yellow fever, or from an unknown fever where yellow fever had not previously been reported. In order to have access to the deceased, Soper’s group received government authorization to “prevent burial of anyone dying of a fever until a ‘viscerotomia’ had been performed.”39 Greater access to cadavers allowed for some 14,000 examinations that resulted in the

38 Farley, To Cast Out Disease, 95.
39 Farley, To Cast Out Disease, 100.
discovery of yellow fever in seven states and 25 rural municipalities in which the disease had never before been reported or suspected.\(^{40}\)

The systematic way in which information was gathered and stored gave Soper’s commission a wealth of epidemiologic data with respect to where people lived, what they did, and how they might have become infected with the disease. Included in these findings was the recognition of a higher prevalence of disease in rural locales, as opposed to urban/port areas, a different outcome than previously expected. The increased etiological and epidemiological knowledge of the disease garnered during this phase of research proved important for implementing the next stage of research that included vaccine development.

The ability to produce a successful vaccine was fraught with challenges that culminated in two mass vaccination campaigns, one targeting Brazilians and the other U.S. and U.K. military personnel. The development of a vaccine proved difficult because of the research team’s inability to standardize a method for replicating the virus. Once they could replicate the virus, they began testing the vaccine on mice. However, rather than developing immunity, mice frequently became sick or died.\(^{41}\) It was not until a third round of experiments, in 1933, that a vaccine was produced. The successful development took place once the virus, “passed through brain-less tissue cultures, became less and less virulent, until after 114 passages none of the monkeys inoculated with the virus showed any signs of the

\(^{40}\) Ibid. While the results of this third commission led to important discoveries, ethical question arise given the foreign influence that Soper and the RHC sponsor had within the region. Secondly, the communities in which they worked were disproportionately poorer than their city counterparts. Third, and perhaps most troublesome, the research priority allowed Soper and his team to usurp any family preferences of what to do with a family member after he or she died. Essentially the bodies functioned as cadavers from which the scientists could learn.

Once the vaccine was deemed safe for mice and monkeys, a massive campaign began in 1937. During this campaign, 59,532 workers in the coffee plantations of Minas Gerais, Brazil were vaccinated. The success of this vaccination efforts, led to the 1940 recommendation that all military personnel be vaccinated with the newly tested vaccine. Between 1940-42, over six million doses of the vaccine were distributed to the U.K. and U.S. armed forces.

The research on yellow fever points to a confluence of factors that made it an important field of research, the most influential being new trade possibilities because of the Panama Canal and the threats during two World Wars. Though this research was not without its setbacks, particularly those of Noguchi and the death of several military personnel during the inoculations campaigns, the three yellow fever commissions demonstrated the importance of translating research from basic science and epidemiology research to vaccine development and “clinical trials.” While these were not official clinical trials, at least in the way one thinks of trials today, it is worth noting that earlier versions of the vaccine were repeatedly tested on those workers who played prominently in trade practices running through the Panama Canal, while others who had no business associations

42 Farley, To Cast Out Disease, 173.

43 Here one can see the economic concern of the government. For them, the health of coffee plantation workers was essential given that coffee was historically the mainstay of the Brazilian economy. Thus, a real incentive existed for them to give the Rockefeller Foundation free reign in addressing the yellow fever virus, which stood to benefit both the health of a particular population and allow for important advances in medical research, not to mention the interests of the newly empowered Brazilian government.

44 Farley, To Cast Out Disease, 173. In these instances, cases of jaundice were being reported; however none were positive for yellow fever. These reports were staggering in numbers, averaging about 15% infection rates amongst those injected with the vaccine. Long-term research continued to be done on jaundice that indicated when the vaccine was mixed with human serum one of the strands was infected with Hepatitis B. This did not lead to an immediate halt of vaccinations, but rather resulted in a couple of long-term studies. One such study, in 1974, followed 22,000 Taiwanese who had been given the vaccine and later showed liver cancer in “1,952 of 3,454 hepatitis B carriers, compared with only nine from 19,253 non-carriers.” That is over 50%. With over 300,000 military personnel vaccinated with the contaminated lot greater emphasis was placed on follow-up studies from the developed yellow fever vaccines. Fortunately, these results were quite different than those from the Taiwanese study. Only 26 of the 1056 cancer carriers, however, died of cancer.
were left untreated. Over 60,000 Brazilians were vaccinated in the initial rollout of the vaccine. It was only after those vaccines proved successful that over six million service men from the U.K. and U.S. were then vaccinated.45

By the end of the yellow fever vaccination developments, research on disease and injuries affecting soldiers during the war had to take utmost priority. The addition of prophylactic health measures, such as vaccinations, proved crucial in preventing many non-war related deaths. However, these preventive and public health measures were not the only life saving innovations during World War II. Individually-focused research proved crucial for treating injuries suffered in the midst of battle was also needed, given the advances in weapons technology. These surgical techniques for reconstructive surgeries resulted in truly experimental medical care.

Maxillofacial Reconstruction

The surgical procedures undertaken to repair and reconstruct facial and head injuries during both World Wars took an experimental approach to the practice of surgery. The experimental nature of these surgeries began with the development of new surgical techniques to the diversity of persons who comprised the surgical teams. At the time of the First World War (1914-1918), much of the medical community remained unprepared for the injuries soldiers would face.46 The trench warfare presented debilitating and grotesque

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45 The inequity in the benefits of research and the burden placed on the research subjects raises a pertinent topic for research ethics. While informed consent has been seen as one of the ethical hallmarks of the yellow fever experiments, other socio-ethical questions remain. Questions of justice arise when considering the use of vulnerable populations for research that will not benefit the same community, or vaccinating only a portion of the community that proved most likely to have negative consequences international trade. Although the rationale of containing the international spread is certainly important, it does not obviate the responsibility to ensure that the community in which the disease is endemic is also protected. In this case, the yellow fever experiments disproportionately benefited those financially invested in the Panama Canal and U.S. and U.K. soldiers.

wounds that, when not resulting in death, led to extreme pain, disfigurement, and the need for immediate medical attention. The medical care received, however, was primitive and in a constant state of development. The field hospital, in many ways, was transformed into a clinical laboratory in which new surgical, anesthetic, and dental approaches were explored. Though particular types of cosmetic surgery existed already, few techniques demonstrated the capacity for confronting the sheer volume of never before seen injuries.  

It seemed impossible to evaluate, let alone to operate on all of those who needed surgery. However, the large volume of patients allowed for a pool of patients on which to learn and develop new innovative surgical techniques. In the 1916 Battle of Somme, a surgical team headed by Australian Harold Gillies saw 2,000 patients in a single day. Gillies served as one of the pioneers in skin grafting. Skin grafting made reconstruction possible through by utilizing a “tube pedicle enable[ing] surgeons to transfer skin in stages from one location another while maintaining the blood supply, which helped ensure that grafts would

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for over 40 years, in which the innovations of rifles and modern artillery was not of use. British surgeons found themselves in better position following their involvement in the Second Boer War, fought over land rights in South Africa from 1899-1902. Despite this preparation the introduction of trench warfare and the proximity of violent attacks provided a unique challenge.

47 Charles Conrad Miller, *The Correction of Featural Imperfections*, (Los Angeles, CA: University of California Medical School, 1908). Miller’s work focused on what today would be considered cosmetic surgery, but this work was certainly unique during the 1920s. While these injuries were unique, the foundation for some of these surgical techniques had been developed through, what he described as, “featural surgery.” Charles Miller, one of the pioneers in the field, wrote a book on featural surgery describing the type of imperfections that might benefit from surgical intervention. His list included: the head, folds, bags, and wrinkles about the eyes, face lifting, palpebral fissures, “double chin,” wrinkles of face and neck, softening of nasolabial lines, forming dimples, various nasal reconstructive surgeries, external era, the notorious “unduly large mouth.” Miller’s work in correcting imperfections signaled one of the earliest instantiations of cosmetic surgery. His efforts, more importantly, laid conceptual groundwork from which further innovative procedures could develop, giving at least a starting point for helping some of the patients that these surgical teams saw.

take.” This procedure allowed for better cosmetic results and improved health outcomes in these life and death situations.

Those with the most severe injuries received as urgent care of as possible from the surgical team on-site. Some of the soldiers suffered multiple bullet wounds to the face and eyes, while for others the bullets passed completely through their head. While these surgical teams included experts from highly respected universities, Yale, Harvard, Colombia, they all remained relatively inexperienced in tending to these types of wounds. The inexperience and diversity of the teams, coupled with the challenges presented by war-wounds, resulted in the development of different approaches to treat the same problem.

For certain neurological wounds, the Germans opted to leave parts of the brain exposed in order to allow for free drainage in an effort to prevent infection. Conversely, the British favored swift operations focused on removing foreign bodies and quickly closing the scalp. In 1917, American neurosurgeon Harvey Cushing utilized an electromagnetic procedure to extract iron shell fragments and “devised a simple method of debridement by suction and he urged water-tight two-layer scalp closure. Most importantly, he maintained meticulous records and surgical audits, finishing with a case mortality of 28.8%, which was then a marked improvement.” Cushing later published his findings, laying the groundwork for other surgeons working in the field to learn how to treat head wounds beyond the battlefields. Credit for successful treatments was the result of the interdisciplinary nature of the surgical teams.


51 Ibid., 75.
The successful approaches to treating the wounds seen during World War I incorporated an interdisciplinary approach comprised of nurses, doctors, surgeons, anesthesiologists, dentists, and perhaps the most unique addition to the team came from the use of artists in facial reconstruction. Artists created masks initially to give a rendering of what the patient’s face should look like following surgery, but also for a patient to wear whose surgery was unable to be completed to the team’s or patient’s satisfaction.52

Furthermore, the interdisciplinary nature of the team, at its most basic level, resulted in fresh ways of thinking through the complex problems that presented in their operating rooms and led to significant surgical advances.

The increased level of education and the experimental approach to surgical treatments led to significant advances in patient care. One commentator told the *New York Times*, “that medicine and surgery had advanced half a century in four years.”53 While this statement may tend towards hyperbole, the advances were nevertheless dramatic. Interdisciplinary teams brought together professionals who had never worked or trained together to care for patients. The patients they treated would have died in ordinary circumstances, but were saved through the use of procedures that had never been attempted. Teams utilizing the different techniques and publishing the results, as Cushing did, allowed for education to spread beyond the battlefield and into hospitals and medical schools throughout the world.

The techniques developed not only applied to battle wounds, but also would be applied to a variety of reconstructive surgeries brought on by disease and non-war related

52 Ibid.; Haiken, *Venus Envy*, 33; Alexander, “Faces of War.”

53 Haiken, *Venus Envy*, 31. The *Times* quote comes from Major George A Stewart of the Rockefeller Institute’s War Demonstration Hospital.
injuries. Positively, one can say that an interdisciplinary approach to research that targeted patients with critical needs resulted in rapid advances in the field and cultivated new approaches to reconstructive surgery, even leading to the development of the field of cosmetic surgery. Negatively, however, one might see this type of surgery lending itself to the objectification of the body when done outside of an emergent medical need. Yet, non-emergent procedures were becoming more frequent throughout the 1930s as beauty and the striving towards perfection was increasingly becoming a priority. The arguments for perfection, however, extended beyond the operating room and into eugenic research centers focused on enhancing particular individuals, while at the same time limiting the participation of several other individuals and social groups deemed less desirable, in the hope of building a stronger society.

Eugenics

Discussions of eugenic-based research typically center on Nazi scientists during World War II, but the groundwork for this type of research was well established globally prior to the war. Eugenics research focused on experiments aimed at genetically enhancing and improving upon certain genetic traits, and the elimination of others, in the hope of developing a more advanced society. In a certain sense, the approach was very individualistic and seemingly beneficial to society. The goal was to find and enhance particular individual characteristics that made for healthier, stronger, and more independent individuals. This meant eliminating negative characteristics such as physical disabilities and proclivity for disease. Yet, while eugenics focused on individual procedures, the intended aim was the good of society. Sterilizations and even the killing of racially ethnic, and/or religious “sub-
groups” were just some of the control methods considered by eugenicists that relied on the contributions of science.  

From the perspective of eugenics, science served as a tool to maximize the potential of human beings for the betterment of society. Science focused on improving the quality of human beings responsible for continuing society’s progress in a variety of forums. Ultimately, it “would allow man to conquer space, conquer time, overcome ‘the dark and evil elements in his own soul,’ and ultimately refashion ‘his own body and those of other living beings.’” For eugenicists, science was about human progress and improvement. The prevalence of this vision made eugenics appealing globally, especially in the economic depression following World War I. It was thought that by maximizing human potential, hope would emerge from that the stark economic reality, health challenges, and disabilities that people faced.

At the turn of the twentieth century, Sir Francis Galton’s research built on the earlier genetic research of Gregor Mendel to fulfill what he understood to be the duty and responsibility of a scientist to engage in research aimed at improving the human species as a whole. Galton saw eugenics as a process of “supplanting inefficient human stock by better...
strains, and to consider whether it might not be our duty to do so by such efforts as may be reasonable, thus exerting ourselves further over the ends of evolution more rapidly and with less distress than if events were left to their own course.” For Galton, science was not about observing nature, but rather taking control of nature. His scientific focus resulted in a research fellowship in National Eugenics at the University College of London. In 1904, Galton and his team of researchers engaged in work that sought to understand differences in human beings based on race. Galton’s emphasis on race was not unique and fell in line with much of the work of other eugenic researchers, influencing one of the U.S.’s leading eugenicists: Charles Davenport.

In 1910, Charles Davenport followed Galton’s lead by starting the Eugenics Record Office in Long Island, New York. This office focused on establishing “research via house-to-house surveys and by studying records from prisons, almshouses, and institutions for the mentally deficient, deaf, blind, and insane…the Office supported scholarship students to study human heredity and collect data, primarily on the subjects of ‘feeblemindedness’…” To this end, Davenport’s research concentrated primarily on research subjects who would have been mostly physically or mentally disabled and were considered unable to contribute to society. Davenport’s work can best be characterized as negative eugenics because his efforts centered on methods of eliminating particular characteristics from certain persons. In the U.S., his research extended beyond the Eugenic Record Office and resulted in state-

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enforced sterilization practices based on any number of “disabilities,” including race. By 1934, sterilization laws were on the books in 27 U.S. states for “feebleminded” persons.\textsuperscript{59} These race-related protocols were made possible by the research of Galton in Britain and Davenport in the U.S. The efforts of Galton and Davenport were furthered by the work of the Kaiser Wilhelm Institute during the rise of German nationalism.

The Kaiser Wilhelm Institute operated as one of a number of research institutions that pursued eugenics research for the advancement of society as a whole. By 1922, Germany joined Great Britain, Switzerland, Sweden, and the United States in establishing its own research center for eugenics.\textsuperscript{60} Germany, in many ways, built on already established eugenics programs, but was divided as to the type of research that ought to be pursued, positive or negative. A “positive” approach would focus primarily on the promotion of improvements that could be offered by pairing genetically desired characteristics together. While initially taking this path, the rise of German nationalism gave way to a negative focus of genetics research that emphasized the elimination of undesirable characteristics, similar to the U.S. approach, through sterilization. This type of negative research was exemplified in the work of Otmar Freiherr von Verscheur.

Von Verscheur became the director of the Kaiser Institute in 1942, and played a key role in establishing the research priorities in the concentration camps.\textsuperscript{61} He was a noted “racial hygienist” who, in his primer on race hygiene, took six pages to detail the “racial

\textsuperscript{59} Harriet A. Washington, \textit{Medical Apartheid: the Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present}, (New York: Doubleday Press, 2006), 202-203. By 1941 somewhere between 70,000-100,000 people had been sterilized, and, as Harriet Washington notes, a disproportionate number of those people were black.


It is the relationship between race and genetics that becomes the driving force, not only of his research, but also that of much of the research conducted in Nazi Germany. Moreover, Von Verscheur’s previous work on genetics and twins proved important to the work of the notorious “camp doctor” at Auschwitz, Josef Mengele.

Mengele’s research agenda in Auschwitz centered on race and infectious disease, which included experiments that required the killing of and subsequent dissection of Roma twins. He attempted to decipher genetic differences among “Jews, [Roma], and others who proved resistant to various infectious disease in particular to tuberculosis and typhoid.”

Many of Mengele’s experiments focused on infectious disease, genetics, and resistance to specific diseases including tuberculosis and typhus. Mengele’s hypothesis was that genetics, inclusive of race, proved indicative of those likely to contract and/or disseminate disease. While his research did not prove this to be true, it did not disprove the theory either. In fact, his research bias has been influential in the way in which research developed throughout the remainder of the century, which initially focused exclusively on white males, and certainly contributed to some of the current debates in health disparities and outcomes research.

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62 Müller-Hill, “The Blood from Auschwitz and the Silence of the Scholars,” 338; O’Neil, Basic Principles of Genetics: Mendel’s Genetics. Given the negative and derogatory connotations of the word “gypsy” I will substitute the term “Roma” the generally agreed upon term adopted in official language of the European Union. “The term “Roma” used throughout the present text refers to Roma, Sinti, Kale, Travellers, and related groups in Europe, and aims to cover the wide diversity of groups concerned, including groups which identify themselves as Gypsie.”

63 Ibid., 340.

64 Ibid., 340.

Though eugenics research may have prompted broader ethical considerations in research—explored in Chapter Two—it nevertheless focused on the importance of research that benefited the health of society, even if only the minority within society. In fact, all of the research in this period tried to balance the needs of individuals with those of society. The scientific efforts of the Rockefeller yellow fever commissions, the emergence of plastic surgeons, and even eugenic researchers used medical research—at least from their perspective—to improve society. Vaccine development addressed the health needs of workers in South America in developing a vaccine that was useful with the opening of the Panama Canal and the onset of two World Wars. The surgical techniques, while focused on improving the health of individuals, the real impact was on the interdisciplinary nature of the surgical team and the unique procedure being performed. These efforts were so unique that a new medical specialty, cosmetic surgery, was born. The post World War era, however, saw a shift in the types of medical research projects pursued. The Wars brought a new perspective to the importance of controlling diseases and the global impact that research can have on the health of persons.

**Medical Research: More of the Same or a New Era?**

The third phase in the development of medical research began in the late 1950’s and endures through the present. This phase of research begins to take into account the global reality of disease and the potential role of medical research to alleviate some of these burdens. The paradigmatic examples in this period focus on diseases that potentially affect everyone. Though individual expertise within the disciplines of basic science, clinical, and epidemiologic research constantly improved, addressing the complex challenges of global health required a collaborative and interdisciplinary approach to research. The epidemiologic emphasis on the eradication of smallpox, the first example, demonstrates the need for both
interdisciplinary and multi-national collaboration between basic scientists, health care workers, and public health experts. The process of eradication took years to achieve, but still provides a model for preventing the global spread of disease by focusing on the low-income countries where the infectious disease was endemic.

The second and third examples, the Veteran’s Administration (VA) clinical hypertension studies and developments for treating malaria through synthetic biology, focus on the importance of institutional collaboration to treat two global threats to health.66 The VA hypertension studies demonstrate the importance of clinical trials and introduce the “gold standard” of the double-blind placebo controlled trial. At the time of the VA study, there was much debate surrounding the health risks of high blood pressure, and the double-blind placebo control trial removed researcher bias in observing the different outcomes of those being treated compared to those in the control group. Unfortunately, malaria research, the third example, is not at the clinical trial stage.

It is, however, the hope of U.S. researcher Jay Keisling that, through synthetic biology, new treatments will emerge from his work. Synthetic biology is a relatively new field of research that has played an important role in the creation of new and previously unknown biological phenomena through scientific engineering. Most recently, it has been applied to the production of artemisinin in the hope of addressing the global health challenges

66 World Health Organization, “The Top 10 Causes of Death,” http://www.who.int/mediacentre/factsheets/fs310/en/index1.html (accessed December 20, 2014). It is worth noting that stroke and ischemic heart disease are the leading causes of death in lower-middle, upper-middle, and upper-income countries. In low-income countries stroke and ischemic heart disease are four and five, respectively. In Chapter Three, I will return to the importance of taking social and economic factors into consideration in establishing research agenda. While malaria does not rank among the leading causes of death when considering all countries, it does rank in the top five causes of death in low-income countries. Thus, at a time when millions of resources are being focused on genetic research, synthetic biology represents a unique approach to addressing problem primarily of low-income countries.
presented by malaria. It is the hope of Keisling and his team that their work can make progress towards discovering a cure for one of the great challenges in global health.

These three examples address a range of needs in global health research, which provides the context for research today. Global health research focuses on health concerns that exist on both a local and international level. In this way, research undertaken locally has global ramifications. Yet, as will be described in Chapter Four, pressing global health needs do not always receive priority in research. These examples represent a departure from the type of research that tends to focus more on individual or personalized approaches to research. On the contrary, global health research emphasizes the importance of the health of the community and communities. While this emphasis is not assumed at the exclusion of individual health concerns, it certainly prioritizes research that will improve the health status of a large portion of the community both locally and globally. It is the focus on research that is both local and global that characterizes the multifaceted effort to eradicate smallpox.

Smallpox

In 1980, the World Health Organization (WHO) officially declared the eradication of smallpox. The eradication process was a complex journey driven by a confluence of factors, the least of which was the scientific capability of eliminating the disease. Though the ability to inoculate against smallpox was discovered in 590 BCE in China, it took over 2,000 years for smallpox to be eradicated. Smallpox represented a constant health threat that had historically passed indiscriminately between the rich and poor. The disease seemingly struck at random and was fueled by prolonged human-to-human contact during the critical period of contagion. As living conditions improved in most of the global north, the conditions for

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the majority of the world in the global south remained unchanged and ripe for the spread of a disease such as smallpox. The facility with which the disease was transmitted made it a challenge to contain.

Smallpox was a variola virus that presented as a rash and appeared in both a major or minor form. Variola minor was less common and less deadly, resulting in the death of approximately 1% of persons that contracted the virus. In contrast, the variola major accounted for about 90% of all smallpox cases, of which 30% proved to be fatal. Characteristics of its transmission included relatively close contact, either through the air or physical contact with another person, and were secondarily transmitted through clothes, sheets, and rags. Historically there were persons who proved more likely to contract the disease than others. Medical students, nurses, doctors, hospital staff proved more susceptible to the disease because of their work with the unprepared bodies, skin legions, shrouds, and dissection. The incubation for smallpox typically lasted from 7 to 17 days, and averaged 12 to 14 days. Once a person had become infected there was no cure, though if they survived...

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69 Koplow, Smallpox the Fight to Eradicate a Global Scourge, 12.


71 Center for Disease Control and Prevention, Smallpox Disease Overview; Youde, Biopolitical Surveillance and Public Health in International Politics, 65. My subsequent understanding and explanation of smallpox’s disease process relies the descriptions offered by the CDC and Youde. The second phase of the disease was associated with high fevers ranging from 101-104, aches, chills, vomiting, and could last from 2 to 4 days. At this point a person had become contagious though not the most contagious, which took place during the third stage. It was in this third stage that a rash spread from the mouth and tongue to the arms and legs. This rash took approximately 24 hours to spread over the entire body. The sores in the mouth broke open and released a large amount of the virus. The rash that covered the body now became a series of raised bumps that resembled chickenpox. At this point sores filled with an opaque fluid forming a depressed center. This depressed center was the key differentiator between smallpox and chickenpox. This marked the most contagious period of a person with smallpox and lasted about four days. The bumps formed pustules that were firm to the touch, and the pustules began to scab over and fall off within three weeks. While the person was most contagious during...
they had lifelong immunity to smallpox. The challenging aspect of the disease was that a person initially became contagious with relatively mild flu-like symptoms that quickly escalated into a rash and raised bumps that secreted a highly contagious fluid passed easily from individual to individual. Thus, the most crucial aspect of the global effort to eradicate smallpox was the urgency of identifying the individual who was the source of the infection and to develop a coordinated effort at containing the disease.

By the latter half of the twentieth century, smallpox had been virtually eliminated from high-income countries, leaving the disease burden resting on low and low-middle-income countries in Asia, Africa, and South America. In 1958, the World Health Organization (WHO) considered mounting a global campaign to eradicate smallpox at the behest of Viktor Zhdanov of the Soviet Union. He noted that there remained only 59 global states in which smallpox existed, and proposed an effort to inoculate 80% of the world’s population within two years. This quick turnaround, however, required the immediate training of health workers to respond more readily to the disease.

Zhdanov’s insistence proved important not only for the validity of the argument he was making, but also for the reemergence of the Soviet Union as a member of the WHO assembly for the first time since 1949. Zhdanov and his country were crucial to the plan, because it could demonstrate an eradication plan for smallpox that mimicked important features of a global plan, i.e. a large land area with a varied climate and a diversity in population and cultures. Though the Soviet plan took longer than expected due to a constrained budget, an increase in financial resources—by 1966 $2 million would be given

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72 Youde, Biopolitical Surveillance and Public Health in International Politics, 69. The last reported case from the U.S. was 1949 in Texas, while Western Europe saw its last case from Portugal in 1953.
annually to the cause for the next five years—facilitated more effective results. By 1973, Brazil and Indonesia both were declared free of smallpox. India, who had been home to over half of the world’s smallpox cases, joined the list of smallpox-free countries by 1975. Finally, in 1977, Ali Maow Maalin, a Somalian man who ultimately survived the disease, contracted the last known case of smallpox.

The eradication process of this disease was made possible through the collaborative efforts of different nations and the coordinated training of health workers, financial support, political good will, scientific ingenuity, and timely action on the part of on the ground surveyors. The targeted efforts on smallpox allowed for the translation of medical research beyond the laboratory and clinic to transform the health of persons. While individuals ultimately benefited, it was out of concern for public health that the WHO eventually championed the issue. The coordination through the WHO made the eradication of smallpox possible by facilitating international collaboration and sharing of scientific findings amongst the research team. The collaborative approach espoused by the researchers, which proved crucial to Zhdanov’s plan, remained essential for addressing future challenges in global health.

Given the recent outbreaks of the Ebola, the lessons of smallpox eradication efforts prove relevant once again. Focus on controlling or eradicating a disease requires moving beyond political differences, economic concerns, and making a concerted effort to involve a variety of health professionals. While many national research programs have been reluctant to take on the health challenges that plague primarily low-income countries, Ebola heightens

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73 In part the slow start was due to the then director of the WHO, Macolino Candau, was uncertain of the possibilities of a successful eradication campaign, particularly since none of its kind had been attempted before and the current malaria campaign had been floundering. See “Smallpox: Dispelling the Myths,” Bulletin of the World Health Organization, 86, no. 12, 2008. It is also worth noting that the U.S. alone spent $150 million in 1967 and 1968 to mitigate the spread of smallpox within the U.S. Youde, Biopolitical Surveillance, 75.
the international challenges of infectious disease. Institutions, like the WHO and others, need collaborative partners to focus on eradicating and controlling the spread of infectious disease. These responsibilities, however, extend beyond research, to call on these institutions to work for social change.74 Medical research, in the case of smallpox and the present case of Ebola, demonstrates one way change might come about.

Although global infectious disease remains a pertinent issue, many Western and high-income countries have opted, instead, to focus research efforts on discovering cures for chronic diseases facing individuals. The rise of research on chronic disease became a focus of high-income countries by the 1960s. One of the first priorities that the NIH addressed on a large-scale clinical trial was hypertension. While today many are aware of and treated for hypertension on a daily basis, it was once not thought of as a serious threat to health. The VA study demonstrated that it was in fact a real health concern that benefited from treatment.

VA Hypertension Study

Though evidence of hypertension existed as far back as 2600 BCE, measuring of blood pressure only became a consistent medical practice within the last century.75 One of the earliest references—around the second or third century BCE—to high blood pressure came from the Chinese medical textbook, Yellow Emperor’s Classic of Internal Medicine. Early Chinese research identified too much salt in foods as a factor that contributed to increase blood pressures. Other descriptions described dangerous blood pressure as “firm, rapid, and

74 The 2014-15 Ebola outbreak will be revisited in more detail in Chapter Four (p.172), and the role of potential collaborative solutions, particularly as they pertain to the Catholic university, will be explored in Chapter Five (p.222).

75 John H. Laragh, Hypertension: Pathophysiology, Diagnosis, and Management (New York: Raven Press, 1995), 2741.
large…”\textsuperscript{76} These descriptions offered by Chinese-medicine, however, lacked the capabilities to prove their hypothesis. However, life insurance companies, not physician researchers, led the way in studying the associations between hypertension and mortality.

In the early 1900s, life insurance companies in the United States began to take concerted interest in discovering why and how their clients were dying. Their inquiries led them to conduct clinically relevant research into the health concerns of those with high blood pressure.\textsuperscript{77} The research consistently showed a higher mortality rate with those who had higher blood pressure. Despite the evidence, however, hypertension was dismissed frequently as a cause for concern in the medical community. In 1912, Sir William Osler, a foundational figure in medical educational, dismissed high blood pressure as a medical problem and advised against its treatment. He stated, “The extra pressure is a necessity—as purely a mechanical affair as in any great irrigation system with old encrusted mains and weedy channels. Get it out of your heads, if possible, that the high press is the primary feature, and particularly the feature to treat.”\textsuperscript{78} While Osler saw high blood pressure as natural, others regarded it as a potential health risk and began treating it through surgical interventions. Surgery, however, was often seen as a last resort and gave way to less invasive pharmacological remedies. With the shift to pharmacological treatments, clinical trials were needed to confirm if treatment would decrease a patient’s blood pressure.

By the 1940s, James Shannon stood at the forefront of establishing standards for clinical research beginning with the development of anti-malarial drugs, which had

\textsuperscript{76} Laragh, \textit{Hypertension: Pathophysiology, Diagnosis, and Management}, 2741.

\textsuperscript{77} Theodore Kotchen, “Historical Trends and Milestones in Hypertension Research: A Model of the Process of Translational Research.” \textit{Hypertension} 58, no. 4 (2011). It is important to note that insurance companies in the early part of the twentieth century were not the large corporations that are frequently thought of today, but rather small independent companies that had

\textsuperscript{78} Ibid., 522.
unforeseen effects on hypertension research. One of the key drugs that Shannon and his research team used was chloroquine. However, through the research process it was noted that some malarial strains were resistant to chloroquine and that an alternative or complementary drug was needed to ensure its success. The supplement drug, pentaquine, came to have a significant role not only in the treatment of malaria, but also as an initial treatment for hypertension.

By the end of the decade, Shannon became the lead researcher at the National Heart Institute and brought a familiar colleague with him, Edward Freis. Freis had already given pentaquine to 17 patients with moderate to severe hypertension, and after several days of treatment their supine blood pressure—taken when the person is lying down, which allows blood to flow more easily throughout the body—fell between 10% to 40% below baseline. This immediate drop lowered their risk of heart attack, stroke, and heart failure. Though pentaquine came with some debilitating side effects, it demonstrated an initial benefit of treating patients with high blood pressure, while simultaneously underscoring the need for more research.

In 1964, Edward Freis continued his research by conducting an unprecedented collaborative study between 17 VA hospitals, utilizing a previously untried methodological approach to clinical research. Given the skepticism about the need to treat high blood pressure at all, any study undertaken had to demonstrate, without bias, a clear benefit for treating patients. In order to achieve unbiased results, Freis coordinated a multi-site randomized double-blind placebo-controlled study. In this type of study, multiple VA


80 Laragh, Hypertension: Pathophysiology, Diagnosis, and Management, 2744. At the time moderate to severe hypertension was classified as blood pressure 180/120, today treatment begins with anything more than 140/90.
hospitals were used and neither the researchers nor participants knew who received
treatment and who received the “placebo” or non-therapeutic treatment. Both groups were
selected at random, and were not deliberately chosen by any particular criteria. This type of
research, and on such a large scale, had never been tried before. Yet, neither the size nor
scope of the study was as impressive as the results that forced important changes in clinical
practice.

The results of the VA study demonstrated the effectiveness of a drug combination of
thiazide diuretic, reserpine, and hydralazine at lowering blood pressure.\(^{81}\) In total, 523
patients were enrolled and randomized into a treatment group and a control group. After 18
months of treatment, the study of the placebo group had to be stopped because of the
disparity that existed in the morbidity and mortality outcomes. Freis reported the following:

Four of the 70 patients in the control group died as a result of cardiovascular
complications as compared to none in the 73 treated patients…17 patients in the
control group developed non-fatal complications, such as the malignant phase of
hypertension, severe congestive heart failure, cerebral hemorrhage, or disabling
cerebral thrombosis… an additional 6 control patients developed non-terminating
events, including mild congestive heart failure, myocardial infarction, and non-
disabling strokes… over the period of follow-up the incidence of cardiovascular
complications was 27 in the placebo group versus only one in the treated group…19
deaths due to cardiovascular causes had occurred in the control group versus 8 in the
treated group. The most frequent cause of death was either myocardial infarction or
sudden cardiac arrest… 11 occurred in the control group and 6 in the treated group.
Stroke was the next most common… eight in the placebo group versus only one in
the treated group…. 56 (28.9 percent) of the control group developed cardiovascular
complications during the trial, compared to 22 (11.8 percent) of the treated group.\(^{82}\)

Freis’ observations demonstrated a clear benefit to those in the treatment group, and the
consequences for those not being treated were so equally clear and dangerous that the trial

\(^{81}\) U.S. National Library of Medicine, “The Edward D. Freis Papers,”
http://profiles.nlm.nih.gov/ps/retrieve/Narrative/XF/p-nid/155 (accessed January 2, 2015); Laragh,
Hypertension : Pathophysiology, Diagnosis, and Management. The following description draws on Freis’s own narrative
of the case in an historical essay as well as the summary of the VA study compiled by the National Library of
Medicine.

\(^{82}\) U.S. National Library of Medicine, “The Edward D. Freis Papers.”
had to be stopped. The results pointed to a conclusive link between mitigating the effects of hypertension through treatment and positive health outcomes. The conclusiveness of the study led to increased funding from the NIH for developing safer and more effective drugs, setting in motion a series of initiatives for further improvements in the treatment of hypertension.

Over the next three decades, hypertension research continued to build on Freis’ VA study through clinical research aimed at controlling hypertension, reducing mortality, and increasing nutritional intervention. After 30 years of exclusive focus on pharmacological treatments, more studies began to explore the effectiveness of reducing hypertension in patients through a combination of therapeutic drugs with nutritional and hygienic intervention. More recent focus has centered on studying the combined effects of other diseases, such as those suffering with hypertension and diabetes. While much progress has been made in anti-hypertension research, Freis’ study distinguished itself as the first to address treatment options for high blood pressure by utilizing a new type of clinical research. Perhaps more prominently, his work demonstrated the potential of a collaborative project by coordinating the research and staff of 17 VA hospitals. Both the new methodological approach and the participation of multiple hospitals contributed to a process that tried to eliminate bias, which proved fundamental for a study surrounded by so much skepticism.

Freis’ research on hypertension, which has now become a global health challenge, has allowed for research to continue in low and middle-income countries. However,

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83 Kotchen, _Historical Trends and Milestones in Hypertension Research: A Model of the Process of Translational Research_, 529-30; Henry R. Black, _Clinical Trials in Hypertension_ (New York: Marcel Dekker, 2001). Kotchen has a helpful table that focuses on the highlights of global hypertension research with brief descriptions of each study. Black offers an edited volume that details the research being done in anti-hypertensive research in a more formal way.

chronic disease, such as hypertension, in lower income countries is often experienced along side infectious diseases. In these areas, infectious disease remains a more persistent health threat. One of the more prominent diseases faced in low-income countries is malaria, which ironically played a crucial role in the story of hypertension research. While there are treatment protocols in place, malaria still remains a global problem that has defied traditional therapeutic remedies. To this end, alternative approaches to searching for anti-malarial treatments and cures have been undertaken with promising discoveries surfacing through synthetic biology.

**Synthetic Biology**

As breakthroughs in chemistry saw the deconstruction of molecules and geneticists were able to observe entire strands of DNA, synthetic biologists focused on isolating genes and reconfiguring molecules in order to study the effects of their interaction in a newly created environment. The breakthroughs in chemistry, genetics, and biology throughout the 1960-1990s provided the foundation for the development of synthetic biology in the early 2000s. Two of the key elements necessary for synthetic biology to function rely on the building blocks of biology and systems biology. Biology focuses on the micro level by studying life through its functions, structures, developmental stages, environment, species, etc. In contrast, systems biology operates on the macro level, organizing the vast diversity of

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biological study into a “quantitative understanding of natural biological systems.” This quantitative understanding creates opportunities for deeper knowledge about the way in which particular biological processes function as a unit. For synthetic biology, it is important to have the biological understanding of how these units function and to be able to both break down and rebuild them.

The reconstruction and deconstruction of biological units requires engaging with principles of engineering and biotechnology in order to create phenomena that do not exist naturally. In terms of deconstruction, synthetic biology uses available biotechnologies to break down existing biological entities into distinct and unique properties that do not otherwise exist independently in the natural world. An example of deconstruction would be the unraveling biological life by breaking it down to minimal set of genes that when separated can be utilized in artificially creating simple and manageable structures. Likewise, the constructive nature of synthetic biology requires the technological capabilities to reconstruct the previously deconstructed biological bits.

Isolating a genome of one organism and, constructively, inserting that isolated genome into the cellular properties of a completely distinct, albeit related, organism creates a new entity by utilizing biotechnology and bioengineering. First, a new entity is created because the cellular properties of isolated genome A do not exist as a part of organism B. In this complex processes, it is the combination of biotechnology, engineering, coupled with an understanding of biology, and systems biology that make these developments possible. In this light, one can see how synthetic biology inherently functions interdisciplinarily.


89 This type of technology is frequently described as nanotechnology, which is the technology necessary to build genetic structures. “Companies have already developed techniques with which the four nucleotides, can be attached to each other in any desired order.” See Rinie van Est, Huib de Vriend, and Bart Walhout, Constructing Life: The World of Synthetic Biology. (The Hague: Rathenau Instituut, 2007).
Furthermore, while its interdisciplinary nature is unique, what truly sets synthetic biology apart is the creation of new biological phenomenon or phenomena with the potential for a variety of applications as indicated by patenting trends pertinent to synthetic biology.

Since the early 2000’s, patents for synthetic biology developments have been on the rise. While more time will be spent on the function of patents in Chapter Four, for now suffice it to say that a steady increase in patents indicates a certain level of scientific innovation and prioritization of a particular type of research with the potential for generating an economic return on investment. The U.S. has shown the most success for patenting innovations related to synthetic biology. A recent survey indicated that the U.S. is responsible for approximately 45% of the global patents in synthetic biology from 1990-2010.\(^90\) Synthetic biology patents with potential application in the area of medicine constitute a small percentage, 13.8%, of the overall percentage of patents held. Most of these patents are filed for by businesses, followed by universities and colleges, individuals, and research institutions.\(^91\) The focus of these patents for medical research centers on both treatment for and understanding of disease mechanisms. Currently, one of the efforts in synthetic biology research that holds the potential to have significant consequences for global health is the work being done on artemisinin, used in the creation of antimalarial drugs.\(^92\)

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\(^92\) Anne E. Osbourn, Paul E O’Maille, Susan J. Rosser, Keith Lindsey, “Synthetic Biology,” *New Phytologist* 196, no. 3 (2012), 673. In this example, rather than turning to artemisinin one could also look at In 2012 in Bristol, UK, Northwestern University (Chicago, USA) professor Sam Stupp presented strategies in which chemical structures were capable of signaling the mechanisms necessary for tissue growth, which hold “enormous potential for the formation of human tissues and organs in regenerative medicine and for the development of cell-like micro scale objects that can be targeted for therapeutic purposes (e.g. artery repair, drug delivery).” Stupp’s research is an example of the constructive and applicative nature of synthetic biology to medical research.
The WHO estimates that 3.4 billion people are at risk of contracting malaria, and in 2013 the disease was responsible for close to 600,000 deaths, most of whom were African children.\(^93\) African children are the most vulnerable population for contracting malaria, and despite reducing mortality rates by 58% since 2000, one child in Africa dies each minute as a result of the disease.\(^94\) Given malaria’s disproportionate inclination to infect persons living in low and middle-income countries in the global south and the limited resources for research on the disease within these areas, taking up malaria research addresses an unjust disparity in research and disease burden that affects the global south. Yet, the possibilities of eradicating or controlling malaria are often cited as being too costly due to drug resistant strains.

Drug resistant strains of malaria are typically treated with artemisinin-based combination therapies (ACTs); however, acquiring artemisinin naturally is a costly and labor-intensive process. To harvest the necessary artemisinin-base begins with its extraction from dried leaves of the herb \(a.\ annua\), a sweet wormwood plant found in Asia and East Africa. In order to produce five kilograms of artemisinin, 1000 kilograms of dried leaves have to be planted and cultivated from approximately 17,000 hectares (ha) or 42,000 acres of land.\(^95\) While recent efforts at increasing the total acreage have begun, the global yield falls far below the global demand. This has led Jay Keasling, and others conducting research in synthetic biology, to explore the possibilities of producing the precursor to artemisinin, artemisinic acid.


\(^94\) Ibid.

Keasling’s research looks to construct a new metabolic pathway that allows for the possibility of producing the artemisinic acid necessary for ACTs. He and his team at the University of California-Berkeley developed a biosynthetic pathway that consists of bacteria, yeast, and the plant’s own gene, to identify the specific genes that initiate *a. annua*’s production of artemisinic acid. The bacteria, yeast, and genes were placed into a “bacterial chassis,” an instrument capable of synthesizing a plentiful supply of “isoprenoid precursors” that do not typically function outside of the biological acid producing process in the *a. annua*. Through the synthesizing process, researchers were able to identify a single gene that catalyzed the three oxidation steps necessary to produce artemisinic acid. Though the process detailed above is complex, it can be broken down in a way that demonstrates how all of the parts work together to create this synthetic product. The biological part is the *a. annua*. The biotechnology used is both the chassis, which allows for the systematic deconstruction of the genes to their microbial function, and the technology that enables the insertion of the specific biosynthetic gene into this process of creating artemisinic acid. It is the reproduction of the naturally occurring three-step oxidation that makes this a work of synthetic biology.

The work of Keasling serves as one example, though an important one, of the possibilities that basic science research holds for future breakthroughs in global health research. While the focus on this particular endeavor is highly technical, its potential for broad application could go a long way in addressing the injustices of malaria’s disease burden. One challenge, however, is that this type of research is not cheap. Keasling’s work has been made possible in part by a $53.3 million gift from the Bill and Melinda Gates Foundation and the collaborative efforts of UC-Berkeley, the nonprofit organization PATH, Amyris a leading synthetic biology innovator, and the France-based pharmaceutical company
While successful collaboration is important and implementation of the project could provide ACT treatment to over 200 million malaria infected persons, Keasling and his researchers have only been able to produce the artemisinic acid necessary for initial testing of new ACT-based malaria treatments. Thus, uncertainty still surrounds this research, which will be costly and in need of support without a guaranteed return on investment.

Nevertheless, the success of Keasling’s project reinforces a common theme throughout the development of medical research in this third phase, which is the importance of an interdisciplinary and institutionally collaborative approach. The example of malaria research, requires the efforts of educational, pharmaceutical, biotechnology, private foundations, and non-profits entities to put the research efforts of Keasling and his team into practice. Without this collaborative approach global health challenges that unjustly affect the lower income countries of the global south might continue to go unmet.

**Conclusion**

Medical research from the end of the nineteenth century to the present day has balanced prioritizing the health needs of individuals against those of the larger community. The definitions of medical research given by international institutes for research, described at the beginning of the chapter, articulate the wide range of values operative when considering the rationale behind investing in medical research. The U.S., U.K., and France each emphasize the importance of health research focuses on economic returns and technological innovation. In contrast, India’s Council for Medical Research places a higher value on research that demonstrated clear public health benefits with little value focused on the technological or economic contribution of research. A low-tech public health approach was

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characteristic of the first period of research highlighted by John Snow, Robert Koch, and the 
multiple sanitary commissions, where efforts centered on improving the health of the 
international community. The goal of improving public health served both the interests of 
the community in which research was being conducted, but also held political and economic 
importance for those communities.

The second phase of research, from the early 1900s into the 1950s, was characterized 
by focusing on the health of particular communities. The efforts of the yellow fever 
experiments of the Rockefeller Foundation centered on communities in South America 
upon the opening of the Panama Canal, in order to ensure that yellow fever did not easily 
spread through the new trade routes. Perhaps initially unexpected, yellow fever research 
came to provide a great benefit to the war efforts by enabling the vaccination of some six 
million U.S. and U.K. military personnel, contrasted with only 60,000 Brazilians. This 
disparity in benefits of research is one that will continue to be raised throughout the 
dissertation and highlights the importance social justice when considering research ethics.

Research ethics—the focus of the next chapter—has more traditionally focused on 
protecting the rights of research subjects. While the protection of research subjects has been 
vital, particularly during the periods when the rights of certain minority groups have been 
ignored, research ethics should also be concerned with social ethics issues. One such 
concern should aim to ensure that research efforts do not become too narrowly focused on 
one particular group, neglecting more urgent health needs of other groups. It is the 
temptation to focus on particular health needs of individuals and particular groups over 
others that proves endemic to the examples in the second phase of research development. 
However, the examples from the third phase of the development of medical research
indicates ways in which a balance might be struck between addressing public and individual health needs.

The efforts in synthetic biology signal the type of basic science research needed to address increasingly more complex global health challenges. The smallpox eradication efforts demonstrated the potential that large-scale research and public health efforts can have through institutional collaborations. Collaboration was at the heart of Freis’s successful hypertension studies between the VA hospitals. While at the time hypertension was only emerging as a U.S. problem, the research that has developed from Freis’s work proved foundational to addressing the global problem of heart disease related to high blood pressure. This third period, in particular, demonstrated the importance of institutional and interdisciplinary collaboration, which would not have occurred without financial and intellectual investments in a variety of public and private entities.

This First Chapter has drawn attention to the multiplicity of players that have contributed, and continue to contribute, to the progress and priorities of medical research. While examples from the final phase focused on medical research that specifically addresses global health challenges, these challenges often go neglected. In fact, as will be outlined in more detail in Chapter Four, the most urgent health needs of people in low-income countries tend to be under researched compared to the health needs in high-income countries.

Estimates indicate that 90% of the medical research conducted, stands to benefit only 10% of the global population. This unjust disparity indicates that the current state of

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research priorities needs to be reevaluated if global health needs of the majority of the world are to be addressed. While research ethics, the focus of the next chapter, offers a way of protecting the rights of research subjects, it fails to address the social inequities within the practice of research itself. Thus, after considering the important role of research ethics—despite its limitations—Chapter Three will argue that an epistemological shift of medical research is needed in order to consider more seriously the health needs of the “poor majority” that often go neglected.
CHAPTER TWO
THE CODIFICATION OF RESEARCH ETHICS

Introduction

In the midst of the medical research innovations from the middle of the Nineteenth Century to the current technological practices of the Twenty-first Century, human subjects begin to play an increasingly important role in the process of conducting research. The paradigmatic examples in the previous chapter trace the development of medical research, but paralleling these developments were questions about the ethics of research and the rights of research subjects. These debates reach a crescendo after the Holocaust with the development of the Nuremberg Code.

The code, while responding to the use of unethical and illegal practices against Jewish prisoners, draws upon prior unethical practices of research. The previous legal cases raise questions pertaining to research perpetrated against prisoners and prostitutes, who were frequently enrolled as unknowing or uninformed participants in scientific research. However, even after the condemnation of Nazi research at the Nuremberg trial, violations of the rights of research subjects continues to occur. The continuance of unethical research practices results in the development of guidelines aiming to prevent the unethical and illegal conduct of medical research.¹

The Nuremberg Code, followed by Declaration of Helsinki (1964), and the Belmont Report (1978), establish necessary ethical foundations intended to guide research on human subjects. In one way or another, each of these international codes takes up ethical and legal questions arising from medical research practices that reflect social questions of the day. Despite the complex social and ethical questions surrounding the origins of these documents, the implementation of normative guidelines foster only a minimum ethical requirement protecting individual rights or the urging the physician to take responsibility to do no harm. Therefore, regulations guiding the ethical conduct of research concentrates on the individual participants, at the expense of the socio-ethical questions that surround the origins of the documents.

The social and historical context provides a necessary dialectic for developing a research ethic capable of responding to question of individual and social ethics for research. Without this dialectic, research ethics functions more as a formulaic checklist of do’s and don’ts. While a checklist proves beneficial, it cannot be the sole consideration when evaluating the ethics of a research study. Moreover, the parameters of the ethical conduct of research have to consider the social contexts in which research takes place.

This chapter emphasizes the importance of the socio-historic contexts in which these foundational international documents took shape, a nuance that becomes minimized in their practical application to research. It does so in the hope of reconsidering discussions around both medical research and research ethics within a framework of social ethics. Part one explores the Nuremberg Code, which is often considered to be the first document detailing the ethics of human experimentation. The Nuremberg Code served as a reflection and
codification of already established ethical norms that the Nazis simply disregarded.\textsuperscript{2} Even after the issuance of the Nuremberg code, researchers were slow to fully adopt some of its key elements. In part, this was due to the historical events surrounding Nuremberg, which made the code difficult to translate to “normal” settings of research. Thus, shortly after Nuremberg, in 1954, the doctors of the World Medical Association (WMA) began their own conversations to develop ethical guidelines for the practice of research.

The Declaration of Helsinki, finalized in 1964, is the second set of guidelines explored in this chapter and draws from both the Nuremberg Code and the Declaration of Human Rights, promulgated in 1948. Despite Nuremberg, the Declaration of Human Rights, and Helsinki, research practices in the U.S. still made it necessary for another normative document targeted at U.S. researchers. The third section of this chapter focuses on the \textit{Belmont Report}.

The Belmont Report, more than Nuremberg or Helsinki, remains foundational to the U.S. approach to questions concerning the ethical conduct of research but, like the others, cannot be appreciated fully outside of the context in which it develops. Its development came on the heals of Tuskegee syphilis experiments, in which the rights of vulnerable research subjects due to racism and poverty began to take on increasing import. I conclude this chapter with a brief look at global bioethics, an area of research that has become important over the last decade.

Global bioethics addresses questions of population health, distributive justice, and vulnerable populations. All of these topics addressed by global health, are in someway representative of concerns expressed in Nuremberg, Helsinki and Belmont that have been

lost. I suggest that some of the concerns expressed by global bioethicists signal the importance of an epistemological shift for both medical research and research ethics, a topic reserved for Chapter Three. While some of the richness of these international and national guidelines for research ethics have faded over time, their influence on the development of research ethics, broadly speaking, cannot be underestimated.

The Nuremberg Code

An Established Precedent

The Nuremberg Code, while frequently viewed as the first document that established an ethical and legal precedent for conducting research on human subjects, drew upon two key cases of research misconduct that laid the groundwork for a legal case against the Nazi doctors. The first of these came about in 1898 when a case was brought against Albert Nessier, a professor of dermatology and venereology at the University of Breslau in Germany.³ Nessier’s study set out to analyze the success of a vaccine for preventing the spread of syphilis. In order to study the vaccine, he enrolled patients who had been admitted to the university hospital. He utilized patients admitted with syphilis and several others who did not have the disease. For those who did not have syphilis, and in the interest of finding a preventive method, “he injected cell free serum from patients with syphilis into patients who were admitted for other medical conditions.”⁴ He would then test his vaccine on the patients recently injected with the disease, which frequently failed to prevent the contraction of the disease. While this would be reason enough to challenge the research, the unique aspect of his study was that the majority of his research subjects, who did not have syphilis prior to


their hospital admission, were prostitutes. Nessier specifically chose his subjects because he felt that these women had a higher potential of contracting syphilis of their own accord. In his trial, despite it being untrue, he claimed that these women must have contracted the disease by other means. Nessier was brought to trial and fined because he had ignored the Prussian directive on informed consent issued in 1891, which was designed to protect potentially vulnerable research subjects.

In 1891, the interior minister of Prussia issued a directive in response to questions regarding the forced inoculation of prisoners against tuberculosis, which stated that it should not be done against the patient’s will. The directive proved significant in the Nessier case and influenced Nuremberg for a couple of reasons. First, the Prussian Code concerned the rights of the imprisoned to refuse treatment. In this way, a precedent had been established for protecting the right to refuse participation in an experiment or to receive treatment. Equally significant was the extension of rights to those thought to have less worth in society. Secondly, the Prussian Code established the legal responsibility of the medical personnel conducting the treatment, or experiment, to obtain consent. Thus, when Nessier was brought to trial for not obtaining informed consent, his conduct was not only unethical, but also illegal. Discussions surrounding the importance of informed consent and the ethical conduct of research did not end with Nessier.

6 Ibid, 1446.
7 Ibid, 1445. Nessier offered as a defense that the women did not contract syphilis from the injection, but rather from their line of work. The court, furthermore, was less concerned with the scientific risk involved and held an exclusive concern on the lack of consent on the part of the patients at the hospital. A further complication can be deduced that these patients sought treatment at the hospital with the expectation of any injections aimed at improving their health and not involved in a research. An important ethical conversation that continues to evolve is the relationship between medical treatment and medical research, and the overlap that exists in certain instances.
In 1928, the German journal *Ethik* began publishing a series of essays on the ethics of human subjects research. The authors exchanged ideas and methods for conducting research on human beings in a way that minimized harm.\(^8\) One physician stated, “experiments by which patients may be harmed, however, I consider to be completely inadmissible and have never tolerated them in my clinic.”\(^9\) This counter-argument considered the potential of limiting scientific progress. Another commentator posited, “No law and no supervision, no matter how strict will prevent ‘human experiment’…”\(^10\) At least in practice, it seemed that harming one’s patients, who were often research subjects, was out of the question for some but common practice for others. Further commentaries in the issues of the late 1920s raised topics of vulnerable subjects, with a particular emphasis on children and the physician’s obligation to “do no harm.”\(^11\) It was particularly the harm brought to children that forced the issue, resulting in publishing guidelines for research by the Reich Minister of the Interior.

In 1931, the Reich Interior Minister issued guidelines on “medical experiments” intended to curb abuses in human subjects research stemming from a failed experiment involving research on children. These guidelines were issued partly in response to a 1930 experiment that resulted in the death of 75 children in Lubeck, Germany. The Lubeck study focused on developing a vaccine for children against tuberculosis.\(^12\)

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\(^9\) Ibid., 139.

\(^10\) Ibid., 140.

\(^11\) Ibid., 141.

\(^12\) Ibid., 142-43; Grodin, *Historical Origins of the Nuremberg Code*, 129.
name of the guidelines, attempted to balance the public’s interest in research for developing a vaccine for TB or syphilis with the protection of the rights of the research subjects. In both instances, it was the rights of the subjects that rightly gained legal protection. While there was support for experimentation to discover cures and improve patient care, this research required consent from a patient capable of considering the risks and understanding the process of the experimentation. Informed consent, the distinction between therapeutic and non-therapeutic research, and research on vulnerable groups, all proved foundational to the development of the Nuremberg Code.

The Trial

The Nuremberg Trial resulted in the prosecution of 23 Nazi physician defendants charged with human rights violations that, in part, stemmed from scientific experimentation on human subjects. Some of these experiments had a therapeutic purpose and focused on diseases like malaria, tuberculosis, and typhoid. Other experiments, however, reproduced and then attempted to treat the ill-effects that soldiers suffered in the midst of war: high altitude, extreme cold, pressure change, poisoning, and a variety of war wounds. The legal defense argued that during times of war survival was dependent on the knowledge acquired during these experiments and “extreme circumstances demand extreme action.” The experiments, they argued, were further justified by the fact that the research subjects were already prisoners. They considered research on this population to be an acceptable practice.

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14 Ibid. While the Nazis ignored most of these guidelines, they did outlaw cruelty to animals. Grodin noted, “if this law for the protection of animals were seen as including human beings as a type of animal, most, if not, all Nazi human experimentation would also have been outlawed.” Nevertheless, the Nazi’s utter disregard of the key ethical and legal parameters of the Prussian Code and the Reich Circular played an essential role for the prosecution at the Nuremberg Trial.

15 Ibid., 132.
because even prisoners had an obligation to contribute to the war effort. They insisted, moreover, that no legal or ethical code had been established to guide research and that the Nessier case and Reich Circular proved ambiguous in the midst of war. The defense challenged that legal precedent had been established, and the gravity of the experiments proved too much to ignore. Two of the cases cited by the prosecution highlighted the Nazi perspective on therapeutic research, one on infectious disease and the other on treating war wounds.

In his opening statement, U.S. prosecutor Telford Taylor described two experiments that attempted to test vaccines and treatments to be used for Nazi soldiers. The first experiments lasted between February 1942 and April 1945, in which over 1200 involuntary research subjects were given malaria and treated with various drugs to test its efficacy. Dr. Klaus Schilling led these experiments, which led to countless deaths. The second set of experiments took place at Sachsenhausen and Natzweiler concentration camps. Grawitz and Himmler, two of the physicians on trial, described the need to inject humans with germs and diseases from animals—not the reverse. Brandt, another of the physicians on trial, stated, “In order to enlarge our knowledge, so far based only on inoculation of animals with germs taken from humans it would be necessary to reverse the procedure and inoculate human beings with germs cultivated in animals. Casualties must be anticipated.” This statement was reflective of the guidelines instituted by Hitler that placed restrictions on research

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16 Ibid.
prohibiting cruelty to animals. However, these provisions did not extend to human beings.\(^\text{19}\).

Taylor and his team, which included two U.S. physicians Leo Alexander and Andrew Ivy, outlined the known history of research ethics in the prosecution of the defendants. Alexander and Ivy, who played a significant role in the development of the American Medical Association’s (AMA) code of ethics, both presented research guidelines compiled from key thinkers in medicine and medical ethics. They drew upon the thought of Hippocrates—though he never references research explicitly—Thomas Percival (1740-1804), William Beaumont (1785-1853), and Claude Bernard (1813-1878). Each of these thinkers established the ethical necessity of receiving consent from patients and ensuring that no harm was done. Beaumont noted the importance of securing consent from patients, emphasizing that experiments should be discontinued if any stress was brought about for the research subject.\(^\text{20}\) His French colleague, Claude Bernard, also cautioned that scientific advancement should not be placed ahead of the benefit of the patient or research subject.\(^\text{21}\) However, when a benefit could be derived for the patient, Bernard felt that physicians had a duty and right to perform an experiment in order to save a life, cure, or positively impact a

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\(^{19}\) Hazelgrove, “The Old Faith and the New Science,” 110. Prior to the trial, the U.S. prosecutors gathered a group of international representatives at the Pasteur Institute in July 1946 to discuss the medical experiments for which the Nazi doctors were being prosecuted. At the table were representatives from the U.S., Britain, and France, all of whom together formed the first International Scientific Committee to collectively examine informed consent. While the lack of consent was the least egregious ethical violation, legally it proved an important precedent. Lack of consent, doing harm to one’s patients, and killing in the name of science provided some of the key items that prosecutor Telford Taylor focused on at the Nuremberg Trial, but these items resulted from conversations at the Pasteur Institute.


\(^{21}\) Anderson, “Public Participation in Human Research,” 7-8.
patient’s health. More broadly, Thomas Percival, in his book *Medical Ethics*, argued that while research itself was rooted in the public good, all research should be undertaken only after extensive conversation with other colleagues regarding the nature of the case and potential benefits and burdens that could come about from its undertaking. Thus, the prosecution’s use of Percival, Bernard, and Beaumont highlighted three important aspects of medical research that emphasized the tension between individual rights and obligations and the social dynamic of research.

Ivy and Alexander’s articulation of the ethical norms for research emphasized: 1) the rights of research subjects and patients; 2) the responsibility of the researcher to do no harm; and 3) the social nature of research, which included a consultative process to weigh the benefits and burdens of research beyond its impact on the subject. Ivy’s understanding of research ethics appeared in the Journal of the American Medical Association (JAMA), while Alexander submitted his argument as a memorandum to the United States Chief of Council for War Crimes. Their essays not only provided information on the Nuremberg Trial to those in the U.S., but also described the framework for the ethical conduct of research to the medical and legal community.

In drawing together this diversity of thinkers, Alexander and Ivy established key components of research ethics, including: informed consent; the necessity of balancing the burden or risk of research against its potential benefit for the patient; the importance of research that promotes the common good—or as Alexander referenced it, “humanitarian

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24 Grodin, “Historical Origins of the Nuremberg Code,” 134. Grodin notes that there is some dispute as to who is the primary author of the ten points of the Nuremberg Code. Regardless, Ivy and Alexander both played fundamental roles in its writing.
benefit”—and the importance of dialogue about the experiments that cite the common good as a rationale for its pursuit. Their guidelines, coupled with those issued by the Reich Interior Ministry in 1931, and the Prussian code of 1900, supplied the prosecution with ample evidence that the Nazi experiments were outside the boundaries of established legal and ethical norms for research. However, the Nuremberg Code, while incorporating many of these norms when it was issued, failed to initiate a broad impact on the practice of medical research.

Impact of the Nuremberg Code (1949)

When the dust had finally settled on the Nuremberg trial, the testimony of 85 witnesses had been heard, resulting in 11,538 pages of transcript that laid groundwork for the ethical and legal parameters for human subjects research. Though the trial was about far more than research ethics, the arguments of the prosecution at the trial established a normative foundation for research ethics. The code itself incorporated much of Ivy and Alexander’s testimony, including the importance of informed consent, researcher responsibility, balancing of risks and benefits, and establishing human benefit as a standard for ethical research. However, the atrocities of the experiments made it difficult for other researchers to relate to the ethical violations of the Nazi doctors. In many instances the code simply could not break free from the context in which it developed.

Few researchers, even those who were also violating the rights of their research subjects as described in the Code, saw their experiments as unethical or illegal because of its relationship to the Shoah. In many ways, the single most important takeaway that researchers considered following the Nuremberg Code was informed consent, which was

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25 Pappworth and Beecher, whose works are described below, serve as important reminders that while the research conducted by other may not have been as illegal or unethical as the Nazi research, unethical and/or illegal research was still ongoing after Nuremberg.
only the first point of the code and, given the other violations of human rights, was the least obvious grievance against the Nazis. While informed consent was, and is, crucial to ethical research practices, the document emphasized equally that research ought to offer a benefit to humanity and, when possible, to the research subject directly. The socio-ethical considerations within the code have become somewhat muted over time, though they prove fundamental to the legacy of the document and essential to the function of research ethics overall.  

Beyond informed consent, the first point of the code, the remaining nine focus on the tension between the individual responsibilities and rights within the research process and the social aim of research itself. Thus, the second and third directives underscore that research should anticipate its potential to “yield fruitful results for the good of society.” The

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26 “The Nuremberg Code.” Health and Human Services, http://www.hhs.gov/ohrp/archive/nurcode.html (accessed May 25, 2014). 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility, which may not be delegated to another with impunity. 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature. 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment. 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury. 5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects. 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death. 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment. 9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible. 10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.
onus for this responsibility does not fall exclusively on the researcher, but extends to the research community as a whole. This is a crucial point in the Nuremberg Code that becomes lost over time, but is worth reconsidering.

Nuremberg’s lasting norm for the ethical conduct of research rested on ensuring the protection of the research subject. However, Nuremberg also suggests that the research community as a whole should affirm whether a research experiment has public value. It is the responsibility of the research community to ensure that research stands to benefit the society; presumably this protection extends to the majority of human beings suffering from poor health conditions. However, institutional policies, not just international guidelines, need to reinforce this notion.27 Ultimately, the historical context from which Nuremberg developed limited its reception, but failures to adopt the Nuremberg code as a political and institutional standard undercut its potential reception, as well. Given the limitedness of its reception and the continuance of unethical research practices, the Nuremberg Code gave way to other ethical guidelines to guide research.

**The Declaration of Helsinki**

**Preparing the Declaration**

Between 1949-1952, the WMA established a permanent committee on medical ethics that concerned itself with violation of human rights within the medical community. After Nuremberg and the United Nations (UN) Declaration of Human Rights in 1948, there was an emphasis placed on the importance of protecting rights globally. Though the rights of research subjects were never explicitly included in the UN Declaration, the WMA saw these

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27 In Chapter Four and Five, I will give examples of how universities in particular have failed to do this for the majority of human beings who are most susceptible to poor health conditions.
topics intimately connected. After several years of conversations at the WMA, which first convened in 1946, formal discussions of guidelines for research ethics began.\textsuperscript{28}

In 1953, the ethical questions that arose about the use of human subjects in research generated dialogue both within the WMA and the ethics committees of its member nations. Among the member nation delegates was Paul Cibrie of France. Cibrie served as the chair of the WMA’s medical ethics committee responsible for leading the inquiry around human subjects research.\textsuperscript{29} By 1954, Cibrie’s committee developed a formal document, largely reflective of his previous work in France, that highlighted important distinctions between research conducted on healthy subjects versus research conducted on sick subjects.

Beginning in France and continuing through his work at the WMA, Cibrie concluded that physicians had both a right and duty to conduct experiments on human subjects, but only if they were informed volunteers who capable of accepting or rejecting interventions.\textsuperscript{30} While the Nuremberg Code generally emphasized the necessity of fully informed consent—raising questions about research on children, mentally disabled, and the imprisoned—the WMA committee nuanced these parameters to include provisions for parents and guardians to consent when the subject was unable.

The 1954 document stated that individuals should understand the nature of the experiment, the rationale behind it, and the risk posed to the research subject. In the event that the patient or subject were unable to make an informed decision “consent should be


\textsuperscript{30} Ibid, 202.
obtained from the individual who is legally responsible for the individual.”31 Additionally, questions concerned whether sick persons in need of treatment could offer consent, particularly when the therapeutic benefit was unknown. In many ways, the working documents of the WMA between 1954 and 1959 focused on identifying particular groups of persons for whom consenting to participate in a research study might be either compromised or impossible. In part, these efforts reinforced the focus on informed consent within the research community. Yet, the work on “compromised” subjects, led to the identification of research subject populations that could be taken advantage of more easily.

In 1959, Hugh Clegg assumed the responsibilities of the WMA’s ethics committee and began building on Cibrie’s 1954 document by identifying groups whose ability to consent voluntarily was in question. The first group Clegg considered were medical students. Medical students were frequently used to study the side effects of the medication. The second focused on research with already sick persons regarding the possibility of using preventive inoculations on certain persons, while having an uninoculated control group which would remain untreated. The third group focused on research involving hospital patients and their ability to distinguish between research and clinical treatment. The fourth focused on those participating in controlled therapeutic trials of a new drug, while the fifth took into account the use of prisoners or the institutionalized in controlled prophylactic or therapeutic trials.32 The identification of these groups signaled the importance of considering ethical issues beyond those pertaining to the researcher and research subject.


32 Lederer, Research without Borders, 205
In September of 1960, after considerable debate about how to address the issues of these populations, Clegg and the committee considered simply adopting the Nuremberg Code as the standard guide for research. However, the group “found it necessary to draft a code which could serve at least as a guide to doctors working in different conditions and in different countries.”\(^{33}\) The working group demonstrated concern not only about the vulnerability of particular groups, but also enabled successful implementation of realistic guidelines for physician researchers in diverse working contexts. Given the reality that many physician-researchers ignored the ethical guidelines of Nuremberg, the WMA’s attempt to re-contextualize ethical guidelines for research proved important, and so they circulated a draft for discussion in 1962.\(^{34}\)

The publication of the 1962 “Draft Code of Ethics on Human Experimentation” in the British Medical Journal allowed for peers to review the document that had been devised after years of conversation. The document was divided into three sub-headings: General Principles and Definitions, Experiments for the Benefit of the Patient, and Experiments Conducted Solely for the Acquisition of Knowledge. This working document essentially summarized the efforts of Clegg’s and Cibrie’s committees by detailing the practice of informed consent and identifying groups whose ability to consent voluntarily could be compromised. While the first section defined an experiment as “an act whereby the investigator deliberately changes the internal or external environment in order to observe the effects of such a change;” the second point clarified the conditions under which an

\(^{33}\) Ibid., 206.

experiment could take place.\textsuperscript{35} Here one saw the efforts of the WMA to re-contextualize the guidelines for research ethics and informed consent outside of Nuremberg’s shadow.

In order for a research study to begin, the risks had to be explained in order to obtain consent from the research subject or his/her proxy. Research subjects had to demonstrate that they understood they could withdraw from the study at any time and that the researcher conducting the experiment was qualified.\textsuperscript{36} The latter two sections on the Helsinki draft of 1962, focused on clarifying the ethical standards of research when applied to the immediate benefit of persons versus research undertaken with the primary objective of furthering scientific or medical knowledge.

In the case of experimentation for the direct benefit of a patient, it was important to maintain the patient’s trust and have completed sufficient tests in a laboratory or on animals prior to human experimentation. However, “the doctor should be free to perform an experiment for the first time if in his judgment it offers the only hope of saving or alleviating pain and suffering” but only after consent had been obtained.\textsuperscript{37} If the research would not be of direct benefit to patients on whom the research was being conducted, then extra caution should be utilized to ensure that the subject had the “mental, physical, and legal state as to be able to exercise fully his power of choice.”\textsuperscript{38} Here, the discussions of Clegg and his committee proved of particular importance for those who have a limited ability to consent.

In many ways, this section affirmed the Nuremberg Code’s inclusion of restrictions involving prisoners of war or civilians detained because of a military invasions or political

\textsuperscript{35} Ibid.

\textsuperscript{36} Ibid.

\textsuperscript{37} “Draft Code of Ethics on Human Experimentation,” 1119.

\textsuperscript{38} Ibid.
reasons, but Helsinki re-framed the guideline in an effort to distance from Nuremberg and extended protections to other vulnerable groups.

The Declaration of Helsinki (1964)

The 1964 Declaration of Helsinki on the ethics of human experimentation matured from its 1962 draft into a more linguistically precise document that the WMA adopted at its eighteenth meeting. While the document maintained the three-fold structure of the previous draft, a key change shifted the language of “experimentation” to the term “clinical research.” The use of clinical research again signaled a move away from the use of “experimentation” in the Nuremberg Code, and represented another effort to establish itself as a distinct document that took a more medical and research focus than its precursor.\(^39\) The document explicitly referenced its own International Code of Medical Ethics, which aligned itself specifically with all doctors involved in clinical research.\(^40\) Helsinki emphasized both the researcher’s obligation to uphold the right to health and well-being and the rights of the research subject’s to informed consent.

The Declaration’s three sections reflected the themes of informed consent by distinguishing between consent for therapeutic and non-therapeutic clinical research. Though these themes had been reflected in the 1962 draft, the language became more precise in the official declaration. Therapeutic research was defined as caring for a sick patient “if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering.”\(^41\) This can be contrasted with the purpose of non-therapeutic research, which enhanced the understanding of scientific knowledge as its true aim. In this case, the research

\(^{39}\) Lederer, Research without Borders, 203-210; Ashcroft, The Declaration of Helsinki, 143.


\(^{41}\) Ibid.
subject does not stand to benefit from the investigation directly. In both instances, however, the doctor continued to have the obligation to “remain the protector of life and health of that person on whom clinical research is being carried out.” This obligation extended to research subjects with a limited ability to consent directly to participating in a study. The idea of consent being granted from a person other than the research subject represented an important development, but one that placed additional responsibilities and formalities for the researchers to address.

Constructed by physicians and, at the time, for physician-researchers, the document was framed from the outset with the intention of guiding responsible research. Thus, the “Basic Principles” focused specifically on the obligations that the researcher undertook. The research must be rooted in standard moral and scientific practices and established fact. The researcher should be qualified to conduct the scientific study and it should be carried out “in proportion to the inherent risk to the subject.” The burden to assess the risk, and benefit in therapeutic research, was placed squarely on the physician. This was particularly true when the “personality of the subject...is to be altered by drugs or experimental procedure.” While consideration of whether to participate or not rested with the decision-making capacity of an individual or her surrogate, the primary onus placed on the researcher was deciding whether a research project ought to be pursued or not. One of the critiques, though lasting influences of the document was its emphasis on the responsibility of the researcher to lead experiments rooted in the promotion of health and well-being. While Declaration of Helsinki has seen several revisions, its connection with the promotion of health and well-being has remained a

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42 Ibid.


44 Ibid., I.5, 1964.
constant. Subsequent revisions, however, continue to revisit new challenges in the ethical conduct of research that have influenced the way in which countries, as well as international organizations, have articulated their own guidelines for research.

Helsinki’s Impact

Since its original pinning, the Declaration of Helsinki has undergone seven revisions of varying degrees, as well as issuing two notes of clarification in 2002 and 2004. The latest revision took place in October 2013 at the 64th General Assembly of the WMA held in Brazil, while the first revision occurred at the WMA’s meeting in Tokyo in 1975. The consistent revisions of the document continue to address ongoing developments within the landscape of research ethics. The constant updates signals the importance of creating a document that reflects the context in which research and research ethics is practiced.

The 1975 Tokyo revision emphasizes the context by further developing the protection of research subjects by arguing that their interest should always prevail over those of science and society. In an effort to institutionalize this practice, this revision centered on the necessity of forming committees to review of research studies by an institutional review board (IRB) or research ethics committees. By emphasizing the importance of IRBs, the 1975 revision pointed to the importance of institutional practices focused on maintaining responsible research. Through local control of research initiatives IRBs can identify more easily potentially vulnerable research subjects and questionable research practices on the local level.

A second impact of the Helsinki revision came from Edinburgh in 2000. The protection of research participants continued to be a primary focus of the document. In this version, these protections were tied explicitly to the health and human rights, which

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45 Ashcroft, *The Declaration of Helsinki*, 144.
represented new language for the document itself and more explicitly acknowledging the
origins in the internationalization of human rights following World War II. The 2000
revision included the importance of recognizing the economic status of particular groups as
a potential source of a research subject’s vulnerability. A group that became a central focus
in this document, were vulnerable research populations that reflected concerns for those
suffering from HIV/AIDS. It stated, “research risks are justified only ‘if there is a reasonable
likelihood that the populations in which the research is carried out stand to benefit from the
results of the research.’”\(^\text{46}\) These particular concerns are specifically addressed in paragraph
30, and recommended against the use of placebo control trials in vulnerable populations,
which are standard in the development phase of a new drug.\(^\text{47}\) This proved to be one of the
more controversial revisions, and one that caused the U.S. to drop references to Helsinki
beyond its 1989 revision.\(^\text{48}\) The guidance on the use of placebo-controlled trials was
reiterated in the latest revision, 2013, and included that extra consideration should given to
ensure that vulnerable groups receive a “fair level of additional benefits.”

A final impact generated from the Helsinki declaration has been the international
influence of the document itself. The importance of Helsinki can best be attributed to the
emphasis placed on the development of guidelines that address the changing reality in which
research is conducted. The Declaration contributed greatly to the development of other
international documents produced by the World Health Organization (WHO), Council for


\(^\text{47}\) Placebo trials are used in two instances. The first, and accommodated for in the Declaration, is the use of a
placebo when no proven standard of treatment exists. Thus, for disease x there may exist a treatment that has
not been widely accepted as a best intervention. In this case a placebo drug may be used as the standard of
comparison with a new treatment being researched. However, when a particular treatment has been accepted as
the best standard the control group ought to be studied using the best proven treatment at that time, rather
than a placebo in order to study the effectiveness of a new treatment.

the International Organizations of Medical Sciences (CIOMS), and also countries that have established their own ethical standards for research.

A representative, though not exhaustive, list of countries that have referenced the Declaration in developing their national standards for research includes: Australia, Belgium, Brazil, China, Germany, India, Israel, Japan, New Zealand, Norway, Switzerland, Uganda, United Kingdom, United States, and South Africa. In addition to its influence on national policies, the Declaration continued to make contributions to the development of standards within research and particularly the research ethics focused on lower income countries. The focus of the CIOMS/WHO guidelines draw on Helsinki to describe:

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.

The introduction to the CIOMS guidelines explicitly referenced Helsinki and further contextualized the document’s concerns about research conducted in low and lower-middle income countries. The further revisions of both Helsinki and the CIOMS guidelines, in many ways, have led to increased efforts within the area of global bioethics—considered in the final section of this chapter—that promotes the ethical conduct of research in a way that more justly considers the needs of the communities in which it works.

Helsinki has proven important in constructing ethical research guidelines that take seriously the social context and impact of research can have on health and well-being of both persons and communities. The initial document and subsequent revisions draw

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attention to the reality of vulnerable persons and populations due to disease and socio-economic factors. While the document has been well received in most parts of the world, it has seen limited reception in the United States, appearing neither in the Common Rule nor the Food and Drug Administration’s guidelines for research since its elimination in after 1989. Despite its omission from the FDA guidelines, Helsinki provides an important reference point for the discussions regarding the ethical conduct of research and the protection of human subjects when they began in the U.S. through the work of the National Commission for the Protection of Human Subjects (National Commission).

The Belmont Report

Concerns Before the Report

The circumstances that led to the creation of the National Commission, and the subsequent Belmont Report, stemmed from developments in the U.S. that brought attention to unethical and/or illegal research practices following the increased funding of research between World War I and II. As shown in Chapter One, the period surrounding the World Wars led to necessary innovations in medical research that continued after the the Second World War. In the years following the Wars, research funding from the U.S. National Institute for Health (NIH) increased from $700,000 in 1945 to over $36 million by 1955. Within 20 years, funding had increased to an astonishing $436 million dollars that resulted in 11,000 grant awards, one-third of which required experiments to be conducted on human beings.51 Included in this study were some of the catalysts for the ethical reform of research brought about by the National Commission, Willowbrook, Tuskegee, and a lesser known

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51 Rothman, Strangers at the Bedside, 53-54; Henry K. Beecher, “Ethics and Clinical Research,” New England Journal of Medicine 274, no. 24 (1966), 36. In five years, the funding would cross the one billion dollar mark. Chapter Four (p.149) will revisit the increased funding for research and describe the confluence of factors between the U.S. government, Academia, and the Pharmaceutical Industries that contributed to the “golden age” of research.
syphilis study conducted over several years in Guatemala. Given increasing concern about the responsible conduct of research internationally and the growth in research domestically, James Shannon, who directed the NIH and worked closely with Dr. Freis during his VA anti-hypertensive studies, sought to implement changes to ensure the ethical conduct of research.

In 1964, Shannon formed a committee through the NIH Division of Research Facilities and Resources to review ethical issues in human experimentation. In developing their guidelines, the committee drew from the Livingston Report that critiqued the guidelines of Helsinki and Nuremberg because they placed too much responsibility on the researcher. Shannon’s NIH group, taking into consideration the previous critiques, proposed that research protocols should be reviewed by outside committees so as to alleviate some of the burden placed on researchers. Of secondary importance, however, was the self-interest of the NIH, which did not want to assume responsibility for potentially inhibiting the development of future research.

While Willowbrook and Tuskegee, both of which are discussed below (p. 75), the Guatemala research study has only come to light in the past few years. The Guatemala study drew from children, prisoners, soldiers, and sex workers as their research subjects. The research team attempted to infect prisoners and soldiers without syphilis by using sex workers. This was because it was known that the disease was not easily injected into research subjects, from the Terre Haute, IN prisoner study, described in the opening section of the President’s Commission for Bioethics Report. While the report details the history—Charlene Galarneau, “‘Ever Vigilant’ in ‘Ethically Impossible’: Structural Injustice and Responsibility in PHS Research in Guatemala,” Hastings Center Report 43, no. 3 (2013): 36-45—points to the socio-political dimension to this study that built on U.S. Guatemala relations, deliberately targeted vulnerable populations, and involved Guatemalan physicians who had worked with members of the U.S. research team as collaborators for this projects. In short, the Guatemala experiment, along with Tuskegee and Willowbrook, point to the complexity of the practice of medical research. Unethical research does not just take place at the hands of researchers, but necessarily involves other institutions willing to support a particular research undertaking. Presidential Commission for the Study of Bioethical Issues, “‘Ethically Impossible’: STD Research in Guatemala from 1946 to 1948,” Washington, D.C.: Presidents Commission for the Study of Bioethical Issues (2011), http://bioethics.gov/sites/default/files/Ethically-Impossible_PCSBI.pdf, (accessed: May 1, 2015).

The group arrived at the decision to empower local ethics committees to oversee and approve institutional research initiatives to more evenly distribute the responsibility and commitment to ethical research to a wider group. These local ethics committees charged with evaluating research were referred to as Institutional Review Boards (IRB), instituting a practice called for in the 1975 revision of the Helsinki Declaration. The utilization of IRBs could not have been better timed given the concurrent release of two exposés of unethical and/or illegal research practices in the U.K. and U.S.

Maurice Pappworth and Henry Beecher raised important issues surrounding the nature of research ethics and the need to protect the rights of research subjects by calling attention to unethical and/or illegal research in the U.S. and U.K. Pappworth, from the U.K., highlighted these questionable studies in both a 1962 essay and 1967 book. Beecher, a U.S. physician, exposed his concerns about ethically questionable research in a 1966 essay published in the *New England Journal of Medicine*. While Beecher has frequently received more credit for his essay, Pappworth’s efforts should not be overlooked.

Both Pappworth and Beecher highlighted unethical research that targeted vulnerable populations, failed to obtain informed consent, and engaged in practices that not only

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56 Allan Gaw, “Exposing Unethical Human Research: The Transatlantic Correspondence of Beecher and Pappworth.” *Annals Intern Medicine* 156, no. 2 (2012): 150-155. This recent article points the dialogue that developed, and dissolved, between Beecher and Pappworth. Their obvious common concern for research ethics led to correspondence between the two. However, both took different positions with how the research should both be exposed and corrective measures. Pappworth was of the opinion that the research projects and researchers should be made public. Beecher, however, perhaps being considered more of an insider when it came to research had higher hopes of his research colleagues. In their correspondence Beecher thought that simply raising the awareness of the ethical issues surrounded these projects would be sufficient to curbing their practices. When Pappworth continually pushed and challenged Beecher on these issues, Beecher seemed to be the one to discontinue the dialogue. Though Pappworth’s work came first, Beecher’s became the more often cited source.
offered no benefit, but deliberately brought harm to patients. In a 1990 retrospective, Pappworth described one study in which 43 diabetic patients were induced into a diabetic coma by having their insulin deliberately withheld. Once in the coma, the researchers biopsied liver and kidney samples in order to better observe the effects of the coma on these organs.\(^\text{57}\) In his *New England Journal of Medicine* piece, Beecher’s 22 post-war research studies drew attention to unethical research practices out of concern that “bad ethics would undercut the pursuit of good science, and the result would be widespread ignorance and old-fashioned quackery.”\(^\text{58}\) Though Beecher recognized the complexity of research and that properly obtaining informed consent was laden with difficulties, he found it imperative to the practice of research. One of the more infamous studies that both Beecher and Pappworth included in their retrospectives was the Willowbrook Study.

Willowbrook was an intuition for mentally handicap children in Staten Island, NY where Saul Krugman led a study trying to understand and mitigate a strand of hepatitis that chronically affected the health of the residents. Beecher described the experiment, which began in the mid-1950s, as a “study directed toward determining the period of infectivity of infectious hepatitis…carried out in an institution for mentally defective children in which a mild form of hepatitis was endemic.”\(^\text{59}\) At the time, Krugman estimated that 40-50 patients per every 1000 would contract the disease annually. By injecting them with a mild form of the disease, Krugman hoped that the residents would develop a resistance to more potent hepatitis strains. The residents were unable to consent as minors, but also because of their diminished cognitive function that made them unable to understand the risks or benefits of

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\(^{57}\) Pappworth, “Human Guinea Pigs,” 1456.

\(^{58}\) Rothman, *Strangers at the Bedside*, 71.

\(^{59}\) Beecher, *Ethics and Clinical Research*, 371
the study. In keeping up with the norms of proxy consent, however, Krugman did acquire consent from the children’s parents or guardians, the caveat being that parents were under the impression that the school would close if the hepatitis problem was not controlled. Pappworth argued that this constituted a form of coercion because parents thought that participation could help them keep the school open.

A second concern raised by Beecher and Pappworth focused on the deliberate infection of individuals without therapeutic or prophylactic indications. Beecher charged, “There is no right to risk an injury to one person for the benefit of others.” Pappworth likewise argued that therapeutic benefit should be a prerequisite for any research done with children. Moreover, both men raised the objection that these children appeared to be targets for questionable research because they were vulnerable and “devalued” members of society. In other words, this type of experiment would not have been able to be conducted on other non-institutionalized children or children of more advanced cognition. The fact that this research targeted marginalized members of society has led some to refer to Willowbrook as the “Pediatric Tuskegee.”

“The Tuskegee Study of Untreated Syphilis in the Negro Male,” came to be the example of unethical research practices in the U.S. The study targeted a marginalized population, lacked any therapeutic benefit, and never informed the research subjects that

60 Ibid.


they were participating in a study. The study itself, however, was very clear in its aim. The study would focus on black males with syphilis and observe, without intervention, the natural progression of syphilis if left untreated.

The study began in 1932, and received repeated approval by the Alabama Health Department. At that time, no cure existed for syphilis, though there were varying treatment options. None of these options were extended to those used in the study.\(^\text{64}\) By 1945, penicillin had emerged as an effective treatment for patients with syphilis, but these research subjects were barred from receiving the treatment or seeking medical attention outside of the medical exams provided as participants in the study.\(^\text{65}\) From 1945 until the conclusion of the study in 1972—predicted originally to last only six months to a year—patients continued to suffer from painful procedures and the ill-effects of the disease while a medical treatment existed.\(^\text{66}\)

In that time over 399 African-American men with syphilis were enrolled unknowingly in the study aimed at understanding the effects of the disease on black males. However, none of these men consented to participate in an “experiment.” Rather, they believed they were receiving treatment for “bad blood.”\(^\text{67}\) In addition to the 399 men with syphilis, an additional 201 men without syphilis were also recruited to serve as a control group. It has been estimated that 100 men died as a direct result from the study. However,


\(^\text{66}\) Anderson, “Public Participation in Human Research,” 34.

\(^\text{67}\) Harriet A. Washington, *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present* (New York: Doubleday, 2006), 162. The men were told that they suffered from “bad blood.” Washington notes that bad blood referred to a host of symptoms “anemic blood to muscle aches, general malaise, disorders such as parasitic infections, gonorrhea, syphilis and other venereal disease.”
once the study was brought to light—though not by Beecher or Pappworth, but rather by a story by Jena Heller from the Associated Press—a special commission led by Edward Kennedy closed the study. Kennedy then began pushing for national reforms for the conduct of research. In 1974, the National Commission was established, beginning a national conversation about the ethics of research that resulted in the development of the Belmont Report.

The Belmont Report (1978)

The National Commission first convened in December of 1974 and concluded with its 43rd meeting on September 8, 1978. The task of the Commission was to develop guidelines for the ethical conduct of research involving human beings. In 1976, the commission requested several leading scholars to contribute essays in philosophy and ethics to be incorporated as a part of the ongoing conversation for constructing guiding principles of research.68 Two essayists prominently influenced the position of the Commission on the ethics of research, though neither were a part of the commission initially.

The essay by H. Tristam Engelhardt, a physician and philosopher, crystalized the aims of the commission by distilling the ethics of research into translatable principles that explored the breadth of research practices into a coherent and accessible format. He described his principles as: “respect for persons as free moral agents, concern to support the best interests of human subjects in research, intent to assure that the use of human subjects of experimentation will on the sum redound to benefit society.”69 Engelhardt points, like


many of the other documents before, distilled the ethics of research into goals of protecting research subjects in pursuing only research that would benefit society. What the commission found lacking in Engelhardt’s essay, however, was an articulation of the role justice played in research ethics.

Thomas Beauchamp—who was not a member of the national commission, but eventually wrote the Belmont Report—penned an essay, “Distributive Justice and Morally Relevant Differences,” highlighting not only the importance of justice in establishing ethically appropriate volunteers for research, but also for determining whom should benefit from the fruits of research itself. Beauchamp’s essay was the only essay the Commission considered that referenced justice as related to the importance of selecting research subjects. Though not explicitly expressed, the just-selection of subjects was rooted in a concern for vulnerable research subjects. Secondly, a particular nuance of his essay—ultimately lost in the practical application of the Commission’s report—emphasized distributive justice. With the focus on distributing the fruits of research as an explicit goal of the commission, research ethics took on a social dimension that proved important for the structure of the document itself, even if limited in the document’s reception.

The National Commission’s Belmont Report settled on three principles as the bedrock of ethical research: respect for persons, beneficence, and justice.\textsuperscript{70} Though the report itself did not mandate specific regulatory recommendations, it did advise that the overall construction and utilization of these three principles be adopted in their entirety as a guide for all research endeavors. The document was divided into three parts. Part A offered

important clarifications about the boundaries of medical practice and research, while parts B and C, which constituted the substance of the document, explained the principles and their application.

Given that the practice of medicine and medical research can and do occur together, it was often challenging for patients and research subjects to distinguish between the two. Thus, the commission offered a working definition of both medical practice and medical research. It defined practice as, “interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventative treatment or therapy to particular individuals.”71 In medical practice, the purpose was always to be focused on the health and well-being of a specific individual. Research, however, “designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge…is usually described in a form a protocol that sets forth an objective and a set of procedures designed to reach that objective.”72 In contrast to medical practice, medical research functioned more objectively, placing an emphasis on generalizable knowledge with the potential to benefit society. The remainder of the document focused on describing ways that the Belmont principles could guide the ethical practice of medical research.

The principles—respect for persons, beneficence, and justice—established an accessible way to articulate the ethical values at stake when conducting research. While the content and conversation surrounding the development of the principles was academically


72 Ibid.
robust, the descriptions incorporated into the document had to be intelligible and applicable to a wider audience. In an effort to achieve this, principles were broken up into two sections. The first, section (part B) defined the principles and part C discussed their application.

The first principle, “respect for persons,” found practical application in informed consent. Respect for persons articulated that autonomous choices were not to be overridden or disrespected, and “that persons who are not adequately autonomous be protected by the consent of an authorized third party likely to appreciate their circumstances and who will look after their best interest.” This principle also included the requirement that researchers ensure that the research participants have comprehended the information they had been given about the study. Here the burden of responsibility was placed on the researcher, which was particularly important with subjects who had diminished autonomy. The committee, moreover, wanted to ensure respect for persons and noted three possible applications: 1) ensuring that participants understood the information pertaining to their participation in the study; 2) that the individual knew their participation was voluntary and could withdraw at any time; and 3) that the subject comprehended the risks/benefits of the study. In the process of obtaining consent, the researcher had to take into account the well being of the research subjects, which formed the bedrock of the second principle, beneficence.

The Hippocratic ideal of “do not harm” provided the minimal aim of the principle of beneficence. The importance here was that the possible benefits were to be maximized

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74 Thomas Beauchamp and James Childress, Principles of Biomedical Ethics, 6th ed. (New York & Oxford: Oxford University Press, 2009). It is important here to distinguish the work of Beauchamp and Childress from the efforts of the National Commission. Though both adopted a principles-based approach, Beauchamp and Childress were already into the drafting of their own influential principle-based document Principles for Biomedical
while minimizing harm.\textsuperscript{75} Furthermore, these risks and benefits were to be systematically, not arbitrarily, presented to the individual and also considered by an IRB. In this way, beneficence extended beyond the responsibility of individual investigators to their subjects and more broadly to representatives of the community—local, institutional, and scientific. The Belmont Report empowered IRB committees to weigh the benefit and risk that a proposed study posed to society at large. They were “obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.”\textsuperscript{76} The intent of the principle of beneficence was to take into account the need for application of the principle within the social context of research in which both individual participants and potential beneficiaries are affected. It was the final principle of justice that sought to balance more deeply the effects of research and its impact on society.

The principle of justice focused on both the selection of research subjects and the distribution of post-research results by more broadly considering those who ought to receive benefits of research versus those forced to bear its burden. The report required fair distribution of both burdens and benefits of research with special levels of protection for vulnerable and disadvantaged parties. Included in the principle of justice, developed from Beauchamp’s original essay, was concern over the competition that existed for benefits of research. This competition has only increased since the early 1980’s. While research continues to be heavily funded, it has been funded disproportionately for a small minority of

\textit{Ethics.} Beauchamp, in \textit{Belmont Revisited}, notes his disagreement with the way in which the principles were articulated in the Belmont Report, which in many ways differed from what Childress and he were up to in \textit{Principles}. On this point in particular, Beauchamp and Childress described the principle of non-maleficence as distinct from that of beneficence used in the report.

\textsuperscript{75} Beauchamp, “The Belmont Report,” 151.

the population’s health. Given the scarcity of certain benefits, it was, and continues to be, important to ensure that resources developed from research receive just-distribution. Reflecting on the description of the principle of justice in the document, Beauchamp described his concern as follows:

The over utilization of readily available, often compromised, segments of the U.S. population was a matter of deep moral concern to the National Commission. The theme of justice and proper selection of research participants was the Belmont Report’s way of saying that because medical research is a social enterprise for the public good, it must be accomplished in a broadly inclusive and participatory way.77

The social dynamic of research aimed at benefit of the public good demonstrates the principle’s emphasis on both the inclusivity of research, particularly concerning the benefits and burdens of research, but also the importance of public participation in shaping research as a social enterprise.

Belmont’s Impact

The Belmont Report established a framework for an expansive discussion of the ethics of research from both an individual and social perspective, which laid the foundation for the U.S. Common Rule. The U.S. Common Rule outlines the federal regulations that guide the conduct of research in the U.S. The clearest expression of the report’s enduring impact was its inclusion as the foundation for revisions to the 1981 Code of Federal Regulation 45 part 46 (45 CFR part 46), later known as the Common Rule. 45 CFR part 46 was originally published in 1974 as a part of the National Research Act, and was revised initially in 1981 and again in 1991. A third revision of the Common Rule began in 2013 in an effort to reflect the changes that have taken place in the conduct of research since 1991. Despite these revisions, the core of the document remains rooted in the initial principles of the Belmont Report.

The Common Rule places significant emphasis on instructive guidelines for the practice of IRBs and other departments within the federal government. 45 CFR part 46 is into four parts, subparts A-D. Subpart A, which is the part of the regulations referred to as the Common Rule, establishes necessary provisions in order to protect human subjects by providing key definitions and descriptions of the requirements for the composition and operation of an IRB. One key stipulation in subpart A contains important guidance regarding the conduct of research outside the U.S. In these instances, the Common Rule should be used unless stricter regulations existed in the country in which the research was being conducted. While subpart A defined the parameters of the regulation of research involving human subjects, subparts B, C, and, D detail additional regulations for the protection of vulnerable population. Subpart B concerns, pregnant women, human fetuses, and neonates, subpart C, prisoners, and subpart D, children. Noticeably absent from these descriptive guidelines however, is explicit reference to any of the Belmont principles. While legal regulations prove to be fundamental to the protection of human subjects in research, ensuring compliance with them waters down the robust personal and social implications for research ethics that were foundational to the Belmont Report. The National Commission’s conversations that resulted in 45 CFR part 46 focus on implementing a minimum standard for protecting the rights of research subjects lacks the fullness to which the Belmont principles aspired.

78 15 U.S. federal departments abide by the Common Rule. Included in this list are: the Departments of Agriculture, Energy, Commerce, Housing and Urban Development (HUD), Justice, Defense, Education, Veterans Affairs (VA), Health and Human Services (HHS), and Transportation, the National Aeronautics and Space Administration (NASA), Consumer Product Safety Commission, Agency for International Development (USAID), Environmental Protection Agency (EPA), and National Science Foundation. Additionally, though not articulated in the Common Rule regulations, the Central Intelligence Agency, Department of Homeland Security, and the Social Security Administration also are in compliance.
Lost in the application of the Belmont principles and their role in the formation of the Common Rule is the broader social considerations of research, foundational to the origins of the document. In a retrospective volume recounting the development of the Belmont Report, Karen Lebacqz criticizes the lack of the social dimension and the simple application of complex principles. Lebacqz, one of the original members of the National Commission, argues that the vagueness of the principles allows for reinterpretations that elude the depth of their original meanings. Of particular concern for her is the emphasis placed on respect for persons. “First, respect for persons became interpreted solely in the language of respect for autonomy. Second, autonomy itself became interpreted in restricted ways.” The principle shifts its focus to center on a person’s opinion and the need to respect their desire to refrain from pursuing, or deciding to pursue, certain choices and/or activities. A further contributing factor that influences the reception of Belmont are Beauchamp and Childress’s own distinct principle-based ethic.

In Tom Beauchamp and James Childress’s, *The Principles of Biomedical Ethics*, respect for autonomy serves as one of the foundational principles for bioethics. Though Beauchamp notes that the Belmont principles differ greatly from his and Childress’s approach, and emphasize equally the importance of beneficence and justice. Nevertheless, respect for persons has translated into autonomy and continues to rule the day. Lebacqz laments:

As respect for persons is reduced to autonomy and autonomy to self-determination or freedom of choice, the logical outcome is that the broad ranging principle of respect for persons is then truncated into the rule of ‘informed consent.’ The only question we ask is whether one consented to medical interventions or use of technologies. Any question as to whether such interventions or technologies are right

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The social dynamic of the human person and the Belmont principles can become lost. Moreover, when the principles themselves are reduced, as Yesley surmises, to informed consent, weighing of individual risk/benefit, and the selection of research subjects, the scientific endeavor itself loses its social context. Yet, it is precisely the social context from which illegal and unethical violations of the rights of human subjects arose, not only in the U.S., but globally.

In an application of the Belmont principles, it is worth considering the broader social contexts that bear on the way in which the regulatory efforts are applied. While broader applications, and in some instances expansion, of the principles have begun in newer areas of bioethical inquiry, such as global bioethics, a broader framework capable of keeping the focus on the social dimension of research in tension with the regulatory protections of individual human rights research proves crucial. Global bioethics is an area of ethical inquiry that has developed over the last two decades and focuses on the role of research, health, and human flourishing.

**Global Bioethics**

Global bioethics concerns itself with three areas: 1) the discourse pertaining to international research; 2) the importance of benefit sharing and protection that promotes human existence and flourishing; 3) the cognizance of participation in global community or world moral community. These categories are interconnected and raise the awareness of one's mutual participation in the construction of a global community. The concept of global

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80 Lebacqz, *We Sure are Older but are we Wiser*, 102

bioethics originated in 1988 with Van Rensselaer Potter, a U.S. oncologist whose work in bioethics focused on human survival and flourishing. Potter’s influential text *Global Bioethics*, which has been more influential outside of the U.S., serves as a follow-up to his 1971 *Bioethics: Bridge to the Future*. His earlier argument, nevertheless, laid the groundwork for considering global bioethics as a field that linked humanitarian values with the disciplines of science and medicine. Potter integrates concerns about the development of society and care for the environment as constitutive issues for bioethics to address. His global approach to bioethics, however, has been rarely taken up by U.S. bioethicists, until recently.

The groundwork Potter laid in global bioethics has increasingly become a subject of interest within current trends in bioethics, reflecting on bioethics as a discipline at the intersection of science and human values in a socio-political context. Daniel Wikler and Dan Brock describe global bioethics as taking a “birds-eye” view of bioethics, moving beyond the particularly individual focus of bioethics, instead settling on issues of justice and politics of health. With a more comprehensive approach to bioethics, questions regarding global preparedness for the spread of infectious disease, distributive justice, and practices that promote or limit positive health come into focus. This broader perspective de-centers autonomy as the dominant bellwether for bioethics and lends itself to consider the the

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85 Green, et. al., *Global Bioethics*, 32.
Eric Meslin and Ruth Macklin have distinguished themselves as two of the leading figures taking up issues of justice related to research in a global context. For Macklin and Meslin, justice functions as the lynchpin to debates concerning medical research and its distribution. Macklin argues that concerns regarding global bioethics come at the intersection of questions about global justice and research ethics. She raises the importance of the particular question of reducing the gap between health status and life expectancy between the rich and the poor. With respect to ensuring justice between the rich and the poor, questions of justice have to be raised at a policy level in order to address, not only the health gap between the rich and the poor, but also the research gap.

The research gap, discussed in greater detail in Chapter Four, refers to the disparity in research in which 90% of research stands to benefit only 10% of the population. Eric Meslin argues that concern over the research gap needs to be addressed from the “bottom-up.” Meslin characterizes Macklin’s approach to justice as global bioethics “from above” or a “top down.” In contrast, he proposes that the issues of justice in global bioethics focus on capacity building and collaboration with those communities that lack the ability to participate and govern their own research practices. Meslin describes the approach taken by Indiana University’s Medical School in building its own hospital, developing an exchange program for training medical students, and helping to support a local IRB in the Rift Valley in

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86 Ibid, 38.
87 Ibid, 142.
Eldoret, Kenya as an example of an approach from below. Meslin’s approach in many ways echoes the approach of this dissertation.

While Meslin and Macklin rightly highlight justice as the place to consider challenges in global research ethics, these considerations have to be done in conjunction with collaborative partners and from the experience and place of those that suffer injustices. Thus, it is not only important that collaboration occurs with communities of need, but that the projects developed truly reflect their needs, and not those of an outside institution—a challenging task. Therefore, even a preconceived notion of justice can prove difficult to reconcile with the experience of injustices within local communities. In order to address this important distinction, I turn to the perspective of liberation theology, in which questions of justice begin with experiences of injustice.

**Conclusion**

The Nuremberg Code, Declaration of Helsinki, and Belmont Report develop as a result of illegal and/or unethical practices in medical research from particular socio-historic contexts. These contexts provide a basis for the content of these documents. To interpret and implement these documents as regulatory requirements absent of a consideration of the communities from which they developed undervalues their importance for research ethics. The narrative of individuals and the communities that were victimized in the process of research form the foundation of each of these documents. Ezekiel Emanuel has been an outspoken critic of both the revisions of the Declaration of Helsinki and the Belmont Report in large part because of their inadequate consideration of communities. He articulates the importance of incorporating “respect for communities” as a key component of ethical

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89 Green, et al., *Global Bioethics*, 172.
research. Yet, respect does not go far enough, and global bioethics articulates more clearly the challenge as one rooted in justice.

For global bioethics, justice allows for a social ethics approach to burdens of disease, standard of and access to care, foreign research practices, and the development of bioethics internationally. Global bioethics highlights the increasingly global impact of medical research, which has become lost particularly in many of the international documents. While the applicative dimensions of Nuremberg, Helsinki, and Belmont remain essential for the protection of individual rights included in research ethics, emphasizing the current injustices within research practices proves necessary. “[A] broader understanding of justice would require looking not simply at the selection of research subjects but at entire systems and structures and how they distribute power and privilege.” While this approach inevitably creates new challenges and potential obstacles for research and research ethics, it would also promote a more serious consideration of the social dynamics of the practice of research itself. The next chapter proposes that increased consideration of justice within the practice of medical research, however, will require an epistemological reframing of the task of medical research itself.

Chapter Three draws on the work of Ignacio Ellacuría who provides important insights as a philosopher, theologian, and university president. As a former university president, Ellacuría readily acknowledged the important role that research plays for institutions, insofar as that research remains grounded in historical reality. For Ellacuría,


91 Lebacqz, *We Sure are Older but are we Wiser*, 107.
historical reality comprises the object of philosophy by considering “history’s actors, authors, editors, players, and parts of all the parts that make up reality.” The ethics of research, rooted in reality, maintains the importance of protecting the rights of human subjects, but in a way that remains cognizant of those who benefit and bear the burdens of research. By attending to issues such as participation, power, economics, culture, and politics, one can better account for the complexity of ensuring a consideration of the social and ethical conduct of research.

CHAPTER THREE

LIBERATING MEDICAL RESEARCH

Introduction

The historical development of research ethics has centered on the protection of the individual rights of the research subjects without considering adequately the social context in which research develops. Thus, the horizon of research and research ethics has concentrated its efforts on preservation and protection, rather than prospectively addressing any social inequalities created by the practice of research itself. By considering more seriously social questions within research ethics, a greater awareness of the social injustices present within medical research emerge. In this chapter, I argue that an epistemological shift proves necessary in order to recognize the injustices present within the practice of medical research. While the current epistemology of medical research centers on the development of new objective knowledge, it fails to adequately consider the research needs for the majority of the world. Recasting medical research from the epistemological lens of liberation theology requires the reimagining of medical research in concert with the needs of the poor.

The epistemological importance of a preferential option for the poor, foundational to a liberationist and Catholic approach, requires an agenda capable of addressing the structural injustices of medical research. Before addressing the structural inequalities, the focus of Chapter Four, it proves necessary to articulate what it means to address the practice of medical research from the perspective of the poor. In describing this process, I follow the thought of philosopher, theologian and university president Ignacio Ellacuría.
The chapter will develop, first, by considering the person and thought of Ignacio Ellacuría, followed by the influence of his mentor and collaborator Xavier Zubiri, a twentieth century Spanish philosopher. Section three reflects on Ellacuría’s anthropological vision, which understands the human person through the Zubirian term, reality animal. With this anthropological foundation, the fourth section will explore Ellacuría’s three-fold understanding of intellection as a praxis-based encounter with historical reality. It is this praxis-based encounter that not only informs the task of human intellection, but also the tasks of socio-historic institutions, e.g. university-based medical research. The final section of this chapter, then, takes up the Ellacuría’s understanding of the university as an institution positioned to confront the social injustices that exist in reality and begins to move towards transforming that reality. Drawing upon the thought of Ellacuría, the Catholic university, given its prioritization of the poor and commitment to justice, should be a place from which the socio-ethical and theological dimension of medical research is considered.

Why Ellacuría?

Ellacuría was a Spanish-born Jesuit priest who spent most of his professional life living and working in San Salvador, El Salvador. Up until his death, on November 16, 1989, Ellacuría served as the president and rector of the University of Central America. On that ill-fated night, he and five other Jesuits, the cook for the seminary, Elba Ramos, and her daughter, Celina, were all murdered by a government death squad, a special group of military personnel trained for assassinations. While the details and political motivations have been well documented elsewhere, what holds significance for the purposes of this dissertation is
Ellacuría’s influence as the president of the UCA. Buttressed by his philosophical and theological vision, Ellacuría urged the Catholic universities, and in particular his own, address the injustices present in historical reality.

Key Terms

“Historical reality,” a term frequently utilized by Ellacuría to describe the world as a presently experienced, complex, and deliberate construction that results from choices made in the past, are currently being made, and will continue to be made in the future. While this may seem simplistic—historical action creates the present reality—historical reality necessitates not just a deeper exploration of the present reality and the injustices present within it, but also of one’s individual and collective role in creating these injustices. Reflecting on historical reality reveals that the minority of persons have utilized their power in a way that has created a reality in which the majority have limited access to resources and a diminished capacity to participate in shaping historical reality. Thus, they are subjected to participate in a reality neither of their own choosing, nor one in which they have the capacity to alter. Ellacuría references the term frequently in his philosophical, theological, and political writings, and is interested not only in how historical reality is understood, but how it can be transformed from the perspective of the “poor majority.”

From the perspective of the poor majority, i.e. the majority of human beings unable to fully participating in construction of historical reality, injustices become more readily visible. The poor majority includes human beings that suffer from illness, premature death, and lack the opportunities to participate in the political and economic construction of

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society. For Ellacuría, the poor majority has both a political and theologically function.

Politically, they force reflection on the structures that perpetuate disparities and inequalities and look for avenues through which to transform them. Theologically, Ellacuría argues the poor call attention to God’s revelation in scripture as taking place through those who are rejected in history. He gives particular attention to the Exodus account, Isaiah’s suffering servant, and, finally, to the person of Jesus. More will be said about the theological function of the poor majority in fourth section of this chapter (p. 114) when discussing Ellacuría’s epistemology, but it bears mentioning here, because it is his epistemological framework that framed his political and theological vision as the president of the University of Central America (UCA) in the midst of civil war in El Salvador.

Social Projection and the UCA

The history of El Salvador resulted in stark divisions between the economically and politically rich and poor. Ellacuría saw the task of the Catholic university to project the Salvadoran reality in the university’s tasks of teaching, research, and service. “Social projection” at the university argues that these university practices should study and reflect upon the reality—socio-economic, political, theological, philosophical, etc.—in a way that sets out to transform it in favor of the poor majority. One of his efforts at social projection of the Salvadoran reality was a series of dialogues established by the UCA to discuss, in a neutral setting, the challenges of living in a war-torn country. Rather than joining sides with the right-winged government or the left-leaning FMLN (Frente Farabundo Martí para la Liberación Nacional), Ellacuría proposed a third force by sponsoring a series of dialogues at the university between the poor majority and the wealthy minority about the realities of El Salvador.
Through this third way not only did the poor majority find a voice, but the wealthy minority also began to hear their voice. Lassalle-Klein notes, “Ellacuría stresses that this third force is not a political organization but a social one, and he links it to an emerging theme in Catholic Social Teaching, namely, social organization and civil society as an important means through which individuals’ interests can be defended against oppressive state power.” While any university could hold these talks, Ellacuría sees it as the unique task of Catholic universities to serve as places that promote social movements that allow greater inclusion of the poor in society.

The UCA promotes the participation of the poor and the social projection of reality through academic writing in university-run journals, to students through course instruction, and as a guide for the university’s research agenda. Ellacuría argues that the Christian university serves as a place that ought to engage in the practice of social projection, a process that takes on the injustices present in reality and works to transform these injustices present in society. The university has a responsibility to take up these concerns as their own, prioritizing the poor as constitutive to their institutional priorities, actions, and practices.

For medical research, the epistemic shift requires the gathering of information to improve health, but to gather information aimed at improving the health of those who are most likely to have poor health. This reprioritization would require a research agenda to shift from one that has focused increasingly on individual health to one that focuses on the health of the public. Prioritizing the poor offers an epistemological corrective for research and research ethics by drawing attention to the majority of humanity that is excluded from

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2 Lassalle-Klein, Blood and Ink: Ignacio Ellacuría, Jon Sobrino, and the Jesuit Martyrs of the University of Central America, 172.
receiving the benefits of medical research. Moreover, the epistemological shift calls Catholic universities engaged in medical research to take up that practice from the place of the poor.

The Catholic university, like other institutions of higher education, has become entangled in the social structure of medical research that tends to benefit a select few rather than a suffering majority. Though liberation theologians and philosophers have taken up the option for the poor as the ethical lens through which historical actions should be considered, science and research has always prided itself on objective and neutral perspective. Nevertheless, the research decisions are not made from a place of neutrality and, in fact, this false impression has contributed to the disparities in health which medical research aspires to address. While these tasks are not explicitly theological, they are deeply theologal.

The theologal is a term that Ellacuría develops along with his mentor Xavier Zubiri to describe the “God dimension” of reality. The theologal dimension of reality is all-encompassing and the choices made within history participate, in some way, in that ultimate sense of reality. Ellacuría’s utilization of the term theologal is borrowed from his mentor Xavier Zubiri, and is described in more depth below (p. 100-101). While the theologal grounds the thought of both Ellacuría and Zubiri, Zubiri’s influence extends beyond that and affects the way in which Ellacuría understands a wide variety of topics, in particular, his understanding of human intellection and the role of science.

**Zubiri’s Influence on Ellacuría**

For Ellacuría, no mentor had greater influence on his thinking than that of the Spanish philosopher Xavier Zubiri. Zubiri’s philosophy came to be understood as a phenomenology of “fundamental reality” that develops through his encounters with some of

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the great scientific, mathematic, and philosophical minds of his day: Einstein, Schrödinger, Zermelo, Jaeger, and Plank. Immersed in their world, Zubiri starts grappling with new ways of envisioning the philosophy of science. While Zubiri’s understanding of science is important to understanding the function of medical research, ultimately his understanding does not differ from his description of human intellection. For Zubiri, the notion of intellection is a process that functions both rational and sentiently and greatly shapes Ellacuría’s own thinking. For Zubiri, and Ellacuría, all knowledge is situated within particular space and time. This understanding leads to Zubiri’s critical stance towards the epistemology that guides science.

Zubiri on Science

Zubiri’s critique of scientific knowing counters science’s claim of neutrality and objectivity as the highest form of intellectual pursuits. The privileged status of scientific thinking, while having its origins in the Enlightenment, becomes synonymous with Francis Bacon’s articulation of the scientific enterprise. For Bacon, science functions as way to constantly improve upon the condition in which humanity finds itself.\(^4\) Scientific experiments allow for a deeper understanding about the material world in which human beings exist. Bacon’s method of improving knowledge centers on an evidence-based process that increases scientific understanding through “progressive stages of certainty.”\(^5\) Medical research, and medicine in general, tends to operate within this perspective. Thus, the more research conducted and applied to the improvement of medicine, the more progress is achieved. Jeffrey Bishop, a physician and philosopher, reflects on Bacon’s scientific

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\(^5\) Ibid.
epistemology and cautions, “medicine tends to perpetuate a certain naïve understanding of its progress. Namely, we are moving to more and better knowledge and we will be able to deploy new technologies to assist in bettering the human condition.”

This imperative for research and improvement can still be seen in the efforts within biotechnology and genetic innovations of today.

In the scientific efforts at the beginning of the 20th century through to the present day, there has been an increased shift toward reasoning rooted in materialism. “Science,” Bishop argues, moves single-mindedly, without regard for sentient life.” In disregarding the sentient and intellectual nature of human beings, the science of medicine effectively reduces life to notions of cause and effect. Thus, the more information accumulated the better chance of understanding, and controlling, the cause of disease through treatment. Research understood in this sense, however, centers on control, not knowledge. For Zubiri, the knowledge derived from scientific inquiry was not about control, but rather about deepening an understanding of the pluriformity of reality.

Zubiri did not understand science as an isolated and objective discipline that operates separate from reality. Instead, Zubiri argued that acquiring knowledge both contributes to and shapes reality. Zubiri’s corrective to a Baconian understanding posits a non-materialism that perceives reality thorough the senses and reason. “While we do directly perceive reality, we do not do so in an absolute, detached sense envisioned by classical science.” Thus, scientific knowing represents only one of the necessary pieces for

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7 Ibid.
comprehending reality. While scientific understanding represents an important piece of the puzzle, it does not represent the highest form of knowledge. It is science, coupled with other disciplines, like philosophy, that benefit from and need each other to more deeply understand the infinitely open reality in which they exist. Zubiri’s philosophy came to more seriously consider the limitedness of all forms of human knowing, including philosophy and science. It is the limited perspective of intellectual disciplines, however, that makes research fundamental to understanding reality.

Zubiri describes research as an investigation of reality by seeking the precise and detailed constitution of reality. “To research is to dedicate oneself to the true reality…this force consists in configuring and conforming our mind according to the demonstration of reality and to offer that which is seen for others.”

However, Zubiri notes, not unlike Bacon, that given the openness of reality research functions as an infinite task of observation and communication of that which is seen. Though, in contrast to Bacon, the results of the research are always situated, partial, and pluriform. The pluriformity of reality exists, “not only because things have many distinct properties, but also for the reason that from my perspective there is always something deeper: because that which is open is its own proper character of reality.” It is scientific task that takes up the study of reality in itself, as it is seen and experienced materially, while philosophy works cooperatively with science to reflect

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9 Xavier Zubiri, “¿Que es investigar?” The Zubiri Foundation of North America, October 19, 1982, (http://www.zubiri.org/works/spanishworks/investigar.htm, accessed January 15, 2015). All translations provided are my own, unless otherwise noted. When possible, I will provide the original Spanish text in the corresponding footnotes. Investigar es dedicarse a la realidad verdadero…esta fuerza consiste en configurar o conformar nuestra mente según la mostración de la realidad, y ofrecer lo que así se nos muestra a la consideración de los de más.

10 Zubiri, “¿Que es investigar?” “no solo porque las cosas tienen muchas propiedades distintas, sino también por una razón a mi modo de ver más hondo: porque lo que es abierto es su propio carácter de realidad.”
on the reality experienced, “there is always something deeper” to explore. For both Zubiri and Ellacuría, within reality lies a constitutive and inaccessible dynamic that they describe as the theologal dimension of reality.

The Theologal Dimension of Reality

Zubiri posits that the theologal dimension of reality imbues and forms the fundament of reality itself. It is important to underscore that the theologal not be confused with the theological. Zubiri does not intend to offer proofs for God’s existence, nor to place God “on top of” reality. Instead, the theologal conveys the endless desire for human beings to know more and discover “something deeper.” Zubiri posits it is God, not the God of theology, but the God of reality that drives the endless task to know more about reality. The totality of reality, however, is not increasingly understood through the advances and control achieved through science, nor the musings of philosophy. However, both philosophic and scientific inquiry together can lead to a deeper understanding of reality, but not exhaust it.

The theologal power of the real is that which propels and compels human beings forward, to discover more, with the expectation that the more one comprehends reality, the more aware one should become of power one has to shape reality itself.

Reality is a “more,” but not one that is in addition to a thing, but rather a ‘more’ in the thing itself. That is why in being with “this reality,” where I am is in “reality.” Likewise, it is because of that “which this reality” can impose on me that it adopts a form in “reality.” It is not a question of concepts, but of a physical character of the power of the real. 

The emphasis Zubiri places on the shaping of reality comes to influence Ellacuría’s own thinking and the importance of human actions that shape history. Thus, reflecting on one’s

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actions and understanding the reality in which those actions occur are fundamental to the sentient and intellectual function of the human knowing.

Sentient Intelligence

Zubiri refers to sentient intelligence as the process of human intellection in which one is always interpreting, understanding, and acting from a particular perspective and out of a set of experiences that make sensitive impressions on the intellect. This impression, however, is only experienced contextually and partially. The impression, while contextual, sentient, and partial, remains infinitely open to the possibility of other realities and to a deeper understanding of one’s own personal reality. In an example used by Zubiri, he argues that one cannot isolate a piece of reality, e.g. the color red, without at the same time considering a multiplicity of factors being present within that experience. Moreover, one has to recognize that the impression “I” have when seeing “red” might be different than “your” impression, but neither renders the other less “real.” It worth noting that Zubiri does not equate the “real” with truth; thus, one can have a false perception of reality by not taking into account other valid experiences from different places. Continuing with his example of color, while a person who is colorblind experiences “red” differently than a person without color-blindness, it does not render either experience less real, even if the scientific reality of their experience of red does not match the material properties of the color red.  

Comparatively, science offers material insights into reality, though the knowledge acquired is only partial. By uniting the senses and the intellect Zubiri demonstrates his efforts to

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12 Lassalle-Klein, *Blood and Ink*, 206. Lassalle-Klein draws from an example of Zubiri’s to make the point of sentient intelligence via the way in which human beings perceive color. The passage, taken from *Inteligencia Sentiente*, is worth noting: “The color is not produced by the wave (as critical realism holds)...the visual perception of color is the electromagnetic wave in the perception...within the ambit of perception (an only there), the [perceptual] qualities and the [electromagnetic] waves are...one and the same thing, not two, as they would have been if the waves had been caused by the qualities. Sensible qualities are realities, within the ambit of perception...of something beyond them in the cosmos...”
overcome the prioritization of reason and observable reality within scientific and philosophical thought in an effort to counter what he describes as the “logification of intelligence.”

Zubiri observed a similar trend in western philosophy, similar to Baconian science, in which the intellective process tends to be reduced to a rational function that only needs to be understood through reason isolated from the senses. He describes the logification of intelligence as the process through which intellection becomes rooted in reason alone and reduces the senses to the interpretation of sense data. “This form of intellection comes to function formally as a faculty of affirmation in a way that neither reality, nor the beings of things would be accessible to human beings without this modality of intelligence characterized by logos and reason.”

Reason only allows for an interpretation of reality in itself and reality makes an impression that is at once sensitive and rational. This sensitive and rational impression of reality, however, makes the whole of reality present, not just what is most immediate. Reality in its totality, though formally present in the intellective process, cannot be reduced to a purely rational function, as science is wont to do.

Through sentient intelligence, science takes on the role of deepening the knowledge of reality as it is materially, while philosophy searches for the meaning of reality in its totality. It

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13 Héctor Samour, Crítica y Liberación: Ellacuría Y La Realidad Histórica Contemporánea, (Madrid : Universidad Carlos III de Madrid, 2012), 95. Por logificación de la inteligencia Ellacuría entiende aquella consideración de la inteligencia por la cual se la concibe formalmente como la facultad de afirmación, de tal manera que ni la realidad ni el ser de las cosas les serían accesibles al ser humano sin en esa modalidad de la inteligencia caracterizada por el logos y la razón. Translation is my own.

14 Zubiri also raises another philosophical concern in which meaning is reduced to “being”. While this concern goes beyond the scope of this section, the entification of reality was another epistemic concern. The Spanish ente or entity, thing—and the logification of intelligence converge when reason is reduced to being and being comes from the ability to reason. From Zubiri’s perspective, “being” can only be understood in and through reality and is not the ground of that reality. That which is considered intellectively and sensitively, is a “being” in and of itself, but a being who participates within a reality that exits beyond itself and beyond the immediately perceived reality.
is the “of its ownness” of intramundane reality that functions as the object of philosophy, and science proves a necessary complement to the philosophical task through the exploration of reality that is perceptually—intellectively and sensitively—present “in itself.”

Moving toward the real that exists outside the perception of sensible qualities. Every quality is perceived not only in and of itself as such and such a quality, but also as a pointing toward. The reality of the qualities that are only in the perception is exactly what constitutes their radical insufficiency as moments of the real. They are real, but they are really insufficient. In their insufficiency, however, these qualities...are...pointing toward the real that is outside the perception. Indeed, this is what gives rise to science.  

For Zubiri, science and scientific research functions as a mode of more deeply reflecting on reality as it is experienced. However, the reflection on perceived reality does not exhaust reality, an understanding that was not lost on Ellacuría. The theological dimension of reality, sentient intelligence, and the role of science serve as three aspects of Zubiri’s thought that Ellacuría embraced. The influence of Zubiri on science can be seen in Ellacuría’s role as president of the UCA and the way in which he spoke of the importance of research, along with service and teaching as the means by which the university reflected reality. It is the term reality, however, from which Ellacuría began to build on the work of Zubiri. For Ellacuría, Zubiri’s notion of reality did not sufficiently describe the praxical dimension of reality in which human actions continually give shape to reality as it is experienced. The next section describes Ellacuría’s understanding of reality and the role of human beings in shaping that reality.

From Intramundane to Historical Reality

Ellacuría nuances Zubiri’s description of intramundane reality by describing the object of philosophy as historical reality. Historical reality, as briefly mentioned in the

introduction, is a unified and global understanding of all “real things,” which constitute a physical and dynamic unity through which all things come to be through one another and, in one way or another, constitute the interdependent structure of the real. Ellacuría’s notion of historical reality is not merely a theoretical exploration of historical circumstances, nor is it simply the sequential retelling of historical events and occurrences, though it includes these components. Kevin Burke notes that Ellacuría’s definition of historical reality refers:

to the field, sphere, or area of reality that serves as reality’s realm of ultimate realization, and to the unity underlying the various historical happenings, the contents of realization...It emerges through the totality of history’s actors, authors, editors, auditors, all the players, all the parts, the audience, the stage, and every other aspect of cosmic theater, but the unity as such is not imposed by any of these.

Insofar as reality is made up of a diversity of historical players and places, a key distinction develops between Ellacuría’s description of historical reality and Zubiri’s intramundane reality.

The Importance of Praxis

The key distinction between historical reality and intramundane reality rests on Ellacuría’s emphasis on the praxical dimension of reality. In this way, Ellacuría nuances the Zubirian focus on the apprehension of reality through sentient intelligence. For Ellacuría, one comes to know in order to transform. Intramundane reality does not emphasize strongly enough the fact that, through human action in reality, human beings make history and shape historical reality. Thus, Ellacuría gives particular attention not only to human thought, but also human actions as the grounds through which historical reality—i.e. the pluriformity of conditions, contexts, and circumstances—is experienced and transformed by human beings.

16 Ignacio Ellacuría, *Filosofía de la Realidad Histórica* (San Salvador, El Salvador: UCA Editores, 1990), 45.

Ellacuría describes human beings as reality animals—a description borrowed from Zubiri—who operate through both social and individual dimensions in which historical reality comes to be realized. Ellacuría describes the human person as a distinct kind of creature that remains open to the immediate reality in which she is situated but aware that other realities are simultaneously present and shape the experience of one’s particular reality. Human beings, like animals, are immersed in situations and are “subjects to” all that situations require of them. However, human beings also have the capacity and responsibility to transcend the particularities of their circumstances and recognize the reality of others. For Ellacuría, it is the fact that human action alters historical reality that marks an evolution from Zubiri’s notion of intramundane reality and emphasizes the fundamentally ethical dimension of the human person.

Ellacuría argues that historical reality is “of itself,” and that reality’s “of itselfness” is, in part, a result of human actions that lead to the construction of reality as it is. This reality is reflective of both one’s own actions and the actions of others, which jointly shape a unified reality for one’s self and other selves. In this way, the ethical construction of historical reality necessarily moves beyond the individual experience, because that particular experience, though holding on to a dimension of reality “itself,” is a reality that is conterminously shaped by and with others. Thus, reality as it is experienced is a function of a dialectic between one’s self and other selves, both of whom give shape to the experienced historical reality. Historical reality then is “co-real,” meaning that each of these experiences or encounters can only be understood as real with others, “because the reality of the others forms part of my

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own reality.”\textsuperscript{19} This co-construction of reality takes place through options and decisions made by oneself and others by responding to options as presented naturally, in the midst of conditions that have been commonly constructed.\textsuperscript{20}

\textbf{The Biological Fundament of Ethics}

Ellacuría reflects on what is “common” to humanity as a biological fundament that provides the most basic commonality amongst human beings. Thus, what is most common to human beings is biological in nature and does not necessarily pertain to a community or society.\textsuperscript{21} Rather, the construction of communities and societies evolves from deliberate human choices, which have the capacity to foster a sense of community and to form just-societies that allow for the equal participation of all its members, or not.

It may strike one as odd that Ellacuría grounds ethics in biology, however, this move is deliberate and not intended to argue some “ethics gene” inherent in human beings. Ellacuría argues that injustices can be seen where people continually lose their lives at a disproportionate rate than is biologically necessary. In this way, the biological fundament takes a socio-ethical position that calls one’s attention to the perspective of people who, as Gustavo Gutiérrez says, “die before their time.” The biological fundament, moreover, requires critique of systems or structures that perpetuate this injustice.\textsuperscript{22}

\begin{itemize}
\item \bibitem{Ibid.} Ibid., 255; Burke, \textit{The Ground Beneath the Cross: The Theology of Ignacio Ellacuría}, 79-80.
\item \bibitem{Ellacuría} Ellacuría, “Fundmaentación biológica,” 256-67.
\item \bibitem{Ellacuría2} Ignacio Ellacuría, \textit{Filosofía De La Realidad Histórica}, (San Salvador, El Salvador, CA: UCA Editores, 1990), 386.
\item \bibitem{Chapter Four} Chapter Four will focus explicitly on the construction of the social practice of medical research through collaborations between the U.S. government, academia, and the pharmaceutical industry. These collaborative efforts have participated in the shaping of a research structure that denies opportunities to gain the benefits of medical research, which are due in large part to the economics of research.
\end{itemize}
By calling attention to this socio-ethical position, Ellacuría raises the possibility that choices made by particular people tend to have more influence on the shape of history than the choices of others. It is the disparity in loss of life between high-income and low-income countries that Ellacuría points to as demonstrative of unjust social arrangements. Thus, in order to correct these injustices, greater attention needs to be focused on those places in society in which people die, not of natural causes, but because of unjust structures. For Ellacuría:

Society and history, above all, are not able to be (ser) what human beings decide; what society and history are going to be depends on the structuring of real and complex factors following the structure of law, but also between these factors, how we see them in their place, they have there proper place (puesto), their own position (posición), what human beings do and want to do.23

Thus, Ellacuría’s initial socio-ethical question is not, what ought one do, but rather, where ought one begin to think about what one ought to do. It is the place from which one enters into a praxis-based encounter with reality that proves crucial to Ellacuría’s philosophical and theological method.

A Praxis-Based Encounter with Reality

Ellacuría’s three-fold praxical encounter with reality and its particular impact on theology is described in a 1975 address that develops his philosophical foundations of a Latin American theology. Ellacuría argues that if intellection is a process that is simultaneously sentient and rational, then, “Every reading, every interpretation is motivated by interests, be they existential or social. The important thing is realizing what this interest is

23 Ellacuría, Filosofía de la Realidad Histórica, 387. La sociedad y la historia, sobre todo, no pueden ser lo que los hombre decidan; lo que la sociedad y la historia vayan a ser depende de la estructuración compleja de factores reales según leyes estructurales, anquè entre estos factores, como veremos en su lugar, tenga su puesto propio, su posición propia, lo que los hombres hacen y quieren hacer.
and how this interest conditions our way of approaching and comprehending reality.” The way in which one uncovers the motivations for particular interpretations of reality is rooted both in the hermeneutic through which one interprets reality and also the process by which one engages it.

Ellacuría offers a three-fold method of engaging with reality that argues the human person comes to understand, interpret, and take responsibly for historical reality through a praxis-based encounter that begins from the place of the poor. While there are three aspects to his method, these should not be seen as sequential developments. Rather, each of these components functions as a spiral and proves necessary for responsibly encountering reality as it is, in order to shape it as it ought to be. This process, however, does not stop with finite conclusions. Once one acts, the reality in which one has acted is now transformed to some degree. Therefore, the entire process begins again from a new point and within a new reality.

In order to act responsibly, according to Ellacuría, one must realize the weight of reality (el hacerse cargo de la realidad); shoulder the weight of reality (el cargar con la realidad); and take charge of the weight of reality (el encargarse de la realidad). Ellacuría’s methodology is designed not as an intellective move to observe, judge, and act from a third party standpoint;

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25 Burke, The Ground Beneath the Cross. The translations of the three components of Ellacuría’s method follow those that Burke, Ashley, Lee, have used. Gandolfo, Lassalle-Klein opt for a slightly modified translation. I follow Lee, Burke, and Ashley to maintain consistency in translation. Additionally, Lee has an important and helpful note that these three phrases El hacerse cargo de la realidad; El cargar con la realidad; El encargarse de la realidad, could all be correctly be translated as “taking charge of reality,” though the Spanish uses are more nuanced than their English counterparts, which is what the varied translations aim to articulate. Interesting to note, that a more literal translation of the Spanish phrases each contains a phrase in which one bears responsibility for the reality with which not only one confronts, but this responsibility weighs one down. In a sense there is not just the intellectual knowledge of this responsibility, but rather one feels it weighing on her, i.e. it is sentient.
but to see oneself as intimately involved with and responsible for the reality as it is continually being co-constructed.

Realizing the Weight of Reality

“Realizing the weight of reality” means being present to it formally. In other words, realizing reality’s weight is more than a rational or cognitive task; it is a task that requires an active mediation.26 Jose González Faus emphasizes, “Realizing the weight of reality involves a conception of knowing more profound than the mere objective accumulation of data. Spanish expressions such as ¡ahora me hago cargo! (Now I get it!) or hazte cargo (you must understand) allude to a comprehension which goes far beyond mere objective knowing and links knowing and empathy.”27 These type of expressions point not just to the intellectual grasping of a concept, e.g. an algebraic equation, but to an owning of the concept so much so that it becomes a part of one’s identity. Therefore, the knowledge becomes one’s own and is literally “taken on.” By realizing reality, one comes to understand one’s own participation in the shaping of reality as it is. In the midst of realizing reality, one has to bear responsibility for a historical reality in which the majority is poor and vulnerable. Upon realizing the weight of reality, one is confronted with an ethical responsibility within a commonly shared reality.

Shouldering the Weight of Reality

*El cargar con la realidad,* could be literally translated as “loaded with reality,” which gives the physical sense of what Ellacuría intends to convey. As one recognizes the role of reality to be an inherently ethical role, the question then shifts to how one should “shoulder the weight of reality.” As reality imposes itself on the reality animal, one necessarily has to

26 Lee, Ignacio Ellacuría, 80.

decide how to act and react within the environment. The fundamentally ethical character of intelligence “has not been given to us so that we could evade our real commitments, but rather to take upon ourselves what things really are and what they really demand.”

It is in this aspect of his methodology that the place from which one encounters reality shapes how one acts.

Making an option regarding the place—not necessarily a physically location but more of an intellective/ethical locus—from which one acts is important. Theologically, Ellacuría describes an ethical place as that which is “most likely to inspire a living faith in Jesus and a corresponding praxis of discipleship (the praxis-oriented dimension), and the place most apt to stimulate a lively, authentic theological understanding of faith (the noetic dimension).”

Ellacuría describes the place from which human beings, of faith and no faith, should opt to act is from the place of the poor.

Ellacuría describes the poor as:

the vast bulk of humanity whose standard of living is such that they can scarcely satisfy their most basic needs; this majority whose material standard does not permit them sufficient human development, who do not have access in an equitable way to the resources now available to humanity and who are marginalized in relations to elite minorities who...dispose of the greater part of available resources for their own immediate benefit; and those majorities whose dispossession is not due to natural law or personal or group laziness, but rather to historic social arrangements that have relegated them to situations in which they not only lack, but are deprived of, what they should have, whether because of exploitation in the strict sense or because they have been hindered indirectly from enjoying the fruits of either their labor or their political initiative.

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28 Lee, Ignacio Ellacuría, 80.


30 Ignacio Ellacuría, “The Challenge of the Poor Majority,” in Towards a Society that Serves its People: The Intellectual
Thus, this is not a unique subset of the population, but the collective of individuals that comprise the majority of persons within historical reality. He argues, moreover, that the poor are poor because, “The rich have dispossessed the poor from what was theirs…if the poor are impoverished, the rich are the poverty-makers; if the poor are dispossessed, the rich are the possessors; if the poor are the oppressed and repressed, then the rich are the oppressors and repressors…”31 The disparity between the rich and the poor is present, too, in medical research.

In the last chapter, I referenced the research gap in which 90% of medical research benefits only 10% of the population. In large part, these disparities stem from the institutions that establish the research agenda—high-income resource rich nations or high powered economically solvent pharmaceutical industry—whose priorities primarily focus on how to yield an economic return on investment.32 However, for Catholic universities, while economics cannot be dismissed, they cannot occupy the central concern of what research opportunities to pursue. Insofar as medical research at Catholic universities reflects the national funding priorities that do not benefit the poor majority, an issue addressed in Chapter Four, then these institutions participate in the dispossession of the poor as Ellacuría rightly points out. The importance of place, highlighted in the ethical dimension of Ellacuría’s epistemology, is helpful in framing the ethical problem, however, it does not readily identify a solution. Thus, from the place of the poor one not only has to interpret and

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31 Ellacuría, “Los pobres, lugar teológico.” Si los pobres son los empobrecidos, los ricos son los empobrecedores; si los pobres son los desposeídos los ricos son los poseedores; si los pobres son los oprimidos y reprimidos, los ricos son los opresores y los represores.

32 This claim will be more fully considered in the next chapter.
understand, but ultimately one has to take responsibility for the transformation of historical reality.

Taking Charge of the Weight of Reality

The final dimension of Ellacuría’s methodology focuses on “taking charge of the weight of reality” (el encargarse de la realidad) by engaging in responsible action that considers more broadly one’s responsibility not only to oneself, but also for and with others. For Ellacuría, it is the praxical character of intelligence that proves necessary for human intellection to become a completed process. The “praxical character of intelligence…only fulfills its function, including its character of knowing reality and comprehending its meaning, when it assumes as its burden doing something real.” In other words, what takes place in human intellection only comes to fruition when one takes charge of reality in a way that leads to an active transformation of that reality to make it more “real,” meaning more human(e). The only way to shape reality, however, requires “engaging, remembering, and ultimately undoing its terrible negativity. In a word, it demands conversion, a conversion of the human heart and a conversion in historical reality.” The conversion of the human person starts with taking the poor majority as the heuristic through which one interprets and critiques reality, thus, opening oneself to a praxis-based engagement with reality that “comes from and returns to the configuring of a specific social structure.” Thus, there is a need to take seriously the praxical responsibility one has in shaping social structures grounded in the theologal dimension of reality.

33 Lee, Ignacio Ellacuría, 80.

34 Burke, The Ground Beneath the Cross, 106.

35 Lee, Ignacio Ellacuría, 82.
The Theological Dimension of Reality (Reprised)

In the theological dimension that Zubiri develops and Ellacuría takes up, God does not exist above or along side of historical reality, but rather God’s transcendence takes place in and through reality. Thus, there are not two realities—God’s and humanity’s—but a single historical reality that God and humanity share. Ellacuría points to the story of God’s revelation in the Exodus story, Isaiah’s suffering servant, and finally through the life, death, resurrection of Jesus. God’s transcendence comes to be made known, not by taking something away, but rather by pushing something forward. In the Exodus account, Moses leads God’s people from captivity and oppression to the Promised Land. In Isaiah, while the suffering servant, “has bourne our infirmities and carried our diseases…wounded for our transgressions, crushed for our iniquities” (Is. 53:4-5), the servant also serves as a light to the nations “that [God’s] salvation may reach the end of the earth” (Is. 42:6, 49:6). While not superseding the suffering servant, through continuing the story of God’s revelation in and through those who suffer, Jesus’ suffering and death emerges as the central Christian narrative through whom God comes to be known most fully. It is through the oppressed and marginalized and in the person of Jesus that demonstrates most fully God’s presence in history.

Thus this fundamental article of faith does not refer to God alone, to a God apart from human history, nor even to a God who gives meaning to individual life and whose fullness is projected beyond history. On the contrary, it is from and in history itself that God becomes present as the fundamental and foundational religious event,

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36 This is Ellacuría’s foundational insight that forms the bedrock of his soteriology. Kevin Burke and Michael Lee have both written on the implication of Ellacuría’s theology, Burke more exploratory and Lee on its implications for Christian discipleship.

not only not separated from the sociopolitical processes but established and re-lived in that process.\textsuperscript{38}

Here Ellacuría calls attention to the structural transformation implied through God’s action in history in which captives are freed, the suffering serve as a light to the nations, and the dead are raised.

**Utopia and Prophetism**

In one of Ellacuría’s final essays, he argues that the God’s action in history takes on both a utopic and prophetic function that must remain dialectically in tension.\textsuperscript{39} He argues, “The Christian utopia can only be constructed from propheticism, and the Christian propheticism must take into account the necessity and the characteristics of the Christian utopia.”\textsuperscript{40} Propheticism in this sense does not mean simply a critique of the structures, but it is a critique that calls for structural change, change that is more in line with the utopic vision of God’s kingdom. The dialectic between prophetism and utopia “gives present reality to what is formally an historical possibility…”\textsuperscript{41} The formal and historical possibilities are made known because of God’s transcendence in and through history and have been revealed most


\textsuperscript{40} Ellacuría, “Utopía Y Profetismo Desde América Latina: Un Ensayo Concreto de Soteriología Histórica,” 142. *La utopía Cristiana sólo puede ser construida desde el profetismo y el profetismo cristiano debe tomar en cuenta la necesidad y las características de la utopía Cristiana.* Follows Ashley and Burke translation.

\textsuperscript{41} Ibid. Actualizarlo significa…dar realidad actual a lo que formalmente es una posibilidad histórica…”
fully in those who suffer on the margins of society. He argues that the place from which theology most authentically develops should be set by the historical reality of the people of God, most fully witnessed in the poor and marginalized as the continuation of the incarnation of the crucified Jesus in history.\(^\text{42}\)

Ellacuría and his contemporary, Jon Sobrino, note the historical suffering of the majority of the world today functions as the historical sign of Jesus’ continued crucifixion in history. The “crucified people” represent the result of the deliberate choice and freedom for human beings to choose against God. “This crucifixion results from historical decisions, actions, traditions, and structures and represents, in Ellacuría’s view, the most urgent and theologically dense of all the contemporary signs of the times.”\(^\text{43}\) The crucified people, continue to make the crucified Christ present in history, also making present the reality of his, and their, ultimate resurrection. Thus, the crucified people push forward within the present reality a utopic vision in need of actualization.

Catholic universities participate in this propheticism in a particular way by taking up this Christian utopic vision that prioritizes the poor. This vision calls attention to the injustices that exist in the world, and works towards reform of those structures. Ellacuría saw this as a vital role that universities could and should play. For Ellacuría, the Catholic university functions as a mission-based institution striving to embody the Christian utopic vision rooted in an option for the poor. This perspective on the role of the Catholic university proves fundamental to his leadership of the UCA and continually calls for action in the midst of an unjust reality.

\(^{42}\) Lee, Ignacio Ellacuria, 84; Burke, The Ground Beneath the Cross, 109.

\(^{43}\) Burke, 181.
Ellacuría and the University

In the immediate years preceding his assassination, Ignacio Ellacuría served as an important public figure in El Salvador as the president and rector at the UCA. In his time there as both a professor and administrator, his philosophy and theology of liberation reflected the way in which he viewed the function of the university. While he wrote only a few essays on the topic of the university, his inquiries led him to reimagine its role as an institution that addressed social injustices, and the injustices in El Salvador at the time were plentiful. Faced with that reality, he argued that a Catholic university, like the UCA, should undertake social projection (proyección social) as its fundamental task.  

Social Projection

Social projection conveys that all components of the university—faculty, students, staff, teaching, service initiatives, and research, etc.—ought to reflect the socio-historical reality in which the university operates. The work of the university, then, goes against the “ivory tower” or disengaged notion of the university, arguing that it should reflect and aim to transform the social context in which the university exists. “Social projection understands itself here as a function that puts the totality of the university, although through its parts, in

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44 Adolfo Nicholas, S.J., “Depth, Universality, and Shared Ministry: Challenges to Jesuit Higher Education Today,” (presented at Networking Jesuit Higher Education: Shaping the Future for a Humane, Just, Sustainable Globe, Mexico City, April 23, 2010) http://www.sjweb.info/documents/ansj/100423_Mexico%20City_Higher%20Education%20Today_ENG.pdf; Brad Hinze, “The Tasks of Theology in the Proyecto Social of the University’s Mission” Horizons. 39, no.2 (2012): 282-309; Dean Brackley, “Higher Standards for Higher Education: The Christian University and Solidarity,” address delivered at Creighton University (Omaha, NE), November 4, 1999, http://onlineministries.creighton.edu/CollaborativeMinistry/brackley.html. The term social projection has increasingly been influential on reflecting on the way in which Jesuit universities themselves operate. While Ellacuría uses the term “Christian” university, he is speaking more specifically about Catholic universities and his thought has been most frequently been incorporated into the thinking of Jesuit universities. Referencing the above description, if it is faith in Jesus that lay at the foundation of the action of these institutions, then it is faith in Jesus who continually targeted his mission to the poor and marginalized of society. Given this foundation in Jesus, rather than the institutional churches themselves, my argument in particular is addressed to Catholic universities, which already exist as part of an organized and unified network through which international projects and policies play an important role, especially when considering issues of global health.
direct relationship with social forces and processes." While each of the parts of the university, departments, academic disciplines, students, etc. have their particular roles to play, these develop most effectively and beneficially through relationships with those persons and institutions outside of the university itself and amongst the community in which it operates.

Rather than using the university’s teaching, education, and service for self-promotion and/or aggrandizement, these tasks, which are fundamental to the university, should most clearly reflect the needs and concerns facing historical reality. “[Social] Projection operationalizes the contribution to the creation, modification, and configuration of the collective conscience in its totalizing structural dimension or partial structural dimension.”

David Gandolfo comments that the university as social projection must insert itself effectively in society. In so doing, the university recognizes its responsibility by allowing the needs of society to penetrate and permeate the university “determining its curriculum and research agendas.” Therefore, the university projects reality on to reality by being reflective—the intake of data for processing—and projective—identifying solutions, critiques, and working to provide the necessary resources in order to transform the unjust immediate reality.

Thus, social projection functions representatively of the social situation and, additionally, strives to transform that same situation as needed. The university’s method of social projection, however, remains focused on the central tasks of the university. Teaching,

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45 Ignacio Ellacuría, “Universidad y Política,” in Escritos Universitarios (San Salvador, El Salvador: UCA Editores, 1999), 186. Por proyección social se entiende aquí aquella función que pone a la universidad como totalidad, aunque a través de su parte, en relación directo con las fuerzas y los procesos sociales.

46 Ellacuría, “Universidad y Política,” 186. La proyección se operativiza en la contribución a la creación, modificación y configuración de la conciencia en su dimensión estructural totalizante o en dimensiones estructurales parciales.

research, and service rooted in social projection aims at the transformation of society beyond educating students for a profession, providing instead, an education that addresses the complexities and injustices of reality. At the time, Ellacuría argued, “the UCA needs to look, to offer, and to support universities the process conducive to more justice, freedom, and solidarity in El Salvador and Central America.”48 It is this emphasis that points to the political function of the university, a function that holds up the poor majority as the horizon for university action.

University Politics

Structuring the university’s activity from the place of the poor majority and striving to transform the injustices of the present reality makes the university political. The politics of the university does not mean explicit support for a political party, but the political task of the university results from engaging and confronting political structures that create an unjust situation for the majority.49

The university is in and of itself, a reality that moves within the camp of social forces and that, in the abstract, is able to prescind from this political environment of state power, even though not from the environment of social classes, nevertheless, here is where the state converts into a sustainer of social structures that are fundamentally unjust and irrational and constitute themselves as a validator on the part of society against the other, this is, in favor of one social class, here the university necessarily enters the conflict as a social force, it is here where the university puts itself on the side of truth and justice.50


49 Ellacuría, The Challenge of the Poor Majority, 171

50 Ellacuría, Universidad y Política, 185-186. La universidad es de suyo una realidad que se mueve en el campo de las fuerzas sociales y que, en abstracto, puede prescindir del ámbito político del poder estatal, aunque no del ámbito de las clases sociales; sin embargo, allí donde el Estado se convierte en sustenedor de una estructura social fundamentalmente injusta e irracional y se constituye en valedor de una parte de la sociedad en contra de la otra, esto es, en favor de una clase social, necesariamente entra en conflicto con esa fuerza social que es la universidad, si es que ésta se ha puesto de lado de la verdad y de la justicia
The university’s political task emerges in its recognition as an institution that operates as a counter-structure to unjust structures. While this does not mean siding with a political party, it does require that the university honestly reflects on, critiques, and offers solutions for the injustices present within its context. One way in which it critiques injustices stems from Ellacuría’s epistemology.

Ellacuría holds that all knowledge is derived from a particular perspective and from experiences. Therefore, he encourages the UCA, and implicitly other Catholic universities, to readily call out any “pretense of scientific neutrality and professionalism that negates ‘interestedness and ideologizationally,’ the political reality of the university in order to make it, surreptitiously, a political instrument at the service of the dominate structure, which may or may not conflict with society.” 51 Rather than encouraging objectivity in its research practices, which does not exist, Ellacuría challenges the university to embrace this lack of “disinterestedness” and to embrace an ideology that explicitly prioritizes justice for the poor. Thus, while engaging the community through the public and private interests of business and government therein, the university must be conscious and vigilant in its mission to socially project reality in a way that prioritizes justice for those who have none. An explicit focus on justice from the perspective of the poor requires an epistemological shift that emphasizes the theological mission of the Catholic university.

Theological Mission

The option for the poor captures both an epistemological insight and theologically shapes how the Catholic university realizes, shoulders, and takes charge of reality. The

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51 Ellacuría, Universidad y Política, 186. Nos encontramos, en un extreme, con la pretensión de la neutralidad científica y profesionalizante que niega ‘interesada e ideologizadamente’ la realidad política de la universidad para hackear de ella, subrepticiamente, un instrumentos politizado al servicio de la estructura dominante, haya o no haya conflictividad en la sociedad
Christian inspiration of the university necessitates engagement in activities that foster the continuation of the actions of Jesus in history. Yet, there is certainly a counter-cultural dimension to Jesus’ mission, which was preached in a particular way to the marginalized—the economically poor and the social outcasts, including those who were ill. Epistemologically, for Christians knowing changes with the experience of Jesus in history. God is understood as human, not one of privilege, but one who was marginalized. Jesus did not live a long life, but rather one cut short by dying an innocent death. His mission was one of inclusion that challenged existing social structures. The Catholic university participates in the continuation of this theological mission by consciously embodying an option for the poor.

A university is a Christian university when its horizon is the people of the very poor who are demanding their liberation and struggling for it. [Thus, it is] a university whose fundamental commitment is to change both structures and persons with a view towards a growing solidarity; a university which is willing to engage in dangerous struggle on behalf of justice; a university whose inspiration for making ethical judgments of situations and solutions and for the means to use in moving from such situations to solutions is the inspiration of the gospel. It is also—some of us believe—the different university that our country needs.52

Thus, the way in which Ellacuría frames the Catholic-nature of the university does not rest on a doctrinal assent, but on the commitment of a praxis that engages the world as Jesus did, by making an option for the poor. Making this option, however, will narrow the focus of how the Catholic university goes about its tasks of teaching, service, and research.53

Teaching, research, and service that take the poor majority as the horizon of its

52 Ignacio Ellacuría, “Is a Different Kind of University Possible?” 207.

53 For medical research this poses a particular challenge. The breadth of what can be researched is expansive, however, funding for research that addresses the health needs of low-income countries is relatively limited. Chapter Four highlights the injustices within the current structure of medical research, while Chapter Five concludes by offering possibilities of challenging these existing structures.
activity, aims at the transformation of society by promoting the common good, but minimally avoiding common harm.\textsuperscript{54} In a brief essay, Ellacuría argues that the common good offers a formal and abstract horizon that attempts to shape one’s actions. However, it is difficult to agree on the exact characteristics that make up the common good, which Ellacuría argues is not the sum of all individual goods. Thus, he proposes that a focus on the common harm might generate some consensus on morally responsible actions.

He describes the common harm as those actions that result in harm to the majority of persons.\textsuperscript{55} While the common good can be defined inversely, it still remains somewhat nebulous as to how to construct the common good, particularly in the midst of unjust situations. Thus, in educating against the common harm, the UCA aims to develop initiatives that worked against “the structural oppression of the majority of Salvadoran people, the UCA should look, offer, and support univerisitarily the process conducive to more justice, freedom, and solidarity in El Salvador and Central America.”\textsuperscript{56} Yet, the way in which this is to be done is not uniform, but rather is a dynamic process that works interdisciplinarily through the activities of the university by beginning with the experiences of those who suffer injustices. Beginning with experiences of injustice requires that scientific and medical research be reimagined in order to address the needs of those who suffer most.


\textsuperscript{55} Ellacuría, “El mal común,” 448.

\textsuperscript{56} Ellacuría, Funciones fundamentales de la universidad y su operativización, 107. En y ante una situación real de opresión estructural de la mayoría del pueblo salvadoreño, la UCA debe buscar, ofrecer y apoyar universitariamente los proceso que propicien una convivencia mas justa, libre, y solidaria en El Salvador y Centroamerica.
Research and the University

Research prioritizes the objective pursuit of knowledge by more deeply understanding reality and discovering new ways of engaging it. One of the potential pitfalls of research is its tendency to understand itself as an isolated and neutral task, devoid of interests, aside from scientific progress. An argument for objectivity proves particularly challenging in the pursuit of research that explicitly strives for technological or scientific advancements that fails to address the immediate needs of the present reality. Research for advancement becomes, in essence, a “race to stay ahead,” rather than socially projected research. Ellacuría notes:

other research agencies are so far ahead of us in this respect we can never catch them. Rather, it would be a kind of research that can help resolve the huge problems of a national reality whose chief defining feature [now] is the existence of popular majorities who see their fundamental human rights violated and a blockade of the potential pattern towards a life emerging from the true cultural and political self-determination.\footnote{Ignacio Ellacuría, “The University, Human Rights, and the Poor Majority,” in \textit{Towards a Society that Serves its People: The Intellectual Contribution of El Salvador’s Murdered Jesuits}, ed. John J. Hassett and Hugh Lacey, trans. Phillip Berryman (Washington, D.C.: Georgetown University Press, 1991), 218.}

For medical research, Ellacuría’s insight is important to consider. University funding for medical research at Catholic universities is limited. Insofar as Catholic universities attempt to keep up with the Harvard’s, Oxfords, and Freiburgs, there success will often fail to address the “big problems” in need of addressing, like malaria, TB, Ebola, etc.\footnote{Harvard University, Oxford University, and Freiburg University represent globally some of the leading research institutions. League of European Research Universities, “Membership Criteria,” http://www.leru.org/files/general/leru_membership_criteria.pdf. (accessed: April 10, 2015). Chapter Five will give greater attention to the way in which Catholic universities can participate continue to participate in medical research, but to do so by deliberately and collaboratively addressing injustices in health.} Ellacuría’s challenge requires that research focus on addressing “huge problems” that violate the rights of individuals and communities and inhibit full participation in society both culturally and
politically. Positively asserted, then, medical research has a responsibility to target those places where a lack of health restricts a person’s ability to flourish. Ellacuría describes research that allows for greater participation in the shaping of historical reality as humanized and historicized research.

Humanization, Hominization, and Historicization

Humanized research strives for outcomes that allow for greater participation and flourishing of human beings, which becomes historicized in and through human praxis. In short, Ellacuría’s notion of humanized research is rooted in the biological fundament of ethics, namely, that research should promote biological possibility of participation in history (hominization). By this he does not mean biological enhancement or a constant perfection of human beings, but simply research that sustains life where life is most often threatened, amongst the poor. Research for biological sustenance, hominization, represents the baseline criteria for ethical research. Ellacuría argues, however, for a move beyond “hominzed” research in pursuing the humanization of research.

The humanization of research allows for the historicization of fewer injustices that limit human persons from greater participation in the actualization and shaping of historical reality. “Humanization of the species presents itself as an ethical corrective and prolongation of the biological process of hominization. Humanization has to be conceived, then, as a process that optionally and projectively, continues and prolongs the biological process of hominization.”59 The process of humanization, therefore is not separated completely from hominization. The goal of humanized research, however, is not the postponing of death, and instead, humanized research allows for those who have historically

been limited from participating in historical reality a better opportunity to shape the reality in which they live. The verification of the success or failure of humanized research takes place through the historicization.

The historicization of research requires some verification of the fuller participation of those who have been dispossessed by history is realized. The historicization of research takes place through the increased ability of human persons to “make history from nature and with nature…and educes the determinative influence of human praxis upon historical reality.”60 With respect to medical research, greater attention needs to be paid to measures such as Quality Adjusted Life Years (QALYs) and Disability Adjusted Life Years (DALYs). These quantitative public health measures, described in greater detail in the next chapter, give tangible content by which to measure research’s historicization. For Ellacuría, humanized and historicized research is socially responsible research that allows for human flourishing for those whose lives unjustly end before their time.61

While human existence is not all about biological life, it constitutes the first of human rights, a right that is not always realized.62 Often, this inability to realize this basic right to life can be limited by the technological capacity to deliver what is necessary to further human life. This is certainly true in many areas of the world in which not only medical technology is limited due to a variety of factors, but also basic necessities such as access to healthy foods, clean water, or health care remains unavailable to the majority. Thus, historicization and humanization of research, particularly medical research, cannot be

60 Burke, _The Ground Beneath the Cross_, 123.

61 Ellacuría, “Fundamentacion” 261.

discussed apart from the science and technology that can address these pressing health needs.

The Role of Technology

Technology and scientific advancements form a creative potential in the world that has resulted in both the ability to sustain itself against environmental threat and a desire to seek absolute control over that same environment.\(^6^3\) While both technology and science have been used in positive and transformative ways, Ellacuría notes that technology itself has been utilized increasingly as an instrument of control over the physical world that has resulted in the domination of the other. “Domination, above all, of the physical nature, by the knowledge of its laws and potentialities; domination of other human beings, but managing its disabilities and desires; domination of people, those that appear impotent before those that hold the power of technology.”\(^6^4\) Recalling the historical examples of medical research, the positive uses and the abuses of emerging research technologies can be seen throughout.

In particular, the juxtaposition of the development of the yellow fever or small pox vaccines with that of the global eugenic practices of the early 1900s reveals a stark contrast in the use of technology. While the vaccine programs sought control of a disease that was disproportionately affecting large groups of people, eugenics research sought to manipulate and control human beings by using technology that enabled certain lives to be valued more than others. Thus, it was not about enhancing participation in the construction of historical


\(^6^4\) Ibid., 235, Dominación, ante todo, de la naturaleza física, mediante el conocimiento de sus leyes y potencialidades; dominación de los otros hombres, mediante el manejo de su debilidades y apetencias; dominación de los pueblos, que se bien impotentes ante quienes detentan el poder técnico.
reality, but rather further restricting this participation. Today, though perhaps less maliciously, the vast majority of human beings who have limited access to benefits of technological advancements in medicine tend to be those economically disadvantaged in the two-thirds world. Thus, an ethical approach to the use and distribution of the benefits of research ought to be considered. This is particularly important because greater access to these technologies correlates with greater participation in the co-construction of historical reality.

Just-Research

For Ellacuría, just-research confronts and takes responsibility for reality by addressing the fundamental necessities of the poor majority, a responsibility that can be easily be lost in the technological and financial scope of medical research. Technology and research holds the power to “create a humane or inhumane world, it can be an oppressor or a liberator, it can construct or destroy.” 65 Without historicizing the use of technology, its potential impact on greater participation of the majority in the development of historical reality can be lost. He argues, “A technology taken as a whole, that produces bad effects for the majority of humanity or that simply does not put their resources towards resolving the fundamental necessities for the majority of humanity is a bad technology.” 66 If Christian universities continue to engage in medical research, then it is a theological, ethical, and epistemological imperative that this engagement prioritizes an option for the poor.

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65 Ellacuría, “Tecnología,” 240. La técnica puede hacer un mundo humano o inhumano, puede ser opresora o liberadora, puede construir o destruir, puede ocultar o revelar.

66 Ellacuría, “Tecnología,” 248. Una tecnología que, tomada en su conjunto, produjera males profundos a la mayoría de los hombre o que simplemente no pusiéra su recursos actuales a resolver las necesidades fundamentales a la mayoría de la humanidad, es una tecnología mala.
The university, in taking up social projection of reality as a fundamental task, has the option of focusing on the needs of the poor majority, or not. Ellacuría argues that the Christian university is in a unique place to choose to focus on the needs of the poor and vulnerable. “The university can best offer a scope for action in basic ways for political and structural change and begin to organize appropriate techniques for dealing with an independent voice; provide a number of upright professionals working for deep rapid change primarily in education and public sector; serve as a voice for the voiceless; provide immediate help to neediest through social outreach.”

Essentially, the teaching, research, and service that takes place at universities has the opportunity to transform the way in which students, faculty, and staff contemplate issues of justice and how they can confront the injustices in society. While I will explore examples of just-research more comprehensively in Chapter Five, Ellacuría lays the groundwork for a just-research agenda that targets both preventive and curative research that stands to benefit those who consistently and unjustly bear the global burden of disease.

Advancing a global medical research agenda necessitates intentional and local collaborations with institutions outside the Catholic university who hold a shared sense of the mission of social projection. “Whether the new mission of the university is carried out, however, will depend primarily on what it is prepared to do in its own proper sphere of activity. The university must embody and implement its professed dedication to changing social structures in its threefold functions of teaching, research, and social outreach.”

Given the limited control institutions have over available grants for investigations that aim at social

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67 Ellacuría, “Is a Different Kind of University Possible?” 197-198.

68 Ellacuría, “Is a Different Kind of University Possible?” 198.
transformation of the poor majority, this socially projected task presents unique challenges that I will address in the next chapter. However, despite these challenges, Ellacuría’s vision of a Catholic university—in particular his emphasis on social projection and the historicization of humanized research—offers valuable insights from which certain parameters can be established that allow for a more socially responsible approach to medical research.69

Towards Socially Responsible Medical Research

Medical research functions as multi-disciplinary endeavor that requires the input of biologists, chemists, businesses, governmental and non-governmental agencies. At times, however, the most important people in medical research, the people affected by disease, remain excluded. Thus, developing a socially responsible and socially projected research agenda requires an emphasis on working with those in need of the benefits of medical research and against the very structures limit research on these diseases. For Catholic universities, in following Ellacuría’s liberationist approach, this necessarily considers research that promotes health and humanization globally.

Given that universities themselves are a part of a global network of institutions throughout low, middle, and high-income countries, it is important that global issues are reflected in their research agenda.70 If Catholic universities were to project that reality in their research agendas, tangible repercussions would develop that would affect the way in which research priorities and methods were established. Building on Ellacuría’s insights as a

69 In addition to the challenges that one might pose to Ellacuría’s approach, examples will be given of instances of medical research project that demonstrate the possibility of a different approaches to medical research.

70 This in fact was one of the key points of Fr. Adolfo Nicholas’s, Superior General of the Jesuits, address in Mexico City in 2010. He argued that there is increased competition amongst Jesuit universities and that the globalization of the world has not resulted in more collaboration, but rather increased isolation amongst institutions.
university president, philosopher, and theologian the five theses below draw out implications of his thought that would be reflected in the construction of a medical research agenda with an option for the poor. These five theses provide the foundation from which the rest of this dissertation will develop.

Thesis One

*Medical research functions “communally” and shapes historical reality, which is unified and shared.*

Ellacuría argues that what human beings share in “common” pertains to our biological nature, which is concretely affected by the historical actions of human beings. As the shapers of a unified historical reality in which all things come to be through one another, human beings, in one way or another, constitute the interdependent structure of historical reality. These unified historical actions undertaken by human beings, participate in the co-construction of our commonly experienced reality. Medical research necessarily participates in the formation of the “common,” but medical researchers, often believed to be acting objectively making, can overlook the potential impact of research on society. Thus, medical research’s impact on society happens accidentally rather than deliberately.

A deliberate and targeted approach to medical research more intentionally participates in the development of research that aims to reflect research priorities that can transform the interdependent historical reality in which it exists. If historical reality is a unified reality, and human actions participate in the co-construction of that which is real, then medical research necessarily shapes the commonly experienced historical reality, both

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71 While Ellacuría anticipated, perhaps sooner than others, the globalized world in which the university operates, the “community” in which research is conducted necessarily includes the institutions immediate and local community. However, given the internationalization of university collaborators, this “community-based” approach would necessarily include the social projection of the local and global community, as applicable. This opens up its own unique set of challenges and possibilities that will be taken up in chapter four.
currently experienced and in the future. It therefore follows that those engaged in the practice of medical research are faced with an epistemological option of choosing the place from which they will engage this task. Within this understanding, place can function both as a physical location and as the capacity for human beings to transcend one’s place and put oneself in the place of another human being.

Thesis Two

*Medical research from the place of the poor reflects the Christian university’s mission and should promote research that allows for both homonization and humanization.*

For Ellacuría and the perspective of liberation theology, it is the place of the poor—understood as both a physical and intellectual place embodied by the socially, economically, and biologically disadvantaged—that provides the most authentic ground from which medical research ought to begin its inquiries. In many respects, the injustices and limitations experienced by the poor disproportionately result in premature death and higher propensity for contracting disease than those living in high-income countries. Insofar as medical research, at least at its most fundamental level, is about the promotion of human health then it holds a minimum obligation to concentrate research efforts that allow for the hominization of the human person.

The hominization of research provides the foundation upon which a person is more fully able to participate in the construction of historical reality. At its most basic level, medical research focused on allowing for biological development to continue proves

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72 A contemporary of Ellacuría’s and one of the foundational figures of liberation theology, Gustavo Gutierrez, defines the poor quite simply as those that die before their time. While this definition may raise questions, when this definition is applied to notions of healthcare and medical research there are people to whom this definition directly applies. More often than not they are correlate with Ellacuría’s socially and economically based definition above, see n. 35.
constitutive of human activity in history. Ellacuría’s emphasis on the place of the poor draws attention to the socio-historic locations where unjust poverty and the burden of disease limit the full participation of human beings in the co-construction of reality. Yet, the homonization of research does not adequately address the injustices often suffered. Rather, it is the humanization of research that proves most needed and serves as the goal of Catholic medical research.

The humanization of medical research promotes investigations that allow for greater participation of the poor majority who are de-humanized through a research process that ignores their needs. If homonized research promotes life, humanized research works to allow for the greater functioning of that life. However, consideration of the exact research endeavors needs to begin by considering de-humanized research, i.e. those practices that fail to address the needs of the poor majority. If medical research does not foster the possibility of, and not necessarily the realization of, greater participation of the poor in the co-construction of historical reality, then this research fails to meet the standard of research that should be conducted at Catholic universities.

Thesis Three

_Historicized medical research works through social structures to understand and reflect back a research agenda that is representative of reality._

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73 In Chapter Five, I describe Comparative Effectiveness Research (CER) as a type of research currently supported by existing national funding structures that promotes improving quality health care outcomes by focusing on disease prevention, diagnosis, and treatment. CER centers its efforts on community participation in developing targets for research, as well as ensuring that the same community benefits from the research undertaken.

74 An example of dehumanizing research practices are those that allow disease like Ebola and cholera to continue to go under researched until arriving at a crisis point that is likely to impact Western, high-income nations. I consider both of these examples of neglect in medical research in the next chapter, focusing explicitly on the Ebola outbreak that started in 2014 and Haiti’s cholera epidemic that began in 2010.
The historicization of medical research provides the verification of humanized research through witnessing greater participation of populations that have statistically and experientially failed to thrive. The task of historicization is a foundational component of the university’s social projection. It is in and through the socially projected reality that the university is better able to target its approach to research approach in a way that allows for fuller participation of the poor majority in history. The historicization of research is not validated by making “historical” breakthroughs in medical research, but rather through participating in the development of new populations with whom to collaborate. Thus, through the process of historicizing medical research, it is necessary to identify barriers to humanized research and collaborators with whom overcoming these obstacles is possible.

**Thesis Four**

*Medical research, which develops from sentient intelligence, should work cooperatively with other academic disciplines, including theology and philosophy, to ensure that its interests and values address reality as it is seen and experienced by others.*

A tendency exists in medical research to pursue newer technologies and innovations in a presumed objective and scientific way. However, if all intellection—inclusive of scientific thought—is sentient and rational, then despite medical research’s attempts to be objective, it operates within a particular and defined set of values, motivations, and interest. Moreover, following Zubiri and Ellacuría, these values, motivations, and interests are not necessarily intrinsic to medical research itself, but have been shaped by other historical actors whose interests, motivations, and values co-construct the reality in which research takes place. Therefore, those engaged in medical research must pay attention to the extrinsic influences on the priorities established for research agendas by collaborating with other
academic disciplines. The intra-university collaboration on the specific task of medical research, particularly, with the disciplines of theology and philosophy, broadens the reflective nature of the research task and its foundation in the university’s mission with respect to justice.

For liberation theology, questions of justice arise from stories and experiences of injustice, presenting a unique set of concerns and values that can complement, challenge, and/or affirm the task of medical research. Liberation theology and philosophy, in particular, would be highly critical of medical research that appeared to be motivated by economic incentives or that deliberately sought to benefit the wealthy majority who could pay for treatments and medications, over the poor. By approaching medical research from the perspective of liberation theology, an emphasis would be placed on validating the experience of suffering and working with the poor in search of an alternative. It is here that other academic disciplines prove necessary in an effort to reimagine medical research through the lens of under-researched populations.

Thesis Five

*Developing a research agenda focused on the poor majority functions as a necessary political task that leads to both confrontation and collaboration with public and private institutions engaged in medical research.*

A university-based medical research agenda developing from the place of the poor occurs in an historicized way and necessarily turns to partners outside the university to serve as collaborators. These collaborative partners prove fundamental in determining the appropriateness of medical research within a particular population. In this way, it is not the university grantees or the public/private grantors who establish the medical research agenda, but rather those immersed with in the social reality of the poor majority. However, given the
current process for funding research initiatives, humanized research aimed at addressing social inequalities in health requires a targeted approach to pursuing grants currently available in existing funding structures, but also with the flexibility and willingness to seek alternative sources for funding.

Ensuring that a university’s research agenda takes the poor majority as the horizon of its activity may require the partnering and dialoguing with institutions that do not necessarily share the same mission. As will be explored in the final two chapters, academia and industry have two different objectives—education and profit—and have historically been important collaborators that have allowed for the development of both institutions. However, the university’s task—guided by social projection—also operates within its own sphere of the values, one of which is justice.

Just-research, then, works to create structures that can contribute to social change. One strength of Ellacuría’s model for the university is its openness to dialogue with others that elicits the stories and experiences of injustice in order to transform structures that perpetuate its prevalence. By engaging the ideological other and remaining grounded in the values and motivations at the heart of the Catholic university, potential collaborative partners may emerge that advocate for a broader understanding of medical research that will better enable and promote value-based research that takes the poor majority as the horizon. While this liberated approach to medical research presents its own challenges and critiques, in certain instances, examples of this type of research already exist. Before taking up these examples in the concluding section of Chapter Five, I now turn to the injustices prevalent in the practice of medical research itself.
Conclusion

University-based medical research that meets the needs of the poor majority presents a challenging task given the diverse actors that shape the research agenda. However, Ellacuría’s philosophical and theological project provides a fundamental epistemological shift from the scientific agenda that characterized the Enlightenment and Baconian science.\textsuperscript{75} The emphasis on expanding the horizons of science and developing new technologies perpetuates a social practice that ignores those who suffer from the most acute forms of health challenges that remain neglected. Through the socio-critical lens of liberation theology, the injustices within this practice are unmasked when viewed from the perspective of the poor.

For Catholic universities the option for the poor represents a normative foundation from which to address issues of justice. While the universities articulate their commitment to justice with respect to service and education, it remains unclear how justice shapes the practice of medical research. In the next chapter I will describe the development of the social practice of medical research and how it has emerged within academia as increasingly economic driven task. The task of the Catholic university, explored in Chapter Five, centers on how to be an institution that participates in the shaping of a more socially responsible research agenda.

\textsuperscript{75} Bishop, \textit{The Anticipatory Corpse}. Bishop takes up a genealogical approach, drawing on Foucault, to describe the way in which the technologization of the body has generated a fundamental discord between the medical approach to death and dying compared to one rooted in Christianity. What I want to do is similar, but using medical research and the emphasis on the poor as an epistemic category by which to make a similar shift. Thus, by maintaining a Baconian and technology perspective, one loses the context in which research is conducted and who stands to benefit.
CHAPTER FOUR
RESEARCHING REALITY

Introduction

In this chapter, I follow Zubiri and Ellacuría’s claim that human intellec
tion functions simultaneously as a sentient and rational process to argue that science and medical
research, therefore, never operate as a purely neutral or objective practice. Scientific research,
like all other forms of human activity, both shape and are shaped by historical reality. Thus,
the context from which research one approaches medical research influences how it
develops and who benefits from those developments. In this chapter, I am particularly
concerned with socio-political values within the development of medical research, who has
benefited over time from the development of research, and, conversely, who did not. Finally,
I address the ways in which research can begin to recognize and advocate for those who
have been unjustly overlooked within the practice of medical research.

In his neo-Aristotelian ethics, Alasdair MacIntyre argues that all practices have a
social dynamic that must be established as a “good” activity. The good of a particular activity
both comes from and develops in relationship to social contexts. Within this activity, agreed
upon goods of particular practices emerge that prove constitutive of the human activity in
and of itself. Thus, a practice is:
any coherent and complex form of socially established cooperative human activity
through which goods internal to that form of activity are realized in the course of
trying to achieve those standards of excellence which are appropriate to, and partially
definitive of that form of activity, with the result that human powers to achieve
excellence, and human conceptions of the ends and goods involved, are
systematically extended.¹

Here, MacIntrye speaks to the cooperative nature of human practices and the inherent goods
particular to them. At the same time, these goods have to be identifiable and, through
“human powers,” are brought to fruition. In Chapter One, I addressed the notion of medical
research as a practice that at its most basic level concerns itself with the promotion of health.
In this chapter, I argue health has not always been seen as the goal of medical research.
Within the development of research funding, serious questions emerge whether the
improvement of health played as prominent of role as it should have in creating funding
structures for medical research.

A variety of factors influenced the development of funding practices for medical
research. These developments, however, should not be viewed as distinct from the goal of
medical research itself, serving instead as a complement to the process. Chief among these
developments has been the important relationship between industry and academia. Industry,
in this case, is understood as businesses whose primary aims are the buying, selling,
marketing, and development of goods able to be sold as they pertain to health. The first
section of this chapter focuses on the gradual development of the relationship of academia
with the pharmaceutical industry.

The origins of this collaboration in the U.S. center on developments both prior to,
and in the midst of, the World Wars. It was at this time that the U.S. government formed

¹ Alasdair C. MacIntyre, *After Virtue: A Study in Moral Theory* (Notre Dame, Ind.: University of Notre Dame
2, (1999), 311-29.
collaborative relationships with universities. During the Wars, government, university, and industry officials focused on developing wartime technology. However, at the conclusion of the Wars, there was a desire to both continue the progress made in research and to find new researchers capable of expanding these efforts to fields beyond wartime technology.

The second section of this chapter, then, describes the evolution of the collaborative relationships between government, industry, and academia as essential to the way funding structures were established for research, with economics becoming a key motivator of both. The prioritization of economic gain influences the decision to pursue certain research endeavors over others. These choices contribute to disparities between those who benefit from medical research and those whose needs go unnoticed in the establishment of research priorities.

The disparities in research manifest themselves between the diseases suffered by persons from low and middle-income countries compared to those of high-income countries. People living in low and middle income countries comprise the majority of persons in the world who, incidentally, disproportionately bear the global burden of disease, as measured by disability adjusted life years (DALY). DALYs serve as a statistical measurement for the total number of life-years lost due to death and/or disability. Thus, in order to create an agenda that aims to improve health, DALYs prove an important tool that indicates the geographic location of those whom have the greatest unmet health needs. Yet, despite knowing those who suffer the greatest burden of disease, relatively little has been done to significantly close the research gap, which I will explore in section four. In fact, the research efforts of high-income countries largely ignore the needs of these countries. One need look no further than the most recent failures of the global management of the Ebola
outbreak, which resulted, in part to insufficient attention to a disease that had confined itself primarily to West Africa.

In section five, I turn to a commentary by Paul Farmer, physician, global health expert, and medical anthropologist, on the recent Ebola outbreak. Farmer argues that improving a population’s health begins with a health care delivery system, public health infrastructure, and general readiness with developments from medical research to care for the health of another human being.\(^2\) It was only when Ebola entered the Western world that a bevy of concerned persons began to raise awareness about the need to research Ebola and other global diseases that disproportionately target the poor majority.

The final two sections address the importance of raising awareness about diseases by highlighting the role advocacy groups have played in altering the research agenda. One of the primary successes of advocates, particularly within the HIV/AIDS movement, has been their ability to communicate the stories of the patients to the general public. Too often, the stories of the poor and marginalized go unheard. If medical research is going to be a practice that improves health, then the stories of the “unhealthy” have to be heard. While advocacy and narrative efforts are not cure-alls, they can impact the way in which research is conducted.

The social practice of medical research functions as a complex and financially incentivized collaboration that often undervalues the health needs of the majority of the world. Yet, within this structure institutions have a responsibility to maintain the focus of medical research on health. Advocacy efforts prove important to this process by speaking for the research and health needs of those who unjustly bear the burden of curable and/or

controllable diseases. While this chapter takes up the social challenges within medical research, the final chapter will draw examples of research practices that maintain a focus on health and just-research practices that befit Catholic universities.

**The Industry-Academia Collaboration**

Policies adopted by the U.S. government fueled collaborative efforts between academia and industry. As shown in Chapter One, during World War I and II, the government had partnered with universities and industry officials to develop new technologies for the immediate use in war. As the war drew to a close, it was realized that a model had been established for generating new knowledge that, at the same time, provided an economic stimulus for the U.S. The creation of new knowledge allowed for the production of goods that could then be sold on the market. However, a challenge after the war arose from the need to put new knowledge and products to non-wartime use.

While some health related research had been going on as part of the war efforts—development of vaccines to be used in the geographical areas in which soldiers were fighting, as described in Chapter One—the investments made by the government were minimal. Post-war, the U.S. continued to invest in technology-based research but also expanded its scientific research relating to health. The leader of this effort was Vannevar Bush, head of the U.S. Office of Scientific Research and Development (OSRD) during and after World War II.

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3 The focus of this chapter centers on U.S. based research practices because they are the largest funders of government-based bio-medical research. Moreover, the intellectual property policies developed here are similar to, and in certain cases established the model that many other high-income countries follow.
Bush’s proposal to Roosevelt outlined the importance of the government’s post-war investment in research through the education of soldiers who would serve as the next generation of scientists, and emphasized the importance of continuing to fund university-based research. On both fronts, the hope was that these efforts could lead to a source of revenue for the U.S. economy through the production of new knowledge. Bush’s landmark report, *Science the Endless Frontier*, signaled two important concerns that the nation faced following the war’s conclusion. The first highlighted the need to put soldiers to work returning from war, and the second concerned continuing the economic dividends that the U.S. reaped by investing heavily in scientific research during the war. While these investments were primarily technology-based, Bush argued for new forms of research that would invest in the public good, one of these goods being health. As Bush’s ideas began to take form, the National Institute of Health started investing its research dollars into universities and medical schools.

Medical schools and universities served as the ideal places to make investments in scientific research because of their ability to serve as centers of education and their track record of collaborating with government and industry. First, universities were able to meet the need of educating returning soldiers for new jobs in scientific research. Bush commented, “Many had begun their studies before they went to war. Others with capacity

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5 Richard C. Atkinson and William Blanpied, “Research Universities: Core of the US Science and Technology System.” *Technology in Society* 30 (2008): 30-4. Chief among these collaborations came from University of Chicago, Columbia University, and Massachusetts Institute of Technology, all of which had made important contributions to the development of the atomic bomb. Thus, not only were universities collaborating with government and industry, they were doing so on some of the most top secret and significant developments—albeit a quite sinister one—of the twentieth century.
for scientific education went to war after finishing high school. The most immediate
prospect of making up some of the deficit in scientific personnel is by salvaging scientific
talent from the generation in uniform.”6 Bush saw academia as playing the role of re-
supplying the scientific work force with returning soldiers for future research. Bush and
others, moreover, hoped that increasing the number of scientists at work in education held
potential for stimulating industrial development emerging from new innovations.

At this time, most of the health-related research centered on diseases that could be
contracted overseas during the war: yellow fever, typhus, malaria, and various sexually
transmitted diseases. The funding for this research came from a combination of private
investment, e.g. Rockefeller Institute, and public grants targeting academia and industry
researchers willing to participate in the war effort. The OSRD was working closely with both
industry and academia “to develop penicillin, synthetic antimalarial drugs, steroids, and
replacement blood products, the companies used their preexisting connections with
academic researchers to meet the wartime demands.”7 Thus, the collaborative relationship
Bush proposed was nothing new, but rather an attempt to expand the success generated
during the war effort.

Post-war research efforts shifted, however, to focus on cancer, cardiovascular, polio,
sexually transmitted diseases, e.g. syphilis, and the development of neurological drugs.8 While
Bush understood that scientific progress itself was not a “panacea for individual, social, and
economic ills,” it was essential for ensuring “health, prosperity, and security as a nation in

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6 Bush, *Science, the Endless Frontier.*
the modern world.” As an example, research efforts around cancer engendered widespread marketing campaigns and fundraising efforts, which helped to raise awareness about the positive impact that research can have on the lives of Americans. In addition to generating public support, the U.S. government saw investment in research as a way to emphasize the importance of strong science behind the development of new drugs.

Scientific Support

The U.S. government’s emphasis on the basic sciences as the heart of a medical education allowed for the strengthening of the regulations for new drugs with the support of scientific data. Thus, universities with schools of medicine saw an influx of scientific researchers and an opportunity to interrogate the questionable science behind many of the drugs on the market in the early half of the twentieth century. One such case resulted in the death of some 107 people following the consumption of a new drug Elixir Sulfanilamide.

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9 Bush, Science, the Endless Frontier.


11 Abraham Flexner and Daniel Updike, Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching (New York: Merrymount Press, 1910); Lawrence H. Diller, “100 Years Later, the Flexner Report is Still Relevant,” Hastings Center Report 40, no. 5 (2010), 5.; Starr, The Social Transformation of American Medicine, 118-126. By turning to medical schools, the government sought benefit from the renewed emphasis on the basic sciences as the heart of a medical education. The influx of scientific researchers in university and medical education would allow for the government to be more assured that the scientific developments that could be applied would be more rigorously studied. The government’s concern about the questionable science behind many of the drugs that were on the market in the early half of the 20th century was reflected in the tightening of regulations controlling the selling and marketing of drugs. In short, universities and medical schools came to serve as an important interchange between publicly funded research and potential economic returns in an increasingly regulated drug industry.

Though there were prior Food and Drug Administration regulations, the 1938 regulations reinforced the importance of sound science behind the development of new drugs.

The regulation standards for the marketing and selling of drugs had come under heightened scrutiny by the FDA through policy developments in 1906 and 1938. In 1906, the “Pure, Food, and Drug Act” outlawed the use of false or misleading drug labels. In 1938, the “Food, Drug, and Cosmetic Act” adjured these same companies to demonstrate the safety of their products before the FDA approved them for marketing. Academic scientists found their domain of expertise in demand on multiple fronts, as educators, as regulators, and as innovators. From the government’s perspective, universities and medical schools provided the space in which new discoveries could be made and the science behind the new drug discoveries could be verified. Industry, given the increased regulations, likewise, needed to partner with academia in order to comply with FDA guidelines. The drug industry knew that it needed its products to be more scientifically sound, but additionally saw future possibilities in collaborating with academic researchers.

Through the initial relationships between industry and academic institutions, the drug companies ensured their products were up to FDA standards, which led to financial arrangements with academic research centers. In detailing the history of industry and academic partnerships, Tobbell described how one of Harvard University’s vice-presidents courted a relationship with George Merck to “advance biomedical education and research…”13 When this courtship succeeded, the money received did not have any stipulation that Harvard would put it toward a particular research endeavor, but rather would be used for the overall development of students and infrastructure. From the perspective of

the industry, however, these relationships built up academic allies who could offer scientific support for their products. Recognizing the need for collaborating with scientists, industry officials, e.g. George Merck, Eli Lilly, reached out to universities to form partnerships.

As the possibilities of collaboration were realized between universities and industry officials, the government increased funding for research, and the FDA increased regulations. The tightening of regulations further strengthened the partnership between academia and industry. By the late 1950s and early 1960’s the partnerships had grown to the point that both academia and industry became leery of any “non-scientific” government influences for fear that they would begin to dictate what they could research, exerting control beyond regulations. “Academic physicians and the industry regarded the scientific weakness of the FDA as a very real threat to the integrity of pharmaceutical innovation and to clinical research, and thus to the public’s health.”14

The scientific weakness of the FDA, however, did not stop them from tightening their regulations on newly developed drugs.

The 1962 FDA regulations allowed the FDA to take greater authority over the testing, manufacturing, and marketing of drugs and served to solidify the relationship between academia-industry. The increased regulations by the U.S. government strengthened the relationship between and academic researchers and industry because industry officials needed to ensure that their products could pass FDA regulations. While the details of this arrangement lie beyond the scope of the argument, the nexus of relationships between government, academia, and industry create a story in which all three entities mutually relied on and influenced the others.

14 Tobbell, *Allied Against Reform*, 888.
The collaborations between the three players—industry, academia, and politics—though complex, have shaped the way in which research has developed. The U.S. was concerned with maintaining the collaborative research efforts that had made significant contributions to the public good during the war efforts. Academia, facing a renewed dedication to science and medical education, sought to collaborate with government and also industry officials regarding the scientific aspect of drug development. Industry saw these partnerships as opportunities to deepen the science behind their products, and also to increase its marketability though allying with physician-researchers to explain the validity of the product. This junction of collaborations, forecasted in Bush’s proposal, was solidified by the hefty investments in research made by the NIH.

**Funding Research**

The NIH’s budget dramatically increased U.S. investment in health-related research between 1945-1970. In 1947, NIH funding for research was slightly over four million dollars. Within ten years, the total dollars invested would reach $100 million. In addition to investing in research, the government also saw the need to develop the research infrastructure of the NIH. Thus, the NIH saw its own budget—not just that portion used for grant awards—expand from $8 million in 1947 to more than $1 billion by 1966.\(^{15}\) This significant public investment created jobs, and generated practical health benefits and products that could be invested in by private industry in the hopes of making a return on their investment. This period of research is often referred to as the “golden age” of research, where the resources being invested were rapidly yielding new knowledge and financial gains through grant-based initiatives.

The NIH grant awards were intended to support research projects and any additional costs incurred by the research institution itself. Howard Schachman, a researcher, professor, and an influential figure in the development of grant review process, described the landscape of research in the 1950s as modest. He held a $7,000 grant from the National Science Foundation to help fund his research. Though he realized the possibility of other larger grants, he was content with the one that he had.\textsuperscript{16} The grant offered support for his research and provided minimal assistance for ancillary staff. “Graduate students in the early 1950s were supported as teaching assistants or research assistants funded by small grants to faculty members or departmental funds. A typical laboratory would have one or two graduate students, a technician, and perhaps one postdoc, a far cry from the research group of today.”\textsuperscript{17} In a short time, the size of a research team, which is today composed of multiple graduate students, post-docs, and research assistants, the source of paying for those researchers evolved from a university-incurred expense to one absorbed frequently by grant awards.\textsuperscript{18}

Grants were, and still are, awarded through a peer-review process that considers a wide-range of factors: research design, purpose, experience of researcher/s, budgets, and appropriate “fit” for the aims of the grants itself. Peer-review serves as the standard process

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\textsuperscript{17} Schachman, “From ‘Publish Or Perish’ to ‘Patent and Prosper.’” 6891
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\textsuperscript{18} This represents an important distinction from today that will be described in a bit more detail below. The distinction is between “hard money,” i.e. built into the university’s budget, versus “soft money,” salaries that are only received through the procurement of grants.
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for determining grant awards. At NIH, the review process is divided into two levels. The first review takes place with a team of “expert reviewers” who consider the scientific and technical value of the projects. This is an appointed review board of individuals who have expertise relevant to the proposed grant. The initial panel is responsible for scoring the application from one to five—one being the top score and five the lowest—and compiling comments from the grant reviewers. The grant and its score are passed on to the second level of review.

The second level of review takes place with both public representatives and scientific experts who are appointed to the NIH review council. They evaluate the project based on seven core values of NIH peer review: expert assessment, transparency, impartiality, fairness, confidentiality, integrity, and efficiency. While the 1-5 score is taken into account, the priorities of the NIH, special projects, potential overlaps, and the “general fit” of research needs are considered.

It is important to note that the research needs have been determined historically from within the scientific research community, though different types of researchers are represented—i.e. basic, epidemiologic, clinical, quantitative, and qualitative investigators—their discipline is science. In this way, the focus of the research review process remains rooted in an epistemology that views science as an objective practice. Yet, with the

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epistemological shift called for in the previous chapter, the transformative effects of research on historical reality have to be viewed more broadly than their scientific impact.

As seen below, the impact of research decisions on poor and vulnerable populations cannot be viewed as neutral. Therefore, the needs of the community in which the research is intended to benefit needs to play a part in setting priorities for awardees. While this process continues to be improved upon, it was not even on the radar of the award committee during the research’s “golden age.”

During the research boom, grant applications in the 1960s and into the 1970s enjoyed a near 60% success rate. This high success rate in grant awards allowed universities to use research dollars for needs beyond the scope of the research process itself. The influx of research dollars due to successful grant applications from university researchers led to the allocation of that money to cover a host of costs that the university attributed to research. These costs included construction costs for new buildings, administrative fees, graduate and post graduate fellowships, and eventually faculty salaries. Research costs would eventually be used to justify two or three months worth of salary, but this gradually led to “establishing ‘soft money’ faculty positions.”

Soft Money

Soft money positions signify that the faculty-researcher is responsible for raising a small to significant portion of one’s salary through grants. This is opposed to hard money positions, in which the faculty member is guaranteed and accounted for in the university’s

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21 This review process can be contrasted with that of Comparative Effectiveness Research (CER) described in the next chapter. CER grant review intentionally focuses on the input of the community that the research intends to benefit.

budget. Schachman notes that this has become common practice, particularly in medical schools. He recalls that one institution in California has been allocated state funds for 30 full-time faculty salaries, and approximately 300 faculty members held those 30 slots. In the case of this institution, faculty members are required to raise around 90% of their salary from grant awards. With this type of system, universities were able to create much larger science departments than before, thereby justifying the construction of new buildings and research facilities to house their growing faculty. The researchers raising funds for their own salaries, coupled with the construction of new campus buildings, however, leads to discontent between university administrators and research faculty.

Given the amount of public funds used to support faculty time and construction of research buildings in the 1970s, complaints surfaced about too little of the grant money being used to support research. “Research scientists, faced with stringent budgets and with ratings on their grants below the funding level, argued strenuously that indirect costs amounting to billions of dollars annually, should be reduced markedly. In their view, the money saved could then be used to support more research.”23 As more questions arose about the university’s use of funds, so too did difficulties regarding the university’s ability to cover “indirect costs” with grant money. While successful applications from the mid 1960-1970s were consistently near 60%, this figured dipped significantly in the 1980s and settled closer to 20%.24 This shift can be attributed, in large part, to changing priorities within the U.S. budget, which led universities to look for new sources for research funding.


The economic benefit research afforded for universities increased throughout the 1960s only to level off at the dawn of a new decade, forcing universities to explore alternative sources of funding for researchers. Paula Stephan noted two factors in particular: the Vietnam War and the Mansfield Amendment. The 1969 Mansfield Amendment barred any research that was not directly targeted for the benefit of military function, and therefore restricted the use of government funds for university-based research.\(^\text{25}\) However the government had not been the only entity investing in research throughout this “golden age.” Universities’ own contributions “increased by 55 percent, and by contributions from all other sources, which included philanthropic organizations, that grew by 68 percent. Industry’s expenditures on academic research increased by almost 70 percent.”\(^\text{26}\) Thus, given the multiple investors and competition for research dollars, universities had to find a way to keep sources of revenue flowing in order to invest in new buildings, pay top researchers, and continue the philanthropic investment, all while NIH funds had stalled. Nevertheless, universities were determined to find ways to pay their researchers and generate some return for the intellectual property being developed at their institutions.\(^\text{27}\) While there was much debate about the patenting of research for industry purposes, universities themselves remained disinterested in patenting rights until the mid 1970s.


\(^{27}\) Ibid. The number of institutions offering science PhDs almost tripled from 80 at the end of the war to 224 by 1974. This made acquiring grants most difficult, particularly as NIH investments slowed. Thus, with hundreds of PhDs being produced each year, industry began to be able to pick off researchers and could also pay much better than academia. Here one can see the convergence of science, business, politics, and education affecting the way in which research is structured. While university researchers had to earn their soft-money salaries, industry PhDs were guaranteed theirs.
Patents and Current Research Funding

The slowing of NIH funds that emerged in the late 1970s and early 1980s, began to shift the position of universities with respect to patenting rights. As funding sources began to wane throughout the 1980s, universities sought other ways of maintaining the revenue flow to which they had grown accustomed. Concurrently, research itself became a more expensive undertaking, while pharmaceutical and newly emerging biotechnology companies tended to reap the financial benefits.

While no one would doubt the importance of ensuring the quality and safety of a drug, this comes at a cost. Significant resources, both financial and employee time, are devoted to clinical trials. This has been particularly true as researching targeted the defeat of certain diseases, e.g. Nixon’s famous declaration of “war on cancer.” Therefore, not only were universities engaged in basic science research, but medical campuses— institutions with both a university and a hospital— were now more heavily engaged in expensive and time-consuming clinical trials. While technological breakthroughs and a spike in resources devoted to clinical trials led universities to seek alternative funding sources, it is was legal action that allowed universities to patent their intellectual property.

Bayh-Dole and Diamond v. Chakrabarty

Two important events, the passage of the Bayh-Dole Act and the U.S. Supreme Court ruling Diamond v. Chakrabarty, both in 1980, solidified efforts to allow for the patenting of intellectual property derived from federal funds. The first of these developments, the passage of the Bayh-Dole Act, offered an opportunity for researchers, their university, and

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private industry to more fully participate in the economic aspects of research.29 The act established a uniform patent policy in which universities and other non-profit research entities could “retain the title to inventions made under federally-funded research programs.”30 This was a reversal of years of policy that allowed the government to retain the intellectual property rights of developments that came from government funds. This legislation was reinforced by another development, the Supreme Court ruling in *Diamond v. Chakrabarty*.

The *Diamond v. Chakrabarty* ruling allowed for the patenting of a biologically engineered microorganism that was designed to be able to break down crude-oil spills.31 The consequences of this ruling were two-fold. Most importantly, it marked the first instance of patenting a product derived from federal funds. Secondly, the patent was for a biologically created organism. Thus, as biotechnology has become more sophisticated, the ability to create biologically engineered organisms has continued to grow and patents increase.32 While the Supreme Court ruling promoted a close 5-4 decision, it paved the way, along with Bayh-Dole, for patenting of new biotechnology and the potential for generating a substantial financial gain from those research endeavors.

29 The act’s passage enabled greater collaboration with industry representatives and served as an instantaneous model for way in which research was conducted globally. The move to be open to the commercialization of publicly funded research was not exclusively a U.S. phenomenon. Similar legislation has been enacted in: Brazil, China, Denmark, Finland, Germany, Italy, Japan, Malaysia, Norway, Philippines, Russia, Singapore, South Africa, South Korea, and United Kingdom.


Today, patenting practices at universities and non-profit organizations have become commonplace in the basic science research. The Association of University Technology Managers, the association of managers that oversees technology transfers at universities, serves as a gauge for the interaction between academia and industry. Since the passage of the Bayh-Dole Act, Callahan notes that as of the early 2000s, “American universities now own more patents than the twenty-five largest pharmaceutical and the biotechnology companies put together.”33 Patenting rights generally allow the intellectual property holder to maintain sole possession of the patent for 20 years from the time of application. This exclusive period of ownership, has allowed American universities to develop more than 4,000 companies and, according to AUTM survey data, has generated significant financial rewards, netting $36.8 billion in 2012 alone.34 Patenting, while not problematic in and of itself, does complicate the motivations and values operating within research efforts, particularly as industry assumes more and more control over the research and development of new drugs. This shift, both within the university and industry engagement with research, has raised concerns within the research community about the purity of research efforts and the challenges of doing research in an environment with multiple interests and billions of dollars at play.35


Conflicts of Interest

One approach to addressing emerging ethical questions between financial rewards, patents, and the goal of medical research centered on the issue of conflicts of interest. Conflicts of interest can arise for a variety of reasons, and when they do, they have been shown to affect decisions that researchers make. Josephine Johnston, a researcher at the Hastings Center, describes academic studies with financial ties to industry have tended to be favorable to the sponsor of the research and holding back negative publications. While financial conflicts can lead to disproportionately favorable outcomes in experiments, they have also been shown to improve the likelihood of a drug’s approval.

In a recent study, exclusive industry partnerships with researchers who serve on regulatory boards, e.g. the FDA, tend to approve drugs at a 10% higher rate than those with no financial ties or multiple ties to the sponsor and a competitor. This is not to say that conflicts of interest cannot be balanced, however, it raises important questions regarding the motivation of research approval and consequences of patenting. Moreover, conflicts of interest raise questions regarding the validity of the approval process itself. In other words, are new drugs simply being approved because they offer an opportunity for financial gain or because of the health benefits they might bring? Questions regarding conflicts of interest retain central importance and should continue to be investigated, as billions of dollars flood the global research market.

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37 Tobbell, *Allied Against Reform*, 894-897.

38 Genevieve Pham-Kanter, “Revisiting Financial Conflicts of Interest in FDA Advisory Committees,” *Milbank Quarterly* 92, no. 3 (2014), 457-458. The average approval rate is about 50%, with exclusive financial ties to a sponsor it rises to a little over 60%.
Global Investments

Global investment in research and development, taking place through both public and private funding sources, reached over $1 trillion in 2014. Battelle, a company that tracks the business aspects of innovation across various industries, estimates that about half of that trillion is divided amongst basic science research and applied research throughout various public and private research institutions. The United Nations Education, Scientific, and Cultural Organization (UNESCO) derived close to the same figure as Battelle, with the U.S. leading the way in investments for health related research totaling over $475 billion, spending approximately 2.8% of its GDP on research. According to UNESCO, the funding sources for research come from one of several categories: business enterprise, government, higher education, private non-profit organizations, or “abroad.” Despite the breadth of funding sources, the majority of investments in research and development come from pharmaceutical and biotech industry re-investing their own money and utilizing their own scientists in an effort to keep costs down.

The estimated cost of bringing a drug to market can be upwards of $1.5 billion and take 15 years for approval. Most drugs, moreover, fail during the second and third phase trials, after which significant investments have already been made in research. In short, the ten leading pharmaceutical companies have spent over $58 billion on research and

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39 Recalling from Chapter One (pp. 6-8), basic science research is research aimed at more deeply understanding the biological foundations of life; whereas applied medical research looks to take that information and translate it into treatments, pharmaceuticals, technologies, etc. to improve the health of persons.

40 UNESCO Institute for Statistics, “Global Investments in R&D,” UNESCO, http://www.uis.unesco.org/FactSheets/Documents/sti-rd-investment-en.pdf (accessed January 6, 2015). The 2.8% figure is based off of the latest data UNESCO had, which for the U.S. was the latest UNESCO estimates was 2.8%.

41 Ibid.
development activities in 2009. However, as Valverde points out supporting Marcia Angell’s critique of the early 2000s, pharma companies exhaust “more time and resources on generation, collation, and dissemination of medical information than it does on production of medicine.”42 Thus, while R&D costs may be upwards of $1.5 billion there is debate about whether this is the actual cost of research itself, or ancillary marketing and dissemination that the companies deem necessary.

Marcia Angell, former editor of the New England Journal of Medicine, in addition to her critique of what “counts” as Research and Development (R&D), has been equally critical of industry’s proclivity to research primarily profitable drugs. She specifically highlights research practices focused on the development of “me too drugs.” “Me too” research centers on the development of new drugs to replace already serviceable pharmaceuticals in the market place. The hope is to develop an alternative drug with different chemical properties that will allow for the pharmaceutical company to hold a new patent on their product, regardless of whether or not it is more effective than the product already on the market.43 Here the lines between the health outcomes of research and the economics of research seem to switch places, with financial gain serving as researchers true goal. While medical research can be for-profit, institutions of higher education and non-profit private investors, who account for


around 40% of the total investment in R&D, need to ensure that their research focuses on health outcomes over economic gain.44

Amongst the top ten research contributors, the United States, China, and Japan account for over 50% of investments made into research, a small portion of which flows through institutions of higher education.45 However, the question centers on what these institutions are doing with the funds. China, for example, invests no money for research in higher education, whereas the U.S. and Japan funnel a modest 10% through universities. Brazil, also in the top-ten of global investors, devotes the most, around 40% of their total research expenditures, India 4%, and the U.K. and France invest around 20% into universities.46 In other words, globally, university-based research still plays a role in shaping the landscape of, albeit not as significant as in the “golden age.” The question is how ought universities use those resources at their disposal?

Established Priorities

If medical research is a practice, as proposed at the beginning of this chapter, and there are internal goods to the practice, then one of those goods has to be the actual improvement of people’s health. Yet, given the allocation of the NIH budget, it seems more investments are being made on the potential impact on people’s health than more immediate

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45 Ibid. This figure represents all forms of funding, both public and private. In the U.S., a little more than 60% of funding for R&D comes from business enterprises, 32% government, and approximately 8% divided between higher education and private non-profits. The U.K.’s business contributions are down to about 45% and government about 25%, with a larger portion left for funds coming from abroad, while only about 5% are higher education and private non-profit. India’s research is almost exclusively funded by their government, just shy of 70%, and business funding comprises about 30%. China is increasingly a factor in research with 75% coming from business, 24% from government, and the remaining 1% coming from “abroad.”

needs. A look at the 2014 NIH “Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)” notes that over $16 billion went to research pertaining to Genetics ($7.3 billion), Biotechnologies ($5.7 billion), and Bioengineering ($3.3 billion). These three categories, while having the potential of generating future benefits, offer little immediate impact—particularly when considered in a global context. On the other hand, $14 billion—not an insignificant amount—was devoted to research for Women’s Health ($3 billion), Pediatric Research ($3 billion), HIV/AIDS ($2.9 billion), Cardiovascular ($1.9 billion) Nutrition ($1.5 billion), Orphan Drugs ($809 million), Stroke ($300 million), Tuberculosis ($279 million), Infant mortality ($268 million), Malaria ($169 million), and Malaria Vaccine ($36 million).\(^47\) In other words, $2 billion more went to three research categories, as compared to the 11 categories that roughly correspond with priorities recognized by the WHO and the United Nations (UN) Millennium Development Goals as representing global health challenges. While genetic, biotechnologies, and bioengineering, no doubt, hold scientific promise of improving health, they also yield a high return on investment.\(^48\) Thus, it is unclear whether they are being prioritized for health or financial gain. Moreover, given that cutting-edge research is not likely to be realized for the majority of the world, ought high cost-high yield research be prioritized more than Women’s Health, Pediatric care, or HIV/AIDS?


Minding the Research Gap

When reflecting on the historical developments in medical research, the health improvements experienced globally tend to originate in the Western world and to offer greater benefit to persons from those countries. Although there are exceptions, such as the previously mentioned smallpox, applied research typically leads to the development of new medical treatments and interventions that center on the health of those who can afford these developments. David Resnik argues the economics of research creates disparities in research priorities. Disparities “exist because biomedical research on the health problems of the developing world is neither financially lucrative nor politically popular. Although some private foundations spend a great deal of money on the health problems of the developing world, their contributions are not enough to close the gap.”

In short, the global medical research priorities, not just those of the U.S. described above, disproportionately improve the health of particular persons, i.e. those who those of high-income countries. This blind spot in establishing research priorities has resulted in a consistently unjust burden of disease that affects the majority of humanity.

The “10/90 gap” is a phrase coined by the Global Forum for Health Research that represents the disparities in medical research, in which 10% of the population benefit from 90% of the research conducted. Conversely, this means that 90% of the world’s population receives only 10% of research’s benefit. These numbers were originally developed in the early 2000s by a WHO working group that calculated an “estimated 93% of the world’s burden of preventable mortality (measured as years of potential life lost) occurs in the

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developing world... [yet] only 5% [of research] was devoted specifically to health problems of developing countries...”\textsuperscript{50} While these figures have been challenged, and by most estimations decreased over the last two decades, the phrase stands as a symbolic point of reference for the continued disparity and underfunding for research that benefits the those bearing most of the global burden of diseases.\textsuperscript{51} Epidemiologic measurements of the global burden of disease demonstrate geographically which populations bear the heaviest burden of disease and serve as indicators of the need for improved medical care and treatment.

Burden of Disease

Measuring the burden of disease provides important information about who is suffering from particular diseases, where they are located, and the estimated life lost. There are two measures frequently used in public health to estimate the number of life years lost due to disease or premature death, QALY (quality adjusted life years) and DALY (disability adjusted life years). QALY estimates the number of quality life years lived and is more frequently used to establish a cost effectiveness strategy for investments in health. DALY, which is the measurement used by the WHO, is calculated by adding the number of years lived with a disability to the number of years lost due to premature death, based off of an


\textsuperscript{51} While certain essays have been more dismissive of the continued use of the 10/90 gap for neglected diseases, there is a need to address the more prevalent chronic diseases that are now appearing in the low and middle income countries that cannot afford the same treatments that are being given to those in high income Western countries. For an argument against the usefulness of the 10/90 gap, see “Diseases of Poverty and the 10/90 Gap” http://www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf.
ideal standard, i.e. years of living without disease and/or disability.\textsuperscript{52}

DALYs prove helpful when trying to trace the burden of disease on particular populations. The highest concentration of DALYs is located in Sub-Saharan Africa with Sierra Leone having the highest number of adjusted life years due to death or disability, over 117,000 years. The lowest number of years lost is in Singapore (14,354 years), followed by Japan (15,700 years).\textsuperscript{53} A glance at the WHO numbers for morbidity and mortality indicate that there are vast disparities in the communities who bear the global disease burden. While research alone will not address the DALYs completely, they do serve as a focal point for what diseases are pertinent to these areas and to consider the role research could play.

According to the WHO, the top ten causes of morbidity and mortality cut across geographic and economic lines, but the number of deaths due to preventable diseases primarily plague low-income countries.

\textsuperscript{52} Annette Prüss-Üstün et al., \textit{Assessing the Environmental Burden of Disease at National and Local Levels} (Geneva: World Health Organization, 2011), 27-38. This resource provides a helpful breakdown of the various calculations utilized to arrive at the DALY and QALY measurement.

\textsuperscript{53} The U.S. number (22,775) is higher than all of Western Europe and Canada.
Figure 1. The 10 Leading Causes of Death in the World, 2012

Figure 2. The Top 10 Causes of Death in Low Income Countries, 2012

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Table 3. The Top 10 Causes of Death in Lower-Middle Income Countries, 2012

<table>
<thead>
<tr>
<th>Cause</th>
<th>Deaths per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischaemic heart disease</td>
<td>95</td>
</tr>
<tr>
<td>Stroke</td>
<td>78</td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>53</td>
</tr>
<tr>
<td>COPD</td>
<td>52</td>
</tr>
<tr>
<td>Diarrhoeal diseases</td>
<td>37</td>
</tr>
<tr>
<td>Perinatal birth complications</td>
<td>28</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>23</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>22</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>21</td>
</tr>
<tr>
<td>Cirrhosis of the liver</td>
<td>19</td>
</tr>
</tbody>
</table>

Table 4. The Top 10 Causes of Death in Upper-Middle Income Countries, 2012

<table>
<thead>
<tr>
<th>Cause</th>
<th>Deaths per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>126</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>107</td>
</tr>
<tr>
<td>COPD</td>
<td>50</td>
</tr>
<tr>
<td>Trachea bronchi, lungs</td>
<td>31</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>23</td>
</tr>
<tr>
<td>Lower respiratory infections</td>
<td>23</td>
</tr>
<tr>
<td>Road injury</td>
<td>21</td>
</tr>
<tr>
<td>Hypertensive heart disease</td>
<td>20</td>
</tr>
<tr>
<td>Liver cancer</td>
<td>18</td>
</tr>
<tr>
<td>Stomach cancer</td>
<td>17</td>
</tr>
</tbody>
</table>
Table 5. The Top 10 Causes of Death in High Income Countries, 2012

As can be seen in Figure 1, the leading causes of death globally are comparable between those countries of varying economic status as seen in Figures 2-5. What proves significant about these deaths, however, is the combination of preventable causes of death that appear primarily in low-income countries and, to a lesser degree, in lower-middle income countries. However, these preventable health-related deaths—diarrheal diseases, birth complications (pre and post partum), and malnourishment—also appear alongside chronic diseases—TB, diabetes, heart disease, etc. Preventable health complications presenting alongside increasing numbers of chronic diseases result in higher incidence of death. As a country’s income level increases the burden of disease related to public health causes and lack of access to health care correlatively dissipate.
“A Pathogenic Situation”

Paul Farmer notes—and the above statistics corroborate—these disparities demonstrate a propensity for preventable, or at the least treatable, diseases to disproportionately affect people living in low-income countries. He describes these disparities as epidemiological in nature.

Most often, diseases themselves make a preferential option for the poor. Every careful survey, across boundaries of time and space, shows us that the poor are sicker than the non-poor. They’re at increased risk of dying prematurely, whether from increased exposure to pathogens (including pathogenic situations) or from decreased access to services—or as is most often the case, from both of these ‘risk factors’ working together.55

What Farmer means by “pathogenic situations” is that the very conditions in which people live, not just the disease pathogens, make individuals more susceptible to contagion. Farmer highlights that, in this way, diseases tend to disproportionately affect persons who lack both socio-economic and health resources. Analysis of the global morbidity and mortality statistics for low and low-middle income countries demonstrates that they suffer unique health circumstances that do not create problems for higher income countries who have greater access to both economic and health resources. However, what also gains increased clarity is that health problems of higher income countries—cancers, cardiovascular disease, diabetes—are now beginning to afflict lower income countries. The introduction of chronic diseases compounds the already unique challenges presented by high incidence of child deaths from diarrhea, lower respiratory tract infections, and neonatal deaths in low-income regions.

Two recent examples that reflect the challenges of combining disease, poor health infrastructures, and poverty are the continuing cholera epidemic in Haiti that began in 2010, and the recent, 2014, Ebola virus disease (EVD) spread in three West African countries, both of which exemplify Farmer’s analysis. These situations, while illustrating the importance of sound public health and health care delivery systems working together, also highlight the necessity of having adequate medical research develop from all areas: clinical, epidemiologic, and basic, to address emerging needs. Moreover, these case studies point to the continued complexities of under-researched diseases that exist primarily in low-income countries.

Two Case Studies

Cholera

In January of 2010, a massive earthquake struck Haiti, killing over 200,000 people and injuring another 300,000. Only ten months later, in October, an “unlikely” occurrence of cholera appeared that has led to the additional death of 8,000 people over the past four years. The source of the introduction of the disease, ironically, came from one of the UN workers from Southeast Asia sent to aid in the earthquake relief efforts. While the epidemic

56 Paul Farmer, et al., *Haiti After the Earthquake*, (New York: PublicAffairs, 2011), 383. Here Farmer notes a report from the CDC that cites the occurrence of cholera in Haiti was low: “While the current water, sanitation, and hygiene infrastructure in Haiti would certainly facilitate transmission of cholera (and many other illnesses), cholera is not circulating in Haiti, and the risk of cholera introduction to Haiti is low. Most current travelers to Haiti are relief workers from countries without endemic cholera, and they are likely to have access to adequate sanitation and hygiene facilities within Haiti, such that any cholera organisms they import would be safely contained.” Center for Disease Control, “Acute and Watery Diarrhea and Cholera: Haiti Pre-decision Brief for Public Health Action,” CDC, http://www.cdc.gov/cholera/haiti/pre-decision-brief.html, (accessed: February 9, 2015).

57 Rober Tauxe, “Cholera: Fourth Year of the Epidemic in Haiti; Sixth Decade of the Global Pandemic,” *Pathogens and Global Health* 108, no. 1 (2014), 1; Ezra Barzilay, et al., “Cholera Surveillance during the Haiti Epidemic--the First 2 Years.” *The New England Journal of Medicine* 368, no. 7 (2013), 599. “In 2008, an estimated 63% of the 9.8 million persons in Haiti had access to an improved drinking water source (as defined by the World Health Organization [WHO]), with only 12% receiving piped, treated water; only 17% had access to
in Haiti is now in its fifth year, this particular strain is in its 53rd year and has affected 58 countries. These countries where the disease has both endured and recurred are predominately lower income countries. Haiti is a country of limited economic resources, poor sanitation infrastructure, and minimal health care and public health resources. Thus, the challenge the country faces is a complex one. In order to address the challenge, a group of health care workers: physicians, nurses, public health experts, industry, and government officials gathered to begin strategizing to stop cholera’s spread.

Cholera, recalling from chapter one, is a bacterial-based disease that spreads through contaminated water, a common experience in Haiti. The disease can be controlled through sanitation efforts, effective rehydration, and, the use of vaccines. The debate around how to control cholera in Haiti, as Farmer describes it, ultimately has come down to a minimalist vs. maximalist approach. The minimalists argue that it would be “too difficult” to control the spread of the disease, and opposed vaccinations in favor of water protection. Farmer notes, “Safe, effective, and affordable oral vaccines exist, and yet remain unavailable in Haiti—as do, too often, timely diagnosis and care. When some suggested integrating vaccination into the response, public health officials were quick to note that vaccination was not cost-effective (as if “cost” were fixed in stone and “effectiveness” well understood).” On the contrary, the maximalists argue that all possible ways to stop cholera be implemented or at least explored: improved sanitation, chlorine tables, effective and safe vaccines, rehydration adequate sanitation.”

58 Farmer, Haiti After the Earthquake, 199.

therapies, and antibiotics. Farmer reports that conversations tended to default to the positions that academics and researchers had held for years and could not move beyond them to address the emergent situation at hand. The continued discord between experts resulted in a series of conference calls in the hope of developing a unified approach, the second of which was hosted by Harvard Medical School.

Harvard Medical School served as the host of the conference call focusing on health outcomes, and was not tied to a particular methodological or policy-based approach. The school and its officials—including Farmer as a professor of Global Health and Social Medicine—sought to mitigate the tensions between the two groups by assembling a team of cholera experts. The call included over 80 such representatives from Haiti, the U.S., Geneva, Korea, and beyond. The group was tasked with developing a consensus statement, generating the a clear focus for the group and, by hearing from people on the ground in Haiti, to appreciate the complexity of the situation at hand.

Haitian policies, lack of sanitation, lack of access to care, and a broken infrastructure, contributed to an already challenging recovery from the earthquake. While the government itself sought “a 10-year, $2.2 billion plan to eliminate cholera, including $1.6 billion to improve water and sanitation,” political corruption is a rampant problem, and therefore a major increase in aid was a tenuous solution at best. The university-mediated call resulted in a more unified group, aware of the problems and differing positions, but willing to approach treating the cholera epidemic interdisciplinarily and focused on those suffering from the disease

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60 Ivers and Farmer, “Cholera in Haiti,” 212.

The cholera epidemic is one example of a disease that, within the last 60 years, has primarily affected lower income countries with limited access to necessary treatments. Farmer and his colleague, Louise Ivers, sum up the challenge quite well: “One hundred fifty years after John Snow took the handle off the Broad Street pump, more than a century after his suspicions of bacterial origin were confirmed, 60 years after antibiotic therapy was discovered, and 30 years after a safe and effective oral vaccine was developed, cholera remains—among the world’s poorest—a leading infectious killer.” While this disease exists nowhere in high-income countries, except in instances of health relief workers bringing it back, its continued prevalence points to the inequity that exists with respect to disease burden. The fact that the disease persists, moreover, signals a lack of expectations that curative and/or preventive treatments, when available, will be provided for resource poor populations. This reality led Farmer and Ivers to put forward a rather simple explanation, namely, that the failure to cure tropical diseases results from lowered expectations to cure “diseases that disproportionately afflict poor people.” Despite the existence of proven treatments, including a vaccine and means of disease prevention, there is a dearth of medical care and a limited public health infrastructure, aside from any research limitations.

Cholera demonstrates the complexity of coordinating efforts between the public health, medical care, and available treatments. In this instance, the lack of medical research in and of itself was not a limitation. In fact, the research developed could serve as a supplement to prevention and rehydration. Therefore, the research has been done on cholera in the event of widespread outbreak, and vaccinations represented an option that could have been

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62 Ivers and Farmer, “Cholera in Haiti,” 7-8.

63 Ibid, 8.
utilized within a better health care infrastructure. In many ways, cholera represents a disease that has been prepared for adequately through medical research, but that needs a solid public health and health care delivery research structure to be successful. At the same time, cholera prevention. However, this has not been the case with the recent Ebola epidemic, where neither the research, prevention, nor treatment options have been adequate.

Ebola

There is no clearer example of the disproportionate response that the Ebola epidemic in West Africa received, compared to the frantic responses to isolated cases of the disease in the United States. In 2014, the Ebola virus disease (EVD) originated near the border of three West African countries, Guinea, Liberia, and Sierra Leone, and has caused the death of close to 9,000 people.\(^6^4\) Various practices have been implemented to attempt to contain the disease at its source. In Liberia, the government attempted an area-wide quarantine in its capital city, Monrovia. “60,000-120,000 people lived in deplorable, unsanitary, slum like conditions. Barbed wire and live bullets confide these desperate people; there was little or no health care available and highly infectious dead bodies lay in the streets for hours and sometimes days. After 10 days, the scheduled 21-day quarantine was halted.”\(^6^5\)

Large-scale quarantine, however, proves a fairly ineffective strategy for containing a disease


Both articles, in basic terminology, emphasize that though Ebola is deadly it is not a highly contagious disease. The epidemiological term to describe the contagiousness of a disease is “rough” a “Ro” number. This indicates a disease’s basic reproduction rate. Thus, on average every one person with EVD will infect two other persons. The Ro for EVD is roughly 2. The Ro of EVD can be compared to influenza 2-3; HIV Ro 4; Polio 6; and the Ro for measles can be as high as 18. In short, vaccinations make a huge difference.

spread. Treatment options, however, are also limited given the disparate number of doctors available.

Even if both public health measures and medical delivery system were in place, no adequate treatment of the disease exists. While ensuring that medical care and public health structures are in place would exponentially increase survival rates, a lack of a vaccine provides an obstacle for preventing future outbreaks. Yet, the reason that the disease has received so much global attention is not because a vaccine does not exist, nor the deplorable conditions of Liberia’s quarantine, nor the deaths of thousands in West Africa. Rather, the national and international fervor was stirred by the death of one Liberian on U.S. soil. That one Liberian man’s name was Thomas Eric Duncan.

Mr. Duncan presented to a Dallas hospital emergency depart after exhibiting common symptoms associated with EVD: high fever, weakness, and abdominal pain. After being attended to, he was ultimately sent home, only to return two days later more contagious and highly symptomatic.66 When he returned, the disease had progressed dramatically, and he ultimately died. In the process of caring for the patient, two nurses became infected with EVD. Upon presenting with symptoms, both were treated and given immediate care and proper precautions—including the quarantining of one patient’s dog—were put into place. The response was immediate. A systematic health care response was in place, public health precautions taken, and treatment was delivered quickly and effectively.

In contrast, the health care system in which the majority of people are contracting the disease is one in which a few dozen physicians care for the 4.2 million people of Liberia. Moreover, the lack of a public health infrastructure, where basic hygiene and removal of infectious and deceased bodies proves challenging, contributes to the spread of the epidemic. While challenges resulting from a lack of an efficient health care delivery and public health practices are known, these weaknesses are exacerbated by the comparatively little research that has been done on EVD. The lack of research has resulted in the reality that no vaccine or 100% curative treatment exists. Nevertheless, the epidemic did spur some international conversation towards investing in research to develop a vaccine.

The WHO convened an urgent meeting from September 29-30, 2014 to evaluate and discuss the production of a safe and effective EVD vaccine. 70 scientists, public health officials, and representatives from industry, and regulatory bodies gathered to discuss two vaccines in particular: cAD3 from GlaxoSmithKline and U.S. National Institute of Allergy and Infections Disease (NIAID), and rVSV from NewLink Genetics and the Public Health Agency of Canada. Both vaccines have demonstrated 100% efficacy in nonhuman primates, and the action items resulting from the meeting stressed that phase one trials should be expedited and their results shared broadly to facilitate rapid progress in phase two. The continued neglect of research for EVD, despite outbreaks dating back to the 1970s,

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67 Rothstein, "The Moral Challenge of Ebola." Rothstein “in Liberia, the government imposed an area-wide quarantine on the West Point section of the capital city, Monrovia, where 60,000-120,000 people lived in deplorable, unsanitary, slum like conditions. Barbed wire and live bullets confide these desperate people. There was little or no health care available, and highly infectious dead bodies lay on the streets for hours and sometimes days. After 10 days, the scheduled 21-day quarantine was halted.”

necessitated a fast-tracking process and the immediate institutions of new policies breaking with WHO research norms.\textsuperscript{69}

While these developments come too late for Mr. Duncan and the thousands of others who have died, international conversations have begun that raise awareness about the need for research for under-researched diseases that affect vulnerable populations. Farmer argues that what is needed is:

specific therapy, better and faster diagnosis, and effective vaccines. The vaccines and drugs required to treat so-called ‘emerging infections diseases’ do not exist because of what James Surowiecki has called ‘Ebolanomics’. When disease victims are both poor and not very numerous,’ he says, ‘that’s a double whammy. On both scores, a drug for Ebola looks like a bad investment.\textsuperscript{70}

Again, the importance of prioritizing research based on health, not economics proves fundamental.

The cases of EVD and cholera confront medical researchers and health care workers with a clear option in making research and treatment decisions. Farmer, again, puts the choice into perspective by challenging “doctors and other health providers to make an option—a choice—for the poor, to work on their behalf. The insight is, in a sense, an epidemiological one: most often, diseases themselves make a preferential option for the poor.”\textsuperscript{71} Farmer’s epidemiological insight, also presents a similar epistemic option to that of Ellacuría’s in the previous chapter, and one that has historically not been one taken up in medical research agenda.

\textsuperscript{69} This hurried approach to developing research to meet a pressing need points to the importance of having research ethics that is focused on protecting individual research subjects, and in particular those who are considered vulnerable subjects. Yet, it also points to the need for social bioethics to be attentive to under-researched diseases in order to avoid the situation described above.

\textsuperscript{70} Paul Farmer, “Ebola.”

\textsuperscript{71} Farmer, \textit{Pathologies of Power}, 140.
Broadening the Scope of Research

Reflecting on the developments of the practice of medical research through the interactions of government, universities, industry, and burdens of disease demonstrates a nexus of priorities that research agendas can reflect. However, it seems economic returns receive more attention than improvements to the health of persons bearing a significant burden of disease. A 2012 Global Health Forum Report estimates, “for each year of potential life lost in the industrialized world, more than 200 times as much is spent on health research as is spent for each year lost in the developing world.”72 While access to health care and public health provide two strong pillars for a healthy society, access to and participation in the development of affordable treatments is essential.

From Vannevar Bush to present day discussions of research priorities, innovations in medical research focus consistently on its financial benefits. However, insofar as medical research functions as a practice, there are both intrinsic and extrinsic goods to that particular practice. Moreover, the epistemological reframing of the practice of medical research requires an examination of how research shapes historical reality. In the first few sections of this chapter, I have argued that governments, the pharmaceutical industry, and academia have gone a long way to shape research to prioritize returns on investment first and health second. While research, as seen in the case studies, serves as one piece of the puzzle, it proves an important dynamic in improving health. When establishing research priorities on both social and individual levels, medical research cannot be isolated from its constructive dynamic that contributes to the injustices present in the global burden of disease. Therefore,

it is necessary to reflect on the development of the relationships that make medical research possible, as has been done above, but also to reflect on the impact that these relationships have had.

**Revisiting Responsible Conduct of Research**

In Chapter Two, I discussed that responsible conduct of research focuses primarily on respecting the rights of research subjects and fulfilling an obligation to non-maleficence. However, when considering responsibility on a social and relational level as I have proposed, responsible research should take more seriously its obligation to engage in research that serves the vulnerable groups that research ethics aims to protect. When the economic gains of research become the focus over health, the health needs of those to whom Ellacuría referred to as the poor majority, become neglected and/or under-researched.

Focus on the economics of research lends itself to prioritization of technological innovation that requires a significant financial investment and tends to yield profitable returns that fails to benefit a significant portion of humanity.

The emphasis placed on finances and being on the cutting edge of research tends to mask the health needs of the majority. Desires of individuals, predominately from high income, western countries, obfuscate true need of the global majority. In looking at the NIH funding priorities, it is not that funding does not exist to address concerns of the majority, but the allocation of those funds are disproportionate to health needs as indicated by the global burden of disease. Hille Haker argues that research choices are framed in a way that prioritizes individual choices, which reinforces the importance of technological innovation.
that delivers health to some, while neglecting the needs of many. Lisa Sowle Cahill likewise posits that the accumulation of individualized choices made by a select few “affect society as a whole, changes expectation of health and normality, and reinforces economic and class stratification.” Thus, in the scenario Cahill describes, certain people will be expected to be healthy, while others are accepted to be at a higher risk of disease. This bears out in the reactions to Ebola, until it began to effect Western and high-income countries. However, if medical research considers its role in affecting the health for all, then interests have to move beyond a subjective and individualized understanding of health.

Haker proposes that a rights-based framework can more adequately take up the question of justice within scientific research ethics. She argues that linking human rights “to a general concept of well-being… needs to be spelled out under the conditions of modern medicine and needs to be negotiated in the process of ethical deliberation in general.” However, who does the negotiations for rights? Who is obligated to ensure that these rights are met? How does the prioritization of medical research ensure that the voices of those most in need are heard?

Cahill, in some ways answers these questions, by arguing for a participatory model of justice frames needs, in this case health needs, as fundamental to any notion of the common good. Given the above discussion of the organizational players in the construction of medical research, the only ethical discussions that arose in research were worries over conflicts of interest and violation of individual rights. A participatory model of justice would

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75 Haker, Viewpoint,” 370.
look first to the participants in the establishment of a medical research agenda, and also to those who stand to benefit. To begin to discuss the ethics of medical research beyond an economic and/or technological framework necessitates a consideration not just of interests, but of the health needs and rights from the perspective of those who have seemingly “no health” and “no rights.”

Cahill and Haker both begin with positive considerations, rights and the common good; however a liberationist ethics adopts a socio-historic perspective that begins from injustices. Though Haker, Cahill, and Ellacuría find common ground in their collective concern over the need to address global injustice, their starting points differ. Ellacuría starts with injustice through the biological fundament of ethics—i.e. to see what is unethical or unjust one only needs to turn to the places where people continually die prematurely. Haker, calls for an ethical analysis of the research beyond the individual focus demonstrated in a technology-based ethic, to one that focuses on rights through “the interpretation (articulation and analysis) of values and norms articulated in different and pluralistic settings, and to confront them with moral principles considered to be essential for human life and human flourishing.”

While Cahill argues for a common good and participatory bioethics that considers “a more international, dialogical, multilayered, and multifocal approach …to handle the quandaries of globalization, including those posed by genetics-based biotechnology.” Each starting point has its own value, however, if the socio-ethical

76 Hille Haker, “Ethical Reflexions on Nanomedicine,” in Nanobiotechnology, Nanomedicine, and Human Enhancement, ed. Johann S. Ach and Beate Lüttenberg (Berlin: Lit Verlag, 2008), 58, n.22.

framework of medical research is to be re-imagined in a way that considers the global burden of disease, then hearing from and understanding the experience of those suffering from these diseases proves fundamental.

Shifting the Agenda

Publications generated from public and privately funded research initiatives tend to attest to a gap in research that does not benefit people living in lower income areas. In 2002, a study showed that out of 1393 new chemical entities (NCEs) marketed between 1975 and 1999, only 16 targeted “tropical diseases” and tuberculosis.78 Within the world of research, publications are the best insight as to where the field is focusing its efforts and which projects are receiving funding. Given that publications trend away from addressing the needs of the majority, awareness must be raised within the scientific community, not only about their needs, but also about the potential of the scientific community to address those needs.

The WHO and United Nations have implemented international mechanisms and standards that raise awareness of disparities in access to health care, public health infrastructures, and medications. The most discussed of these awareness-raising platforms are the Millennium Development Goals (MDG). The MDGs devise an action plan aimed at alleviating poverty and focus on those people suffering from hunger, malnutrition, and disproportionately infected by disease.79 Of the eight goals, four come to bear directly on health: reducing childhood mortality (MDG 4); improving maternal health (MDG 5); combat HIV/AIDS, malaria, and other diseases (MDG 6); and establishing global

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partnership for development (MDG 8). To meet each of these goals would require a highly strategic approach to the way in which medical research can contribute to improving maternal and child health, but also improving upon distribution of its fruits can participate in decreasing the gap of those who bear the burden of HIV/AIDS, malaria, TB and other diseases that disproportionately affect low-income countries. MDG 8 specifically focuses on the necessary development of global partnerships for addressing health inequalities.

The MDGs propose a different way of addressing and prioritizing a research agenda. Instead of a financially driven model, their model is rooted in the health needs of the poor majority. However, in order to move towards these realities, other institutions have to commit to the priorities that the MDGs highlight. In this way, a radical shift is necessary in setting research priorities that explore the underlying values and injustices endemic to the practice of medical research. It is here that bioethics and Catholic universities can play a crucial role.

Social Bioethics

Though arguments within the last decade have emerged in the bioethics literature about research inequalities, described at the conclusion of Chapter Two, the focus has primarily centered on research practices within low-income countries and only limitedly focused on priorities setting. Norman Daniels argues that this focus has resulted in “a myopic view that misses the institutional context in which clinical relationships operate and can overlook factors that affect health more broadly than do exotic technologies.” Haker has likewise called attention to the necessary broadening of bioethics to consider the

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contexts in which research is implemented.\footnote{Hille Haker, “On the Limits of a Liberal Bioethics: A ‘Critical Ethics of Responsibility’ Approach,” in \textit{The Contingent Nature of Life: Bioethics and Limits of Human Existence}, ed. Marcus Düwell, Dietmar Mieth, and Christoph Rehmann-Sutter, 2008), 191-208.} Although bioethicists have been attentive to promoting responsible conduct of research that protects vulnerable persons, it has overall neglected the applicative dimension that disproportionately burdens the same people.

Henk ten Have argues that the traditional framing of vulnerability has been understood as an individual deficiency, rather than the result of a social situation. “Being vulnerable is often the result of a range of social, economic and political conditions, and therefore beyond the power and control of individuals.”\footnote{Henk A. M. ten Have, “Vulnerability as the Antidote to Neoliberalism in Bioethics,” \textit{Revista RedBioética, UNESCO} 5, no. 1 (2014), 88.} Therefore, bioethics cannot be content to consider issues only within the medical realm, but must take up broader socio-political factors that affect health statuses and medical realities. While bioethicists are not responsible for developing policies addressing health inequalities, they (we) have a responsibility of calling attention to issues within medical research that perpetuate the vulnerability of a given population. In this case, as Farmer noted, the poor majority consistently represent the sick majority, for whom diseases make their own preferential option. Thus, in order to establish more equitable research practices, and distribution of the developments from that research, broader participation is needed in the shaping of the research agenda.

Thomas Pogge argues for a broadening of research priorities in an effort to move beyond the disequilibrium present in current research efforts. Pogge roots his critique in one of the four key principles of bioethics, as articulated by Beauchamp and Childress, non-maleficence. He argues that if non-maleficence hinges on “doing no harm,” then it is
fundamental for bioethics to take up and offer a corrective to the current system that does harm to the majority of human beings. He wants to broaden the approach academics take in their addressing injustices within the distribution of drugs, treatments, healthcare, while at the same time incorporating industry in this task through the development of the Human Impact Fund (HIF).

The HIF would financially incentivize innovators and industry to participate in a system that would more reliably insure the development of “high-impact” medicines for disease that disproportionately burden poor and vulnerable populations. This is the type of structural and innovative change necessary to reshape the research agenda from its current construct; this approach will be explored in more detail in the next chapter. Yet, any restructuring of a research agenda must include necessarily the perspective of those often excluded.

Advocacy and Research

Another type of approach aimed at reshaping the research agenda developed through the efforts of HIV/AIDS research advocates who brought attention to the harm being done to them by current research practices. The participatory action of HIV/AIDS research advocates gradually allowed for more equitable access to medications and clinical trials. While advocacy efforts can have potential drawbacks, the advances made by HIV/AIDS research advocates identify the influence that they can have on reshaping the process, funding, and distribution within medical research. Most importantly, HIV/AIDS research


advocates were able to tell humanizing stories of those suffering from the effects of a relatively unknown disease.\textsuperscript{85}

HIV/AIDS Research Advocates

The discovery of HIV and the subsequent onset of AIDS became a central focus of health researchers in the 1990s due, in part, to the efforts of HIV/AIDS research advocates. These advocates lobbied, protested, wore red ribbons, educated themselves to become a part of the research community itself, and educated the research community about who the people were suffering from this new and unknown disease. In the early 1980s, as information was emerging about the disease, it increasingly became thought of as a “life style disease,” a disease of drug users and gay men. This understanding has been proven to be patently untrue. Nevertheless, by framing HIV/AIDS as a disease associated with personal behaviors, society was able to distance itself from “those” people who had AIDS. Epstein notes that to have AIDS at that time “is bound up with the cultural understandings of what such groups are like, while the very identity of the groups is shaped by the perception of them as ‘the sort of people who get this illness.’”\textsuperscript{86} In part, the early efforts of research advocates was about reclaiming the identity of the affected individuals as human beings and persons with stories and struggles that challenged the popular narrative. As the stories emerged, it became clearer “who these people were.” They were able to tell their story and the story of others who also suffered from the disease.\textsuperscript{87}


\textsuperscript{87} Aana Marie Vigen, \textit{Women, Ethics, and Inequality in U.S. Healthcare: “To Count among the Living”} (New York: Palgrave Macmillan, 2006). This is one of the key contributions of Vigen’s book. She points to the continued
AIDS research advocates were uniquely positioned in the U.S. because of the community organizing that had already taken place in the gay community. Thus, a unique strength of AIDS research advocates was that they were already organized within the communities and could easily “mobilize to meet a new threat…” Advocacy was nothing new to this community, and they quickly developed effective strategies that raised awareness of their health needs. AIDS research advocates utilized “creative approaches rather than following established rules of lobbying, [created] drug buyers’ clubs…red ribbons…and telephone ‘zaps,’ wherein the telephone switchboard of a specific company was jammed by a coordinated barrage of incoming calls.” These were not only influential awareness raising practices at the time, but they greatly shaped the way in which other disease-based research advocacy groups would develop.

Collective efforts through “buyers’ clubs,”—made more famous by the Academy Award winning “Dallas Buyers’ Club,”—placed pressure on the FDA to grant quicker and larger volume access for patients to experimental drugs through clinical trials, as opposed to importing and distributing unproven treatments. Due to advocacy efforts, the wait time for an application approving a new drug dropped from 34.1 months in 1986 to 12.6 by 1999.

Yet, just as important, HIV/AIDS activists did not just raise awareness of their plight, they

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educated themselves on the science and began to actively participate in discussions about the ongoing research.\textsuperscript{91}

HIV/AIDS research advocates became credible sources of the language of medical science and research, in addition to bringing their own cultural perspective and stories about the realities of suffering from the disease. After their gradual success with the FDA, the community recognized, however, that while they had increased access to experimental medicines there were few treatments in development. These advocates shifted their efforts beyond the FDA and towards the NIH’s “AIDS Clinical Trials Group of the National Institute of Allergy and Infectious Diseases.”\textsuperscript{92} This shift prompted an increased emphasis on the ability to speak the language of research in order to be informed about the ongoing experiments, trials, and for advocates to keep researchers informed about the needs of the community. As they increased their knowledge of medical research and the science behind it, they were able to present “themselves as credible \textit{within} the arena of credentialed expertise. At the same time, these activists succeeded in changing the rules of the game, transforming the very definition of what \textit{counts} as credibility in scientific research such that their particular assets would prove efficacious.”\textsuperscript{93} Not only were the activists able to speak the language of research, they were able to share with them the effects of research on the community, identify those within the community who needed access, note the side-effects of medications, and personalize the stories of those living with the disease. Thus, advocacy efforts were able to allow researchers to think beyond the mechanisms of the disease in

\begin{itemize}
  \item \textsuperscript{91} Ibid, 414.
  \item \textsuperscript{92} Epstein, “The Construction of Lay Expertise,” 416.
  \item \textsuperscript{93} Ibid, 409. Author’s original emphasis.
\end{itemize}
order to consider their research in the context of helping another human being suffering from a disease.

Their contributions, moreover, effectively reshaped how NIH clinical trials were conducted. Within ten years, due to pressure from activists, there were three ways in which AIDS research was conducted: standard clinical trial protocols through the AIDS Clinical Trials Group, community-based programs, and the Division of AIDS Treatment Research Initiative. The latter of the three was important for advocates because their “hallmark is speed in conducting ‘clinical trials and related research that evaluate new therapies and novel treatment approaches for those with HIV disease.’” Yet, their work did not stop there. Advocacy efforts played a key role in increasing access to trials for women and people of color through parallel clinical trials and increased community-participation in research. In the 1990s, their efforts increased access and participation in research within the U.S. New research advocates emerged, particularly from NGOs, who broadened the efforts to address the global problem of access and treatment for those unable to afford treatments particularly in Sub-Saharan Africa.

While the U.S. advocates were successful in shifting the research agenda to devote more resources to the development of treatments, those treatments, due to the high cost of development and patenting, were rarely affordable outside of high-income countries. Larger organizations, such as Oxfam and Doctors without Borders, began advocating for distribution of necessary medications to low-income countries. This debate was a much

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harder fight against the claim of the pharmaceutical industry that lower costs in low-income countries could ultimately lower revenues in high-income countries, thereby diminishing the profit margin and the amount available to be spent on research and development.96

These changes became all the more important when South Africa implemented a requirement that all pharmaceuticals be made available in their generic forms. This led to vociferous objections from pharmaceutical companies. However, despite their objections, advocacy efforts ultimately resulted in a 2001 amendment of a framework for intellectual property called the “Trade Related Aspects for Intellectual Property Rights Agreement” (TRIPS). TRIPS, up until this point, had given patent-holding pharmaceutical companies a virtual monopoly on necessary drugs.97 After this agreement, however, access to these drugs was seen as a right, but what remained unclear was whose responsibility it was to carry out this right, that of sovereign nations or pharmaceutical companies.

This lack of clarity came to a head in a lawsuit brought by the drug industry against South Africa, who had modified its laws to ensure an affordable price of generic medications for its citizens. After a long legal battle and public advocacy campaign for HIV/AIDS patients by Oxfam, one of the major players in drug development and patenting, GlaxoSmithKline, eventually declared it would not enforce its patent on its HIV/AIDS drug, Zerit, and granted a license for the production of a generic version in South Africa.98 Ultimately, the pharmaceutical industry withdrew their suit, enabling negotiations between


particular countries and the development of lower-cost effective treatments for
HIV/AIDS.99

Despite these successes, however, lower costs for treatment did not always result in
increased access. Though this is not necessarily a problem medical research itself can solve,
attention to the necessarily collaboration with public health organizations and local
organizations working in low-income countries is essential. In other words, advocating for
drug access or development without participation from the targeted community will
inevitably result in a less than ideal outcome, as could be seen in the early stages of
HIV/AIDS research advocates in the U.S. This example shows the importance of those
institutions who participate in the process of medical research, including universities, and the
distribution of benefits can play in ensuring that products reach those most in need.
However, over time these advocates were able to demonstrate the important contribution
that advocates can make in altering the research agenda.

The Good and the Bad

As can be seen from the example above, advocacy for research can positively
influence, not only where research dollars flow, but also put a human face to the disease.
This is an area in which all universities can contribute, and Catholic universities ought to be
uniquely obligated. Their efforts were able to first put a human face to the disease through
stories, struggles, and hopes expressed by advocates, dissociating the research from the
immediate financial burdens and potential economic gains in order to situate the disease and

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99 João Guilherme Biehl, “Pharmaceuticalization: AIDS Treatment and Global Health Politics,” Anthropological Quarterly 80, no. 4 (2007), 1083. Brazil became the first country to provide free access to Antiretroviral drugs (ARVs) and did so through a combination of activists, policy makers, and corporate actors within the pharmaceutical industry.
the research in the context of a person in need. \textsuperscript{100} However, given that the economy is so closely tied to research, funding decisions often become just another policy decision. Nevertheless, these representatives are accountable to their public and to government agencies. By hearing from those suffering from the disease and their representatives, advocates raise awareness for those suffering from disease and announce their role as members of the public to whom the policy makers are accountable. Advocacy breaks the exclusive business or political focus that the patent and profit model of the intellectual property system encourages. In the case of HIV/AIDS, delinking access to medications and participation in research from intellectual property rights and linking them with human rights was a crucial step.

A second positive outcome of advocacy efforts increases the fluidity of information exchange between researchers, patients, and industry representatives. This open flow of information is something that HIV/AIDS advocates made possible, and that the WHO working group on research and development believe to be essential in order to generate better and more cost effective treatments for drugs globally. The CEWG on research and development argues that to facilitate this open flow of information, it is necessary to create a database in which open source content of various investigations could be held.

Creating a Global Observatory on Health for R&D could play a crucial role in priority setting.\textsuperscript{101} Much like the advocates for HIV/AIDS research were able to increase the flow of information and access to information for patients, an information database would


\textsuperscript{101} This is a possibility that Catholic universities should consider as will be described in the next chapter.
enable all users to: analyze data on financing for global health R&D; produce analysis to inform national R&D portfolios management; guide R&D priority-setting at different levels; establish benchmark activities with other users; and monitor and evaluate trends against national, regional and global strategies.\textsuperscript{102} Thus, rather than duplicating efforts and guarding secrets, sharing information between the key players—universities, private industry, non-profit organizations, government, etc.—would be encouraged.

In essence, HIV/AIDS research advocates were able to reimagine the way in which patients participated in research for their diseases. Through their efforts, advocates were able to increase the flow of information between researchers, patients, and industry. They demonstrated the value of community-based research in developing more targeted and widely accessible clinical trials. Perhaps most impressively, they were able to alter the research agenda by increasing the allocation of resources—both financial and human—for a marginalized population, both locally and globally. Although the benefits continue to be unevenly distributed, advocates took positive steps to make the benefits of research more accessible to marginalized populations. Yet, advocacy participation, despite the many successes, presents challenges too.

Rebecca Dresser, overall, offers praise for advocacy work in her seminal text, \textit{When Science offers Salvation}. As can be deduced from the title, Dresser is concerned with the amount of faith that is placed in the scientific and research community and the concerns it presents for research ethics. There are two concerns that prove relevant to the discussion at hand. First, Dresser cautions that advocates tend to stress the positive dimension of research.

Namely, that the studies they are participating in are understood as “new treatments” and “life-saving research.” The reality is, however, that in certain instances the trials may not actually benefit them, and the “life-saving research” may save someone else’s life not their own. She notes that when HIV/AIDS activists campaigned and received more resources for studying, they did not like what they saw. There was discontent with the randomized controlled clinical trials, the “gold standard” of research, because it was unknown whether one would benefit or not from the research. When research participants and patients, moreover, were asked to discontinue other medicines, they often withdrew from the trial if there was any chance they could receive a placebo, “a standard thereby they deemed unsatisfactory.”

While their advocacy efforts pushed forward more just distribution of resources—something definitely needed—they also presented other challenges with respect to conducting an effective clinical trial.

A second concern Dresser raises concentrates on increasingly political dimension of advocacy work that offers only those with a seat at the table—or the ability to pay for one through lobbyists—the opportunity to shift the research agenda. In this way, advocacy efforts could result in increased funding for a particular disease simply because they have a seat at the table, and thereby exacerbate social inequalities. Given that research funding allocation functions as a political process, it would be detrimental to the just distribution efforts highlighted in the global work of HIV/AIDS research advocates if advocacy began to take up the more partisan lobbying efforts.

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103 Rebecca Dresser, *When Science Offers Salvation Patient Advocacy and Research Ethics*, (New York, NY: Oxford University Press, 2001). This is referred to as the therapeutic misconception, and is widely prevalent when people enroll in research. Often, when patients see that a treatment is not working the electively withdraw from the trial, limiting the effectiveness of the trial. Thus, when seeking informed consent ensuring that patients understand that they are not enrolling in new treatment, but rather participating as a research subject.

In coupling her first concern, therapeutic misconception, with her second concern, politically advocating for a cure, Dresser expresses a final concern that advocates can become so involved, alongside their scientist collaborators, that the possibility of not finding a cure becomes unimaginable. Both scientific researchers and advocates must necessarily maintain a perspective, that is not without hope, but that is inclusive of a wide range of available research options and alternatives. These alternatives and options, however, cannot happen without mutual communication between the researchers, those suffering from disease and their advocates, private industry, and public funding sources.

Communication concerning research priorities often lacks the multiple perspectives necessary to create a socially responsible research agenda. The advocates for HIV/AIDS research demonstrate the complexity of factors—political, economic, personal—that play a part in establishing a research agenda. Most importantly, however, these factors put a human face and social condition to those suffering with the disease. Yet, for the vast majority of the world, those suffering the global burden of disease have no one to speak for them. They have no advocates and, as Dresser rightly cautioned, only those with a voice receive funding.

It is worth noting that even those who received and participated in the shaping of the HIV/AIDS research agenda—and perhaps a cause of their success—were predominately white males who were the primary participants in research in the 1980s and those who were deciding what agenda items ought to be pursued. Thus, the critical question for research advocates with a horizon for the poor majority is, who are their advocates? What ought these advocates advocate for? How can one ensure—insofar as possible—its successful implementation?

105 Epstein, Inclusion, 66.
Conclusion: Towards Responsible Advocacy

In a 1987 essay, Jürgen Habermas focuses on the discursive dynamic that takes place within the learning process at the university. It is through this discourse in which “specialized internal public spheres coalesce and branch apart again in the university’s programs.”\(^{106}\) This learning process, however, is not idealized within the university, but rather creates space for discourse. Habermas argues that even though a researcher “appears to work alone in the library, at his writing desk or the laboratory, his learning processes are inextricably interwoven with a public ‘community of investigators.’”\(^{107}\) For medical research, patients in need of new drugs, physicians working with these patients, and public health officials aiming at disease prevention form a part of this essential community. Thus, to engage in responsible medical research one needs to broaden the horizon of investigation. This role is not exclusively the responsibility of a scientific researcher, but must engage the entire community.

For Catholic universities, this discourse takes on an important facet when confronted with injustices around complex structures in which they participate. The structure of medical research is one such challenge that Catholic universities should reflect on in light of the concern for justice. In the globalized context of research, however, the conversation about how to prioritize justly particular contexts, populations, and needs with the allotted research dollars is ongoing.

Drawing from the previous chapter, the insights of Ellacuría and liberation theology emphasize the importance of the place or the context from which one begins the necessary


\(^{107}\) Habermas and Blazek, “The Idea of the University,” 21.
dialogue. If the place of the poor, or option for the poor and vulnerable groups, is to have an epistemological impact, then it is necessary to begin reflecting on a research agenda from their perspective. Beginning from this perspective does not necessarily mean physical location. This consideration can take the form of an intellectual stance that prioritizes experiences of injustice and suffering that can be omitted often in establishing research priorities. Starting from the intellectual place of the poor shifts the conversation to concerns about equity, distribution, and need. These concerns come into focus by reexamining the morbidity and mortality statistics above or looking at the World Health Organization DALYs—just as John Snow looked at London’s Weekly Returns to target his investigations—and in so doing, recognizing those who have historically been marginalized.

The task of the Catholic university, however, is not just to know who these people are, but also to engage in practices and dialogue that aim to reshape participation in academy-industry relationships, targeting diseases that ought to be researched, and participating in global advocacy networks. These challenges necessarily take the university beyond intercampus dialogues and create conversations within the larger Catholic Church, businesses and non-profit organizations, and the communities who are in need. While research cannot cure everything, it has historically provided a necessary piece of the puzzle—alongside a solid public health infrastructure and access to medical care. Catholic universities are in a unique position to be leaders in this type of research effort because of their established global network which better enables these institutions to serve as advocates for and with others and to ensure a more just distribution of the benefits of medical research.
Ellacuría describes the function of the university as inherently political, and thus one of its tasks is to confront structures that perpetuate injustice. The structure of medical research is one that, at least benignly, neglects the majority of the world in its efforts. Advocacy efforts at the university level, and particularly engaging academic scientists, can take place through targeting publications to highlight under researched diseases, grant efforts that seek to benefit the majority of humanity, and focused hiring practices that demonstrate the universities’ commitment to bringing in the best researchers who share both a deep commitment to excellence in research, but also a shared concern for justice. The goal, then, is to engage others more broadly to participate in the “community of investigators”, as Habermas describes it. By implementing an advocacy-based institutional model of research, the goals would be to: raise awareness around the distortion of the distribution and priorities of medical research; restore health as the most important intrinsic good of the practice of medical research; and to participate with partner organizations in establishing a more just framework to distribute the benefits of the research undertaken. While this will not, unfortunately, eradicate diseases or eliminate disparities entirely, it hopefully will position Catholic universities as institutions engaged in a practice of medical research that prioritizes justice and solidarity through targeted research efforts and serve as an example for others to follow.
A socially responsible medical research agenda needs to reflect on the research structures that allow the health needs of the majority to go under researched. As seen in the previous chapters, the development of medical research has occurred alongside the production of technologies and drugs that have consistently promoted health benefits tied to potential economic gains, over those with greater health benefits for more people. An analysis of the empirical data on morbidity and mortality statistics, reviewed in Chapter Four, reflects these disparities in research and burden of disease.

The unjust burden of disease that afflicts the poor majority, however, emerged over time through political, economic, and university-based decisions. The tension in creating a medical research agenda exists between research that benefits individual persons and research poised to benefit larger groups within the population. This unjust distribution of research, which came to prioritize particular individuals, e.g. soldiers, and diseases from high-income countries, can be seen through the historical development of medical research described in Chapter One.

Chapter One maintains an intentional focus on research that targeted improvements to the health of the general public. Yet, even this research was not without its injustices. While John Snow’s cholera research focused on his immediate neighborhood and the development of international public health practice, distortions about what type of research
truly benefited the public became the contentious. The tension between the priorities of public health over the future health of particular individuals, peaked with the unethical research practices associated with eugenics. The practice of negative eugenics, a popular method in the U.S., UK, and in Nazi Germany, served as the watershed event that prompted a more concerted effort to focus on the ethical conduct of research and protecting the rights of research subjects.

Despite the complex socio-historic origins of research ethics, in practice the focus centered on protecting the individual rights of research subjects by relying on the physician’s obligation to do no harm. This individualistic approach, however, ignored why unjust research practices continually affected particular groups of persons, e.g. racial minorities and those of lower socio-economic status. While consideration was given to the protection of individuals from vulnerable populations, little ethical reflection concerned itself with the vulnerability of these particular groups. It was, and to a large extent still is, problematic that the application of research ethics virtually ignores the socio-historic context in which research takes place. Particular groups continue to be excluded from the benefits of the social practice of medical research. The historical analysis from Chapter Two, coupled with the disparities in research described in Chapter Four, demonstrates the lacunae of a socio-ethical analysis of research that considers the injustices within the priorities and distribution of medical research.

The injustices associated with the priorities of medical research, I hypothesized, were not due to lack of good science, but rather, an epistemological problem that allowed for science to be interpreted as morally neutral and objective practice. The turn to the work of Xavier Zubiri and Ignacio Ellacuría in Chapter Three provided a needed epistemological
shift for scientific research. Ellacuría and Zubiri both acknowledged scientific research as fundamental not only for understanding, but also for shaping the way in which historical reality is experienced. This experienced reality, however, is one in which the majority of persons disproportionately experience poor health and economic poverty. While science is often thought of as a neutral and objective practice, I follow Ellacuría and Zubiri’s argument that the practice of scientific and medical research itself has in fact participated in shaping the injustices within historical reality.

An epistemology of historical reality emphasizes that human actions in history contribute to the way in which reality is constructed and that no practice should be considered morally neutral. Given the current global health disparities, certain persons and institutions have continually received priority, while the health needs of the economically and socially poor have been neglected, creating both a moral and ethical dilemma. In order to right this historical wrong, I argue that a liberationist, social, and Catholics ethic must begin from and with the perspective of the poor majority, a majority whose health needs go largely ignored resulting in premature death and disability of millions of individuals.

Reflecting on the social ethics of medical research begins with an analysis from, if not physically, then at least intellectually, the places where lives are consistently lost before their time. In this way, the health research needs of the poor majority that become the starting point for establishing an ethical research agenda. While anyone can take up research that focuses on the health needs of the poor majority, this approach proves constitutive for Catholic universities that emphasize the moral importance of social justice.

This final chapter argues: Catholic universities have a moral responsibility to prioritize medical research for health that demonstrates the effectiveness of its commitment
to social justice, perhaps most clearly articulated after the Second Vatican Council. At the Second Vatican Council increased attention was turned to the places in which the Catholic Church lived and worked. The context of many Liberation Theologians was one of poverty and oppression, and many argued for the Catholic Church to actively address the political and social structures that permitted the oppression to continue. In El Salvador the Catholic university, the UCA, came to play a prominent role in shedding light on present injustices. Ellacuría, among others, emphasized that the functions of the university: teaching, research, and service, should socially project the injustices present and challenge them. It is taking up the preferential option for the poor that allows the injustices to be seen most clearly. The option for the poor functions as more than a rhetorical move to emphasize those that often bear the weight of injustice, and instead should result in institutional practices and policies that socially project the needs of the poor in the daily work of the university.

Research that focuses on the experience and health needs of the poor that signifies the epistemological shift that needs to take place within medical research. Making an option of the poor serves as the standard by which justice ought to be measured.¹ The epistemological function of the option for the poor contains a political task to confront the socio-historic structures that perpetuate poverty, vulnerability, and marginalization of the majority of humanity through the social practices in which one is engaged, which in this instance is medical research.²

¹ Ignacio Ellacuría, “The Challenge of the Poor Majority,” in *Towards a Society that Serves its People: The Intellectual Contribution of El Salvador’s Murdered Jesuits*, ed. John J. Hassett and Hugh Lacey (Washington, D.C.: Georgetown University Press, 1991), 208. Also see p. 19 Chapter 3, n. 33. In this chapter, I maintain the use of Ellacuría’s definition of the poor, “the vast bulk of humanity whose standard of living is such that they can scarcely satisfy their most basic needs; this majority whose standard does not permit them sufficient human development…”

² Ellacuría, “The Challenge of the Poor Majority,” 208.
While Catholic university-based medical research ultimately makes up a small minority of the overall medical research conducted in the U.S., these institutions participate in national and international networks of research. When working collaboratively, these networks can focus their research efforts to confront the health problems that face the poor majority. The first section of this chapter explores the context in which Catholic universities take up their task of medical research. The second section argues that normative values presented in liberationist thought should influence the social practice of medical research by considering the option for the poor, the importance of “place”, and a notion of justice that begins from the experience of injustice. The final section concludes in a similar way to which the dissertation began, by offering paradigmatic examples—not specific proposals—of research efforts that make it feasible to take up the option for the poor in establishing research initiatives and/or cultivating partnerships aimed at benefiting those on the margins of society.

**Catholic Universities and the Context of Medical Research**

It is estimated that over 200 times as many dollars are spent on a life lost in a high-income country compared to that one life lost in a low-income nation. Catholic universities cooperate in the unjust practices of medical research insofar as they do not offer an alternative approach to research that takes up the health needs of the poor. The option for the poor, rooted in the Catholic Church’s social teaching, has become a key source of identity for their universities. However, when it comes to medical research on a global scale, it often fails to be put into practice because of its contradiction to the way in which research is typically funded. If research continually avoids addressing issues that face the majority of humanity, then the practice of research results in a social practice that perpetuates systemic
injustices by ignoring the legitimate health needs of the majority of the world. While this injustice is a question for all involved in medical research, it poses a unique challenge to research at Catholic universities as institutions situated in a globalized world and amidst the tension between the local and universal church.

Between the Local and the Global

John Paul II’s *Ex Corde Ecclesiae* describes the Catholic university as an institution that exists in relationship to the church as both local and universal. The document describes the relationship of the university most strongly in its unity with the local church; however, as an academic institution, he also notes that it participates in the international academic community, whereby “each institution participates in and contributes to the life and the mission of the universal Church…”³ While the exact nature of the relationship of the local churches and the universal church has been the content of much theological discourse, there is little debate from the document that the university itself in fact participates in some ways in both dynamics.⁴ Thus, the context of research for Catholic universities ought to consider

³ John Paul II, *Ex Corde Ecclesiae* (1990), no. 27. “As such, it participates most directly in the life of the local Church in which it is situated; at the same time, because it is an academic institution and therefore a part of the international community of scholarship and inquiry, each institution participates in and contributes to the life and the mission of the universal Church, assuming consequently a special bond with the Holy See by reason of the service to unity which it is called to render to the whole Church.” The quote above is a partial quote of John Paul II’s more theologically charged point that pertains to the relationship between the local and universal church. This is relationship is important because of the general understanding of academic freedom at the university and, in particular, the function of theology within academia. These points have been well elaborated on elsewhere, and lie beyond the scope of this dissertation, but bear noting. Despite the disputations around the exact nature of the Catholic university’s relationship to the universal church, it participation in the universal church and, as John Paul II noted, the international context in which is fundamental.

⁴ Kilian McDonnell, “The Ratzinger/Kasper Debate: The Universal Church And Local Churches,” *Theological Studies* 63, no. 2 (2002). Kasper essentially understood that the church universal exists in and develop from local churches. Conversely, Ratzinger argued that the universal church existed ontologically prior to all local churches, and that the only de facto remnants of the universal “The pope and the curia remain as the only elements in the presentation [of the universal Church].”
local needs, but also the way in which those needs relate to the globalized world in which it is immersed.

The work of the university operates in a globalized world characterized by rapid technological developments, increased interdependence across borders, and a widening economic and health gap between the rich and the poor. Globalization is not a new topic, yet it continues to defy a singular definition. David Hollenbach, for example, borrows from Keohane and Nye to describe globalization “as the increase in networks of interdependence among people at multicontinental distances.” Thomas Massaro settles on the broadest definition possible by describing globalization simply as “everything and its opposite,” and in so doing, “calls attention to rival construals, countervailing forces, and ethical dilemmas unleashed when national borders seem suddenly irrelevant.” Sumner Twiss argues that globalization is “the multidimensional and interactive processes of economic, political, and cultural change across the world resulting in increased social interconnectedness as well as opportunities for social confrontation among peoples.” Finally, Rebecca Todd Peters characterizes it as “economic, social, political, and cultural processes that serve to break down traditional barriers that have separated peoples, nations, and cultures from one another.” These definitions share a common focus on globalization’s ability to transcend boundaries, but also this ostensible absence of boundaries result in new global challenges. In a globalized world, “local” concerns can no longer be considered as confined to a particular

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geographic area. Instead, local actions partake in an interdependent global community that, for good or for ill, is here to stay.

Scientific inquiry, moreover, is not absolved from the effects of globalization. Yet, medical research traditionally remains focused on particular projects of individual researchers that mostly reflect specifically local and national priorities. However, the prioritization of local research, which for high-income countries projects potential future needs, can overlook more pressing health needs that could benefit directly from immediate medical research. Catholic medical research, given the global presence within a Church committed to justice, should presume a fundamental orientation towards research that not just expands a reservoir of knowledge or targets national priorities for which it can receive funding, but engages in medical research that stands to benefit the health of all human beings.9

Catholic Research

Out of the 225 Catholic colleges and universities in the U.S., only about 10% of them engage in medical research.10 For the last five years, these universities have averaged around 400 NIH grants per year, most of which are generated from six awardees: Georgetown University, Saint Louis University, Loyola University Chicago, University of Notre Dame, Boston College, and Creighton University.11 Within this group, Georgetown

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receives the most NIH funding, with a five-year high in 2010 of $69.4 million from 162 grants and low in 2014 of $47.5 million from 104 grants. Their grants consistently double that of the next two Catholic university recipients, which is some variant of Loyola University Chicago, the University of Notre Dame, and/or Saint Louis University.

The grants achieved by the universities are wide-ranging, and in many respects mirror NIH funding priorities. The received grants focus on research in biotechnology, clinical trials, genetics, and also HIV/AIDS, health disparities, preventive medicines, heart disease, etc. In other words, Catholic universities do not distinguish themselves in choosing research priorities from their non-Catholic counterparts. Thus, Catholic university medical research reflects NIH funding, and likewise engages in medical research irrespective of the global inequalities in health. This presents a moral challenge for Catholic universities, and one that liberation theology argues that the Catholic university ought embrace.

**Research and a Liberationist Social Ethic**

If status quo medical research produces inequity and injustice, then Catholic medical research ought to prioritize preferentially the needs of those that suffer from the inequity and injustice, i.e. the poor. Liberation theologians have been the most vocal and consistent at grounding socio-ethical concerns in the needs of the poor. Ignacio Ellacuría’s normative insights for establishing a research committed to solidarity and situated intellectually in the place of the poor, challenges structures that allow for unjust practices. Liberationists take up the concept of justice from the experience of injustice that denies an opportunity for participation in the co-construction of historical reality. In Chapter Three, I noted that the participation in shaping reality proves a fundamental criterion for justice. This concept of justice begins from contextual experiences of injustice, while at the same time creating
counter social and political systems that can more easily realize opportunities for participation and equity.

Solidarity

Solidarity values the interconnectedness of human beings by prioritizing critical reflection that considers the actions of individuals and groups from the perspective of mutually conditioned social relationships. Liberationists theologize the notion of solidarity by locating its foundation in the incarnation of Jesus, through which God enters into a mutual relationship with human history. Liberationists point to the partiality of Jesus' actions on behalf of those groups that were socially marginalized, in particular: women, the poor, and those who were disabled either from birth or illness. However, solidarity is not exclusive to liberation theology, but has a tradition rooted in social theorists who likewise explore this concept as an important social and political value is incorporated into the theological insights of liberation theology.

Émile Durkheim describes solidarity as both a chosen and given interconnectedness within society that shapes the social order. Durkheim distinguishes between two types of solidarity, mechanical and organic. Mechanical solidarity exists *sui generis* through shared social bonds, rules, values, and beliefs that bind individuals and provide an unmediated sense of solidarity within the collective.12 While mechanical solidarity links the individual to society without an intermediary, organic solidarity develops in more complex and cosmopolitan contexts within “divisions of labor” in which each individual is called upon to play a specific role.

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The success of society rests, then, on the capability of individuals fulfilling their role. As industrial societies shifted away from mechanical forms of solidarity, Durkheim expressed concern that the individualization within modern society would make it more difficult to maintain a sense of organic solidarity, which he saw as fundamental for social stability. While Durkheim was concerned about social stability, Weber and Marx focused on the political implications of solidarity.

Politically, Max Weber and Karl Marx build on the sense of solidarity as a connection amongst social groups that translates into political practices. For Weber, it was the formation of meaningful relationships that would yield democratic principles of fairness and equity. Marx, however, was less concerned about this sense of solidarity amongst all individuals, emphasizing the importance of solidarity within one’s social class. In a certain sense, Marx’s solidarity operates as an exclusive form of class solidarity that functions differently than the concept as proposed by Weber or Durkheim. While the approaches of Marx and Weber differ from that of Durkheim, their insights lend themselves to the socio-political vision incorporated into solidarity from the perspective of liberation theology. However, liberation theology views solidarity from the unique perspective of the incarnation, which calls individuals and communities to a shared commitment around solidarity.

For liberation theology, solidarity emphasizes both the importance of social and political stability as prioritized in social theory, but does so through an individual and collective call to conversion. Gustavo Gutiérrez focuses on conversion as fundamental in

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14 Peters, Solidarity Ethics, 21.
15 Ibid.
order to break with the old way and to re-orientate individuals and institutions toward the
way things ought to be. Conversion, he notes, calls for a recognition of the presence of sin
and suffering both in the world and in one’s own life and the desire to turn away from it.
This *metanoia* is not just for one’s own sake, but in recognition of one’s participation as a part
of the collective. “It becomes necessary for us to examine our own responsibility for the
existence of unjust ‘social mechanisms.’ In addition to calling for personal
transformation…[t]he conversion required will have to be radical enough to bring us into a
different world, the world of the poor.”16 Here one can observe the influence of social
theory on liberation theology insofar as it the critical analysis of social structures that allow
one (or many) to recognize the need to change course in order for society to thrive. This
conversion focuses on a new way of acting that allows for the development the whole of
society, an important departure from Marx. In this regard, conversion calls one to act for
and with those who remain most frequently left out of participating in the building up of
society.17

Therefore, conversion does not evoke the generic promotion or defense of human
rights, but one that confronts particular divisions within society. Drawing from Ellacuría, the
only way to fully encounter this reality, “means engaging, remembering, and ultimately
undoing its terrible negativity. In a word, it demands conversion, a conversion of the human

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16 Gustavo Gutiérrez, “Conversion,” in Michael Griffin and Jennie Weiss Block, eds. In the Company of the Poor: Conversations between Dr. Paul Farmer and Fr. Gustavo Gutierrez, Maryknoll: Orbis, 2013, 75.

heart and a conversion in historical reality.”¹⁸ Therefore, while solidarity may require an individual conversion, solidarity is always situated in the political and requires social action that promotes inclusion of those most frequently excluded.¹⁹ For liberation theologians, conversion begins with the recognition of injustices that burden the majority of the world and moves towards a praxis of solidarity that turns to the places where suffering exists and human flourishing is limited.

The Importance of Place and Story

In Chapter One, I cited that India’s Council on Medical Research (ICMR) does not prioritize economics as a goal of medical research, but instead describes it as research focusing on disease prevention and developing treatments for those suffering from chronic and/or acute disease. Unlike the descriptions of high-income countries—France (Inserm), U.K. (MRC), and U.S. (NIH)—that explicitly identify economic profit as a goal of medical research, the ICMR omits economics as a goal of the practice itself. Instead, the ICMR policy articulates the importance of balancing research priorities based on the public health needs of the country with those of individuals. In the description offered by the three western, high-income nations, no mention of public health or reducing disease burden appears as an explicit focus of research. The context from which India articulates its research priorities, however, is undoubtedly shaped by more widespread cases of urgent health need.


¹⁹ Barbara Prainsack and Alena Buyx, “Solidarity: Reflections on an Emerging Concept in Bioethics,” *Nuffield Institute for Bioethics*, 2011, (accessed: April 9, 2015), http://nuffieldbioethics.org/wp-content/uploads/2014/07/Solidarity_report_FINAL.pdf Solidarity, while a tenant of CST and liberation theologies, has more recently gained traction in secular bioethics. A 2011 report from the Nuffield Council on Bioethics emphasizes both the individual and social dimension of solidarity as an emerging—though largely considered a European value—in bioethics literature. Primarily the concept has pertained to public health, equity in health care systems, and global health. There has been no reference to institutional practices of solidarity with respect to medical research, a crucial piece to working for a solution to a global health problem like Ebola.
that in many ways reflect global health needs. Low-income and lower-middle income countries, like India, who make-up what Jon Sobrino refers to as the “world of the poor,” should shape values and social practices that draw our attention to acute social problems.

The “world of the poor” draws our attention to the importance of an epistemological shift that begins by “realizing” the fact that the basic needs of many are not being met. Prioritizing medical research from the place of the poor necessitates addressing the disparities in global research that contribute directly to unjust burdens of disease “shouldered” by the poor majority. Following Ellacuría, human beings through the structures that shape these injustices have an option of “taking charge” of the concerns for and with the majority or ignoring them.

Ellacuría’s three-fold method of realizing, shouldering, and taking charge of the weight of reality is done so from the perspective of the poor, which requires challenging the injustices endemic to the experience of poverty. If this is the place from which medical research becomes reconsidered, then the narrative of research that focuses on cures, breakthroughs, and improved quality of life, must be reimagined. It was the telling of the story of those suffering from HIV/AIDS and humanizing their needs that contributed to changes in policies surrounding medical research practices. Thus, the place and the stories from these places prove fundamental to the re-imagining and evaluation of the medical research agenda.

Distinguished anthropologist and physician, Arthur Kleinmann, describes that sharing experiences of suffering transforms the relationship between the hearer of the narrative and the context from which the experience is being told. Ultimately, “the semiotic iteration of the suffering of lay men and women into the taxonomies of healing professionals
is then shown to distort the moral world of patient and community.”\textsuperscript{20} While some may be reluctant to characterize medical researchers as “healing professionals,” it does not diminish the impact that the personalization of the stories of suffering can contribute to a reframing of the objective of one’s engagement in the social practice of medical research. One possible explanation is that ethnographic work, like that of Kleinmann, allows individuals or groups to “interrogate themselves as much as they seek to learn from the people with whom a study is undertaken.”\textsuperscript{21} Here the option of place emerges. Does one opt to remain removed from the stories of suffering and injustice—as happened for many in the U.S. following the current Ebola outbreak—or does one opt to see oneself as involved in the continuation of these unjust experiences?\textsuperscript{22}

In essence, liberation theology rejects abstract theories that fail to recognize the lived experiences of those communities suffering particular injustices. As sentient-intellectual persons, human beings have the capacity to move beyond these contexts and place oneself in the position of the other and, thus, to be better poised to develop policies that allow for institutional change. Liberation theology and philosophy argue that it is the option for the context and experience of the poor majority that offers the most authentic place from which to critique the unjust construction of reality. “The moment of option, which seeks that place—that offers—truth and does truth, should not be blind but enlightened. It is first enlightened by its ethical assessment of justice and freedom, or better, of ‘no justice’ and ‘no


freedom’…” Rather than an abstract theory of justice, liberation theology argues that justice must be conceived from the place of those who have no justice.24

Justice and Structural Injustices

For Ellacuría, the concept of justice develops from places and experiences of injustice that function on both personal and structural levels, evoking a critical response through a dialectic between utopia and prophetism.25 In Chapter Three, I referenced one of Ellacuría’s final essays, “Utopia and Prophetism.” Utopia, derived from the Christian understanding of God’s Kingdom historicized through the actions of Jesus, exists in tension with prophetism—a critical and historical response that calls for social change. “Utopia and prophetism, if presented separately, tend to lose their historical effectiveness and become an idealistic escapism; and so, instead of becoming forces for renewal and for liberation, they are at best reduced to functioning as a subjective solace for individual persons or for whole


24 Ivan Petrella, Beyond Liberation Theology: a Polemic, (London: SCM Press, 2008), 12, fn.25. Also see Enrique Dussel, Ethics of Liberation in the Age of Globalization and Exclusion., trans. Alejandro A. Vallega, (Durham: Duke University Press), 2013. John Rawls, A Theory of Justice, (Cambridge, MA: Harvard University Press, 1999). Sheldon S. Wolin, Politics and Vision, (Princeton, NJ: Princeton University Press, 2004), 532-533. Iris Marion Young, Responsibility for Justice, (Oxford, U.K.: Oxford University Press, 2012), 64-72. Thus, while liberation theology would certainly be sympathetic to a robust theory of justice like Rawls’s and readily take up his difference principle, it would be critical of his a-historical starting point. The original position would be seen as abstracted, and questions would have to be raised about how one comes to understand and experience injustice. While conversations behind the “veil of ignorance” may have full knowledge of circumstances, the interlocutors would remain unaware of the particulars of race, gender, and economics, which historically contribute to unjust disparities. Aside from an historical starting place, the second point of departure would be the focus on macro political organization. Although liberation theologians and philosophers emphasize structural and political change, this change begins from the micro level in hopes of unmasking unjust structures and enacting practical and historical change.

25 Note here, that the starting place is the concrete experience of injustice that is challenged by the historical teachings and actions of Jesus about God’s Kingdom. While there are resonances of Aquinas’s natural law approach to the common good—especially in the utopic vision— at work in the efforts of liberation theology, their starting places differ. For Aquinas, it is a metaphysical orientation of the will towards justice as a “good,” whereas for liberation theology it is the witnessing to the experiences of injustices and suffering that are endemic to the human condition that serve as the inciting incident. Thus, it is not an abstract concept of justice as a “good” that is the starting point, but rather it is the historical experiences of injustice that demands a response or, as Gutiérrez noted above, a call to conversion and institutional change.
people’s.”

In other words, separating the two can contribute to an understanding of utopia as describing something that ought to be patiently waited for in the future while enduring present sufferings.

For liberation theologians, like Ellacuría, Gutierrez, and Sobrino, present injustices have to be actively worked against in light of an already begun utopia, God’s kingdom, in which suffering ought not exist. The act of seeking justice from the place of injustice requires persons or people who do not directly experience injustice to transcend their own situation in order to contemplate the reality and injustice of the condition of another and to work for and with them to transform it. Therefore, utopia does not represent an escape from, but rather a realization of that which is possible yet unfulfilled within the current social, political, and economic models critiqued by prophetism.

Prophetism makes utopia present in reality through critiques of current unjust structures that call for social change and a new way of life. Prophetism functions as a critical “interpretation of the surrounding social world—and of ourselves—that uncovers a reality in which certain possibilities are realizable while others are not.” Thus, it is not an idealized notion but, instead, a notion grounded in an historical realism that draws attention to the places and contexts in which injustice is experienced as a way of life. From the perspective of injustices, alternatives are sought as a means by which to establish a more just social order. Yet, this social order cannot be understood apart from historical experiences.

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and accounts of injustice.

Justice conceived within the context of liberation hopes for the already begun utopia, which develops through a critical stance towards unjust social structures that create victims and disparities between race, class, and gender.

“[J]ustice, giving to each what is due to each, not only makes freedom possible but also what is moral and just. Liberation from every form of oppression, whatever it is, is a real process of ‘just-ification.’ This justification is the real means of promoting freedom and the conditions that make it possible. In this sense, liberation is a process of ‘ad-just-ment’ with oneself, in that it seeks to break one’s internal and external chains. It is a “just” process in that it tries to overcome manifest injustice; and it is a “justifying” process in that it seeks to create adequate conditions for the full development of all and for an equitable use of the conditions.”

Justice, therefore, is understood as a process that begins from and seeks to rectify inequitable distribution of “what is due,” while working towards conditions that allow for greater and more equitable participation in the process of creating a just society. Ensuring the possibility for justice, however, requires both a personal and a social process of “ad-just-ment” by identifying and challenging those structures that deny human beings the fullness of freedom entitled to them. Once unjust social structures become revealed, alternative policies and practices must be established that counter the structural injustices. In discussing the unjust distribution of medical research, Catholic universities, must serve as one of the institutions of social change by “ad-just-ing” and “just-ifying” their institutional commitment to just-research that prioritizes the health needs of the 90% over those of the 10%.

Catholic universities committed to justice, therefore, have a social responsibility to

29 Ignacio Ellacuría, "Utopía y Profetismo Desde América Latina: Un Ensayo Concreto De Soteriología Histórica," Revista Latinoamericana De Teología 17, Mayo/Agosto (1989), 163. [J]usticia sobre la libertad, pues no se puede ser libre injustamente, mientras que la justicia, al dar a cada uno lo que le es debido, no solo posibilita la liberad, sino que la moraliza y justifica. La liberación de toda forma de opresión, cualquiera que ésta sea, es como proceso real justi- ficación, el medio real de potenciar la libertad y las condiciones que la hacen posible. En este sentido la liberación es un proceso de ‘ajuste’ consigo mismo, en cuanto busca desembarazarse de las cadenas interior y exteriores; es un proceso ‘justo,’ en cuanto trata de superar una injusticia manifiesta; y es un proceso ‘justificador’ en cuanto busca crear condiciones adecuadas para el desarrollo pleno de todos y para un equitativo uso de ellas.
engage in the practice of medical research from the place of the poor and in solidarity with those individuals and communities whose health needs remain under-researched. From the perspective of liberation theology and the function of the Catholic university, narrative and place converge in an act of solidarity that allows for the recognition of victims of injustice and serves as a catalyst to pursue alternative just and inclusive policies. Given the funding for medical research, as reflected on in the previous chapter, it is difficult to argue that current research practices reflect the socio-ethical norms of a liberationist approach to research.

Liberation theology offers a sustained critique that challenges Catholic universities to take up their particular responsibility to ensure that they do not participate within a structure of medical research that allows for injustice. Alternatively, these institutions should strive to establish counter structures that promote justice and target research that benefits the health of those most in need. In opposition to socially unjust structures, Catholic medical research socially projects that explicitly prioritizes the needs of the poor and vulnerable in their research agenda.

Developing a Socially Responsible Agenda

Constructing a socially responsible research agenda that maintains a preferential option for the poor requires a creative approach that requires targeting existing funding structures, cultivating new research partners, and imagining alternative structures that enable research for the poor majority. For some areas of research, funding structures are already in place; however, new ways for structuring research, building capacity in underserved areas, and distributing the fruits of research still need to be explored. This final section, like the opening chapter, offers paradigmatic examples of medical research that reflect research priorities that come from and develop in solidarity with the poor majority. These examples
represent potential dialogue partners and offer alternative approaches for Catholic universities to consider in addressing injustices within the practice of medical research itself.

Existing Structures for Medical Research

Some Catholic universities will be hesitant to take up a justice-oriented research agenda outside of currently established funding sources. While other examples in this section examine potential ways of engaging in research outside of current funding sources, this first example explores research that more closely aligns within socio-ethical norms described above. Comparative Effectiveness Research (CER), recently instituted in the U.S. as the Perspective on Patient-Centered Outcomes Research Institute (PCORI), funds research that focuses on evaluating and improving the quality of health care outcomes pertaining to preventive, diagnostic, and treatment options in order to better inform and support all involved in the research process. While the current concentration of CER initiatives operates out of high-income countries, such as the U.S., France, U.K., Germany, and Australia, efforts have already been made to extend this type of research beyond national borders. Given the global presence of Catholic universities and the Catholic Church, these institutions—assuming they are willing to collaborate—have the opportunity to participate in research that can more easily work with low and lower-middle income countries to build up their research capacity and assist in the development of programs to improve upon health care outcomes.

Comparative Effectiveness Research

In 2009, an Institute of Medicine (IOM) report detailed ten characteristics of a CER. The first priority, and perhaps the most significant for the broad applicability of this type of research, emphasizes that the “prioritization of CER topics should be a sustained
and continuous process, recognizing the dynamic state of disease, interventions, and public concern.”

The process for establishing a CER agenda, therefore, requires continued evaluation of current research needs, including a willingness to forego projects that do not represent current public health needs. The continued evaluation of necessary research from the perspective of the public is something that does not appear—or at the least is not reflected—in the current NIH research agenda, for example.

The criteria for prioritization of CER research focuses on health, disease prevalence, mortality, and morbidity, which will certainly reshape the priorities in need of study. Here CER already takes important steps in developing a globally translatable research program because of its focus on methods that address local health problems and engage in evaluating the resources needed to improve health outcomes. In order to meet these health concerns, however, the IOM report states that CER requires broad participation of key research stakeholders and frequent updates. These updates require wide distribution if they intend to address the most urgent health needs and identify best practices. For CER programs in Europe, this has translated into focusing on the effectiveness of newly developed drugs, pricing, and general availability of those drugs.

The U.K.’s National Institute for Health and Care Excellence (NICE), originally established in 1999 as the National Institute for Clinical Excellence, operates collaboratively with the National Health Service (NHS) to ensure the quality of care and the availability of

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needed treatments throughout the country.\textsuperscript{32} One of the successful means of ensuring treatment availability is through the evaluation of new drug developments. The recommendations of NICE serve as the measure by which a new drug is included in the comprehensive coverage offered through the NHS. Considered in this review process is the cost-effectiveness, which “is particularly important for drugs that have new indications, are expensive, are expected to be widely used, or whose benefits differ by indication or patient subgroup.”\textsuperscript{33} Thus, NICE’s role naturally led to CER’s interface with industry through recommendations regarding the effectiveness of a drug by studying its effects on morbidity and mortality of a given population.

Therefore, the role of CER does not focus on approval or rejection of a drug, instead, once approved, it reviews the efficaciousness of the drug in patient care. In the instances that a “particular health technology is found to have inconclusive or insufficient evidence of a comparative effectiveness analysis, NICE will often make the recommendation that the examined therapy be used only in research.”\textsuperscript{34} In this way, the recommendations from NICE have a bearing on drug coverage through the NHS, but also provide the pharmaceutical industry with a link to continually evaluate their product through further research and hopefully present the efforts of companies to develop “me-too drugs,”


knowing that they will not be brought to market. In addition to interfacing with both drug industry and political institutions, CER engages in research that can evaluate clinical effectiveness across under-researched populations, e.g. underserved communities, racial and ethnic minorities, and/or gender differences.

In the U.S., PCORI, a development from the 2010 Affordable Care Act, focuses on research efforts that more intentionally engage patients in research that supports preventive, diagnostic, and treatment-based options for larger patient populations. The focus of PCORI’s efforts center on improving the overall quality of health care, which takes place by targeting research that more effectively addresses the concerns facing patients within a particular sector of the population. One of PCORI’s initiatives strives to foster engagement with primarily underserved patient populations, in order to develop a collaborative and trusting relationship in which the research comes from and aims to benefit that same community. In this regard, PCORI funding demonstrates a key principle of just-research by working in solidarity with a community that stands to benefit from the research taking place. Developing policies for research that focus on community involvement and benefits in research, coupled with evaluating broadly the effectiveness of existing treatment options, demonstrates some of the possible avenues for implementing CER in a variety of settings.

35 Marcia Angell, *The Truth about the Drug Companies: How they Deceive Us and what to do about It* (New York: Random House, 2004), 74-93. “Me-too drugs” have a different molecular make-up, but do not significantly alter the effectiveness of already existing drugs, and prod the drug companies to produces products that.

36 Underserved patient populations are those populations with limited access to healthcare resources due to a variety of factors, but can typically be broken down by race, ethnicity, and/or gender. Socio-economic status certainly comes to bear on this classification as well.

The methods of CER offer a diversity of approaches, ranging from targeting large-scale systemic challenges in health care, to studying the effects of technology to maximize health needs, to simply identifying basic necessary resources required to treat acute medical needs. Unlike the previously described research typically associated with NIH or NSF, the focus of CER research centers around health outcomes, not projected benefits, with the aim of improving upon or validating best practices. The focus CER places on outcomes and clinical effectiveness lends itself to broad adaptability for research in low-income countries because it is rooted in already existing needs and evaluating the current options for addressing those specific concerns.

Lower-middle and upper-middle income countries, like India and China, have relied on the U.K.’s NICE program to enhance and focus their own research efforts around addressing local health challenges. India, for examples, has worked with NICE to develop clinical guidelines to assess local and national health concerns through retrospective analysis of case studies in an effort to standardize and adapt clinical care to best meet urgent health needs. China has similarly taken up efforts to address its health concerns through partnership with NICE to study its healthcare infrastructure through assessing the impact of technologies on health care outcomes. While both India and China are assessing capacity retrospectively, their approaches have varied. India has concentrated on evaluating the effectiveness of health care systems and concerns through focusing on outcomes more broadly, while China is specifically interested in improving outcomes through the use of technology. While in their infancy stages, the collaborations between NICE, India, and

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China serves as an important model for the possibilities for developing partnerships beyond local borders.  

Positively, CER offers a model of research with prospects for current funding that simultaneously aligns with the social values of Catholic institutions. CER can adopt research practices that target persons typically omitted from medical research with the direct aim of improving health care outcomes of the immediate population. With the focus clearly on health benefits, CER does not ask the question of pharmaceutical trials, i.e. “does it work?” Rather, the question of CER is “which works better?” This research, then, shifts the focus from economics and technology to an evaluation of the effects/influences of economics and technology on the health of a person or population.

A limitation of CER research, however, arises from its need for large and potentially complex data sets to evaluate health care outcomes and the personnel to conduct the evaluations. Moreover, within these complex data sets, specific questions need to be asked to yield results that can translate into reformed practices. A second point of concern is the limited methodological approaches that can yield outcomes that would be helpful for a given

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39 One of the challenges to effective health care delivery is the disparity between access clinical care and the necessary resources to provide that care. The U.S., for example, wastes an estimated thirty-cents on every dollar spent for health care, but arguably has access to the greatest technology necessary to yield quality health care outcomes. However, the latest technology does not equal effective outcomes. CER can enable cross analysis of the type and/or quality of technology needed to work within countries with limited resources. Just as NICE is partnering with other countries to develop CER techniques to assess their health care needs. Catholic universities could similarly take up these CER endeavors on both a local and global scale. This is research, according to the IOM report, that the U.S. is interested in developing and the mission of sustainability and justice as equity that can be pursued through CER is worth fostering. See Institute of Medicine (U.S.)., Committee on the Learning Healthcare System in America, *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* (Washington, D.C.: Institute of Medicine, (U.S.), Committee on the Learning Healthcare System in America, 2013).


population. Even within these limitations, there is room for research that focuses on developing new methodologies as an area of research. In order to develop areas for research, however, collaborative partners need to be established.

In pursuing collaborators and collaborations, Catholic universities should reflect on their role as institutions at the intersection of the global and local research needs. Developing collaborative partners proves fundamental to promote a broad research agenda that not only does research for communities in need, but also aims to develop research capacity within those areas. While establishing partnerships can be challenging, it reflects the institutional commitment to socially projected research, i.e. research that reflects the needs of the community in its research, which can be enhanced by establishing institutional policies that set the transform of societal needs as an explicit goal. One potential partner that has demonstrated a capacity for engaging in social projected health care has been Partner’s in Health (PIH). In this next section, I will introduce a key consideration in developing partnerships, which emphasizes the crucial step of identifying collaborators that challenge existing unjust structures and policies and aim to transform them.

Cultivating New Relationships

Research alone will not result in a substantial change for the global health needs of the majority. Therefore, targeting organizations that have deeply established roots in local communities aimed at providing health care delivery and developing public health infrastructures serve as important collaborators for intended research efforts. PIH serves as one example of a locally embedded collaborative partner that focuses on increasing health care delivery and developing more robust public health infrastructure, but relies on

collaborative partners for research. Collaborating on research projects and building capacity for research is something that Catholic universities can offer an organization like PIH. However, addressing gaps in research and building capacity for research does not ensure necessarily that the benefits of research reaches communities in need, there are also structural and policy challenges that disincentivize medical research on major global health challenges.

Another example of structural reform, focusing on gaps in the research delivery pipeline, appears in the proposal of Thomas Pogge’s Health Impact Fund (HIF). The significance of Pogge’s much criticized efforts, stemming from the complexity surrounding the programs implementation process, posits an alternative patenting structure to address the economic challenges that contribute to the lack of incentive for research focused on the health needs of the poor majority. Rather than a particular form of research, the HIF offers an opportunity for academic researchers to serve as advocates in an effort to ensure that their own research projects have the intended impact, especially for projects that stand to improve access to treatment for low-income communities. While Pogge’s model is not perfect, and in reality has gained little political traction, it serves as a unique example of an approach that tackles the structural and policy issues perpetuated by a patent system that does not reward research on drugs needed to address global health challenges. Both the HIF and PIH offer an example of social institutions that challenge structures that limit health care delivery and access to essential medicines for large segments of the global poor.

**Partners in Health (PIH)**

PIH is a non-profit organization, founded by Jim Kim, Paul Farmer, Ophelia Dahl, Todd McCormack, and Thomas White, that has developed a growing number of global
partnerships with communities in low-income countries to strengthen public health infrastructures and access to health care services. PIH unapologetically grounds its model of health care in a preferential option for the poor:

Our mission is to provide a preferential option for the poor in health care. By establishing long-term relationships with sister organizations based in settings of poverty, Partners In Health strives to achieve two overarching goals: to bring the benefits of modern medical science to those most in need of them and to serve as an antidote to despair. We draw on the resources of the world’s leading medical and academic institutions and on the lived experience of the world’s poorest and sickest communities. At its root, our mission is both medical and moral. It is based on solidarity, rather than charity alone.  

In a sense PIH’s mission statement aligns with what ought to be the goals of medical research *writ large*, but certainly with goals of medical research at a Catholic university. Their commitment to the option for the poor, cultivating local partnerships, utilizing the latest technological and medical advances to benefit those most often excluded, and focus on solidarity—both intellectual and practical—demonstrates the epistemological effects of an organization that begins with the horizon of the poor majority.

PIH has cultivated local/global relationships in Haiti, Rwanda, Lesotho, Malawi, Mexico, Russia, Peru, Navajo Nation, and Boston that focus healthcare delivery and public health education, with an eye towards developing a capacity for research, while also ensuring its distribution in these areas. PIH’s research priorities do not reflect the breadth of NIH research priorities, but rather a narrower agenda with more immediate effects. They cite their health priorities as: Cancer & Chronic Diseases; Child Health; Cholera; Community Health Workers; Ebola; HIV/AIDS; Mental Health; Nursing; Surgery; Tuberculosis; and Women’s Health. These research priorities reflect the health needs of the people with whom they work.

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Collaboration with research partners like PIH, demonstrates a commitment to developing a socially projected research agenda that reflect the needs of a particular community. PIH serves as an exemplar in its focus on local health needs and its cultivation of academic and philanthropic partnerships committed to the same common goal. Through PIH’s alliance with Harvard University and the Brigham and Women’s Hospital in Boston, they have cultivated partnerships that research by exploring “the impact of global health initiatives on national health systems with commissions from the World Health Organization and UNAIDS.”\footnote{Global Health Delivery Project at Harvard University, “Our Work,” Global Health Delivery Project, http://www.globalhealthdelivery.org/our-work/, (accessed, May 2, 2015).} The system for collaboration is in place. Universities educate students about the impact and importance of global health and focus on research that addresses health needs raised by locally embedded partners, global and local. PIH, the partner organization, ensures the delivery of health care, establishes preventive health measures, and implements improvements that come about through research. While PIH, and other similar organizations, demonstrates a commitment to ensuring health care delivery and disease prevention through public health strategies, further work has to develop research capacity within these vulnerable places.

Developing research capacity requires a commitment to working with partner organizations to identify areas of research need and also challenge existing research structures. In order to be leaders in global health research, collaborative relationships must be mutually beneficial. While PIH might not prove capable of taking on widespread clinical trials, they can engage in research similar to CER, as discussed in the first section. In this way, efforts could be made to study the effects and possibilities of improving the quality of care in a given area. On the other hand, if a university wanted to conduct a large scale trial
for an under-researched drug or with a vulnerable population, measures have to be put into place so as to ensure that benefits resulting from that research extend to the research population, which is already built into CER.

The example of PIH highlights the importance of international partnerships, however, the geographic location should not dictate the partnership. Instead, the needs of the community and collaborations with organizations that may have limited access to the fruits of research efforts most aptly define the parameters of the partnership. The important factor in determining a collaborative partner for research is the ability to translate the benefits of research into effective health care. Even with effective health care delivery systems and public health infrastructure, systemic change to the way in which research flows will still be needed. Thus, partnering with PIH represents one way to include multiple vulnerable populations in the process of research. However, developing partnerships alone will not resolve the structural challenges involved in medical research. Advocacy efforts prove essential in an effort to ensure that research developments benefit their targeted population.

Catholic universities have the obligation to advocate for systemic changes that allows for more just distribution of knowledge garnered through medical research to those communities most in need. While establishing partnerships with organizations committed to delivering health care and engaging in research that can affect the health of the poor majority, exploring systemic changes to the unjust distribution of research also needs to be explored. Advocacy efforts around policy change can be significantly enhanced by academic-
researchers who recognize the social enterprise of their research efforts and see the need to address the breakdowns in the drug development pipeline.\textsuperscript{45}

**Health Impact Fund (HIF)**

The HIF proposes to address the challenge posed by economic forces that generate little incentive for medical research to target neglected diseases and/or disease that predominately affect low- and middle-income countries.\textsuperscript{46} While, in reality, university researchers have little to do with the market forces and intellectual property rights restricting essential medicines, they have also done little by way of acknowledging or attempting to reform the injustices of the system in which they participate. Systemic change proves necessary to the consideration of medical research as a discipline that impacts society. The example of the HIF, while not serving as an endorsement of the system, represents an important model for rethinking the complexities associated with medical research.\textsuperscript{47}

The HIF aims to alter both the politics and economics that govern research by deemphasizing return on investments that do not positively affect the health needs of the majority. A large portion of these efforts would require government financing to establish a “pay-for-performance mechanism that would offer innovators the option—no obligation—to register any new medicine or, under certain conditions, also a traditional medicine or anew


\textsuperscript{47} Jorn Sonderholm, “A Reform Proposal in Need of Reform: A Critique of Thomas Pogge’s Proposal for how to Incentivize Research and Development of Essential Drugs.” *Public Health Ethics* 3, no. 2 (2010). Jorn Sonderholm, “A Critique of an Argument Against Patent Rights for Essential Medicines,” *Ethics and Global Politics* 7, no. 3 (2014). In these two essays Sonderholm acknowledges the need for patent reform, or the potential argument that patents for essential medicines be omitted as unjust in low-income countries. While he does not agree with Pogge’s arguments, he recognizes the injustices of the current system.
use of an existing medicine.”48 The funding would be established by and paid for through high-income governments that opt-in. However, there exists no obligation for industry or governments to buy-in. These two entities, nevertheless, must participate in order for the HIF to function, i.e. the greater the number of governments and industries that opt-in, the more financial incentives would exist to research diseases that cause the greatest health challenges for the majority.49 And, while the registration process would function similarly to current patenting practices, the caveat would be that the return on investment takes place based off of actual health impact measured by Quality Adjusted Life Years.50

During the first 10 years on market —half of the typical duration of patent—a drug would be made available in the areas most in need for no more than the lowest possible cost of production and distribution. After 10 years, generic production and distribution of the product would then be allowed. With financial incentives, “HIF would foster the development of new high-impact medicines—also against diseases concentrated among poor, such as tuberculosis, malaria, and other tropical diseases, which are now neglected because innovators cannot recover their R&D costs from sales to the poor.”51 Pogge’s model represents an alternative, structural way of re-thinking the drug pipeline that, unaltered, continues to exclude those most in need of treatment options.


49 Ibid.


51 Pogge, The Health Impact Fund and its Justification by Appeal to Human Rights, 546
The description of Pogge’s HIF is not an endorsement of it, nor something that Catholic universities should necessarily adopt. However, reconsidering the structure of medical research is something that the university should undertake in establishing its research priorities. Pogge rightly calls on university academics to partner with him in support of creating the HIF and demonstrates the complex task that would benefit greatly from the expertise of academic medical researchers. While this may not be the model universities want to endorse, medical researchers offer unique insights into the drug development process at the most basic level. Their perspective is enhanced further by the technical nuance to advocate for systemic change from within the structure of medical research itself.

Medical researchers, implicitly or explicitly, are already contributing to the debate through their research. Advocates prove necessary to shift this agenda and priorities, and “…academic silence can reasonably be interpreted as academic acceptance that the main view represented in the public debate are credible and consistent with the available evidence.” This cannot come from the ivory tower but, rather, the voices of those marginalized by and excluded from medical research benefits need to be heard. In this way, research advocates need to both speak broadly to the research community through publications and presentations and to alter the structures that limit the just-distribution of the produced innovations.

HIF and PIH both offer systemic changes to the way in which medical research is delivered to low- and middle-income countries. HIF takes a political approach rooted in a complex overhaul of the drug pipeline in an effort to treat those with medications for diseases that are often under-research. The approach of PIH, perhaps most consistent with a

liberationist approach, is rooted in a process of community engagement and locally delivery of effective health care. If PIH represents the grassroots approach to assessing health care and medical research needs, then Pogge’s system—even if flawed—represents a type of socio-political overhaul that attempts to interrupt the current injustice within the distribution of medical research.

Catholic universities have an obligation to take up the responsibility beyond simple engagement in just-research, and to advocate additionally for reforms to structures that contribute to its inequitable distribution. Yet, the present reality suggests that the current structures may simply prove impermeable to suggested reform. In this case, alternative approaches to collaboration and advocacy for social justice based on health priorities may need to be considered. This change could necessitate a complete rethinking of the approach to research and the adoption of alternative structures for approaching the health needs of the poor majority.

Exploring Alternative Visions

The final two examples focus on challenging the current inequalities that exist by developing parallel structures that strive for more targeted funding and better sharing of information developed in the research process. The first option takes up the idea of a co-operative university, while the latter considers—following the WHO suggestion—the development of an open source database that lists research being conducted on urgent health needs. While these types of structures represent departures from the way in which the process of medical research takes place, they also draw on a type of ethical imagination needed to think through global challenges.
Mondragón

Mondragón is a co-operative business and educational institution developed in the Basque region of Spain, which has grown into a sustainable Spanish business with multinational locations. The model was developed by Father Jose Maria Arizmendi as a way to institute, what he believed to be, a sustainable business model. The business developed from the local community built and relying on principles of Catholic Social Teaching to inform its mission.

Mondragón has developed into an international, multi-million dollar for-profit co-operative business. It consists of 150 co-operatives, three research and development centers, a university, its own bank, and health care system. While the focus at Mondragón is not on medical research, it does generate patents, currently holding 716, which seems crucial to the practice of research—as presently conceived. These patents have made them one of Spain’s leaders in alternative energy sources of wind power, fuel cells, and solar panels. They emphasize these sustainable projects, not at the expense of economic returns, but also not subservient to the economic demands. The Mondragón co-operative has created a parallel business model and one that pharmaceutical business executives could emulate by incorporating more social equity into the internal structures and priority setting for neglected diseases. One of the key features of Mondragón, aside from the co-operative organizational structure, was the creation of its own research pipeline through its university.

53 David Herrera, “Mondragon: A for-Profit Organization that Embodies Catholic Social Thought,” Review of Business 25 (2004), 56. “The Mondragón Cooperatives have created businesses in four key areas: finance, industry, retail, and knowledge. They have four university campuses, a culinary arts school in San Sebastián, the largest research and development center in all of Europe (with fourteen separate entities), the Caja Laboral Bank with 380 branches in Spain, and an incubation center for creating new products and services.”

Mondragón University understands that integrating the three main activities of a university—education, research, and service—is the most effective way of increasing quality and fulfilling its social mission. It does so, however, with a targeted and collaborative approach throughout the co-op. Research is conducted through a collaborative model “based on research alignment, from oriented basic research to innovation, with the participation of three key actors: universities, technology centers, and businesses through R&D departments.”\(^{55}\) They decide that in order for their research to be cost-effective, but still to meet the socio-ethical principles held by the company, research has to align with the cooperatives interests. The goal, then, is to incorporate researchers in order to “produce top-quality research and bring the university closer to businesses as the key to innovative dynamics and to the training of would-be researchers for businesses and technology centers.”\(^{56}\) A key distinction between current models of university research and Mondragón’s lies in the fact that university researchers do not set the agenda, Mondragón does. Mondragón University considers chooses research in line with its strategies to create wealth in the community. They hire researchers that prove capable of enacting the institutional standards for research—as opposed to letting researchers themselves set the agenda.

To apply Mondragón’s model for medical research presents several obstacles, not the least of which requires a significant financial investment on the part of individuals who see a value in the mission focus and potential success of a co-operative model for business and education. However, it demonstrates a targeted and collaborative approach to research that


\(^{56}\) Ibid.
would more directly be able to address some of the gaps in medical research. Finances aside, Mondragón could serve as an intriguing dialogue partner because of their commitment to Catholic social values, equity within their institution, and their focus on education that yields practical results. A focus on the practical results of health impact, however, will require information sharing. Thus, while a business model and current research practices tend to guard new and innovative information, a model for research that intends to generate the highest health impact will need to openly share its resources in order to demonstrate progress and not duplicate research efforts.

**International Federation of Catholic Universities (IFCU)**

Participation in an open source database and priority setting, as proposed by the WHO’s Consultative Expert Working Group for health research, could prove a successful undertaking of the International Federation of Catholic Universities (IFCU). An open source database and working group on medical research would represent an important step in raising awareness for diseases in need of research. An open source database and collaborations with the IFCU would demonstrate the leading role that Catholic universities ought to play in addressing the global need in medical research.

The IFCU, as part of its mission, aims to develop a collaborative environment for Catholic higher education. It recognizes the importance of research in this social project and holds within its current structure a Center for the Coordination of Research (CCR). “Aware of the concerns, interests and expectations of Catholic universities and their respective fields of action, the CCR offers a platform for encounter, debate, production and circulation of knowledge, in order to permanently question the main challenges posed today to human,
scientific, social and ecclesial development.” There is no specific mention of collaboration on medical research. While a working group on medical research that affects the most vulnerable would be a start and an open source database would be even better. Here, the IFCU could provide a place for intentional dialogue to develop a research agenda that speaks to the socially projected needs from a diverse community of representatives.

Developing a Catholic and international collaborative focused on medical research around diseases that disproportionately affect the poor and marginalized allows for the pooling of resources and streamlining of efforts to address global health needs. Those already engaged in medical research targeting poor and vulnerable populations is currently a small subset of researchers. The hope, as with other initiatives in the IFCU, would be to bring together the leaders in research on global health needs to raise awareness and capacity of Catholic universities to engage in collaborative research. Establishing a network of knowledge would foster, hopefully, effective support and creativity between its members, create space to share information, and save expense by releasing new information more quickly, consequently limiting the duplication of work.

Collaborative research, which has been at the heart of most of these projects, can prove to be a time-consuming and challenging effort. However, when reflecting on the original paradigmatic examples in Chapter One, the most effective forms of research addressing global health needs were collaborative. The above examples are emblematic of the types of approaches, though not necessarily an exact blueprint, that can offer correctives to structural injustices within the research process. Each of the examples challenges the

existing economic or technological epistemology at work in research and offers the global health of the poor as a guiding framework. Targeted research efforts, developing partnerships, and exploring creative alternatives to enhance the health options of the poor majority is fundamental for Catholic university research. And while these examples of signaled potential dialogue partners, universities themselves have to restructure their own institutional approach to medical research. By way of conclusion, the final section sketches some fundamental steps that need to be taken for Catholic university medical research to project an option for the poor onto their research agenda.

**Conclusion: Is a Different Kind of Research Agenda Possible?**

The most fundamental shift for the university has to come from instituting structural and policy changes that ground the norms for medical research through explicitly prioritization of the health needs of the poor majority. Ellacuría clearly articulated the importance of social projection as the way for conducting research at the UCA. The UCA research, however, was not about the task of research *per se*. Research, rather, served the task of the university’s mission to engage in education, research, and service in order to understand and transform the injustices within the community. Medical research must likewise be reimagined in through a similar multifaceted approach. Therefore, relying on the efforts of individual researchers to set up the research agenda of the institution will continue to produce disparate results that fail to achieve desired health outcomes.

When attempting to transform a culture, challenges emerge when change is forced from the top. Thus, while hiring for mission proves important, that mission must include the ability to collaborate and focus on a unified goal. While Catholic universities may speak about the option for the poor, it rarely appears as the subject of research practices or in the
education of students on how to conduct research. Students who engage in research are taught the importance of conducting research that respects research subjects, but more need to be taught about the social reality of those who benefit and those who do not from the research conducted. Conducting research as a social practice and educating for just-research, or socially-projected research, can transform and refocus the intrinsic good of medical research from the knowledge produced to the knowledge produced for the health and care of individuals most in need.

While developing strategic priorities for health research may be possible, financing for this plan proves limited. Thus, given the challenge of finding grants for these particular areas of research, more institutional and hard money commitments prove necessary. Many researchers finance portions of their own salaries through grant projects they have earned. This creates practical challenges when targeting a small sub-sector of grants that one may or may not receive. Increasing the hard money commitment for researchers frees researchers to pursue more competitive grants as long as they maintain a focus for neglected and under-researched diseases. Moreover, reconsidering tenure requirements might also be necessary in order to reward researchers for their commitment to engaging in medical research befitting the institutional mission. With this type of institutional reform, Catholic universities might be able to recruit well-published and higher profile researchers that focus on global health and neglected diseases to working at the university, which reinforces the institutional commitment to engage in a distinct kind of research—one that is socially projected.

The final step, and perhaps the simplest implementation for Catholic universities, is the development of and participation in advocacy networks through publishing. In the research community, publications represent priority. In other words, if something is
considered important, someone is researching and publishing on the topic. What is seldom referenced, except when crises emerge—e.g. Cholera and Ebola—are efforts to bring awareness to neglected diseases more broadly and more consistently. While it is an expectation that researchers engage in retrospective analysis detailing their research efforts, attempting to establish broader areas for funding and research that benefit the poor majority more prospective and collaborative publishing proves necessary in order to bring attention to under-researched areas. This prospective approach will necessitate collaborations interdepartmentally in order to provide ethnographic, sociological, and even theological importance for why certain projects ought to be pursued over others. The strength of the social science efforts, moreover, will be reinforced by the scientific approach that can point to potential practical solutions in development in the lab or clinical trials. Yet, all of this is for naught if the epistemology of research remains the same.

This dissertation began with a focus on paradigmatic accounts of the development of medical research that sought to both improve the health of communities and particular individuals. Gradually, the focus of researching for health was seen along side the possibility of economic gain. Currently, the most economic gain stems from genetic and biotechnology based research. Not only does it hold economic possibilities, it also represents the newest scientific knowledge being discovered as it relates to medical research. However, the epistemic foundation of this research begins from a perspective of new knowledge and economic gain with little mention of health. However, if health became the hermeneutic through which medical research was understood, then medical research agenda would have to shift.

58 These publications likewise need to be included in one’s academic portfolio for tenure, perhaps a break from institutional standards.
When making the epistemological move to reflect on research from the perspective of health, one’s attention has to turn to places in which a lack of “health” exists. As noted in Chapter Four, DALYs serve as tangible markers of the structural injustices endemic to the practice of medical research itself. These injustices develop through a false epistemology for medical research that prioritizes financial gain and future promise for the minority over present and dire health needs for the majority. Thus, research for the common good, a fundamental tenant of Catholic Social Teaching, proves impossible as long as current structures prevail. In a certain sense, medical research is left with the task of avoiding the common harm.

Catholic universities, in solidarity with those most vulnerable, must make a preferential option for the poor apparent in the practice of medical research. While this final chapter has proposed dialogue partners in this endeavor, individual institutions and collaborative networks should take this occasion to reevaluate their own research priorities and policies to see how they participate in the current injustices in medical research. This is not an easy task, and the ways forward proposed here most certainly need nuance. However, this is not intended to be the end of the conversation but the beginning. These pages have focused on the importance of collaborative dialogue and health-oriented research that seeks to transform the ways in which Catholic universities engage in the social practice of medical research. Catholic universities committed to engaging in medical research have the obligation to implement institutional changes that promote and prioritize the health needs of the poor majority in pursuit of justice from places of injustice.
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VITA

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