DUTY TO WARN FOR GENETIC TESTING: THE IMPORTANCE OF UNDERSTANDING HARM WHEN PRACTICALLY APPLYING *THE PRESIDENT'S COMMISSION STANDARDS* OF DISCLOSURE

by © Kristen Byrne A Thesis submitted to the School of Graduate Studies in partial fulfillment of the requirements for the degree of

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Abstract

The field of genetics is unique as test results reveal information about multiple individuals. When a hereditary condition is identified, healthcare professionals face an ethical dilemma between their duty of confidentiality toward their patients and their moral obligation to warn relatives of possible harm. The standards developed by *The 1983 President's Commission*[1] guide healthcare professionals with this decision-making process. This thesis will argue that these standards of disclosure are defensible in the face of common criticisms of genetic information disclosure and are a good guide for health care professionals challenged with this ethical dilemma. However, there are challenges when practically applying these standards because of the standards' reliance on the notion of harm. Harm is complex, and when using the standards, we must distinguish between a harmful action and a wrongful action. This thesis will argue that this distinction must be made when practically applying these standards to avoid a mistake in our understanding of the situation. An improper understanding would result in a moral dilemma as the rights of another would be infringed upon in an unjustified manner.

[1] "Screening and Counseling for Genetic Conditions." National Information Resource on Ethics and Human Genetics. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, February 1983., p. 6.

General Summary

Genetic test results reveal information about family members, and when a hereditary disease is found, health professionals must decide whether to disclose this information. The standards of disclosure developed by *The 1983 President's Commission*[2] help guide healthcare professionals with this decision. These standards are defensible in the face of common criticisms of genetic information disclosure. However, there are practical problems with their application because they rely on the notion of harm. Harm is complex, and when using the standards, we must distinguish between a harmful action and a wrongful action. In this thesis, I argue that we must distinguish between a harm and a wrong to effectively and ethically use these standards. An improper understanding would result in a moral dilemma, and another person's rights will be invaded without good reason.

[2] "Screening and Counseling for Genetic Conditions," p. 6.

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List of Abbreviations

ARVC	Arrhythmogenic Right Ventricular Cardiomyopathy
CMA	Canadian Medical Association
CMPA	Canadian Medical Protective Association
DNA	Deoxyribonucleic Acid
GMC	The General Medical Council
HGP	Human Genome Project
UK	United Kingdom

Chapter 1: Introduction

Genetic testing has changed how we understand preventing, diagnosing, and treating complex disorders. The advancements in this field have generated numerous health benefits for individuals who choose to undergo testing. For instance, test results may provide relief from uncertainty and also allow individuals to make informed decisions about their health and treatment plans. Genetic testing can also significantly impact major life choices, such as the decision to conceive a child.[3] An individual diagnosed with a hereditary disease may forego reproducing so that their children do not suffer from the same condition.

Contrarily, other research suggests that the hype of genetic testing has actually resulted in fewer benefits. First, scholars have questioned the value of the information obtained through genetic testing. A genetic test may reveal the patient is at risk of a disease, but there may be no medical options to deal with that risk (such as with Alzheimer's).[4] Because there is no way to manage or reduce the risk, what is the benefit?[5] Second, even if interventions exist to reduce the patient's risk, a genetic test may not be valuable. Patients who believe they are at risk of a disease already seek regular checkups and practice self-care.[6] Contrarily, a negative test result may cause the individual to become less concerned with their health and become prone to unhealthy habits.[7] Lastly, some believe "knowledge is power" and wish to know everything.[8] Contrarily, others will experience psychological damage (such as experiencing anxiety, depression, and worrisome thoughts) by knowing their susceptibility to a genetic disease.[9]

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[3] "What Are the Benefits of Genetic Testing? - Genetics Home Reference - NIH." U.S. National Library of Medicine. National Institutes of Health, October 29, 2019. https://ghr.nlm.nih.gov/primer/testing/benefits.
[4] Teichler-Zallen, Doris. *To Test or Not To Test: A Guide to Genetic Screening and Risk* New Brunswick, NJ: Rutgers University Press, 2008., p. 92.
[5] Ibid., p. 92-93.
[6] Ibid., p. 93.
[7] Ibid., p. 94.
[8] Ibid., p. 94.
[9] Ibid., p. 94.

As shown, there may be numerous disadvantages and benefits to scientific advancements in the field of genetics. These advancements and the uniqueness of this area has also created significant ethical issues. Genetic testing is not merely a laboratory process; rather, this area of medicine is deeply rooted in social and biological relationships. Genetic tests differ from other medical procedures as test results may reveal information about multiple individuals. Therefore, health care professionals face an ethical dilemma should the genetic test results reveal a genetically transmissible medical condition. The ethical dilemma is between their duty of confidentiality toward their patients and their moral obligation to warn relatives of possible harm. Confidentiality is highly valued within health care and, for the most part, must be upheld. However, the risk of harm to others is one circumstance which would warrant a breach in confidentiality. Therefore, health care professionals are faced with the challenge of determining if they have a duty to warn while simultaneously considering their obligation to their patient.

This thesis will argue that the standards developed by *The 1983 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research*[10] are defensible in the face of common criticisms of genetic information disclosure and are a good guide for health care professionals challenged by the duty to warn and patient confidentiality within the context of genetic testing. However, there are challenges when practically applying these standards to the decision-making process about breaching confidentiality because of the standards reliance on the notion of harm. Harm is complex, and when using the standards, we must distinguish between a harmful action and a wrongful action. This thesis will argue that this distinction must be made when practically applying these standards to avoid a mistake in our

[10] "Screening and Counseling for Genetic Conditions." National Information Resource on Ethics and Human Genetics. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, February 1983., p. 4.

understanding of the situation. An improper understanding would result in a moral dilemma as the rights of another would be infringed upon in an unjustified manner.

Overview of Chapters

This section will provide a detailed description of the purpose and arguments to be made in each of the chapters. The current chapter will provide a detailed overview of the history and process of genetic testing, present which diseases are detectable through genetic testing, and how the results reveal information about multiple individuals. Additionally, an in-depth discussion of the conflict between confidentiality, duty to warn, and the current standards of disclosure will be presented. The challenges of relying on the harm principle and background information on harm will be discussed. The final section of Chapter One will outline in detail the information to be addressed in the subsequent chapters, thereby presenting the intended discussion points and arguments to be made.

Chapter Two will present comprehensive responses to three potential criticisms I have developed of the current standards of practice for disclosure of genetic information. The responses to these three criticisms will clearly establish that the current standards are, in fact, defensible against common criticisms and a good guide for health care professionals. The first potential criticism of the standards is that some scholars may argue that patient confidentiality ought to be absolute. These scholars may claim that breaching patient confidentiality may cause adverse outcomes, including loss of trust, unwillingness to seek future treatment or undergo genetic testing, and withholding personal health information. The second potential criticism is that a duty to warn patient relatives will cause a burden for physicians and deter future doctors from entering this field. The third possible criticism is that patients may feel pressure to agree to disclose their test results. This pressure may come from the physician or other health care workers over a fear of a potential lawsuit from relatives. This chapter will conclude that the

standards developed by *The President's Commission* are a good guide for health care professionals challenged with the decision of whether to disclose genetic information.

Chapter Three will discuss the complexity of harm in the decision-making process of choosing whether to breach confidentiality based on the current standards of disclosure. This chapter will argue that harm must be understood in order for the current standards to be useable and effective. Harm is a concept that many people assume they understand. This concept is typically understood at a basic level in terms of injury, damage or hurt that is inflicted upon another individual.[11] However, the concept of harm utilized within the context of this thesis assumes a higher level of complexity. The basic and ordinary understanding of harm, which appears in everyday conversation, does not capture the critical importance of what this concept demands to support the appropriate application of the standards of disclosure for genetic testing.

The current standards of disclosure have been accepted as a good guide for health professionals; however, as mentioned, their reliance upon the principle of harm creates complex problems. As this chapter seeks to describe the complexity of harm, the first challenge presented will be understanding the term harm in general. The harm principle is challenging to define, and many scholars have sought to explain this term accurately. As we try to define harm precisely, we must also determine what constitutes a harm and a harmful act. For this, the work of Joel Feinberg will be discussed.

Additionally, the distinction between harming and wronging will be provided. To make this distinction, I propose that a line is drawn when the decision (disclosure or non-disclosure) becomes life-altering for one of the parties involved (the patient or their relatives). I will present three factors that health professionals must consider when applying the standards of disclosure to

[11] "Harm." Merriam-Webster. Merriam-Webster, https://www.merriam-webster.com/dictionary/harm.

determine whether the decision will be life-altering. These factors include the long-term, physical and psychological impact of disclosure or non-disclosure. I will also present a second challenge with the harm principle, determining the degree of harm. There are multiple factors to consider to adequately assess the degree of harm that may occur to both the patient and the relative. Ultimately, it is necessary to understand harm in order for the current standards of practice to be useable and effective.

Chapter Four will use two case studies to demonstrate the complexities of the practical application of the standards in light of their heavy reliance on the notion of harm. I will also apply the three factors (long-term, physical and psychological impact of disclosure or non-disclosure) that I have developed to determine when a decision becomes life-altering to determine if an action is unjustified (morally wrong). This chapter will argue and demonstrate that we must ultimately determine whether disclosure without consent is a harm or a wrong. Whether disclosure without consent is a harm or a wrong will determine if we may ethically breach confidentiality. When making the distinction between a harm and a wrong, we must acknowledge that not all harms are wrongs. Not all harms will be classified as wrongs, as there are circumstances where it will be deemed justifiable to cause harm to another individual. Under such circumstances, a harm is not considered a wrong. A justifiable harm is a case where the act in question does not involve doing wrong to another or others. On the contrary, an unjustifiable harm is when the harm in question involves doing wrong to another or others. The first case that will be utilized is a recent case development in the United Kingdom. In this case a woman is suing physicians for their failure to warn her of her father's diagnosis of Huntington's Disease.[12]

[12] Please note that during the writing process of this thesis, this case was resolved in court. The woman in this case lost her legal battle. The court determined that despite the sympathy they have for the plaintiff, there is no proof that she would have terminated her pregnancy had she known her risk of inheriting Huntington's disease. Please see "Huntington's Ruling on Doctors' Duty to Tell Patient's Family." The Guardian. Guardian News and Media, March

The second case will be hypothetical. This hypothetical case will use the genetic heart condition, arrhythmogenic right ventricular cardiomyopathy (ARVC), commonly found in Newfoundland and Labrador.[13] These two case studies use diseases which are *fully penetrant*, meaning that these relatives have a 50% likelihood of inheriting the genetic variant and developing the disorder. If the genetic variant is inherited, the variability is when and how severe the symptoms will present.

Finally, Chapter Five will serve as a conclusion to summarize the arguments, claims, and literature references that have been made throughout this thesis. A synopsis of each chapter will be provided to highlight the important claims made throughout this paper. This summary will demonstrate that the current standards of practice are, in fact, defensible against common criticisms and a good guide for health professionals. However, there are practical challenges with applying those standards in the decision-making process for determining the justifiability of breaching patient confidentiality. The distinction between a harmful action and a wrongful action must be established. Without this distinction the result would be a moral dilemma because the right of another may be infringed upon in an unjustified manner.

Section 1 Background Information

The following section will provide an overall background of relevant information pertaining to the discussion and arguments of this thesis. This background information is necessary in order to understand discussion points presented throughout this thesis. The relevant background includes the history of genetic testing, the advancements and issues in genetic testing, confidentiality and duty to warn, the familial nature of genetics, The Tarasoff Decision

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1, 2020. https://www.theguardian.com/society/2020/mar/01/huntington-disease-ruling-doctors-duty-to-tell-patient-family.

[13] Hodgkinson, Kathy, Dicks, Elizabeth, Connors, Sean, Young, Terry-Lynn, Parfrey, Patrick, and Pullman, Daryl. "Translation of Research Discoveries to Clinical Care in Arrhythmogenic Right Ventricular Cardiomyopathy in Newfoundland and Labrador: Lessons for Health Policy in Genetic Disease." *Genetics in Medicine* 11, no. 12 (2009): 859-65, p. 859. https://doi.org/10.1097/GIM.0b013e3181c20bb3.

and a discussion of two important legal cases. Finally, the position of professional organizations will be presented, the standards developed by *The President's Commission* will be discussed, the complexity of harm will be demonstrated and lastly an overview of the chapter will be provided.

1.1 The History of Genetic Testing

To begin, an understanding of the historical context of genetic testing is required to appreciate the developments and the complexity of this field to appreciate the discussion points surrounding genetics and genetic testing presented throughout this thesis. (Please see Appendix A for a diagram displaying the timeline of the advancements in genetic testing) Over the past several decades, genetic research has developed rapidly, and there are now multiple areas and specialties within this field. When genetic testing first became available, laboratory tests were only performed on patients who were referred by specialists in clinical genetics.[14] There existed two different categories of patients who participated in genetic testing. The first category of patients was children with physical or mental disabilities or children that were experiencing developmental issues. The second group of patients was those affected by Mendelian genetic disorders.[15] However, since this time, the types of patients undergoing genetic testing has dramatically expanded. Genetic testing is now available to any individual who wishes to know more about their health, genetic makeup, or predisposition to genetic disorders. As this testing is now widely available, the disclosure of test results has become increasingly complicated. Disclosure has become more complex as the personal circumstances and the relationships between the patient and their biological relatives may vary significantly. The standards for

[14] Arribas-Ayllon, Michael, Sarangi, Srikant, and Clarke, Angus. Genetic Testing: Accounts of Autonomy, Responsibility and Blame. Florence: Routledge, 2011, p. 15. https://doi.org /10.1080/09687599.2014.964509.
[15] Ibid., p. 15.

assessing third parties' right to this information will be discussed in greater detail in the subsequent chapters.

During the 1970s, two major types of genetic tests were introduced to analyze genetic disorders; these included cytogenic testing and the Guthrie test.[16] Cytogenic testing, which is a chromosomal analysis, is a laboratory process where chromosomes are counted to identify any genetic variances. The second test developed, the Guthrie test, was the first technique used to make screening for newborns with phenylketonuria[17] feasible.[18] Advancements in genetic testing continued throughout the following decade for identifying and studying Mendelian disorders[19] through linkage studies. Information continued to be collected for genetic and DNA sequences and geneticists became capable of identifying genetic mutations that caused hereditary diseases.[20] A genetic map was created, which continued to be improved throughout the 1990s. The advances in this decade led to the Human Genome Project (HGP).[21]

The HGP was a significant development in the field of genetics and for the scientific community as a whole. Scientists could now use the findings from this international research project to identify the genetic bases for diseases. The HGP created a sense of hope within the scientific community that they would be capable of detecting and treating serious disorders. By the following decade, a complete sequence of the human genome was available, and the scientific

[16] Ibid., p. 15.
[17] Phenylketonuria is an inherited disorder where there is an increase in the level of phenylalanine in a person's blood. If this condition is not treated than the build-up of phenylalanine can results in intellectual disability and other serious health issues. For more information please see, "Phenylketonuria." U.S. National Library of Medicine. National Institutes of Health, October 29, 2019. https://ghr.nlm.nih.gov/condition/phenylketonuria.
[18] Ibid., p. 15.
[19] Mendelian genetic disorders "occur in families with a pattern that reflects the inheritance of a single causative gene". Please see, Kennedy, Martin Alexander. "Mendelian Genetic Disorders." *Encyclopedia of Life Sciences*, 2005, 1–7.
[20] There is a difference between genetic disease and hereditary diseases. All hereditary diseases are genetic, but not all genetic changes are hereditary.
[21] Ibid., p. 16.

community gained a better understanding of Mendelian disorders.[22] In 2010 we continued to see advancements in genetic testing, and geneticists continue to chart the human DNA sequence.[23] The scientific and biological aspects of genetics are complex. A basic understanding is required to appreciate the sophistication of this area within the field of medicine.[24]

Each person has twenty-three pairs of chromosomes that are composed of DNA and protein.[25] When discussing genetic testing, a gene is the "section of DNA that contains the sequence which corresponds to a specific protein".[26] Most diseases have a genetic aspect, while others have a combination of genetic and environmental factors.[27] The Congressional Research Service stated recently (2015) that experts in this field have found that society is entering into a "transition period in which specific genetic knowledge is becoming more integral to the delivery of effective health care".[28] Additionally, the importance of genetic testing is expected to increase in the future. Test results will not only guide clinical treatment but also have an essential role in preventative medicine.[29]

Genetic testing is a term that describes a set of procedures that are used to "identify gene variations associated with health, disease, and ancestry and to diagnose inherited diseases and

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[22] Denbo, Susan M. "What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives?" *American Business Law Journal* 43, no. 3 (2006): 561-2. https://doi .org/10.1111/j.1744-1714.2006.00025.x.
[23] Arribas-Ayllon, Michael, Sarangi, Srikant, and Clarke, Angus. Genetic Testing: Accounts of Autonomy, Responsibility and Blame, p. 16.
[24] It is important to note that ethical issues have existed for a long time in genetics. These challenges are not new, and geneticists have navigated these issues for many decades. Additionally, with improvements and advancements in the area, more contemporary challenges will continue to be present.
[25] Sarata, Amanda K. "Genetic Testing: Background and Policy Issues." Congressional Research Service, March 2, 2015, p. 13.
[26] Ibid., p. 13.
[27] Ibid., I.
[28] Ibid., p. 2. Please note that this statement was made in 2015. Please also note that genetics has undergone several transition periods over the past several decades. Duty to warn involving high risk, high morbidity diseases has been and continues to be a pressing issue for geneticists.
[29] Ibid., p. 6.

disorders".[30] Genetic tests are especially unique as unlike other medical tests they have "exceptionally long-range predictive powers over the life span of an individual; can predict disease or increased risk of disease in the absence of clinical signs or symptoms; can reveal the sharing of genetic variants within families at precise and calculable rates; and, at least theoretically, have the potential to generate a unique profile for individuals".[31] The majority of genetic tests are performed to detect rare genetic disorders. However, tests are increasingly becoming available to screen for more common diseases.[32] There are two main categories of genetic tests: diagnostic and predictive. Diagnostic tests are used to determine the "presence or absence of a disease".[33] Predictive tests are used to predict the risk of an individual developing a specific disease in the future.[34]

Genetic tests can detect different types of genetic mutations (See Appendix B). These genetic mutations include somatic mutations and germline mutations. There is a distinct difference between these types of mutations which is relevant to the diseases that are discussed during the case studies in Chapter 4. Somatic mutations are defined as "an alteration in the DNA that occurs after conception".[35] This form of mutation is related to environment and life-style factors and these genetic diseases *are not* passed from parent to off-spring.[36] These types of genetic diseases may include, cancer, neurological diseases (such as epilepsy, autism and

[30] "Genetic Testing." *Britannica Online Academic Edition*, 2019, Encyclopædia Britannica, Inc.
[31] Sarata, Amanda K. "Genetic Testing: Background and Policy Issues"., p. 14.
[32] Ibid., p. 8.
[33] Ibid., p. 8.
[34] Ibid., p. 8.
[35] "Somatic Mutations." National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer terms/def/somatic-mutation.
[36] Ibid.

intellectual disabilities), autoimmune diseases, amongst other disorders.[37] What is most important to understand about somatic mutations is that they cannot be passed from parent to off-spring.

On the other hand, autosomal dominant forms of inheritance are the result of germline mutations. Germline mutations are defined as "a gene change in a body's reproductive cell (egg or sperm) that becomes incorporated into the DNA of every cell in the body of the off spring".[38] These types of diseases *are* passed from parent to off-spring. Germline changes may include common diseases such as diabetes and blood pressure. These diseases have a genetic component that has not yet been fully understood by geneticists. However, it is known that they are related to genetics and the environment. Additionally, as stated, dominant genetic disorders can also form from germline mutations. These mutations follow a Mendelian pattern and can be inherited from one or both parents (See Appendix B). Arrhythmogenic right ventricular cardiomyopathy (ARVC) and Huntington's disease are two clear examples of autosomal dominant inheritance disorders that pose high genetic risk caused by from germline mutations.[39] These two diseases will be used as case studies in Chapter 4.[40]

Genetic tests are only conducted after health care professionals have gathered the necessary pre-requisite information from their patients. The patient must first complete a physical examination and provide a full medical history prior to testing. Additionally, the patient must provide a family pedigree to document any genetic diseases that have occurred in the past three generations. Family lineage is of utmost importance to the genetic testing process as this helps in

[37] Li, Chun, and Scott M Williams. "Human Somatic Variation: It's Not Just for Cancer Anymore." *Current genetic medicine reports* 1, no. 4 (2013): 212–218., p. 213.
[38] "Germline Mutation." National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/germline-mutation.
[39] I would like to thank Dr. Hodgkinson who reviewed this thesis and made these recommendations on her examiner's report. Dr. Hodgkinson provided insightful feedback and a clear explanation on how to improve the genetic section of this thesis by providing an overview of genetic changes.
[40] Please see Appendix C for an explanation of the risk of inheriting a dominant disease.

determining whether or not a disease is hereditary.[41] The importance of examining the family's health information to conduct genetic testing demonstrates the familial nature of this process.

1.2 Advancements and Issues in Genetic Testing

It is necessary to understand the advancements and issues that have occurred in genetic testing to understand the real impact this area of medicine can have on multiple individuals who may be affected by the results found during genetic testing. As previously stated, genetic information is unique as it reveals information about multiple individuals. Therefore, information obtained through genetic testing must be treated differently. There are two primary reasons that scholars view genetic information as exceptional. The first reason is that genetic information "transcends time and space," meaning that genetic tests are capable of revealing information about future diseases and also providing an understanding of current ones. Additionally, as stated, the information obtained through these tests reveals information about biological relatives. [42] The second reason that many scholars view genetic information as exceptional is because of its "primacy over environmental factors in human development".[43] Genetic information can be seen as a "future diary," and many compare a genotype to a document that can detail an individual's future.[44]

Given the current advances in genetic technology and the wealth of information we now possess, it is not surprising that this has generated several legal, ethical, and social policy issues with more expected to arise in the future. The main issue and question that must be answered is, "to whom may genetic information be disclosed?"[45] Many third parties may be interested in

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[41] "Genetic Testing." *Britannica Online Academic Edition.*
[42] Sankar, Pamela. "Genetic Privacy." *Annual Review of Medicine,* 54 (2003): 393–407., p. 394. https://doi.org/10.1146/annurev.med.54.101601.152131.
[43] Ibid., p. 394.
[44] Ibid., p. 394.
[45] Burnett, J W. "A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease." *Houston Law Review* 36, no. 2 (1999), p. 560-1.

accessing this information, such as insurance companies and employers. However, the most notable third party who may want and may also have a legitimate claim over access to this information is biological relatives.[46] Genetic test results reveal information that may impact the lives of family members and consequently lead to serious harm.[47] Therefore, their interest in accessing this information deserves careful consideration. When a patient refuses to warn relatives of their hereditary condition, physicians confront an ethical dilemma. The physician is required to choose between their duty to keep information confidential and their duty to warn patient relatives. These two conflicting duties create a serious conflict as it is impossible to warn without breaching confidentiality, and equally impossible to uphold the principle of confidentiality while simultaneously warning patient relatives. The following section will provide information on confidentiality and duty to warn and the conflicting nature of these two important concepts.

1.3 Confidentiality and Duty to Warn

A thorough understanding of confidentiality and duty to warn is necessary as they are the two conflicting duties being explored throughout this thesis. There has been considerable discussion in bioethics literature and the legal community concerning the disclosure of genetic information to patient relatives. Literature in the field of bioethics has focused extensively on the importance of the doctor-patient relationship. Unfortunately, the wants and needs of patient family members have not been recognized to the same extent. Literature in this field has typically viewed the patient and their relatives as two separate parties.[48] Yet, genetic testing is familial, and therefore more attention must be given to these biological relationships to manage test results

[46] Ibid., p. 561.
[47] Ibid., p. 561-2.
[48] Gilbar, Roy. "Communicating Genetic Information in the Family: The Familial Relationship as the Forgotten Factor." *Journal of Medical Ethics* 33, no. 7 (2007), p. 390. https://doi .org/10.1136/jme.2006.017467.

appropriately. As previously discussed, genetic testing is familial as it reveals health information about biological relatives. However, regardless of the familial nature, patient relatives are not guaranteed access to test results. The main barrier to consider regarding the disclosure of genetic information is the patient's right to confidentiality. The physician's duty to uphold patient confidentiality is important. However, both the legal and bioethics communities have reached a similar consensus.[49] Both areas of study have found that physicians ought to have the ability to use their professional discretion in choosing whether to warn patient family members. To date, there exists no explicit legal duty to warn relatives of information found during genetic testing.[50] However, the four standards developed by the *President's Commission* in 1983 serve as a helpful guide to assist physicians and other health care professionals that are conflicted between their duty to warn and their duty to uphold confidentiality.

Research has found that in some cases, patients refuse to undergo genetic testing that may result in health benefits. They refuse testing because they fear disclosure of results without their expressed consent.[51] The findings of this research demonstrate that disclosure of this information to potentially affected third parties ought to be done with great caution. Disclosure without obtaining appropriate consent is a significant concern for those choosing to undergo genetic testing. Sankar, along with other scholars,[52] agree that results obtained through genetic testing deserve protection.[53] However, Sankar agrees this does not imply genetic test results deserve absolute confidentiality. While patients fear the consequences of having their genetic test results shared with biological relatives, the interests of these relatives must be acknowledged. The past

[49] Ibid., p. 390.
[50] Ibid., p. 390.
[51] Ibid., p. 393.
[52] See, Denbo, Susan M. "What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives?" p. 561-607.
[53] Sankar, Pamela. "Genetic Privacy," p. 394.

decade has seen a shift away from absolute confidentiality within the medical field.[54] This shift ought to also be applied to genetics.[55]

1.4 The Family Nature of Genetics

As demonstrated, results obtained through genetic testing reveal information about multiple individuals. It is necessary to understand the familial nature of genetics as this demonstrates the unique difference between genetics and other areas of medicine. Additionally, the familial nature demonstrates how relatives may have a legitimate claim to test results. Gilbar, in his article, *"Communicating Genetic Information in the Family: The Familial Relationship as the Forgotten Factor,"* states that due to the unique nature of genetic testing, the duty to uphold absolute confidentiality ought to be "relaxed".[56] We ought not to view confidentiality in the field of genetics as all or nothing. Instead, findings through genetic testing ought to, in some cases, be an exception to the principle of confidentiality. Gilbar states that while both patients and physicians value a commitment to confidentiality, both parties acknowledge that certain circumstances warrant a breach in confidentiality without acquiring consent.[57] However, while each of these parties agrees breaching confidentiality may be permissible, they have different views on what constitutes a justifiable circumstance. Doctors believe breaching confidentiality is acceptable when "the relatives' assistance is needed to improve the patients' condition, to relieve the relatives' anxiety, and to prevent harm".[58] Doctors believe these conditions are acceptable as they frequently view relatives as an integral part of the circle of care.[59]

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[54] Knoppers, Bartha Maria. "Genetic Information and the Family: Are We Our Brother's Keeper?" *Trends in Biotechnology* 20, no. 2 (2002)., p. 85. https://doi.org/10.1016/S0167-7799(01)01879-0.
[55] Ibid., p. 85.
[56] Gilbar, Roy. "Communicating Genetic Information in the Family: The Familial Relationship as the Forgotten Factor," p. 390.
[57] Ibid., p. 390-1.
[58] Ibid., p. 391.
[59] Ibid., p. 391.

On the other hand, patients view disclosure without consent acceptable when there is a "close and intimate relationship with relatives, and on the effect that the information has on the relative's lives".[60] Based on the perspectives of both patients and physicians, while confidentiality is both important and necessary, it is by no means absolute. Therefore, establishing and understanding the specific standards that guide the decision-making process for breaching confidentiality is not only important but essential in our evolving health care system.

1.5 The Tarasoff Decision

As expressed, the duty to uphold confidentiality is fundamental in the doctor-patient relationship. However, as I have described, this principle is by no means absolute. One limit of confidentiality is a duty to warn. The principle of duty to warn was the result of the *Tarasoff v. Regents of University of California 1976* decision.[61] The Tarasoff decision was the first case to recognize the concept of duty to warn, which places an obligation on physicians to warn third parties. In the Tarasoff case, the patient of a psychotherapist murdered a young girl. The patient who committed the murder had previously informed his therapist about his intentions to kill the young girl. The therapist treating the man did not warn the victim or her parents of his patient's plans. Following the murder, the victim's parents proceeded to sue the psychotherapist for failure to warn their daughter or themselves of his patient's intentions. The court found that therapists have a duty to warn third parties when there is foreseeable harm; there exists a special relationship between the dangerous person (the patient) and the physician, or the potential victim and the physician.[62]

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[60] Ibid., p. 391.
[61] Stanard, Rebecca, and Richard Hazler. "Legal and Ethical Implications of HIV and Duty to Warn for Counselors: Does Tarasoff Apply?" *Journal of Counseling & Development* 73, no. 4 (1995)., p. 397. https://doi.org/10.1002/j.1556-6676.1995.tb01771.x.
[62] Burnett, J W. "A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease," p. 563-4.

1.6 Case Law: Pate v. Threlkel (1995) and Safer v. Pack (1996)

Since the Tarasoff decision, there have been a few court cases that have dealt specifically with duty to warn related to genetic information. In this section, I consider two cases that are important to discuss as they demonstrate the serious harm that may be inflicted upon the relative if they are not warned of their risk of a hereditary genetic condition. Two notable cases are *Pate v. Threlkel 1995* and *Safer v. Pack 1996*. In the first case, *Pate v. Threlkel 1995,* a patient's daughter, Heidi Pate, sued Dr. Threlkel for failure to warn her of the risks associated with her mother's hereditary thyroid cancer. Pate's mother had been diagnosed and treated for the disease, and three years later, Pate was diagnosed with thyroid cancer herself. This form of cancer had preventative measures, and Pate claims that had she known of her risk, she would have sought early screening and treatment. However, at the time of her diagnosis, she had advanced-stage thyroid cancer. The plaintiff argued that if she had known of her risk in advance, her cancer would have been detected and cured at an earlier stage.[63]

The Florida Supreme Court found that the physician did fail in his duty to warn. The court held that there was a duty to warn "…for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the physician's duty runs to those third parties".[64] However, the court made clear that this does not require the physician to warn the children directly. Rather, the physician should have warned the mother that her condition was hereditary. There were two specific reasons for this decision.

[63] Offit, Kenneth, Elizabeth Groeger, Sam Turner, Eve A Wadsworth, and Mary A Weiser. "The "Duty to Warn" a Patient's Family Members About Hereditary Disease Risks." *JAMA* 292, no. 12 (2004)., p. 1470. https://doi.org/10.1001/jama.292.12.1469.
[64] Petrila, John, and Felthous, Alan R. "Genetic Risk: The New Frontier for the Duty to Warn." *Behavioral Sciences & the Law* 19, no. 3 (2001)., p. 408.

First, the duty to uphold patient confidentiality would not permit disclosure of the mother's personal health information. Second, it would be impractical and an unfair burden to require physicians to find and warn all patient family members.[65]

The second case, *Safer v. Pack 1996*, occurred approximately one year later. The New Jersey court, in this case, came to a similar conclusion concerning the physician's duty to warn patients children of their genetic risk based on their parent's diagnosis. Throughout the 1950s and 1960s, Robert Batkin was treated for retroperitoneal cancer.[66] He was later hospitalized twice in 1961 and 1963 for colon cancer and succumbed to his illness and passed away in 1964. At the time of his death, Mr. Batkin was 45 years old and had two children aged 10 and 17. In 1990, more than 25 years after Mr. Batkin's death, his youngest daughter was diagnosed with the same disease. The daughter sued her father's physician, Dr. Pack, alleging that the physician failed in his duty to warn. She claimed that the physician should have warned her of her own risk of developing the disease. She stated that Dr. Pack, knowing the hereditary nature of this disease, should have warned her to allow preventative measures to be taken. The court dismissed her claim asserting that physicians have no legal duty to warn relatives of genetic risk.[67] Additionally, the court argued that "harm is already present within the non-patient child, as opposed to being introduced… The patient is taking no action to cause the child harm".[68]

As two of the first court cases to address duty to warn involving a hereditary genetic condition, these two cases helped lay the foundational groundwork concerning a duty to warn for genetic testing. Petrila argues that these cases are important for health care professionals that are

[65] Ibid., p. 410-11.
[66] "Sarcoma is a rare cancer that develops in the connective tissues: muscle, bone, nerves, cartilage, tendons, blood vessels and the fatty and fibrous tissues." See, "Retroperitoneal Sarcoma." Sarcoma UK, May 28, 2019. https://sarcoma.org.uk/sarcoma-types/retroperitoneal-sarcoma.
[67] Ibid., p. 408.
[68] Ibid., p. 409.

treating patients where a hereditable condition is present.[69] These cases also show that neither absolute confidentiality nor duty to warn have been deemed as the first-choice option. For the most part, there is a difference of opinion amongst scholars as to whether a duty to warn exists for genetic diseases. Evidently, duty to warn causes a direct conflict with the duty to uphold confidentiality. As previously stated, it is impossible to warn patient relatives and uphold the duty of confidentiality simultaneously. The current standards of disclosure developed by the *President's Commission* demonstrate that confidentiality ought not to be absolute. Within the field of genetics, the principle of duty to warn is essential in order to protect and benefit the health of patient family members. However, practically applying these standards is complex as they rely heavily on the notion of harm. Therefore, we must understand harm and distinguish between a harmful action and a wrongful action in order to make an ethical decision about breaching confidentiality.

1.7 The Position of Professional Organizations

These court cases demonstrate that the law has acknowledged limitations to confidentiality. Additionally, these limitations have also been recognized by professional working groups. It is necessary to discuss the position of professional organizations as they demonstrate that confidentiality is not absolute and that warning patient relatives may be necessary in certain circumstances. For instance, the Canadian Medical Association (CMA) has recognized that there are limitations to the duty to keep information confidential. The policy developed by the CMA acknowledges the importance of maintaining confidentiality in the patient-physician relationship. Confidentiality is a right that each patient is granted and disclosing this information ought not to be done freely. The CMA code of ethics, developed in 1996,

[69] Ibid., p. 411.

however, does state that it is the physician's duty to "respect the patient's right to confidentiality except when this right conflicts with your responsibility to the law, or when the maintenance of confidentiality would result in a significant risk of substantial harm to others…".[70] Harm to others is one instance, as articulated, where the CMA acknowledges that a breach in confidentiality may be warranted.

A second professional organization that has recognized the limitations of confidentiality is the Canadian Medical Protective Association (CMPA). The CMPA states that there are two exceptions to the physician's professional duty of maintaining confidentiality. The exception is when a physician is required by law to disclose personal health information. The second exception is when a physician is permitted by law to disclose personal health information.[71] It is in my opinion, which will be argued throughout this thesis, that disclosure of genetic test results ought to be permitted when there is a risk of harm to the patient's family members. Risk of harm to others is a primary consideration for professional groups when choosing to breach patient confidentiality.[72]

1.8 *The President's Commission* Four Standards of Disclosure

This section will discuss why the standards developed by *The 1983 President's Commission* were chosen and also discuss the four standards developed by this commission. *The 1983 President's Commission* was established to deal with ethical issues in research, and members of the commission varied in their professional backgrounds, ranging from ethicists to lawyers. Important issues in bioethics were assigned to the commission, and their findings

[70] "The Medical Record: Confidentiality, Access and Disclosure (Update 2000)." Canadian Medical Association. 2000. https://policybase.cma.ca/documents/policypdf/PD00-06.pdf., p. 1.
[71] "When to Disclose Confidential Information." CMPA. Canadian Medical Protective Association, March 2015. https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2015/when-to-disclose-confidential-information.
[72] Ibid.

informed policies and policy implementation to protect human subjects.[73] This commission addressed these issues to provide ethical analysis and specific recommendations to the president, national government, and other stakeholders.[74] This commission is directed to "…focus on issues raised by time-sensitive, novel, and emerging scientific advances, and not on broader persistent issues in health care".[75] For instance, this commission has looked at ethical challenges with whole-genome sequencing, direct-to-consumer services, bioterror countermeasures, and other emerging issues.[76]

The standards of disclosure for genetic information were explicitly chosen by myself at the recommendation of Dr. Brunger because this commission was comprised of experts with various backgrounds chosen to inform policy at the highest level. As there were experts from multiple disciplines on *The President's Commission*, the important legal and ethical considerations were explored to produce standards to protect the patient, the relative, and the healthcare professional. These standards were created to inform one specific issue (the disclosure of genetic test results). Further, these standards remain applicable even after 40 years and assist health professionals when confronted with the challenge between confidentiality and duty to warn related to genetic testing. These standards set out a strict criteria to appropriately and effectively evaluate individual circumstances. These standards limit instances where confidentiality would be breached as they restrict the instances of disclosure. They limit these circumstances as the health professional must determine withholding the information would harm

[73] Gray, Bradford H. "Bioethics Commissions: What Can We Learn from Past Successes and Failures?" Essay. In *Society's Choices: Social and Ethical Decision Making in Biomedicine*, 261–306. Washington, DC: National Academy Press, 1995. https://doi.org/10.17226/4771.
[74] Grady, Christine. "Making the Choices Necessary to Make a Difference: The Responsibility of National Bioethics Commissions." *The Hastings Center report* 47, no. S1 (2017): S42–S45., p. S42. https://https://doi.org/10.1002/hast.720.
[75] Grady, Christine. "Making the Choices Necessary to Make a Difference: The Responsibility of National Bioethics Commissions," p. 43.
[76] Ibid., p. S42.

the relative and that the harm the relative would experience would be serious. These standards were developed to address and resolve the dilemma between the duty to uphold confidentiality and the duty to warn. These standards remain a good guide for resolving this issue.

The President's Commission recognized the risk of harm to relatives. This group, therefore, developed four standards under which disclosure of personal health information is warranted. The four standards of disclosure include: reasonable efforts to elicit voluntary consent to disclosure have failed; there is a high probability that harm will occur if the information is withheld, and the disclosed information will actually be used to avert harm; the harm that would result to identifiable individuals would be serious; appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/ or treatment of the disease in question is disclosed.[77] (Please refer to Appendix D for reference to *The President's Commission* standards).

These four standards do not necessitate that there is a legal duty to warn patient relatives. Instead, these guidelines detail circumstances under which would allow physicians to breach confidentiality in an ethical manner. In my opinion, these four standards outlined by the *President's Commission* are a good guideline for ensuring ethical practice in the disclosure of genetic test results. To date, many bioethicists cite the four standards in their work as they provide detailed and ethical justifications for breaching confidentiality.

1.9 The Complexity of Harm

This section will detail the complexity of harm and the challenges of relying upon this notion when implementing the four standards of disclosure. As stated, these standards are challenging when it comes to their practical application as they rely heavily on the concept of

[77] "Professional Disclosure of Familial Genetic Information.," *The American Journal of Human Genetics* 62, no. 2 (1998): 474-83., p. 475. https://doi.org/ 10.1086/301707., p. 266.

harm. Offit et al., in their article, *"The "Duty to Warn" a Patient's Family Members about Hereditary Disease Risks"* acknowledge the standards offered by *The President's Commission* and outline three key elements from the standards which will ultimately require a heavy reliance on the concept of harm.[78] Three key features that rely heavily on harm include:

1. The high likelihood of harm if the relative were not warned
2. The identifiability of the relative
3. The notion that the harm resulting from failure to disclose would outweigh the harm resulting from disclosure[79]

As these standards for disclosure of genetic test results rely heavily on the principle of harm, the complexity of the harm principle must be appreciated and understood if we are to practically apply these standards. First and foremost, we must understand how to define harm. Harm is a complicated term and must, therefore, be defined precisely to have an accurate understanding of the principle. There have been many scholars who have done extensive work in this area, most notably is Joel Feinberg. Feinberg's book, *Harm to Others*, details the different types of harm and most accurately describes the type of harm that we are discussing in terms of harm to relatives with regards to genetic testing.

Joel Feinberg describes the word harm as "both vague and ambiguous".[80] We must, therefore, clearly define the type of harm that is to be used and discussed throughout this thesis. In the most basic sense, when one commits a harmful act, they have, in some way, caused harm to another living being or situation. This harmful act thus places the other person in a harmed state or condition. There is a distinct difference between a harmed condition and a harmful

[78] Offit, Kenneth, Elizabeth Groeger, Sam Turner, Eve A Wadsworth, and Mary A Weiser. "The "Duty to Warn" a Patient's Family Members About Hereditary Disease Risks," p. 1471.
[79] Ibid. p. 1471.
[80] Feinberg, Joel. *Harm to Others.* New York, NY: Oxford University Press, 1984, p. 3.

condition. The distinction made between a harmed condition and a harmful condition demonstrates the complex nature of harm itself. A harmful condition implies that there is the potential for the current condition to generate further harm. For instance, Feinberg states that a blister on one's finger may cause a harmed condition. However, unless the finger belongs to a concert pianist or a professional baseball player, the condition may not be considered harmful.[81] Instead, as opposed to a harmful condition, it is merely a harmed condition, that will not itself cause further harm.

Feinberg defines three senses of harm; however, it is the third sense of harm which is most pertinent to our discussion regarding the duty to warn for genetic testing. According to the third sense of harm, when we say that A has caused harm to B, we are at the same time implying that A has in some way wronged B[82], or that he has been treated in an unfair or unjust manner. Feinberg states that "…one-person wrongs another when his indefensible (unjustifiable and inexcusable) conduct violates the other's right" and at the same time may also "invade the other's interest".[83] When distinguishing between wrongs and harms, we need to remember that not all harms and invasions of interests are wrongs. We are able to determine that not all harms are wrongs, as there are instances when it is justifiable and excusable to invade the interests of another. Furthermore, in some cases, the individual may have no right to have their interests respected. However, we should try to "minimize harm" in all cases that we are able to.[84] So, on this third sense of harm, harm occurs when an individual has been wronged, meaning that they have been treated in an unfair or unjustifiable way.

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[81] Ibid., p. 3.
[82] Please note that there is an important moral distinction between a justified harm and an unjustified harm (which results in a wrong). A justified harm occurs when an individual's interests have been invaded, and it is deemed morally acceptable. An unjustified harm occurs when an individual has been wronged, and the harm is thus morally unacceptable.
[83] Ibid., p. 7.
[84] Ibid., p. 7.

Duty to warn in the case of genetic testing, as expressed, is directly linked to the third sense of harm. It is directly linked to the third sense of harm as we must determine whether disclosure or non-disclosure is a harm or a wrong. This must be established as it will determine whether or not breaching confidentiality may be done in an ethical and justified manner. For instance, if disclosure is determined to be a wrong, meaning the interests of another are being invaded without justification, then health care professionals would not be permitted to breach confidentiality. However, if disclosure is deemed only to be a harm and conversely *non*-disclosure is determined to be a wrong, then the health care professional may proceed to breach confidentiality with appropriate justification.

The decision made by the doctor to disclose personal health information will, in some way, invade the interest of either the patient who has undergone genetic testing or the relative who may be impacted by the information. Ultimately, when using the standards, we must distinguish whether the decision to disclose personal health information is a harmful action or a wrongful action. This distinction will determine whether or not it is ethical and morally justified to infringe upon the rights of another in a justified manner.

As expressed, determining how to define harm is a notoriously complicated matter and contains many meanings. This thesis will acknowledge the complexity of this topic and discuss the challenges of practically applying the three standards of disclosure linked to harm in the decision-making process to breaching patient confidentiality. When it comes to health and the complexities of the decision-making process, professionals using these standards must understand its reliance on harm. Every day, health care professionals confront complex situations. A proper understanding of the complexity of these standards will allow professionals to think broadly about the potential impact decisions have on the lives of others. These standards should not only be considered in terms of the patient but also how they will impact the lives of family

members. The field of genetics adds a dimension to the decision-making process as their needs must also be considered, appreciated, and acknowledged. Instead of health professionals looking at the problem directly in front of them, understanding the harm principle will allow them to look peripherally at the other individuals who may be harmed by the decision they make. In its subsequent chapters, this thesis will present more information on harms, wrongs, and provide sufficient information on analyzing the interest of others.

Chapter Summary

This introductory chapter has provided detailed information concerning the unique nature of genetic testing and also the conflict between confidentiality and duty to warn. Additionally, the limitations of confidentiality have been recognized, and the current standards of disclosure of genetic test results have been discussed. The main issue, the standards reliance upon the concept of harm, has been presented. Additionally, thorough background information on the type of harm we are discussing has been presented. The advancements in the field of genetics have created a new landscape of ethical issues that require special attention. The following chapters will provide further evidence of the complexity of genetics and the challenge of practically applying the standards of disclosure with their heavy reliance on the principle of harm.

Chapter Two: A Comprehensive Response to Three Criticisms of the Current Standards of Disclosure of Genetic Information

Chapter Overview

This second chapter will argue that the standards of disclosure developed by *The President's Commission*[85] are defensible against common criticisms and are a good guide for health professionals. The criticisms found in the current literature are directed at the disclosure of genetic test results in general. Scholars have failed to address their concerns to current disclosure practices specifically. This section will use the three most common criticisms of the disclosure of genetic test results and apply them specifically to *The President's Commission* standards. The fourth standard will not be criticized for two reasons. First, the thesis does not depend on this criticism. Second, upon reviewing the literature, there is no discussion that lends itself as a criticism to the fourth standard.

Chapter two will be divided into two sections for clarity. The first section of this chapter will begin by discussing the standards and the report submitted by *The President's Commission*. The second section will provide a comprehensive response to three criticisms presented in the literature by other scholars.[86] The criticisms do not address the standards in particular but rather general concerns of disclosing genetic test results. The second section will aim to fill in this gap in the current literature.

Section 1 *The President's Commission* Standards of Disclosure

[85] Please refer to Appendix D

[86] For instance, Kottow argues that medical confidentiality ought to be absolute and is a requirement in the health care system. Please see, Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation." *Journal of Medical Ethics* 12, no. 3 (1986): 117-122. Additionally, Mitchell, Ploem, Hennekam and Kaye in their article "A Duty To Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?," thoroughly discuss the three remaining criticisms. These criticisms involve the burden for physicians, the pressure patients may feel to disclose their personal health information and the challenge of patient relatives wishing to now know their susceptibility to a serious genetic condition. Please see, Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty To Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?." *Tottel's journal of professional negligence* no. 32(2) (2016): 120-136, for further information.

As previously stated, the standards developed by *The President's Commissio*n were developed as a response to the rapid advancements in genetics. *The President's Commission* determined that overall, these advances have improved health and well-being.[87] *The President's Commission* states that their "basic conclusion is that programs to provide genetic education, screening and counseling provide valuable services when they are established with concrete goals and specific procedural guidelines founded on sound ethical and legal principles".[88] However, genetic testing has created special challenges, such as the significant conflict between duty to warn and confidentiality. In their report, *The President's Commission* grouped their overall conclusions into five categories. These categories included confidentiality, autonomy, knowledge, well-being, and equity.[89] These conclusions will be discussed in detail, followed by a description of the four standards that have been developed as a response.

First, *The President's Commission* stressed the need for and importance of confidentiality in health care. The principle of confidentiality ensures that an individual's information is not disclosed without their consent. As such, *The President's Commission* finds that, like other information, genetic information should not be given to third parties without explicit and informed consent from the individual who underwent genetic testing. Further, they state that confidentiality ought only to be overridden if the conditions of the four standards are met.[90]

Second, *The President's Commissio*n acknowledged how autonomy is a widely valued concept in our modern health care system. The ability for patients to make their own medical choices is essential in fostering a sense of personal autonomy and empowerment. Therefore, mandatory genetic screening is only justified in instances to prevent serious harm to defenseless

[87] "Screening and Counseling for Genetic Conditions," p. 1.
[88]Ibid., p. 5.
[89] Ibid., p. 6-8.
[90] Ibid., p. 6.

individuals that could be avoided with testing. On the other hand, genetic testing may also be voluntarily chosen. These test results are valuable as they will allow individuals to make informed medical and reproductive decisions.[91]

Third, *The President's Commission* states that knowledge obtained through genetic testing, such as incidental or sensitive findings, should generally be disclosed. However, the interest of the patient should also be considered, and therefore the decision should be made on an individual basis.[92] Ultimately, the purpose of genetic testing is to "make people into informed decision-makers about their genetic constitution, to the extent, it is relevant to choices about their own well-being or that of their family".[93]

Fourth, promoting the well-being of others was an important consideration for this committee. Well-being is an underlying objective in both health care and genetic testing. Genetic screening should only be performed when the results can be relied upon to be accurate.[94] Lastly, *The President's Commission* states that equity needs to be ensured, meaning that there must be fair and equal access to genetic testing for all racial and ethnic groups.[95] Ultimately, genetic testing provides individuals the opportunity to make informed decisions about their health and treatment plans. If done ethically and appropriately, the well-being and health of our society will continue to improve as we are now able to diagnose conditions once incapable of being identified.

These five categories of conclusions presented demonstrate that this committee has carefully considered individual values prior to developing their standards. The individual values

[91] Ibid., p. 6-7.
[92] Ibid., p. 7.
[93] Ibid., p. 7.
[94] Ibid., p. 7-8.
[95] Ibid., p. 8.

considered by the committee include the principle of confidentiality, autonomy, ensuring decisions are made on an individual basis, the promotion of well-being, and lastly, equity (granting fair and equal access to genetic testing for everyone). However, one of the main challenges, as identified by *The President's Commission*, is choosing whether or not to disclose genetic test results to patient relatives. This issue of determining whether or not to disclose genetic information is raised when serious harm is preventable by disclosing the test results to relatives.[96] This is a sensitive matter as the relative would not otherwise have access to this information or be aware of their risk of potential harm. Ideally, prior to testing, patients would be advised of the benefits of warning relatives of their test results and elicit voluntary consent for disclosure. However, the challenge becomes when consent has not occurred to disclose harmful test results, and a discovery concludes there is a risk of harm to patient relatives. There are many possible reasons that an individual may not want to disclose their genetic test results to a family member. Such as fear of stigmatization, belief that the relative may not wish to be informed, they are not currently in regular contact with their family or a variety of other personal reasons. Yet, when there is the possibility of serious harm, a patient's refusal does not dismiss the responsibility of the health care professional.[97]

The President's Commission acknowledges that it may appear that health care workers ought not to disclose information against their patients' wishes. However, both within the field of law and ethics, it is accepted that a health professional may breach confidentiality to prevent harm to others. *The President's Commission* states, however, that all four standards previously listed at the beginning of this chapter must be satisfied to ethically justify a breach in

[96] Ibid., p. 43.
[97] Ibid., p. 44.

confidentiality.[98] The remainder of this section will discuss and explain the four standards in detail.

1.1 Standard #1

The first condition that must be satisfied to ethically disclose genetic test results, according to *The President's Commission,* is that "reasonable efforts to elicit voluntary consent have failed."[99] Informed and voluntary consent is an essential component of the delivery of ethical treatment and research practices in health care. Informed consent is defined as when a "capacitated (or 'competent') patient or research participant to whom full disclosures have been made and who understands fully all that has been disclosed consents voluntarily to treatment or participation on this basis".[100] If a patient is inadequately informed, then consent is not valid.

The President's Commission has specifically indicated that consent must be voluntary. There are three possible challenges to voluntariness, which includes literal coercion, undue inducement, and no-choice situations. First, coercion is defined as a "threat to make someone seriously worse off than she is or should be, unless she consents".[101] Even a threat to cause slight pain, non-treatment, or inconvenience can be considered coercion. When a patient feels that they have no other option but to consent, then this would be regarded as a form of coercion. During the consent process, patients should feel that they have a choice without the fear of consequences if they choose not to consent.[102] For instance, when seeking consent to inform patient relatives, it would be unacceptable for the health professional to threaten the patient not to unveil the results unless they consent to inform their family.

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[98] Ibid., p. 44.
[99] Ibid., p. 44.
[100] Eyal, Nir, "Informed Consent", *The Stanford Encyclopedia of Philosophy* (Spring 2019 Edition), Edward N. Zalta (ed.), https://plato.stanford.edu/archives/spr2019/entries/informed-consent/>.
[101] Ibid.
[102] Ibid.

The second issue that would result in involuntary consent is undue inducement. Undue inducement is defined as "something is being offered that is alluring to the point that it clouds rational judgement, for instance cash in hand or airline tickets in return for kidney donation or risky participation".[103] In these circumstances, the patients' focus is shifted towards the benefit of complying with the health professional's request. This, therefore, does not allow for appropriate consideration of the potential risks or personal wishes of the patient.[104]

The final potential issue to the consent process are no-choice situations. A no-choice situation is when there is a "lack of decent alternatives to accepting a bad offer".[105] Under these circumstances, individuals are forced to choose the option that is presented to them. If the patient feels that their only choice is to consent to disclose their personal genetic information, then consent is not voluntary.[106]

To obtain voluntary informed consent to disclose genetic test results, the first step is to ensure that the patient has the capacity to make an informed decision. Decision-making capacity is defined as the "ability of health care subjects to make their own health care decisions".[107] The capacity to decide is frequently divided into four "sub-capacities".[108] This includes understanding, appreciation, reasoning, and choice. First, understanding is the most basic aspect of capacity. In order for a patient to provide consent, they are required to "have some basic understanding of the facts involved in that decision".[109] The second aspect of capacity is appreciation, meaning that the patient needs to have some form of knowledge and understanding

[103] Ibid.
[104] Ibid.
[105] Ibid.
[106] Ibid.
[107] Ibid.
[108] Ibid.
[109] Ibid.

of the consequences of their decision.[110] Patients must recognize the significance of the information that they have been provided and how this information impacts their decision. Further, they must truly understand that it is their decision to make and that there are potential alternative options.[111]

The third is reasoning and "without the mental ability to engage in reasoning and manipulate information rationally, it is impossible for understanding and appreciation to issue in a decision".[112] In this sense, patients must have the ability to evaluate the risks and benefits and draw a conclusion. Fourth is choice, meaning that the patient must be capable of communicating and expressing their preference.[113]

Once the patient has been confirmed to have decision-making capacity, the process of obtaining informed consent may begin.[114] This process has three steps, which all entail exchanging information between the health professional and the patient.[115] First, in simple language, the physician is required to explain the treatment or procedure and explain the benefits, risks, and any alternative options. To seek consent to disclose genetic test results, the physician would explain that disclosing the results to family members will be beneficial as this will allow them to make an informed decision about their health.[116] Second, the physician must determine if the patient understands the information they have been provided. The patient must have full

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[110] Ibid.
[111] Ibid.
[112] Ibid.
[113] Ibid.
[114] Please note that the issue of informed consent has a body of literature which discusses the challenges of obtaining consent in treatment and in research. Please refer to Nijhawan, Lokesh, Manthan Janodia, B Muddukrishna, K Bhat, K Bairy, N Udupa, and Prashant Musmade. "Informed Consent: Issues and Challenges." *Journal of advanced pharmaceutical technology and research* 4, no. 3 (2013): 134–140., or Beauchamp, Tom L. "Informed Consent: Its History, Meaning, and Present Challenges." *Cambridge quarterly of healthcare ethics* 20, no. 4 (2011): 515–523., for further information that health care professionals face when obtaining informed consent and the ethical challenges with this process.
[115] Ibid.
[116] Ibid.

knowledge and adequate comprehension of what disclosure involves.[117] Lastly, the patient must provide verbal or written consent to disclosing their personal health information. Ultimately, the patient must be provided with adequate information to make an informed decision about whether or not they wish to disclose their test results.[118]

1.2 Standard #2

The second condition that must be satisfied according to *The President's Commission* is that "there is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm".[119] However, there are challenges with accurately assessing potential harm. Neil F. Sharpe and Ronald F. Carter discuss in their book *"Genetic Testing: Care, Consent and Liability"* this challenge.[120] They ask the following important questions that ought to be considered. First, "what will be the outcome of disclosure?"[121] Second, "what are the limitations of specific test(s) and the testing technologies, if any, that could be provided to the family member or relative?"[122] Third, "what is the possibility of an inconclusive or ambiguous result?"[123] Lastly, "What proven therapies and preventive strategies are available, if any; what if treatment will be painful and ultimately could prove ineffective?"[124]

Evidently, this condition that must be satisfied prompts numerous questions concerning the potential harm that would occur. This condition does not have a simple answer and will vary based upon the disease identified and the relative. For instance, a hereditary disease like

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[117] Ibid.
[118] Ibid.
[119] "Screening and Counseling for Genetic Conditions," p. 44.
[120] Sharpe, Neil., and Ronald F. Carter. *Genetic Testing: Care, Consent, and Liability*. Hoboken, NJ: Wiley-Liss, 2006. https://doi.org/10.1038/ng0906-970.
[121] Ibid., p. 407.
[122] Ibid., p. 407.
[123] Ibid., p. 407.
[124] Ibid., p. 407.

Huntington Disease does not express symptoms the same in every individual. The age of onset, degree, and severity of symptoms, and the emotional and psychological impact that disclosure may have will vary.[125] This disease will be used as a case example in Chapter Four, and additional information will demonstrate the challenges in assessing potential harm. The specifics of an individual's situation will illustrate the impact on the decision of whether disclosure is acceptable.

1.3 Standard #3

The third condition that must be satisfied according to *The President's Commission* is "the harm that identifiable individuals would suffer would be serious".[126] It is difficult to assess what constitutes serious harm as it is dependent upon the specific situation of the individual. This thesis argues that the standards developed by *The President's Commission* are defensible against common criticisms and a good guide for healthcare professionals. However, there are challenges when practically applying these standards because of the standards' reliance on the notion of harm. Harm itself is complex, and the distinction between a harmful action and a wrongful action must be made. Chapter Three will provide further information on this distinction and discuss how harm adds complexity to the decision-making process.

1.4 Standard #4

The fourth condition that must be satisfied, according to *The President's Commission,* is "appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed".[127] As previously discussed, one of the main ethical principles outlined by *The President's Commission* is privacy and

[125] Ibid., p. 407.
[126] "Screening and Counseling for Genetic Conditions," p. 44.
[127] Ibid., p. 44.

confidentiality.[128] They state that there are three main concerns over confidentiality with regards to genetic testing. These concerns are:

1. disclosure of information to unrelated third parties, such as employers or insurers;
2. access to material stored in data banks; and
3. disclosure of information to relatives of the screenee, either to advise them that they or their offspring are at risk for genetic disease or to gain information about them for a more accurate diagnosis of the person originally screened.[129]

It is evident that privacy and confidentiality has been acknowledged by the working group, and the potential issues have been recognized. It is for this reason that *The President's Commission* has developed four specific standards for the disclosure of genetic information. *The President's Commission* states that only appropriate individuals should be notified, and the patient should remain anonymous where possible. Further, as this standard indicates, only genetic information relevant for treatment and diagnosis is necessary to disclose. This standard ensures that all reasonable measures are being taken to ensure that the patient remains anonymous, and no additional personal medical information is provided to the relative.

Section 2 Response to Criticisms in the Current Literature

The standards developed by *The President's Commission* were established over thirty years ago and remain effective for the decision-making process of choosing whether to disclose genetic test results to patient relatives. The current literature presents three main criticisms regarding the disclosure of genetic test results in general. The first criticism of disclosing genetic test results is the argument that confidentiality ought to be absolute. For example, scholars like

[128] Ibid., p. 41.
[129] Ibid., p. 42.

Kottow claim that breaching patient confidentiality may result in adverse outcomes for the patient.[130] These adverse outcomes may include loss of trust in their providers and the health care system as a whole, unwillingness to seek future treatment, or an unwillingness to participate in genetic testing. Patients may, therefore, choose to withhold personal health information over the fear of disclosure without consent.[131] Second, scholars have argued that a duty to warn patient relatives will cause a burden for physicians. This burden may deter future doctors from entering the field of genetics.[132] This argument, as will be demonstrated, is weak and does not acknowledge the power that physicians possess. The third criticism is that patients may feel pressure to agree to disclose their genetic test results. The pressure they may experience may come from the physician or other health care workers who are fearful of a future lawsuit from relatives.[133] This form of pressure would indeed be inappropriate. There are professional guidelines, which will be discussed, to ethically manage this situation. Regardless of these criticisms, the responses to these three claims will ultimately demonstrate that the current standards are, in fact, a good guide for health professionals.

Scholars have failed to directly criticize the standards developed by *The President's Commission* in particular. Rather, the disclosure of genetic test results has been criticized as a whole by scholars. There has been a lack of direct criticisms of these standards. As such, this section seeks to make specific reference to each standard based on the criticisms of disclosing genetic information in general found in the current bioethics literature. These criticisms will be

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[130] Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation." *Journal of Medical Ethics* 12, no. 3 (1986), p. 117-118. http://dx.doi.org/10.1136/jme.12.3.117.
[131] Goold, Susan Dorr, "Trust and the Ethics of Health Care Institutions." *The Hastings Center Report* 31, no. 6 (2001): 26-33, p. 30. https://doi.org/10.2307/3527779.
[132] Offit, Kenneth, Elizabeth Groeger, Sam Turner, Eve A Wadsworth, and Mary A Weiser. "The "Duty to Warn" a Patient's Family Members about Hereditary Disease Risks," p. 1472.
[133] Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty to Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" *Tottel's journal of professional negligence* no. 32(2) (2016): 120-136, p. 130.

connected to the standards of disclosure developed by *The President's Commission*. Scholars have not directed the criticisms towards the current standards, and the following section aims to fill in that gap. The responses to the three criticisms will establish that the current standards are, in fact, a good guide for health professionals.

2.1 Criticism #1: Confidentiality Ought to be Absolute

The first criticism of disclosing genetic information, argued by some scholars, is that confidentiality ought to be absolute. The duty to uphold confidentiality is a norm in the patient-physician relationship and is highly valued within the healthcare system.[134] Patients who seek medical treatment and disclose their medical history do so under the assumption this information will not only help with their medical treatment but also remain within their circle of care.[135] Patients may be unaware that exceptional circumstances may warrant a breach of confidentiality if others are at risk of harm. *The Canadian Medical Association (CMA)* states that protecting patient privacy and the duty to uphold confidentiality is "essential to foster trust in the patient-physician relationship, the delivery of good patient care and a positive patient care experience".[136] The protection of private information is a serious concern for patients, and research has demonstrated that patients may withhold important information if they believe their information may be disclosed without their consent.[137]

Upon reviewing the literature concerning confidentiality in health care, it is apparent that scholars, such as M.H. Kottow, believe that confidentiality is an absolute obligation. Kottow, in his article, *"Medical Confidentiality: An Intransigent and Absolute Obligation"* argues that if

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[134] Higgins, Gerald. "The History of Confidentiality in Medicine: The Physician-patient Relationship." *Canadian Family Physician* 35 (1989): 921-26., p. 921.
[135] Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation." p. 118.
[136] "Principles for the Protection of Patient Privacy." Canadian Medical Association. 2017. https://legacy.cma.ca//Assets/assets-library/document/en/advocacy/policy-research/cma-policy-principles-for-the-protection-of-patient-privacy-pd18-02-e.pdf.
[137] Ibid.

confidentiality were not considered absolute in health care, communication between the patient and physician would be negatively impacted and result in sub-optimal care.[138] Confidentiality, therefore, he argues, ought not to be seen as optional. To threaten this long-standing principle is wrong, and confidentiality ought to be considered an absolute requirement in the field of medicine.[139] He further argues that a breach of confidentiality causes more harm than any possible benefits that may be gained in disclosing the information.[140] Any limitations or exceptions to confidentiality would destroy this valued principle in our health system. Patients would no longer feel they could disclose their personal information, and the climate of trust in health care would be destroyed.[141] Kottow states that, "… excusing breaches of confidence on grounds of superior moral values introduces arbitrariness and ethical unreliability into the medical context".[142]

Kottow takes an absolutist approach to confidentiality. I disagree with this absolutist approach. However, I agree that confidentiality is a vital element within our health care system and within the doctor-patient relationship. Alongside confidentiality, trust is another critical component of good health care. For health care professionals to deliver the best care possible, they require honest and full disclosures from their patients'.[143] When there is an atmosphere of trust, patients will be more willing to disclose their most personal and sensitive health information. Trust is required because patients present seeking care at their most vulnerable, often suffering and lacking power.[144] Patients rely upon health professionals for their knowledge, skill, and expertise, and because of this unbalanced relationship, there must be trust. Trust is

[138] Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation," p. 118.
[139] Ibid., p. 117.
[140]Ibid., p. 117.
[141] Ibid., p. 117.
[142] Ibid., p. 117.
[143] Ibid., p. 117.
[144] "Principles for the Protection of Patient Privacy." Canadian Medical Association.

essential as patients must reveal their most private and sensitive personal information in order to receive the best care possible.

Due to the importance of confidentiality and trust in health care, I agree with the statement made by *The American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure*, which states that a violation of trust should only be done in exceptional circumstances.[145] A breach in confidentiality should only occur in exceptional circumstances as a betrayal of the trust that has been built (between the patient and physician) would be detrimental to this relationship and may have unfavourable outcomes for both the patient and the health organization.[146] Goold states that a breach in confidentiality may cause patients to not trust physicians, the organization, or even the field of medicine as a whole. Additionally, patients may feel less inclined to seek treatment in the future if they think their information will be disclosed without consent.[147]

The criticism found in the current literature that confidentiality ought to be absolute has not been directed at any of the standards in particular, rather, as stated, at the disclosure of genetic test results in general. However, this criticism would be most directed at the first and last standard developed by *The President's Commission*.[148] This criticism claims that confidentiality is absolute; therefore, efforts made to obtain voluntary consent would be criticized as they should not be taken. According to the belief of absolute confidentiality, it would be unethical to seek voluntary consent to disclose genetic information even if the physician ensured that only genetic

[145] National Library of Medicine. "ASHG Statement. Professional Disclosure of Familial Genetic Information. The American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure." *American Journal of Human Genetics* 62, no. 2 (1998), p. 474.
[146] Goold, Susan Dorr, "Trust and the Ethics of Health Care Institutions," p. 27.
[147] Ibid., p. 30.
[148] Please refers to Appendix D

information needed for diagnosis and treatment is disclosed. It is unethical as absolute confidentiality would mean that no information should be disclosed.[149]

2.2 Response to Criticism #1: Confidentiality Ought to be Absolute

In response to this first criticism, there is no question that confidentiality and trust are essential in the doctor-patient relationship and within the health care system. However, in my opinion, the traditional way of thinking about confidentiality is merely outdated, and this claim is supported by Mark Siegler in this paper, "*Confidentiality in Medicine – A Decrepit Concept*".[150] Siegler states that confidentiality is an "ancient medical principle" and has simply become "old, worn-out, and useless; it is a decrepit concept".[151] Attempts to conserve the old and precious way of thinking about confidentiality is creating problems as opposed to producing solutions.[152] Absolute confidentiality is harmful and has not been proven to enhance the doctor-patient relationship.[153] Crook states that the argument of absolute confidentiality is not able to provide any supporting evidence that current or future patients would not seek treatment if they were told that their information may be disclosed if necessary.[154] While confidentiality is undoubtedly important, this duty must be balanced against the interests of third parties.[155] Evidently, trust and upholding confidentiality are vital components to the doctor-patient relationship; however, the

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[149] Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation," p. 118. This claim is confirmed with Kottow's statement that "Limitations or exceptions put on confidentiality would destroy it, for the confider would become suspicious and un-co-operative, the confidant would become untrustworthy and the whole climate of the clinical encounter would suffer irreversible erosion. Excusing breaches of confidence on grounds of superior moral values introduces arbitrariness and ethical unreliability into the medical context. Physicians who breach the agreement of confidentiality are being unfair, thus opening the way for, and becoming vulnerable to, the morally obtuse conduct of others."

[150] Siegler, Mark. "Confidentiality in Medicine - A Decrepit Concept," in *Bioethics: An Anthology,* edited by Helga Kuhse, Udo Schüklenk, and Peter Singer, 599- 602. Blackwell Philosophy Anthologies. Chichester, West Sussex: John Wiley & Sons, 2016, p. 599. https://doi.org/10.1056/NEJM198212093072411.

[151] Ibid., p. 599.

[152] Ibid., p. 599.

[153] Crook, M A. "The Risks of Absolute Medical Confidentiality." *Science and Engineering Ethics* 19, no. 1 (2013): 107-22, p. 110. https://doi.org/10.1007/s11948-011-9283-1.

[154] Ibid., p. 109.

[155] Ibid., p. 109.

Canadian Medical Association (*CMA)* does affirm there are exceptions. The *CMA* states that "there are circumstances where there are required… and permitted disclosures of personal health information without patient consent (e.g., where the maintenance of confidentiality would result in a significant risk of substantial harm to the patient or to others)".[156]

The need to protect third parties from harm must be considered and, under certain circumstances where there is the potential for serious harm, a breach in confidentiality will be warranted. The harm that may occur as a result of disclosure or non-disclosure to the patient or family member will determine whether the case warrants a breach of confidentiality. Though either choice will indeed harm one of the parties involved, we must assess which action is a justified harm. To make this assessment, the distinction between harming and wronging must be made. If it is determined that one party will be wronged in the process, meaning their interests are invaded in an unjustified manner, then we may not proceed. For instance, if it is determined that failure to disclose genetic information will result in an unjustified harm (or a wrong), then we must proceed to disclose the information. On the other hand, if disclosing the information is determined to be an unjustified harm (or a wrong), then we may not disclose genetic test results. The distinction and importance of harming and wronging will be discussed in greater detail in the following chapter.

The guidelines developed by *The President's Commission* were created to prevent harm to third parties and are a good guide for upholding good ethical practice in health care. It would be unethical to require a strict rule of confidentiality within the field of medicine. Confidentiality should be acknowledged, and disclosure should, of course, be regarded as serious. The claims presented by those against breaching confidentiality are valid and therefore, the decision to

[156] "Principles for the Protection of Patient Privacy." Canadian Medical Association.

disclose genetic information must be taken seriously. The current standards of disclosure respect the principle of confidentiality as they require health care professionals to be particular in determining what circumstances warrant a breach. These two standards ensure there is an effort to obtain voluntary consent and that only the necessary information needed for treatment and diagnosis is disclosed.

The physician's primary obligation is to his or her patient, and they must act in their best interest. However, the interests of others must also now be considered. Maintaining "strict secrecy" today is impossible in our modern-day health care system as many professionals are involved in patient care and may, therefore, rightfully have access to such records.[157] The previous ideals presented in the *Hippocratic Oath* are described as "outmoded, outworn, decrepit, and inappropriate for the complexity of 20th century health care systems".[158] As our health care system continues to progress and develop, so too must our thoughts surrounding confidentiality. The technological advancements, especially surrounding genetic testing, have produced new ethical dilemmas. If, as health professionals, we do not advance our thinking, then we will be unable to handle these new-age problems. As technology advances, so to must our mindset and ideals.

Mitchel et al. state that for patients to assume their information will be kept confidential under all circumstances is factually wrong.[159] Crook states that there are far too many risks and uncertainties associated with this belief.[160] In my opinion, absolute confidentiality is especially harmful within the field of genetics. Genetics is a unique field, and the idea of absolute

[157] Higgins, Gerald. "The History of Confidentiality in Medicine: The Physician-patient Relationship," p. 926.
[158] Ibid., p. 926.
[159] Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty to Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" p. 130.
[160] Crook, M A. "The Risks of Absolute Medical Confidentiality," p. 107.

confidentiality simply does not fit. The field of genetics does not solely concern the patient that is undergoing genetic testing; rather, this testing may involve multiple individuals.[161] Therefore because of this potential harm to others, breaching confidentiality ought to be considered.[162] Genetic technology only continues to increase in popularity and availability. As genetics does not only concern individual patients, we must view this field as one of the exceptions to absolute confidentiality.

The idea of absolute confidentiality also conflicts with well-established professional codes and legislations. Professional guidelines have been developed to provide advice for disclosing confidential information in circumstances that otherwise may result in harm to others. For instance, when it is required by law because of criminal or potential criminal actions or in the case of a serious genetic disease. Absolute confidentiality itself would impose a large burden upon physicians.[163] Crook asserts that there a few health care professionals that would argue against the importance of patient confidentiality. However, many of these professionals acknowledge that confidentiality may need to be breached, and many professional codes recognize this issue.[164] An absolutist approach to medical confidentiality would undermine not only ethical considerations but also legal considerations.[165] Ultimately, there is no appropriate justification for absolute confidentiality as there is currently "ample guidance and legislation for ensuring a balance and taking into consideration harm to others".[166] Mitchell and al. state that "a very narrow duty to disclose in exceptional circumstances would avoid widespread disclosure

[161] Ibid., p. 111.
[162] Ibid., p. 112.
[163] Ibid., p. 112.
[164] Examples of professional codes that acknowledge this issue include, but are not limited to, *The Nursing and Midwifery Council (NMC), the British Psychological Society, the Council for Professions Supplementary to Medicine, The General Medical Council,* and *The Canadian Medical Council.*
[165] Ibid., p. 115.
[166] Ibid., p. 116.

and maintain trust and confidence as far as possible within a framework that respects fundamental rights".[167] The guidelines developed by *The President's Commission* allow the circumstances to be carefully considered, and the strict standards also allow confidentiality to remain an important element in health care. The guidelines allow confidentiality to remain an important element in health care as they appropriately limit the circumstances that would warrant a breach of confidentiality. The guidelines do so by only warranting a breach when a serious harm (or wrong) will occur without the disclosure of the genetic test results.[168]

2.3 Criticism #2: Duty to Warn Patient Relatives Will Cause a Burden for Physicians

The second criticism of disclosing test results is that a duty to warn patient relatives will cause a burden for physicians. This criticism is mostly directed towards the second and third standards.[169] Each of these standards focuses on evaluating the degree and possibility of harm that a patient relative would experience. These two standards require the physician (if there is a potential for serious harm) to be held accountable to identify and notify relatives and evaluate the possible harm. It is true that the physician's duty would thus extend beyond their responsibility to their patient and onto biological family members, this is reasonable. Physicians possess a great deal of knowledge, power, and resources. This places them in a high-ranking position within society, which requires additional responsibility and accountability. Further, the information they possess has the ability to alter the life of another person. Therefore, in this section I argue that the criticism that this causes a burden for physicians is weak and unacceptable.

[167] Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty to Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" p. 10.
[168] "Screening and Counseling for Genetic Conditions," p. 44.
[169] Please refer to Appendix D

As stated, critics such as Offit et. al believe that a duty to warn is simply not a practical option and will impose an unnecessary burden upon physicians.[170] The authors conclude that physicians should not be placed in a position to have the responsibility of identifying relatives and notifying them that they may be predisposed to a hereditary genetic condition.[171] Additionally, Offit et. al argue that even if the issue of identifying relatives was disregarded, the physician's duty would not be finished. The identified relatives would require education and counselling regarding the hereditary condition, and this would "impose completely unrealistic burdens on the physician" and deter future doctors from specializing in genetics.[172]

The fear is that this burden for physicians would result in a requirement to "warn every single collateral relative of the patients".[173] Offit et. al argue that a universal duty to warn would require the relationship between the patient and physician to be compliant to a "larger public health obligation" as the interests of unidentified individuals are being benefitted as opposed to the interests of the identified patient.[174] The authors assert that it would be wrong to make it universally mandated that all physicians, under all circumstances, ought to be required to contact family members because of a potentially harmful genetic condition. This requirement would be both unrealistic and unethical; furthermore, this may induce fear and doubt for patients accessing genetic testing.[175]

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[170] Offit, Kenneth, Elizabeth Groeger, Sam Turner, Eve A Wadsworth, and Mary A Weiser. "The "Duty to Warn" a Patient's Family Members about Hereditary Disease Risks," p. 1472.
[171] Ibid., p. 1472.
[172] Ibid., p. 1472.
[173] Burnett, J W. "A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease," p. 578.
[174] Offit, Kenneth, Elizabeth Groeger, Sam Turner, Eve A Wadsworth, and Mary A Weiser. "The "Duty to Warn" a Patient's Family Members about Hereditary Disease Risks," p. 1472.
[175] Ibid., p. 1472.

2.4 Response to Criticism #2: Duty to Warn Patient Relatives Will Cause a Burden for Physicians

A duty to warn will not be mandatory in every situation that a physician encounters in the field of genetics. I agree that it would be completely unrealistic and unattainable and result in a burden for physicians. However, physicians will encounter cases where duty to warn will outweigh their duty to uphold confidentiality. A duty to warn may place a small burden on the attending physicians. However, this burden may be overridden by the imminent risks and harms that could be inflicted upon family members. The potential for a serious hereditary condition outweighs the preference of the physicians to forego contacting relatives due to challenges in this process. These scholars are neglecting to consider the serious harm that may occur to family members and also that there are strict standards that have been established to avoid warning in every possible circumstance. Additionally, Burnett states that it is "unlikely that physicians would make a practice of giving warnings beyond immediate family or that the medical community would make a practice of warning about diseases unlikely to be inherited".[176] As a duty to warn will not extend past immediate family or disclose information that is not likely to be inherited, there is truly no undue burden. The physician would need to warn, for the most part, only immediate relatives. Burnett states that the duty to warn is thus "relatively simple to discharge in all but the rarest of circumstances".[177]

There are, however, inherent complexities because genetics involves risk factors[178] to relatives, these risks should not be dismissed lightly. For instance, risks in a family with a

[176] Burnett, J W. "A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease," p. 579.
[177] Ibid., p. 579.
[178] Certain factors such as age, sex, likelihood of inheritance, personal circumstances should all be taken into consideration by the health professional.

dominantly inherited disease (such as ARVC and Huntington's Disease) places first-degree relatives at a 50% risk, second-degree relatives at a 25% risk, third-degree relatives at a 12.5% risk, and fourth-degree relatives at a 6.25% risk.[179] Physicians must assess whether the relative's genetic risk is a high enough risk to breach confidentiality.

To determine whether the relative's genetic risk is a high enough risk to breach confidentiality we may consider the foreseeability of harm to the relative. Keeling states that the "Wrongs Act 1958 (Vic) provides that, for the purposes of foreseeability, insignificant risks include, but are not limited to, risks that are far-fetched or fanciful".[180] Keeling argues that a risk to a first-degree or second-degree relative are not "far-fetched or fanciful".[181] First-degree relatives are at a high-risk for harm as they have a 50% of inheriting the disease, therefore a duty to warn in these cases are unquestionable.[182] However, it is important to note that this risk will vary significantly. Keeling states that if a genetic condition will only have "minimal impact" there is no requirement of a duty to warn.[183] Mendelian disorders, which cause diseases with high genetic risk, such as ARVC and Huntington's Disease, are those that may have a significant impact on a person's life. Keeling therefore argues (and I agree) that a duty to warn is necessary when a condition will shorten the life of a person or result in serious medical issues.[184]

These complex situations will arise and the worst possibility for health professionals is that a patient will sue them for failing to connect the relatives or not having worked hard enough to connect the relatives. Therefore, the idea of duty to warn for physicians creates issues as they

[179] These risk factors may be designated as 1 in 2, 1 in 4, 1 in 8 and 1 in 16. Thank you to Dr. Hodgkinson for explaining these risk factors to patient relatives.
[180] Keeling SL. 2004. "Duty to Warn of Genetic Harm in Breach of Patient Confidentiality." *Journal of Law and Medicine* 12 (2): 235–53, p. 240.
[181] Ibid., p. 240.
[182] Ibid., p. 247.
[183] Ibid., p. 247.
[184] Ibid., p. 247.

do not want legal action taken against them and be found guilty of negligence. Keeling argues in their article "Duty to Warn of Genetic Harm in Breach of Patient Confidentiality" that a "statutory exception to patient confidentiality should protect health professionals against a claim for breach of confidence".[185] Rather than causing physicians to fear breaching confidentiality, our laws should be changed so that a physician (under certain circumstances) may breach confidentiality without the fear of a lawsuit.[186] These circumstances would be very limited. Keeling states, "there is a highly limited duty to warn when an at-risk class of persons is identified, where that warning would require breaching patient confidentiality without consent".[187] I am not arguing that a physician must warn all relatives in every situation. Rather, I am arguing that if possible, if the relative is identifiable and there is foreseeable harm, a duty to warn is required.

Physicians are undoubtedly placed in a precarious position in the current legal atmosphere. However, we must also acknowledge the moral obligations that encompass this position due to their access to information that may result in serious harm to others. Physicians upon entering into their profession, have opted to be placed in a high-ranking position within society. Physicians hold ample knowledge, resources, influence, and power, and it ought to be without question that any action they may take to prevent serious harm to another individual should be seriously considered. As stated, the current standards will not place any undue burdens on physicians because the circumstances which would warrant a breach in confidentiality are limited. Additionally, the duty to warn will be only for immediate family members. Therefore, any burdens that disclosure may place on the physicians is simply not an acceptable argument

[185] Ibid., p. 239.
[186] Ibid., p. 239.
[187] Ibid., p. 239.

when the health and well-being of others are at risk. This is not an acceptable argument, especially if the physicians possess the knowledge to change the direction of another person's life.

Medical sociologists have studied and analyzed the power that physicians possess over the past few decades. They have proposed that the power a physician possesses may be broken into three categories. These categories are Aesculapian, charismatic, and social.[188] First, Aesculapian power is a form of power that a physician holds based upon their education and training within the field of medicine. Physicians possess knowledge, information, skills, and experience that are extremely valuable to everyone within society. They have the ability to diagnose, treat, and cure individuals of conditions which render them at their most vulnerable.[189] Second is charismatic power; this type of power is solely based on the personal qualities of each individual physicians.[190] These qualities may include "courage, decisiveness, firmness, kindness, and so on".[191] Lastly, social power, this type of power is based upon the social status that the physician has within society. Physicians maintain a high status within the social class system because of the knowledge and skills they possess.[192]

It is clear that physicians hold a great deal of power and authority, and therefore, the argument that a duty to warn would cause too much of a burden is weak. Physicians, upon entering into this profession, were aware of the influence they would have over the lives of others. This group of professionals determines the health outcomes for their patients. As expressed, they are solely responsible with the ability to offer treatment plans and cures when

[188] Brody, Howard. *The Healer's Power*. New Haven: Yale University Press, 1992, p. 16.
[189] Ibid., p. 16.
[190] Ibid., p. 16.
[191] Ibid., p. 17.
[192] Ibid., p. 17.

patients are at their most vulnerable. They possess sensitive information regarding many individuals who have confided in them. Physicians, as has been expressed, have a great deal of power, as such "… great power involves great responsibility".[193] Physicians ought to be expected to shoulder the burden as they have chosen to enter a profession that involves a great deal of responsibility as they may determine the outcome of the lives of others.

Further, with the advancement of genetic testing, they now possess information about third parties whose life may be changed with knowledge of this information. To simply argue that it would be difficult for physicians or their team to seek out those who would be impacted by the information is unsuitable for medical practice. The standards developed by *The President's Commission* appropriately limit the circumstances that would warrant a breach without consent. Therefore, physicians will suffer no undue burden as a duty to warn will only be for immediate family members, and when the disease is hereditary. Further, disclosure will only be necessary in limited circumstances when there is a chance of serious harm to a patient relative.

A duty to warn, which we speak of in this thesis, is not meant to cause legal issues for the physician. Instead, the intention is to prevent harm to the relatives and allow them to make informed decisions about their health. These instances must be considered on a case-by-case basis and use *The President Commission's* standards to determine whether disclosure is required. Finally, the burden of warning patient relatives does not need to fall completely under the responsibility of the physician. Rather, Keeling suggests that "this duty could be discharged by notification to a statutory authority".[194] This would remove the burden of disclosure from the

[193] "Franklin D. Roosevelt's Last Message to the American People. [n. p. 1945]." Library of Congress, n.d. https://www.loc.gov/resource/rbpe.24204300/?st=text.
[194] Keeling SL. 2004. "Duty to Warn of Genetic Harm in Breach of Patient Confidentiality.," p. 247.

physician completely. This would require genetic risks to be dealt with by public health in the same way that notification of exposure to an infectious disease.

2.5 Criticism #3: Patients May Feel Pressure to Agree to Disclose Their Test Results

The third criticism of disclosing genetic test results is that patients may feel pressure to agree to disclose their test results.[195] This criticism is specifically linked to the first standard.[196] This criticism is directed at this standard as, during the process of acquiring voluntary consent, there may be coercion, undue inducement, or a no-choice situation. These unethical tactics used to obtain consent would render the consent process involuntary and unethical.

The pressure that patients may feel is strongly linked to harm. This link to harm is the perceived sense of coercion involved on the part of the health care worker and felt on the patient's part. The doctor may feel it is necessary to pressure patients into disclosing results to family members to avoid a potential future lawsuit. This type of inappropriate pressure is against professional standards. There is a manner to address the situation without placing unwarranted pressure on the patient. *The General Medical Council (GMC)* provides guidance for managing these challenging situations.

The *GMC* states that while every patient is entitled to confidentiality, "challenging situations can however arise when confidentiality rights must be balanced against duties to protect and promote the health and welfare of patients who may be unable to protect themselves".[197] Physicians face conflicting duties as they have a duty towards their patients to uphold confidentiality. However, they also have a "wider duty to protect and promote the health

[195] Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty to Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" p. 130.
[196] Please refer to Appendix D
[197] "Disclosure for the Protection of Patients and Others." General Medical Council. The General Medical Council, n.d. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality/disclosures-for-the-protection-of-patients-and-others.

of patients and the public".[198] The *GMC* states that "the benefits to an individual or to society of the disclosure must outweigh both the patient's and the public interest in keeping the information confidential".[199] If it is determined that failure to disclose the information would leave individuals or society exposed to a risk so serious that it outweighs the patients and the public interest in maintaining confidentiality, disclosure of relevant information must be made promptly to an appropriate person or authority.[200]

The *GMC* encourages physicians to discuss the benefits of sharing genetic test results with their family members. However, this guideline also states that if this attempt fails, then physicians may consider disclosure without consent. In order to avoid a potential lawsuit, this should only be considered if the risk of harm is serious and justified. There should never, in any circumstances, be any undue pressure placed upon patients to provide consent to reveal their test results. If the patients determine that they do not want to disclose the information to their relatives, their decision must be respected. However, if the physician still feels that there is a serious and imminent threat to the relatives, then action may be taken in certain circumstances.[201]

2.6 Response to Criticism #3: Patients May Feel Pressure to Agree to Disclose Their Test Results

This criticism is logical and deserves careful consideration. It rests on the assumption that physicians will pressure their patients to disclose their test results or consent against their will. However, by following appropriate guidelines, the patient will not be pressured, nor will they feel any form of pressure. The patient will simply be presented with any concerns from the physicians

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[198] Ibid.
[199] Ibid.
[200] Ibid.
[201] Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty to Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" *Tottel's Journal of Professional Negligence* no. 32(2) (2016): 120-136, p. 130.

and the opinion that the relative should be warned. The benefits for the relative will be offered in a professional manner without placing unwarranted pressure on the patient to disclose their personal health information. If the patient remains adamant about not disclosing their test results to the relative, the conversation must end. The physician has no right to continuously seek out consent when the patient refuses. Instead, the physician must determine whether or not disclosure without consent is the next appropriate step. The physician will look at the four standards of disclosure developed by *The President's Commission* to determine if action is ethically justified and required.

Chapter Summary

Chapter Two has detailed criticisms of the disclosure of genetic test results. These criticisms come from the existing literature and pertain not specifically to *The President's Commission's* four standards, but to the general notion of disclosure of genetic information to patient relatives. I have identified and discussed three of such criticisms from the existing literature and provided comprehensive responses to each.[202] It is evident that there is a serious concern over disclosing genetic test results to third parties to prevent harm. The criticisms permit us to consider potential issues and address them before they arise. The standards developed by *The President's Commission,* however, remain a good guide for health professionals. They are a good guide as they appropriately limit the circumstances which would warrant a breach in confidentiality. However, there are challenges when practically applying these standards to the decision-making process about breaching confidentiality because of their reliance on the notion

[202] Please see, Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation." *Journal of Medical Ethics* 12, no. 3 (1986): 117-122, and Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty To Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" *Tottel's journal of professional negligence* no. 32(2) (2016): 120-136, for further information.

of harm. The following chapter will address the issue of harm in great detail. Chapter Three will demonstrate the complexities of harm and argue that it must be appropriately understood in order for the standards to be usable and effective.

Chapter Three: The Complexity of Harm

Determining how to define harm is a notoriously complicated matter. This chapter probes the complexity of this principle and discusses the challenges of practically applying the standards of disclosure to the decision-making process because of their reliance on harm. To be clear, my position is that these standards remain a good guide for health professionals. Even so, there are challenges to applying them, and in this chapter, I identify and discuss those challenges. When it comes to health and the complexities of the decision-making process, professionals using these standards must understand its reliance on harm. Every day, health care professionals confront complex situations. A proper understanding of the complexity of these standards will allow professionals to think broadly about the potential impact decisions have on the lives of others. These standards should not only be considered in terms of the patient but also how they will impact the lives of family members. The field of genetics adds a complex dimension to the decision-making process as family needs must also be considered, appreciated, and acknowledged. Instead of health professionals looking at the problem directly in front of them, understanding the harm principle will allow them to look peripherally at the other individuals who may be harmed by their decision. It is not only the individual patient that may be harmed in the decision of whether to disclose genetic information. Rather, it is also biological family members who will be impacted by this decision. Therefore, a consideration of the harm that may occur to biological relatives is necessary.

This third chapter will argue that harm is a complex notion and must be well understood in order for the current standards to be useable and effective. It is necessary to understand harm accurately; if not, this will result in a moral dilemma as the rights of another may be infringed upon in an unjustified manner. The rights of an individual will be infringed upon if harm is not

accurately understood as health care professionals would not be able to appropriately assess whether disclosure is ethically justified. The distinction must be made between a harm and a wrong to determine whether or not disclosure is justifiable. I shall argue that a disclosure that amounts to a harm is justifiable, and that a disclosure that amounts to a wrong is unjustifiable. To fully grasp and comprehend the complexity of harm itself, this chapter will be divided into three sections.

Chapter Overview

There are two main challenges of applying the current standards of disclosure due to their reliance on the notion of harm. These challenges include, understanding the principle of harm and determining the degree and probability of harm. This chapter will focus on understanding these two challenges with relying on the notion of harm as they must be understood to practically apply the current standards of disclosure. The first section of this chapter, which will address the first challenge, will begin by discussing the principle of harm. As stated, harm is a challenging concept to grasp; at first glance, many people believe they understand this overused and frequently misunderstood term. We must have a proper understanding of this concept before its complexity can be appreciated. There have been many scholars who have attempted to define harm. However, for this thesis, the description of harm put forth by Joel Feinberg will be adopted.[203] After appropriately defining harm, it must also be determined what constitutes a harm and a harmful act. Lastly, this section will establish the important moral distinction between a harm and a wrong. This distinction will determine whether or not disclosure or non-disclosure is a justifiable harm. The important question is "where is the line between a harm and a wrong?" The answer to this question is key to the decision-making process, and, key to applying *The*

[203] Feinberg, Joel. *Harm to Others.*

Presidents Commission's standards. Therefore, I will present my view that this line is drawn when the decision (disclosure or non-disclosure) becomes *life-altering* for one of the parties involved (the patient or their relatives). In my view, there are three factors that health professionals must consider when applying the standards of disclosure to determine whether the decision will be life-altering. This includes long-term, physical and psychological impact of disclosure or non-disclosure. These factors must be used with *The President's Commission* standards when making the important decision between disclosure and non-disclosure.

The second section of this chapter will discuss the challenges of determining the degree and probability of harm. Determining the degree and probability of harm that will be imposed upon an individual is a complex task. There are many factors that must be considered to adequately assess the degree and probability of harm that may be inflicted upon the patient or relative. The current situation of each individual must be considered, and the outcome of disclosure or non-disclosure must be examined. The considerations concerning the complexity of harm throughout this chapter will validate the challenges of relying upon this notion for the current standards of disclosure.

Section 1 Understanding the Principle of Harm

The avoidance of harm is a prominent concept and has been recognized in many important documents. For starters, the *Hippocratic Oath* states, "I will use those dietary regimens which will benefit my patients according to my greatest ability and judgement, and I will do no harm or injustice to them".[204] Further, J.S. Mill's Harm principle states, "the principle requires liberty… of doing as we like, subject to such consequences as may follow: without impediment

[204] Bradley, Ben. "Doing Away with Harm." *Philosophy and Phenomenological Research*85, no. 2 (2012), p. 390. https://doi.org/10.1111/j.1933-1592.2012.00615.x.

from our fellow-creatures, so long as what we do does not harm them".[205] Finally, the precautionary principle states that "where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically".[206] Ben Bradley, in his paper "*Doing Away with Harm*," asserts that "these statements suggest that there is something especially important about harm, such that we have strong, perhaps overriding reasons both to avoid harming people and to prevent harm from coming to people".[207] There is no doubt that harm is an important principle and has been and continues to be spoken about by various distinguished scholars.

Further, this principle is used in universally recognized documents. However, Bradley states that what harm *means* is rarely discussed.[208] He also says that the lack of discussion regarding the meaning behind this principle would not be an issue if "harm were a primitive, undefinable notion, and if there were no significant disagreements about what counts as a harm".[209] Yet, this is simply not the case. There are serious disagreements regarding what constitutes a harm and how to define this principle. When examining the various explanations of the harm principle, "we find a mess".[210] Various scholars and academics have sought to appropriately define what constitutes a harm.

As expressed in the introductory chapter, many individuals have a basic understanding of the principle of harm. This common understanding and dictionary definition of harm is defined as injury, damage, or hurt that is inflicted upon another individual.[211] This is a too basic and simple way of describing a principle that demands a higher level of complexity. This basic expression of

[205] Ibid., p. 390.
[206] Ibid., p. 390.
[207] Ibid., p. 391.
[208] Ibid., p. 391.
[209] Ibid., p. 391.
[210] Ibid., p. 391.
[211] "Harm." Merriam-Webster.

harm simply does not capture the complicated nature of this term. Nor does this explanation allow us to appropriately apply the standards of disclosure with a consideration of harm in mind. This definition of harm is far too simple to use when considering breaching confidentiality. Further, the harms imposed upon the patient or relative are unable to be acknowledged as this definition contains no method of critically analyzing the situation.

Other scholars have sought to define further the types of harm that may be inflicted upon an individual. For instance, Graeme Laurie, in his article, *"In Defence of Ignorance: Genetic Information and the Right not to know",* classifies harms into three distinct categories to attempt to determine the type of harm that will be inflicted upon a patient or a relative. Laurie states three possible harms that could occur to the patient family members.[212] This includes, "(a) physical harm or death, (b) psychological harm in the guise of unpreparedness, and (c) harm to choice, that is, harm to the facility of being an autonomous individual with a right to choose how to live one's life".[213] First, physical harm will be dependent upon the hereditary condition that has been identified. There may be physical harm through the disease itself or through treatment or preventative measures required following disclosure and diagnosis.[214] Second is psychological harm. Psychological harm is complicated as it is often challenging to determine whether or not psychological harm will occur, and whether or not disclosure will be beneficial.[215] Lastly, harm to choice is also a complicated matter to consider. If the information is disclosed, this information will be a factor in all future life decisions, for instance, in the decision-making process of whether or not to have children.[216] Laurie states that, "what is known cannot then be unknown…".[217]

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[212] Laurie, Graeme T. "In Defence of Ignorance: Genetic Information and the Right Not to Know." *European Journal of Health Law* 6, no. 2 (1999): 119-32, p. 121. https://doi.org/10.1163/ 15718099920522730.
[213] Ibid., p. 121.
[214] Ibid., p. 122.
[215] Ibid., p. 122.
[216] Ibid., p. 123.
[217] Ibid., p. 123.

Therefore, Laurie asserts, the decision of whether or not to disclose information must be taken seriously.[218]

The two above descriptions of harm, the common understanding and Laurie's[219], are two different yet vaguely similar understandings of the principle of harm, which clearly demonstrates the complex nature of this principle. Additionally, this reflects the challenge scholars face in attempting to appropriately and accurately explain this term. While each description of harm provided allows individuals to roughly understand the term, neither captures what is demanded of this principle for the current standards of disclosure. Many other scholars have attempted to capture what this term requires; however, none have been as successful as Joel Feinberg. Feinberg, in his book, *Harm to Others*, articulates three senses of harm.[220] The third sense of harm is what must be used in the application of the standards developed by *The President's Commission* because it makes the important moral distinction between a harm and a wrong. The distinction between a harm and a wrong must be made because this will determine whether or not disclosure is morally justifiable.

1.1 Feinberg's Definition of Harm

Joel Feinberg describes the word harm as "both vague and ambiguous".[221] We must, therefore, clearly define the type of harm that is to be used and discussed throughout this thesis. In the most basic sense, when one commits a harmful act, they have, in some way, caused harm to another living being or situation. This harmful act thus places the other person in a harmed state or condition. There is a distinct difference between a harmed condition and a harmful condition. The distinction made between a harmed condition and a harmful condition

[218] Ibid., p. 123.
[219] Ibid., p. 123.
[220] Feinberg, Joel. *Harm to Others.*
[221] Ibid., p. 3.

demonstrates the complex nature of harm itself. A harmful condition implies that there is the potential for the current condition to generate further harm. For instance, Feinberg states that a blister on one's finger may cause a harmed condition. However, unless the finger belongs to a concert pianist or a professional baseball player, the condition may not be considered harmful.[222] Instead, as opposed to a harmful condition, it is merely a harmed condition, that will not itself cause further harm. The three senses of harm, as described by Feinberg, must be discussed to have a complete and proper understanding of this principle.

Feinberg's first definition of harm is harm in the "derivative or extended sense".[223] Feinberg states that this sense of harm is mentioned only to be dismissed; harm in this sense implies that anything on this planet can be harmed. Feinberg states, for example, that vandals can harm the windows of a property. However, this is a different sense of harm in that we do not feel overly bad for the windows, nor do they become a focus of our sympathy. Rather, we may feel sympathy for those that have an interest in the property and have invested some of their own well-being in the property. Therefore, we may say that the direct harm by breaking the windows was to the property owner. Rather than using the word harm for the windows, Feinberg argues this is a case where one should use the term "broken" or "damaged".[224] This first type of harm I leave aside as it does not apply to our discussion regarding duty to warn for genetic testing.

Feinberg describes the second sense of harm as "that which the transferred sense derives, namely harm conceived as thwarting, setting back, or defeating of an interest".[225] The term interests, he states, is not meant to mean the ordinary common-sense meanings of the word such

[222] Ibid., p. 3.
[223] Ibid., p. 4.
[224] Ibid., p. 4.
[225] Ibid., p. 5.

as "money due on loans" or "the excitement of attention or curiosity".[226] Instead, we are looking at interests in the commercial-legal sense. Here we look at what interests a person has in *X*, such as a stake a person may have in a company. A person has a stake in something when he or she will see a loss or a benefit depending on the condition of *X*. His interests can be impacted by events that are "impersonal in nature or by plain bad luck".[227] However, they can also be blocked by the actions of others. Harm, in this sense, indicates that "one person harms another person in the present sense then by invading, and thereby thwarting or setting back, his interest".[228] Harm, in this sense, is not sufficiently relevant to the topic of this thesis.

Feinberg states that the third and final sense of harm, "while closely related to the second, is in fact a distinct notion that can often be at variance with it".[229] For the third sense of harm, when we say that *A* has caused harm to *B***,** we are at the same time implying that *A* has in some way wronged *B,* or that he has been treated in an unfair or unjust manner. Feinberg states that "…one-person wrongs another when his indefensible (unjustifiable and inexcusable) conduct violates the other's right" and at the same time may also "invade the other's interest".[230] When distinguishing between wrongs and harms, we need to remember that not all harms and invasions of interests are wrongs. We are able to determine that not all harms are wrongs, as there are instances when it is justifiable and excusable to invade the interests of another. Furthermore, in some cases, the individual may have no right to have their interests respected. However, we should try to "minimize harm" in all cases that we are able to.[231] The distinction between harms and wrongs is crucial to the overall argument of this thesis, as I argue that the harmful disclosure

[226] Ibid., p, 5.
[227] Ibid., p. 5.
[228] Ibid., p. 5.
[229] Ibid., p. 5.
[230] Ibid., p. 7.
[231] Ibid., p. 7.

of genetic information is morally justifiable (or at least not morally wrong), where the wrongful disclosure of genetic information is morally unjustifiable.

In short, a person who has been harmed, has not been treated in an unfair manner because their interests were invaded for a justified reason. It is fair to harm a person if this invasion of interests prevents serious harm to another. When a person's interests are invaded without justification, this is a wrong. A person who has been wronged has been treated in an unfair manner. The important question is, where is the line between a harm and a wrong? I propose that the line is drawn when a decision becomes life-altering in the relevant respects (disclosure or non-disclosure of genetic information) for one of the parties involved. To determine whether an action is life-altering in the relevant respects, we must consider a decision's long-term, physical, and psychological impact of disclosure or non-disclosure. Section 1.3 will explain how a health professional may determine if a decision is life-altering in the relevant respects for disclosure or non-disclosure of genetic information.

The above description of the three senses of harm demonstrates the complexities of this term. We must now consider how the application of the third sense of harm may be applied in terms of genetic testing and determining whether disclosure or nondisclosure would be classified as a harm or a wrong. This must be determined because, as previously expressed, this will determine whether or not disclosure is morally justified. This distinction between a harm and a wrong is necessary as a wrong is an indefensible invasion on the interests of another. On the other hand, not all harms are wrongs as there are cases where we may justifiably invade the interests of another. It is without a doubt that in any circumstance that either the patient will be harmed or the relative will be harmed. The patient will be harmed if they wish for their information not to be revealed, and physicians choose to do so based on their application of the standards. In such cases, the patient will not be wronged because the duty to warn outweighs the

patient's right to confidentiality as there is a justifiable reason to invade the individual interests of the patient to prevent serious harm to the relative. Therefore, in these cases, such a disclosure would be morally justifiable. On the other hand, if the physician determines that disclosure is not permitted, the relative may be harmed by not knowing the information. However, they will not be wronged because, in this case, disclosure would be an unjustifiable invasion of the interests of the patient (otherwise known as a wrong).

Duty to warn in the case of genetic testing is directly linked to the third sense of harm. The decision made by the doctor to disclose personal health information will, in some way, invade the interest of either the patient who has undergone genetic testing or the relative who may be impacted by the information. For instance, let us say that a mother has been diagnosed with breast cancer, which was the result of a mutation in the BRCA 1 and BRCA 2 genes. This form of breast cancer is a hereditary condition that has a fifty percent chance of being passed to her adult offspring.[232] The mother states that she does not want her personal health information disclosed. The identified hereditary condition (breast cancer) has preventative measures that can be taken. Preventative measures for this disease may include more frequency in screening to detect early signs of cancer, preventative surgery, or chemoprevention.[233] The children may also choose to undergo genetic testing to determine if they are at risk. However, if no action is taken, the adult offspring are denied their opportunity to initiate informed health choices and possible medical care. If preventative measures are not initiated, then they will endure greater pain and suffering in the future. The children, if later diagnosed, will have to be treated using radiation

[232] Werner-Lin, Allison, Lisa R Rubin, Maya Doyle, Rikki Stern, Katie Savin, Karen Hurley, and Michal Sagi. "'My Funky Genetics': Brca1/2 Mutation Carriers' Understanding of Genetic Inheritance and Reproductive Merger in the Context of New Repro-Genetic Technologies." *Families, Systems & Health: The Journal of Collaborative Family Healthcare*30, no. 2 (2012), p. 166. https://doi.org/10.1037/a0028434.

[233] Godet, Inês, and Daniele M Gilkes. "BRCA1 and BRCA2 Mutations and Treatment Strategies for Breast Cancer." *Integrative Cancer Science and Therapeutics* 4, no. 1 (2017): Integrative Cancer Science and Therapeutics, February 2017, Vol.4(1). https://doi.org/10.15761/ICST.1000228.

therapy, chemotherapy, or surgery. These forms of treatment cause severe physical discomfort and mental anguish.

While it is important to respect the wishes of the mother and her right to confidentiality, in this case, it is my view that the duty to warn her children outweighs her right to confidentiality. The duty to warn outweighs honouring confidentiality to the mother as warning the children causes a justifiable harm to the mother. This decision is directly related to the third sense of harm as we must determine whether disclosure or non-disclosure is a harm or a wrong. The third sense of harm is relevant here because it introduces and explains the important distinction between a harm and a wrong and determines whether disclosure is morally justifiable. In contrast, the first and second sense of harm does not acknowledge the concept of a wrong. In this sense, we can say that we are indeed causing direct harm to the mother; however, it can be argued that we have not wronged her. The mother has not been wronged as there is a justifiable reason to invade her interests. Our actions ought to be deemed justifiable as this allows others to live long, healthy lives and is in her children's best interest. What we must determine to make this decision is whether or not disclosure or non-disclosure is a wrong. Feinberg states that "the overriding consideration would be some allegedly crucial moral difference between wrongfully causing and wrongfully non-preventing".[234]

1.2 The Important Moral Distinction Between a Harm and a Wrong

There is a strong moral difference between a harm and a wrong. The difference between a harm and a wrong is that a wrong is an unjustifiable invasion of the interests of another whereas a harm does invade the interests of another, but this invasion of interests is justified. Ultimately, this distinction is what will justify disclosure or non-disclosure for genetic test results by

[234] Feinberg, Joel. *Harm to Others,* p. 101.

determining if the interests of another are being invaded in a justified manner with good reason. According to the third sense of harm, when we state that *A* has caused harm to *B*, we are at the same time implying that *A* has in some way wronged *B*, or we are implying that *A* has been treated in an unfair or unjust manner.[235] The reason that it is important to make this distinction is that regardless of whether the decision is made to disclose the information or not, someone will be harmed. The patient will be harmed if their information is disclosed without consent.

On the other hand, the relative will be harmed if they are not afforded the opportunity to make informed decisions about their health. Further, the interests of one party will be invaded. Feinberg states that "… one-person wrongs another when his indefensible (unjustifiable and inexcusable) conduct violates the other's right" and at the same time may also "invade the other's interest".[236] When making the distinction between a harm and a wrong, we must remember that not all harms and invasions of interests are wrongs. We are able to make this conclusion as there are instances where an invasion of another person's interests is justifiable and excusable.[237] The case example in the previous paragraph demonstrates the moral significance between a harm and a wrong.

1.3 Where is the Line Between a Harm and a Wrong?

To harm someone and to wrong someone hold different meanings. This thesis uses the work of Joel Feinberg to draw this important distinction. I intend this distinction to help decision-makers apply the standards I have been discussing when needing to determine whether or not disclosing genetic information is morally justified. Feinberg states that according to his third sense of harm, "…one-person wrongs another when his indefensible (unjustifiable and

[235] Ibid., p. 7.
[236] Ibid., p. 7.
[237] Ibid., p. 7.

inexcusable) conduct violates the other's right" and at the same time may also "invade the other's interest".[238] Thus, Feinberg's main distinction between a harm and a wrong is that a wrong occurs when there is an indefensible invasion of another person's interests. By contrast, a harm that is not also a wrong occurs when there is a justifiable and excusable reason to invade the interests of another.

Feinberg's distinction is a helpful starting point in understanding what it means for an action to be considered a wrong rather than a mere harm. Yet, in health care, when a genetic counselor (for instance) applies the disclosure standards and must decide whether disclosure or non-disclosure would be morally wrong, they will require more precise direction than the distinction offered by Feinberg. This prompts the important question, "where is the line between a harm and a wrong?" The answer to this question is key to the decision-making process, and, key to applying *The President Commission's* standards. After all, the main point of this thesis is to argue that this distinction between harm and wrong uncomplicates the application of *The President's Commission* standards. As stated, health professionals need clear guidance to ensure their decision is ethically justified.

I propose that this line is drawn when the decision (disclosure or non-disclosure) becomes *life-altering* for one of the parties involved (the patient or their relatives). But what exactly does it mean for something to be life-altering? In its most basic sense, life-altering is defined as "having an effect that is strong enough to change someone's life".[239] Indeed, many things, such as losing one's arm, can change someone's life. However, the pipefitter who requires his arm to make a living would arguably suffer more than a teacher. The teacher is capable of continuing their

[238] Feinberg, Joel. *Harm to Others,* p. 7.
[239] "Life-changing." Cambridge Dictionary. Cambridge University Press 2021. https://dictionary.cambridge.org/dictionary/english/life-changing

career, whereas the pipefitter must now seek entirely new work. Nonetheless, compared to death, losing one's arm is a significantly lesser life-altering change. So then, how does one measure whether something is life-altering?

In my view, there are three factors that health professionals must consider when applying the standards of disclosure to determine whether the decision will be life-altering. These factors are:

1. Long-term impact of disclosure or non-disclosure
2. Physical impact of disclosure or non-disclosure
3. Psychological impact of disclosure or non-disclosure

These factors are not to be looked at retrospectively after the decision. Instead, these factors must be considered during the decision-making process when applying the standards of disclosure. This section will explain these three factors and the essential considerations for determining whether a decision will be life-altering for one party.

The first factor, the long-term impact of disclosure or non-disclosure, requires health professionals to determine how the decision to disclose or not disclose genetic test results will affect the patient or relative over a long period of time. Health professionals must consider the following factors:

A. How would disclosure or non-disclosure affect them (the patient or relative) over a long period of time?
B. Will the decision prevent the individual from making informed choices about their life?
C. Will disclosure, over a long period of time, bring about more positives or negatives?

The answers to these considerations will vary depending on the personal circumstances of the patient and the relative. If, when answering these questions, we find that our answers cause unjustified harm by preventing informed decisions and, as a result, cause a serious negative

outcome, then the decision would be wrong. For example, a relative is at-risk of a genetic heart condition that, without intervention, can result in sudden death. Unknowingly, the relative chooses to apply for a job as a school bus driver. A few years later, we learn that the man died while on the job, something that could have been prevented with disclosure, and as a result, several children were injured. This is an extreme example, but this demonstrates how withholding the information caused a serious adverse outcome several years later.

When considering the long-term impact, for the first question, we need to consider what long-term changes disclosure or non-disclosure will cause in their life. For the second question, we must determine if disclosing the test results will allow the relative to make informed decisions about their life. For instance, will this enable them to better prepare for their future? Does knowledge of this information change major life decisions? Finally, for the last question, will disclosure or non-disclosure bring more positives or negatives to the individual? For example, will this information lead to the treatment and diagnosis of the disease? The answers to these questions will determine whether disclosure or non-disclosure will result in a wrong. For instance, knowledge of a predisposed genetic condition may promote healthy lifestyle changes and allow the individual to take preventative measures. Disclosure may also allow the individual to better prepare themselves and their family for any future financial difficulties caused by health complications (expensive medical bills or the inability to work). This knowledge may also allow the relative to make informed decisions about their life. For instance, with the potential for a shortened lifespan or passing this condition to their offspring, the individual may decide not to have children when informed of their risk. These examples demonstrate how disclosure may create more positives over a long period of time as the individual can better prepare themselves for their future with this information.

On the other hand, family members may wish not to be informed of any information found through genetic testing. Additionally, there is a risk of psychological harm to the family members if they are told without wanting to know.[240] There is an emotional and psychological dimension to treatment and medical surveillance, which are frequently not taken into consideration. Individuals may suffer from distress, anxiety, depression, or other psychological harms due to being informed of their risk of a serious disease.[241] While this is true, the individual would only be warned if the information would have a drastic impact on their life, and there was foreseeable harm. The issue of relatives not wanting to know their risk of genetic susceptibility to a disease is a debated ethical issue concerning the "right to know".[242]

This issue is complicated as it would be challenging, or in some cases impossible, for a physician to know whether or not a relative wishes to know the information without implying or suggesting there is information that will affect them.[243] "The right to know" is a seriously debated topic, especially in the field of bioethics. It is recognized that there will be cases where the relative wishes not to know their risk of a genetic condition. The assessment must be done in a sensitive manner, and efforts ought to be made concerning the individual's preference. Additionally, professional guidelines should be followed to manage this situation appropriately.[244]

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[240] Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty to Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" p. 130.
[241] Turner, Jane, and Brian Kelly. "Emotional Dimensions of Chronic Disease." *West J Med*172, no. 2 (2000): 124–28, p. 124. https://doi.org/10.1136/ewjm.172.2.124.
[242] Ibid., p. 130.
[243] Laurie, Graeme. "Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications." *The Journal of Law, Medicine & Ethics* 42, no. 1 (2014): 53-63, p. 54. https://doi. org/10.1111/jlme.12118.
[244] Mitchell, C., Ploem, M. C., Hennekam, R. C., & Kaye, J. "A Duty to Warn Relatives in Clinical Genetics: Arguably 'Fair just and reasonable' in English Law?" p. 130.

The second factor requires a consideration of the disease's physical impact. Health professionals must consider the effects that this information will have on the physical body. Health professionals must consider the following factors:

A. Will disclosure or non-disclosure cause death?

B. What are the physical symptoms of the genetic condition?

C. Will disclosure worsen or improve their physical health?

The answers to these questions will depend on the genetic condition identified. Regarding the first question, whether disclosure or non-disclosure prevent death, if disclosure may avoid death, we must disclose the information. Death is irreversible, and a yes answer to this question should automatically require disclosure. In instances where the decision not to disclose genetic test results may cause death, non-disclosure is s a wrong. This decision is a wrong because it is not justifiable. The decision to disclose genetic information may cause harm to the relative (for example, their privacy has been breached). However, we may justly invade their interests to prevent death to a biological relative. For the second question, we need to consider the disease's symptoms. Does this disease present with any onset of symptoms? If so, are the symptoms mild, moderate, or severe? When symptoms present, will treatment be too late? Finally, we must consider whether the disclosure will worsen or improve the physical health of the relative. For instance, if there is an available treatment, this will improve their health and prevent illness and potential death.

The third factor to consider is the psychological impact. Health professionals must consider the emotional or psychological harm that the patient or relative may experience (such as anxiety or depression). Therefore, health professionals must consider the following factors:

A. What emotional or psychological impact will disclosure or non-disclosure cause?

B. Will disclosure or non-disclosure cause severe trauma?

C. If there is psychological impact, how can it be managed?

The answers to these questions will once again depend on the individuals involved. For the first question, we must consider the psychological or emotional impacts that disclosure or non-disclosure will cause. For instance, the patient may lose trust in their physician or the health system as a whole. For the second question, we must consider the type of trauma disclosure or non-disclosure will cause. For example, if the patient has lost trust in the health system, this may cause fear and anxiety and prevent them from seeking future treatment. Similarly, the relatives may also experience psychological or emotional harm (like anxiety or depression) knowing they have a genetic condition.

Lastly, we need to consider if the patient or relative can manage this psychological harm and, if so, how? For example, the patient who lost trust may require counseling to understand why health professionals decided to disclose, and with this understanding may come acceptance. Additionally, after hearing this news, the relative should have access to a genetic counselor and the proper resources to help understand the genetic disease and manage any mental distress they are experiencing with news of their diagnosis. In these instances, when we determine that a disclosure decision will cause psychological harm to the patient, but health professionals have found a solution to manage this psychological distress appropriately, we can justify disclosing genetic information.

Health professionals must refer to these factors when practically applying the standards of disclosure during the decision process. In addition, these factors help health professionals understand the distinction between a harm and a wrong by drawing the line when a decision becomes life-altering for one of the parties (the patient or the relative). Therefore, I have provided three considerations that determine when a decision becomes life-altering. These considerations

will help when applying the current disclosure standards as they assist with the decision-making process by providing clarity in identifying harms and wrongs.

Health professionals must consider these standards and factors simultaneously to render a decision for disclosure and non-disclosure. Disclosure decisions that wrong an involved party or parties are unjustifiable and should be avoided. Therefore, to prevent these unjust decisions, we may, under certain circumstances, cause harm to another when there is a justifiable and excusable reason to invade their interests. Thus, while applying the disclosure standards, health professionals should use these questions to help guide their decision-making and determine whether disclosure or non-disclosure is justified. I will present the importance of considering these factors when applying the current standards of disclosure in Chapter Four in the two case study examples.

Section 2 Determining the Degree and Probability of Harm

The second challenge with *The President's Commission's* standards' reliance on the notion of harm is determining the degree and probability of harm that will occur as a result of the decision to disclose or not disclose genetic test results. Determining the degree and probability of harm that will occur is undoubtedly a challenging task for any individual, including health care professionals. When measuring the degree and probability of harm, we must specifically analyze the personal interests and current situations of both the patient and relative. These two factors will help with the analysis in determining the potential degree and probability of harm that may transpire. However, the complicating component in this analysis is that the interests of each party will change from case to case as the specific situation and vulnerabilities of the individuals involved will vary.[245]

[245] Ibid., p. 160.

The personal interests and situations of the individuals must be assessed in order to measure the degree of harm. This is a challenging task as the interests of the individuals will vary from case to case. For example, a woman is early in her pregnancy and planning to have a family without the knowledge that she will be passing on a serious hereditary condition to her unborn child. Under her circumstances without warning, she is unable to make an informed decision about her life and her future child's life. Arguably, her current position has placed her in a higher degree of harm compared to someone who is currently not in the process of creating a family[246]. These specific interests add more complexity to a set of standards that are already challenging to apply because of their reliance on the notion of harm. However, on the other hand, some interests will be universal amongst a substantial number of individuals. Therefore, in the case of genetic testing, we may, in some cases, be able to use a "standard person" and therefore assume "standard interests" that ought to be protected.[247]

2.1 Measuring the Degree of Harm

It is exceptionally challenging to assess the magnitude and degree of harm that will occur to an individual due to the differences in people's personal circumstances. The current standards of disclosure rely heavily on the principle of harm and therefore assessing the justifiability of disclosure is challenging. The assessment of the degree of harm is challenging as there are further considerations. The additional complicating factor to the assessment that must be performed by health care professionals is determining the probability of harm.

2.2 Measuring the Probability of Harm

[246] The circumstances described are of a current on-going case in the United Kingdom (UK), which will be discussed in greater detail in the following chapter. Please see Dyer, Clare, "Huntington's Case Raises Questions about Passing Gene Test Results to Relatives" for more details.
[247] Ibid., p. 160.

Feinberg states that in order to address the challenge of determining the degree of harm the application of the harm principle must be "based upon empirical generalizations about the likely effects on protected standard interests of various standards and kinds of threatening actions that are likely to invade them…".[248] However, when determining the probability of harm, there is no requirement for there to be a high likelihood for harm to occur. Rather, "if the harm in question is very great, than a very small likelihood of its occurrence will do".[249] Feinberg uses the analogy of people not being allowed to fire guns in the air to justify this claim. He states that it is true that the chances of the bullet hitting another person is low, and therefore the chances of causing harm to another individual is also low. Nonetheless, there is a chance of serious harm should the bullet hit someone and that the "consequences in that unlikely case would be so grave that we cannot take any chance of their occurring".[250] On the other hand, what must we do if the harm in question is relatively small? In this case, there may be a justified reason to run the risk of harm. However, we must consider whether or not the harm would be classified as a wrong.[251] Therefore, to calculate the degree of risk, health care professionals must consider both the degree and probability of harm together.

2.3 Measuring the Risk

As emphasized by the work of Feinberg in the previous paragraph, it is not solely the magnitude of the harm or the probability of harm that must be considered.[252] Rather, it is a combination of these two factors. These two considerations amount to a risk which is "… a measure of the probability and consequences of uncertain events".[253] If there is a risk involved,

[248] Ibid., p. 162.
[249] Ibid., p. 162.
[250] Ibid., p. 162.
[251] Ibid., p. 163.
[252] Ibid., p. 160.
[253] Yoe, Charles E. 2019. *Primer on Risk Analysis: Decision Making Under Uncertainty* (version Second edition.) Second ed. Boca Raton: Taylor & Francis, CRC Press, p. 1. https://doi.org/10.1201/9780429021145.

then there is a chance that the event may result in an unfavourable outcome for one or both of the parties involved. The outcome of a risk could include losses, setbacks, or any other negative consequence based on the decision made.[254] In the case of genetic testing, this may involve adverse health outcomes or a breach of confidentiality.

However, on the other hand, there may be a potential gain by taking the risk. Accordingly, Yoe states that there are two fundamental components to a risk, that is "an undesirable outcome or consequence and the chance or probability it will occur".[255] A risk is frequently expressed by the equation: "risk = consequence x probability".[256] This is a model that helps to critically analyze a risk and allows us to accurately factor in what should be taken into consideration.[257] In the case of disclosing or not disclosing genetic test results, we must critically think about the consequences that may occur to each party and the probability that those consequences will be realized and ultimately what the degree of risk will be. In this case, depending on the situation, the risk may still be taken if we can deem that the decision is not a wrong and is rather a justified harm. Further, we must also consider that there is a chance for a positive consequence.[258] For instance, disclosing genetic test results allows the patient relative to undergo testing and undergo preventative measures which will prevent suffering from the same condition.

Chapter Summary

This third chapter has demonstrated the complexity of harm, which must be understood in order for the current standards to be useable and effective. The first section revealed the

[254] Ibid., p. 1.
[255] Ibid., p. 1.
[256] Ibid., p. 1.
[257] Ibid., p.1.
[258] Ibid., p. 1.

complexities of the concept of harm itself. Harm is challenging to understand; however, the third sense of harm developed by Joel Feinberg allows us to understand this principle and apply it to decisions regarding genetic testing. Additionally, the distinction between a harm and a wrong was discussed to demonstrate instances of a justifiable harm. A wrong is an unjustified invasion of the interests of another whereas a harm may invade the interests of another, but this invasion is justified. This distinction determines whether disclosure or non-disclosure of genetic information is ethically justified. To help make this distinction, I presented three factors that health professionals must consider when applying the standards of disclosure to determine whether the decision will be life-altering.

The second section detailed the challenge in determining the degree and probability of harm. This is challenging as there are many factors to consider, such as the current situation of the patient and family member. Additionally, predicting the outcome of the decision to disclose or not disclose is nearly impossible for any health care professional. Therefore, a risk analysis must be implemented to ensure the decision-maker has considered all possible outcomes. The arguments presented throughout this chapter support the claim that the practical application of the standards is challenging because of their reliance upon the notion of harm. Ultimately, we must appropriately and accurately understand harm. If harm is not understood, then this will result in a moral dilemma as the interests of another would be infringed upon in an unjustified manner.

Chapter 4: A Case Comparison to Demonstrate the Complexities of Practically Applying the Current Standards of Disclosure

Chapter Overview

This thesis has established that the standards developed by *The President's Commission* are defensible against common criticisms and a good guide for health professionals. However, as expressed, the main issue is the standards' reliance on the notion of harm and the complexity of harm itself. This chapter will utilize two case studies to demonstrate the complexities of the practical application of the standards because they rely on the notion of harm. This chapter will argue and demonstrate that we must ultimately determine whether disclosure without consent is a harm or a wrong. As explained above, an action may create a harm (defined as an action or event that invades a person's interests)[259] but be ethically justified when it is used to prevent greater such harm to another. Conversely, an action may create a harm that is unethical and unjustified if the harm in question consists of doing wrong (defined as an unjustified action or event that *wrongfully* invades a person's interests)[260] to others. I will use Feinberg's work on harm and the three factors I have developed to determine whether a decision is life-altering and refer to unjustified harms simply as wrongs. So, we have harms, on the one hand, and wrongs, which are unjustified harms, on the other. Whether we classify disclosure as a harm or a wrong will determine if we may justifiably and ethically proceed in breaching patient confidentiality.

The standards as a whole rely on the concept of harm in order to make an ethical decision about disclosure or non-disclosure. Harm is complex, and when using the standards, we must distinguish between a harmful action and a wrongful action. This distinction must be made when practically applying these standards to avoid a mistake in our understanding of the situation. An

[259]Feinberg, Joel. *Harm to Others,* p. 35.
[260] Ibid., p. 35.

improper understanding would result in a moral dilemma as the rights of another would be infringed upon in an unjustified manner. The standards themselves, however, each rely upon and consider harm in different ways. The first standard[261] indirectly relies upon the concept of harm in two ways as we must consider the potential harm that may occur with disclosure. First, some scholars argue that confidentiality ought to be absolute and any form of disclosure is harmful to the patient and to the health care system.[262] Second, it would be harmful for patients to feel pressure to disclose their genetic test results. It must therefore be ensured that the guidelines for informed consent are followed. With this first standard, health care professionals rely on understanding and assessing the potential harm that may occur to either party (the patient or relative) when choosing to begin the consent process for disclosure.

The second standard[263] of disclosure of genetic information relies on harm as it is necessary for harm to be accurately understood and assessed to adequately fulfill this standard. According to this standard, health care professionals must first determine that there will be a high probability of harm if the information is withheld. Health care professionals must also determine that the disclosed information will be used to avert harm.

The third standard[264] relies on harm as it must be determined that the harm the identified individual would suffer would be serious. We must therefore accurately understand this concept in order to assess the potential severity of harm. This standard relies on health care professionals determining the severity of harm to be significant for this standard to be satisfied.

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[261] Please refer to Appendix D
[262] For instance, Kottow argues that medical confidentiality ought to be absolute and is a requirement in the health care system. Please see, Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation," p. 117-122.
[263] Please see Appendix D
[264] Please see Appendix D

The final standard[265] relies on the concept of harm differently than the second and third standard. This standard, like the first, also indirectly relies on the concept of harm. This standard requires us to consider harm by taking the appropriate precautions to prevent harm to either party (the patient or the relative). It must be ensured, when disclosing the genetic information, that only the necessary information for diagnosis and treatment is disclosed. This standard requires that only appropriate individuals should be warned and that the patient remain anonymous. Health care professionals must work towards preventing harm when disclosing the genetic test results.

Each of the four standards relies on the notion of harm differently. Yet, with each standard, the underlying complicating factor is harm itself. Health care professionals must understand and do their best to minimize harm when disclosing genetic test results. It is evident that the second and third standard rely the most heavily on harm. However, the first and last standard still maintain harm as an underlying component when proceeding in the disclosure of genetic test results. As a whole these standards strongly rely on harm, which ultimately complicates the disclosure process. Further, it must also be determined whether disclosure is a harm or a wrong. This distinction will ultimately determine whether breaching confidentiality may be done in an ethical and justified manner. This chapter will use two case studies to better demonstrate the complicated nature of the standard's reliance on harm and the important distinction between harming and wronging.

The first case that will be discussed is a recent case development in the United Kingdom (UK). In this case, a woman is suing physicians for their failure to warn her of her father's diagnosis of Huntington's Disease. The second case will be hypothetical. This hypothetical case will use the genetic heart condition, arrhythmogenic right ventricular cardiomyopathy

[265] Please see Appendix D

(ARVC)[266], commonly found in the people of Newfoundland and Labrador.[267] These two examples have been chosen as the first case demonstrates that the woman's personal circumstances strongly impacted the decision of whether or not to disclose genetic test results. On the contrary, the second case shows the severity of certain diseases and how the potential harm to the relative overrides the duty to uphold confidentiality even without consideration of personal circumstances. The final section of this chapter will further discuss the important distinction between a harm and a wrong and the importance of assessing the degree and probability of harm. These two diseases are *fully penetrant*, meaning that the offspring have a 50% likelihood of inheriting the genetic variant and developing the disorder. If the genetic variant is inherited, the question becomes when and how will the symptoms present themselves.

Section 1 The Huntington Disease Case

In health care, physicians may be confronted with the challenge between their obligation of confidentiality to their patients and their duty to warn patient family members. Genetic testing has only exasperated this problem as results reveal information not only about the patient undergoing testing, but also biological relatives. This issue has been ongoing, and Dyer explains that physicians may be required to disclose genetic test results for hereditary conditions to biological family members due to a new duty of care.[268] This new duty of care is central to the first case example being analyzed in this chapter.

I will begin by providing specific details of the fatal disease of Huntington Disease. The disease overview will be followed by a review of the case details itself, an application of the four

[266] Please note that ARVC and Huntington's Disease are fully penetrant, meaning that offspring will acquire this disease and it is just a matter of when.
[267] Pullman, Daryl, and Hodgkinson, Kathy. "Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice." *Clinical Genetics* 69, no. 3 (2006): 199-203., p. 200. https://doi.org/10.1111/j.1399-0004.2006.00581.x.
[268] Dyer, Clare. "Huntington's Case Raises Questions about Passing Gene Test Results to Relatives." *BMJ* 357 (2017): J2433, p. 1. https://doi.org/10.1136/bmj.j2433.

current standards of disclosure, and a discussion of the distinction between a harm and a wrong. The analysis will prove that a biological relative's personal circumstances can determine whether disclosure is a harm or a wrong. In this case, disclosure is justified as non-disclosure would be classified as a wrong because of the woman's situation. The woman is early in her pregnancy and about to become a single mother. The risk of inheriting this disease poses a serious threat to the woman and knowledge of the information would have allowed her to make an informed decision about her life and the life of her unborn child. I will argue and demonstrate that this case qualifies as an exceptional circumstance where there is a moral and ethical obligation to breach confidentiality to prevent serious harm. There are two main reasons why patient confidentiality must be breached. First, failure to breach confidentiality and disclose the father's genetic test results poses a direct harm to the woman. Second, the disclosure of these test results would allow her to make informed and knowledgeable decisions regarding her health and future.

1.1 Huntington Disease Information

Huntington Disease is a unique and destructive disease that has no known cure. This hereditary disease is both physically and mentally painful and unfortunately, results in death. This neurological disorder causes "irregular and involuntary" muscle movements caused by a genetic mutation in the brain that controls these movements.[269] The symptoms of this disease are usually first noticed in individuals in their mid-thirties to fifties. The occasional uncontrollable muscle movements progress into what is described as "random, uncontrollable, and often violent twitching and jerks".[270] As this disease progresses, those diagnosed will display signs of mental deterioration which may include, "memory loss, dementia, bipolar disorder or schizophrenia".[271]

[269] "Huntington Chorea," 2014, Britannica Concise Encyclopedia.
[270] Ibid.
[271] Ibid.

Unfortunately, this disease that has no known cure or therapy, and individuals have a fifty percent likelihood of passing this gene to their off-spring. The high probability of children inheriting this disease is an important element when considering the specific details of this case.[272]

1.2 The Huntington Case Details

The identities of the individuals of this case have not yet been released due to confidentiality. However, the personal details and circumstances of each party have been provided. A woman in the UK filed a lawsuit against her father's physician for neglecting to inform her that her biological father had been diagnosed with Huntington's disease. The High Court, Mr. Justice Nicol, declared that the case had no chance of a successful argument and was consequently dismissed. Mr. Justice Nicol stated that this case would have been a "'giant step'… to impose liability in the circumstances, and the proper development of the common law of negligence was supposed to be by incremental steps".[273] However, this initial decision was unanimously overruled by three appeal court judges. The court of appeal cited two court cases from the United States as examples where confidentiality was breached to disclose medical information to third parties.[274]

This case dates back to 2007 when the father of the woman (plaintiff) was convicted of manslaughter after murdering her mother. The father was not sentenced to jail time; rather, he was sentenced to hospital order as there was suspicion that he was not mentally well. Two years later, in 2009, the father was diagnosed with Huntington's Disease, and this disease was determined to be the cause of his actions. Following his diagnosis, a multidisciplinary team was formed to discuss whether the man's three biological daughters should be informed of his recent

[272] Ibid.
[273] Dyer, Clare. "Huntington's Case Raises Questions about Passing Gene Test Results to Relatives," p. 1.
[274] Ibid., p. 1.

diagnosis. However, the challenge was that the patient (father) stated he would not consent to disclose his test results. He did not want his test results disclosed because he had recently discovered that his daughter, the plaintiff, was pregnant. The father feared that the emotional and psychological effects of knowing this information would lead his pregnant daughter to take her own life or have an abortion. In this case, the physicians chose to withhold the man's diagnosis and not warn his daughters of their risk of inheriting Huntington's.[275]

In 2010, following the plaintiff's pregnancy, the woman inadvertently learned that her father had been diagnosed with the disease. The woman did not take any action at the time; however, she chose to undergo genetic testing three years later. The genetic test revealed that she, too, had Huntington's. With this discovery, she proceeded to sue her father's physician for failing to warn her of her likelihood of inheriting this genetic disease. The plaintiff states that she would have chosen to have an abortion if she had been aware of her high probability of inheriting the disease.[276] The woman claims that "doctors owed her a duty of care, even though she was not their patient".[277]

Additionally, she explained that the medical staff was aware that she was pregnant at the time and about to become a single mother with full responsibility for her unborn child. Contrarily, the physician's lawyer did not believe that a duty of care was appropriate under these circumstances.[278] The lawyer stated that this would place physicians "under conflicting obligation" and make them "liable to be sued by their patients if they disclose confidential information or by third parties if they fail to disclose it".[279]

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[275] Ibid., p. 1.
[276] Ibid., p. 1.
[277] Ibid., p. 1.
[278] Ibid., p. 1.
[279] Ibid., p.1.

Section 2 Application of the Standards

This section will apply the current standards of disclosure to the present case. The practical application of these standards is the first step that a health care professional must take to determine whether or not disclosure is ethically justifiable. The analysis will demonstrate the practical challenges of applying the standard of disclosure in the decision-making process to determine the justifiability of breaching patient confidentiality with specific reference to the case details. The distinction between a harm and a wrong will also be demonstrated. Without this distinction the result would be a moral dilemma because the right of another would be infringed upon in an unjustified manner. The findings in this section will demonstrate that disclosure is ethically justified as non-disclosure would result in a wrong. However, the practical application of the standards is complicated by their reliance on the notion of harm.

2.1 *The President's Commission* Standard #1

To satisfy the first standard of *The President's Commission*[280], the physician must first seek consent from the patient (father) to disclose his genetic test results. As previously defined in Chapter Two, informed consent occurs when a "capacitated (or 'competent') patient or research participant to whom full disclosures have been made and who understands fully all that has been disclosed consents voluntarily to treatment or participation on this basis".[281] The physician must ensure that the consent is voluntary, the patient is competent and that the patient has the ability to evaluate the risks and benefits. Lastly, the physician must confirm that the patient is capable of communicating and expressing their decision.[282] As explained in the case details, the physicians

[280] See Appendix D
[281] Eyal, Nir, "Informed Consent," *The Stanford Encyclopedia of Philosophy*.
[282] Ibid.

asked the father to consent to disclosing his genetic test results to his three daughters. The father refused, and this refusal is what has brought about this current legal case.

While the physician appears to have taken the appropriate step in seeking consent, it is not clear that the father was capable of making an informed decision. In 2010, a forensic social worker stated, "I do not think that [the father] is able to understand the implications of his illness, the possible speed of his deterioration, or the effects it will have, both on him and his family".[283] This statement establishes that the father, at the time, was not capable of making an informed decision about whether his children should be warned about his recent diagnosis. The father expressed his concern that his pregnant daughter may take her own life or chose to have an abortion if she was aware of his diagnosis. The social worker's findings demonstrate that he could not fully understand the situation at hand. While the father has a right to have fears over how his children may react, it is evident that the daughter did not want to take her own life. Instead, she expressed that she would have chosen to have an abortion. The father may have believed that abortion is the wrong decision.

Nonetheless, the father had no right to make that decision for his daughter or use his belief that abortion is the wrong decision for his daughter as a legitimate reason for not disclosing his genetic test results. Given that the father's mental state was questionable, the physician was not able to obtain voluntary consent. We conclude that the physician attempted to obtain voluntary consent, but that it was not possible.

In contemplating this standard, we may consider how the principle of harm is indirectly relied upon in two ways. The first argument is that confidentiality ought to be absolute[284] and that a breach would result in harm to the patient. Confidentiality is highly valued in health care and

[283] Dyer, Clare, "Huntington's Case Raises Questions about Passing Gene Test Results to Relatives," p. 1.
[284] Scholars, such as M.H. Kottow, believe that no circumstance will warrant a breach in confidentiality.

patients trust that their information will remain within their circle of care.[285] This is harmful as patients may lose trust in the health care system, be unwilling to seek future treatment or undergo genetic testing and may choose to withhold important health information in the future. These adverse outcomes caused by breaching confidentiality has the potential to harm the health and well-being of the patient in the future.[286] However, in exceptional circumstances, such as in this case, a breach in confidentiality is justified to prevent greater harm (or a decision that would be considered a wrong) to the daughter. It is true that breaching confidentiality will result in harm to the father (as described above regarding harm to patients). Contrarily, non-disclosure would also result in harm to the daughter. Without knowledge of this information the woman's autonomy is limited and she is unable to make an informed and educated decisions about her life and the life of her unborn child. It must be determined which decision, disclosure or non-disclosure, would be considered a wrong. This determination will be made using the second and third standard of disclosure of genetic information.

This first standard, as stated, indirectly relies on the notion of harm as we must consider the potential harm resulting from disclosure or non-disclosure, rather than considering how the standard itself relies on harm. This indirect reliance is a necessary consideration for health care professionals as they must think abstractly about how a patient or relative may be harmed. This standard needs to consider what will occur if the genetic information is disclosed or not disclosed. Further, health professionals must contemplate which decision will result in a harm and which decision will result in a wrong. Which decision will result in a harm or a wrong is a necessary consideration. It will determine whether we may ethically and justifiably proceed with the disclosure of the genetic test results. However, if the disclosure is considered wrong, health

[285] Higgins, Gerald. "The History of Confidentiality in Medicine: The Physician-patient Relationship," p. 921.
[286] Goold, Susan Dorr, "Trust and the Ethics of Health Care Institutions," p. 30.

professionals may not disclose the genetic information. This determination will be used when applying the second and third standards of the disclosure of genetic information.

2.2 *The President's Commission* Standard #2

According to *The President's Commission,* to satisfy the second standard[287] it must be determined there is a high probability of harm without disclosure and that disclosure will prevent harm.[288] As discussed in Chapter Two, these conditions will vary based upon the disease identified and the relative. In this section we must examine the outcome if the information is withheld or disclosed. From this we must ultimately determine whether disclosure or non-disclosure is a harm (which is permissible or acceptable) or a wrong (which is neither).

Huntington's Disease does not express symptoms in the same manner in every individual and has no known cure. The age of onset and the dominant symptoms appear differently in everyone.[289] Additionally, the emotional and psychological impact of disclosure will vary. In this case, we must consider the harm that may come to the father and daughter if the information is disclosed or withheld. The first perspective to be considered is the perspective of the father. If the information is not disclosed, then there will be no harm caused to the father. However, there may be harm if confidentiality is breached. The father was a patient, and an essential component of the doctor-patient relationship is trust. Like the father, patients seek medical treatment when they are at their most vulnerable and are suffering. Health care professionals must recognize this position of vulnerability and create an environment where the patient feels safe to disclose their most personal and sensitive information. The doctor-patient relationship is unequal as the physician is in a position of power and possesses valuable knowledge, whereas the patient, as stated, is

[287] See Appendix D
[288] "Screening and Counseling for Genetic Conditions," p. 1.
[289] "Huntington Chorea," Britannica Concise Encyclopedia.

vulnerable.[290] Due to the uniqueness of this relationship, trust must be established and maintained. A violation of this trust should only occur in exceptional circumstances. Trust is part of the foundation that comforts patients when agreeing to treatment or when following treatment plans.[291]

Additionally, a betrayal of trust may be detrimental to the relationship and have negative consequences. For instance, Goold states that the patient may lose not only trust in physicians, but also the organization, or even the medical field as a whole. Further, in the future, patients may be less willing to reveal sensitive health information and negatively impact their future care.[292]

If the father's genetic information is disclosed, then he would suffer harm from his personal information being disclosed without his consent. The type of harm that the father would suffer is difficult to describe. He would experience psychological and emotional harm caused by the disclosure of his information without his consent and consequently, a breach of his privacy. Emotional harm or emotional distress occurs when an individual has a "highly unpleasant emotional reaction (as anguish, humiliation, or fury) which results from another's conduct…".[293] The conduct of another in this case would be the physician's decision to disclose his genetic test results without his consent. The father will most likely experience an unpleasant emotional reaction if his daughter were told of his test results. He may experience anger towards the health care professionals for disclosing the results or experience anxiety and worry about his daughter's reaction. There is no textbook answer to describe how an individual will express and experience this form of psychological and emotional harm from there test results being disclosed. We may

[290] Goold, Susan Dorr, "Trust and the Ethics of Health Care Institutions," p. 27.
[291] Ibid., 27.
[292] Ibid., p. 30.
[293] "Emotional Distress Legal Definition." https.//www.merriam-webster.com/legal/emotionaldistress

however make assumptions about how they would feel and acknowledge that they will experience harm.

The father may also face significant losses. Stanard and Hazler state that one loss may be a loss of relationships, such as with his children or his current physician.[294] The decision to disclose genetic information "can only exacerbate the difficulties faced by clients already dealing with a life-threatening illness".[295] However, health care professionals must also consider how a failure to disclose genetic test results to biological family members places others at risk. The harm to the woman based on her current situation is greater than the harm to the father. Therefore, the harm is justified and not classified as a wrong.

If the woman is not informed of her risk of inheriting Huntington's, she will experience serious harm as Huntington's poses a serious risk to her. The type of harm that the woman will experience is challenging to describe and is also a form of psychological and emotional harm. For the woman however, this type of harm is caused by not knowing. By not knowing her risk of Huntington's Disease, this woman is incapable of making informed decisions about her life and the life of her unborn. There is harm in not being informed about one's risk of inheriting a deadly disease as there is harm in making plans without that knowledge of one's risk. The woman will only recognize and experience this psychological and emotional harm after the information (her risk of inheriting Huntington's) is learned.

The physician knew personal information about the daughter and that she was early in her pregnancy. Those diagnosed with Huntington's Disease have a high probability (50%) of passing this disease to their offspring. This disease is fatal, and the physical and mental deterioration is

[294] Stanard, Rebecca, and Hazler, Richard. "Legal and Ethical Implications of HIV and Duty to Warn for Counselors: Does Tarasoff Apply?" p. 399.
[295] Ibid., p. 399.

devastating. This disease does not only impact the individual but also their intimate relationships. In this case, the woman stated that the decision to withhold the test results denied her the opportunity to make an educated and informed decision about her life. She states, "… the future is a terrifying place. The doctor's decision not to tell me meant all my choices were taken away from me".[296] The physician's decision to withhold this information limited the woman's autonomy to make informed and educated decisions about her life and the life of her future child. When the knowledge and information that a physician possesses can alter and considerably impact someone's life, as seen in this case, then there must be, without question, a duty to warn.

This standard relies on the notion of harm as harm must be accurately understood and assessed in order to fulfill this standard. It must first be determined that there is a high probability of harm if the information is withheld. Second, it must also be determined that the disclosed information will be used to avert harm. Therefore, in this case, it is accurate to say that there will in fact be a high probability of harm if the information is withheld. The decision not to disclose the genetic information is a wrong as the harm caused to the woman is unjustified and unnecessary. The information being withheld has denied the woman the opportunity to make an educated decision about her life. Further, if the decision was made to disclose the information this would have averted the harm she is now suffering and experiencing. Ultimately, this standard relies on determining the probability of harm, determining if harm may be prevented and assessing which decision (disclosure or non-disclosure) would be a harm and which would be a wrong. Therefore, this standard relies heavily on the concept of harm when analyzing and applying the standard.

[296] Nelson, Sara C. "Mother To Sue Doctors For Failing To Reveal Her Father Had Huntington's Disease," https://www.huffingtonpost.co.uk/entry/mother-to-sue-doctors-for-failing-to-reveal-her-father-had-huntingtons-disease_uk_5bfbdebfe4b03b230fa3faec.

2.3 *The President's Commission* Standard #3

To satisfy the third standard[297] we must determine the harm the relative would suffer would be serious.[298] Not all hereditary conditions will pose the same threat. For this reason, the likelihood of genetic inheritance and the specific nature of the disease must be taken into consideration. The uniqueness of Huntington's Disease and the case details presented will ultimately require health professionals to breach confidentiality in favour of warning biological relatives. Huntington's has a high probability of harm as it has a 50% likelihood of being passed from parent to offspring. There will be serious harm as there is no treatment or prevention for this disease. As previously expressed, Huntington's causes physical, cognitive, and psychiatric disorders that vary from person to person. It is unpredictable which symptoms will be dominant; however, all disorders associated with this disease are unpleasant and incurable. This disease gradually worsens over time and will result in premature death.[299]

Additionally, we need to consider the personal circumstances of the identified individual. The woman, in this case, was in a vulnerable position. She was pregnant at the time and lacked a support system to help care for her unborn child. The decision not to disclose the genetic test results was a wrong as this resulted in serious harm with no justifiable or excusable reason to withhold this information. The physician's decision to not warn her of her risk denied her the opportunity to make an informed decision about her life. Ultimately, the woman's circumstances and the seriousness of this disease warrants a breach in patient confidentiality. This paragraph discusses the harm caused by the decision *not* to disclose genetic information. This does not address the main analytical task (which is that the application of the standards is complicated

[297] Please see Appendix D
[298] "Screening and Counseling for Genetic Conditions," p. 1.
[299] "Huntington Chorea," Britannica Concise Encyclopedia.

because of their reliance on the notion of harm); however, it is an essential consideration for this case. This is essential because it demonstrates what happens when the standards are either not used or improperly applied and how this creates a moral dilemma and a wrongful invasion of a person's interests.

This standard relies heavily on the notion of harm, and therefore the practical application is challenging as we must determine that the harm the identified individual (biological relative) would suffer would be serious. We must first accurately understand harm in order to assess the severity of the harm. Determining the severity of harm is challenging as in many cases the severity will be unpredictable. In this case, as expressed, the uniqueness of Huntington's Disease and the high risk of inheritance ought to make disclosure necessary. Additionally, the personal circumstances of the woman further confirmed that disclosure is required. Ultimately, this standard relies on physicians determining the severity of harm to be significant in order for this standard to be satisfied. Due to the significant harm to the woman and lack of justified reasoning for not disclosing the genetic test results, disclosure is necessary, and non-disclosure has been determined to be a wrong.

2.4 *The President's Commission* Standard #4

To satisfy the fourth standard[300], once a relative has been identified, and the decision to disclose genetic test results has been made, we must only disclose information relevant to the genetic disease in question. The genetic test results must only be presented to the appropriate individuals, and the anonymity of the patient ought to be preserved when possible.[301] Due to this standard, when choosing to breach confidentiality, we must proceed with caution. The daughter must only be told information that is necessary for her to proceed with testing to determine if she

[300] Please see Appendix D
[301] "Screening and Counseling for Genetic Conditions," p. 44.

carries the gene for Huntington's Disease. It is my view that the daughter must not be told who in her family was diagnosed with this condition as it is clear the father wishes to stay anonymous. While the daughter may presume it is her father that has been diagnosed, that is an acceptable risk. This is an acceptable risk as we have determined that due to the uniqueness of this situation, it would be wrong not to inform the daughter of her potential genetic disease. The disclosure of these test results will ensure that the woman has the necessary information to make informed decisions about her life and the life of her unborn child. To withhold this information would amount to a wrong, and therefore we may ethically proceed to disclose the patient's genetic test results. In this case, the uniqueness of both the disease and the relative's known personal circumstances would render disclosure justified and necessary.

This fourth standard indirectly relies on the notion of harm. This standard requires us to consider harm and relies on taking the appropriate precautions to prevent harm to either party (the patient or the relative). We must ensure, when disclosing the genetic test results, that only the necessary information for diagnosis and treatment is disclosed. Privacy and confidentiality are at the forefront of health care and *The President's Commission* has stated its importance.[302] The standard mandates that only appropriate third-party individuals be warned and that the patient remain anonymous whenever possible. We are therefore required to prevent and consider harm that may occur with the disclosure of genetic test results.

Section 3 The Hypothetical ARVC Case

This second case will be, as stated, hypothetical. This hypothetical case will use the genetic heart condition, arrhythmogenic right ventricular cardiomyopathy (ARVC). This case will demonstrate how the severity and treatability of certain diseases and how the potential

[302] Ibid., p. 44.

serious harm to relatives outweighs the duty to uphold confidentiality even without close consideration of personal circumstances. The discussion will begin with an overview of this hereditary disease and will be followed with the case details and an application of the standards of disclosure. In this case, disclosure will be deemed justified as non-disclosure would be defined as a wrong because of the outcome of the disease and recognition that there is an available treatment. The argument will prove that this case also qualifies as an exceptional circumstance where there is a moral and ethical obligation to breach confidentiality to prevent serious harm.

3.1 ARVC Disease Information

There are currently no documented court cases that involve arrhythmogenic right ventricular cardiomyopathy (ARVC). Therefore, this case involving the genetic condition ARVC will be hypothetical. This particular condition was chosen as it is unique for two distinct reasons. First, there is a treatment available. Second, without treatment or intervention, this disease is fatal.

Arrhythmogenic right ventricular cardiomyopathy (ARVC), commonly found in the people of Newfoundland and Labrador, is a lethal genetic condition. This genetic disease is a cause of sudden cardiac death in younger populations. The clinical diagnosis of this disease remains challenging for physicians. Diagnosis is in general based only on observational and descriptive diagnostic criteria. However, this is not the case in Newfoundland (NL), where diagnosis is determined by the presence or absence of the mutation in TMEM43, discovered in NL.[303] The patient's offspring have a 50% risk of inheriting this treatable genetic condition.[304] This disease places males at a much higher risk than females for disease prognosis. An analysis

[303] This statement was made by Dr. Hodgkinson in her Examiner's Report. I would like to thank Dr. Hodgkinson for her clarification on this matter as this fact was not reflected in the articles I read.
[304] Pullman, Daryl, and Hodgkinson, Kathy. "Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice," p. 200.

of families who carry this gene found that "50% of males die in the absence of treatment by 40 years and 80% by 50 years, with corresponding risks for females 5% and 20%".[305] The effective primary prevention for this disease is available with an implantable cardioverter-defibrillator therapy.[306]

This presents the ethical question of whether there is a duty to warn at-risk relatives. As expressed, there is a 50% chance that an offspring will inherit this disease. As Pullman and Hodgkinson expressed in their paper "Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice", due to the deadliness and treatability of ARVC, even individuals who have a highly conservative position concerning sharing disclosing genetic information without the consent of the patient may support a duty to warn with this disease due to its unique nature.[307]

3.2 The ARVC Case Details

In this hypothetical case, a patient has been diagnosed with ARVC. The patient (female) is sixty years old.[308] The patient has three sons, who are all between the ages of thirty-three and thirty-eight. Due to her children's ages and sex, they are in a dangerous category as 50% of males die by the age of forty if this disease is left untreated. The responses to each of the four standards expressed by *The President's Commission* will be discussed in relation to this hypothetical case example. This case will demonstrate that due to this disease's high risk of mortality, the high-risk of inheritance, the lack of visible symptoms, the treatability of the disease and the value of knowing a biological relative has this disease, test results confirming a diagnosis of ARVC, in

[305] Ibid., p. 200.
[306] Ibid., p. 200.
[307] Ibid., p. 200.
[308] The patient was chosen to be female because females live a more normal lifespan and have fewer clinical issues than males.

this case, must be disclosed. Non-disclosure, in this case, would be a wrong as there lacks a justified reason to keep the genetic test results confidential.

Section 4 Application of the Standards

This section will focus on applying the current standards of disclosure to the present case. The practical application of these standards is the first step that a health care professional must take to determine whether or not disclosure is ethically justifiable. The analysis will demonstrate the practical challenges of applying the standard of disclosure in the decision-making process to determine the justifiability of breaching patient confidentiality with specific reference to the case details. The distinction between a harm and a wrong will also be demonstrated. Without this distinction, the result would be a moral dilemma because the right of another would be infringed upon in an unjustified manner. This distinction prevents a moral dilemma as the individual's rights would be infringed upon for a justified reason if the standards are correctly applied. The findings in this section will demonstrate that disclosure is ethically justified as non-disclosure would result in a wrong. However, the practical application of the standards is complicated by the notion of harm.

4.1 *The President's Commission* Standard #1

To satisfy the first standard[309] health care provider to seek consent from the patient to disclose genetic test results. To obtain informed consent, the physician must confer with a competent individual and fully disclose their professional opinion that the genetic test results should be disclosed to potentially affected biological relatives. Further, the health care professional must ensure that the patient understands what will be disclosed and voluntarily consents to disclose such information. It must be assured that the patient can assess the risks and

[309] Please refer to Appendix D

benefits of disclosing their genetic test results to his three sons. Finally, the woman will be required to communicate her decision.[310]

In this case, the mother is fully competent and aware of the risks and benefits of disclosing this information to his biological sons. However, she has stated that she does not want her sons to be informed of her test results and their potential risk to this genetic disease. The mother says that she is worried about her health and is saddened that she has this genetic condition. She wishes not to disclose this information to her children as she does not want them to feel the anxiousness and worrisome thoughts that she is experiencing. She states that her sons are healthy, active, and take pride in living a balanced lifestyle. The mother also argued that her sons receive regular health check-ups; therefore, she believes that because this is a common disease found in Newfoundland, their family doctor will look for this disease without the interference from her results. The mother does not believe that disclosing this information will benefit her sons and will only promote a fearful mentality for their overall well-being. She further adds that five years ago, their father was diagnosed with kidney cancer. She watched as her sons discussed the fear they had for their health and their father's health. She does not wish to put any further stress on her children. Therefore, for the reasons stated, she vehemently denies disclosing, discussing, or warning her children of her diagnosis so that they may undergo testing to determine if they have this treatable genetic condition.

The mother has stated her reasons for not disclosing her genetic test results to her three children. In this case, the physicians sought informed consent and proceeded to take the appropriate steps to obtain permission to disclose her illness to her three sons. The physician explained the nature of ARVC, the treatability of this disease, and the risks and benefits of

[310] Eyal, Nir, "Informed Consent", *The Stanford Encyclopedia of Philosophy*.

disclosing this information. The physician stated that it is in his professional medical opinion that this information ought to be disclosed. The mother, who is fully competent and aware of the impact of her decision, has stated that she does not consent to the disclosure of her test results. While the mother has said that she does not want her genetic test results disclosed, the four standard's first condition has been satisfied. The health care provider, in this case, has made reasonable efforts to seek voluntary consent.

There are two ways that we may consider harm to better manage the practical application of this standard due to the standard's reliance on harm. The first way we may consider harm is the harm of disclosure as some scholars have argued that confidentiality ought to be absolute. Confidentiality is widely valued within the health care system and a climate of trust is essential. Scholars, such as M.H. Kottow, have stated that confidentiality is an absolute obligation.[311] Therefore, seeking consent would be deemed unnecessary. These scholars fear the harm to the relative and the health care system. However, there are exceptional circumstances, such as this case, which warrant a breach in confidentiality.[312] The mother may experience harm by having her test results disclosed. For instance, she may lose trust in her physician or the health care system. She may also experience a strain in her relationships with her children. However, the harm that may come to her children due to the deadliness of this disease far outweighs the potential harm to the mother. Without informing the patient's sons they will be unable to seek treatment and diagnosis for this treatable disease. It must be determined which decision, disclosure or non-disclosure, would be considered a wrong. This determination will be made using the second and third standard of disclosure of genetic information.

[311] Kottow, M H. "Medical Confidentiality: An Intransigent and Absolute Obligation," p. 117-118.
[312] Goold, Susan Dorr, "Trust and the Ethics of Health Care Institutions," p. 27.

The second potential harm that may occur as a result of this standard is that patients may feel pressure to disclose their genetic test results. Patients should never experience any unethical tactics during the consent process such as coercion, undue inducement, or a no choice situation.[313] This form of pressure is harmful and inappropriate behaviour from any health care professional. Physicians may present the benefits of disclosure but may never pressure the patient to agree to consent. This would render the consent process invalid.

This first standard, as expressed, indirectly relies on the notion of harm. This standard indirectly relies on harm as health care professionals are required to consider the potential harm resulting from disclosure or non-disclosure, instead of considering how the standard itself relies on harm. Health professionals must also consider which decision (disclosure or non-disclosure) will result in a harm or a wrong. This is a necessary consideration as this will determine whether we may ethically and justifiably breach confidentiality. Though, should disclosure be considered a wrong, we may not disclose the genetic information. This determination will be further developed when applying the second and third standards of the disclosure of genetic information.

4.2 *The President's Commission* Standard #2

To satisfy the second standard[314] of disclosure we must determine the outcome for both the father and his children, whether the information was withheld or disclosed. This discussion will then determine which action is the least harmful.

I will begin by discussing the harm that may come to the mother as a result of the disclosure of her genetic test results. If the decision is made not to disclose the genetic the results, then no harm will come to the mother as she does not want them disclosed in the first place. However, as with the first case, the mother in this case would also suffer harm from her personal

[313] Eyal, Nir, "Informed Consent", *The Stanford Encyclopedia of Philosophy*.
[314] Please see Appendix D

information being disclosed without his permission. If the decision is made to breach confidentiality and disclose the genetic test results, the mother in this case will suffer harm. If the decision is made to breach confidentiality, then there will be harm to the doctor-patient relationship. Trust is essential to this relationship, and a breach of confidentiality will undermine the current atmosphere of trust that has been developed.[315] The patient is in a vulnerable position as he has been recently diagnosed with a new illness. The physician is responsible for fostering a safe environment for the patient to feel secure in disclosing personal information. Further, due to the uniqueness of this relationship and the unequal power structure, the physician must only breach confidentiality in exceptional circumstances.[316] Therefore, we must assess if this is an exceptional circumstance which necessitates this breach in confidentiality.

The mother may face other personal losses as well. She may experience strained relationships with her children and a sense of embarrassment should her children ask her about the disease and her health.[317] The children, of course, will not be told which family member has this genetic condition. However, it is reasonable to assume that they will seek answers from their mother as he has described them as having a healthy relationship. Nonetheless, when analyzing the negative consequences and harms that would result in non-disclosure, it will become evident that disclosure is necessary to prevent serious harm and possible death to the patient's biological children. In this case, the harm to her children is greater than the harm to the patient (mother). Therefore, the harm is justified and not classified as a wrong.

We must now look at the potential harm that will happen to the three sons if this information is not disclosed. First, there is a high probability that offspring will inherit ARVC

[315] Goold, Susan Dorr, "Trust and the Ethics of Health Care Institutions," p. 27.
[316] Ibid., p. 27.
[317] Stanard, Rebecca, and Hazler, Richard. "Legal and Ethical Implications of HIV and Duty to Warn for Counselors: Does Tarasoff Apply?" p. 399.

genetically from their parents.[318] As explained in the description of this hypothetical case, children have a 50% risk of inheriting this treatable yet lethal genetic condition.[319] Second, because her children are all male, this places them at an even more serious risk at how the disease will express itself. Studies have found that by the age of 40, 50% of men who have this disease will die if they have not received treatment.[320]

Further, by the age of 50, 80% of men diagnosed will die if they have not received treatment.[321] It is evident by these facts that this disease poses a serious threat to the patient's three biological sons. ARVC is a fatal disease if left untreated. However, there is a known treatment that can prevent death. The effective primary treatment method for ARVC is implantable cardioverter-defibrillator therapy.[322] In this case, it would be morally wrong to not warn the three biological children because there is an available treatment method. This would be morally wrong as informing their children of the risk of inheriting this disease may prevent premature death. The information that the mother's physician possesses can seriously alter the life of their patients' children. Therefore, I argue that due to the seriousness of this illness and the treatment option, a duty to warn is mandatory.

The application of this standard is complicated by its reliance on the notion of harm as harm must be accurately understood and assessed to satisfy this standard. According to this standard, it must be determined that there is a high probability of harm if the information is

[318] Please note, for the genetic disease ARVC, the risk to either sex of inheriting the disease variant is equal. The difference is how the disease affects men and woman. Thank you to Dr. Hodgkinson for providing feedback and explaining this important distinction.
[319] Please note, for an autosomal dominant form of inheritance (such as ARVC), one of the parents must be affected by the disease for their children to have a 50% risk of inheriting the disease variant. I would like to thank Dr. Hodgkinson for explaining this important fact.
[320] Pullman, Daryl, and Hodgkinson, Kathy. "Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice," p. 200.
[321] Ibid., p. 200.
[322] Ibid., p. 200.

withheld. It must also be determined that the disclosed information will be used to avert harm. In this case, there will be a high probability of harm if the information is withheld. Arrhythmogenic right ventricular cardiomyopathy is a treatable genetic condition. Withholding the test results from the three children poses a high risk of harm and the potential for premature death. Disclosure would allow the children to seek treatment and diagnosis. This would ultimately avert serious harm including death. Ultimately, this standard relies on determining the probability of harm, determining if harm may be prevented and assessing which decision (disclosure or non-disclosure) would be a harm and which would be a wrong. Therefore, this standard relies heavily on the concept of harm when analyzing and applying the standard.

4.3 *The President's Commission* Standard #3

To satisfy the third standard[323] health professionals must determine the relative would suffer serious harm. In this case, there has been three individuals identified as potentially at risk of inheriting this disease. Without intervention, a large percentage of individuals will succumb to a premature death (50% of men aged 40 and 80% of men aged 50).[324] Due to the seriousness and treatability of this disease, I am arguing that the physician will be required to breach confidentiality. There will be serious harm to the biological relatives if they are not warned of their predisposition to this disease. Without intervention or a warning from the mother's physician, the relatives will lose the opportunity to act and avoid a potentially premature death. Non-disclosure in this case is a wrong as there is no justifiable or excusable reason to withhold this information. Additionally, withholding the genetic test results denies the three sons the opportunity to be tested, access treatment and prevent an early and preventable death.

[323] Please see Appendix D
[324] Pullman, Daryl, and Hodgkinson, Kathy. "Genetic Knowledge and Moral Responsibility: Ambiguity at the Interface of Genetic Research and Clinical Practice," p. 200.

This standard relies heavily on the notion of harm as we must determine that the harm the identified individual (in this case, the patient's three sons) would suffer would be serious. Therefore, we are required to accurately understand harm in order to assess the severity of harm. Determining the severity of harm is difficult and often challenging to predict. In this case, ARVC has a high risk of inheritance and is a lethal yet treatable disease. Therefore, disclosure of the genetic test results is necessary to prevent serious harm. Additionally, non-disclosure would result in a morally wrong action due to the case details and the nature of this disease.

This standard relies on physicians determining that the harm the relative will suffer will be serious in order for the standard to be satisfied. To make this determination is complicated as each case will be different. Therefore, this will present a challenge for health care professionals to determine the harm that a relative may suffer. However, there will be certain diseases that ought to immediately require a duty to warn, such as with this case. Though, health professionals will be presented with cases where it is less apparent, the severity of harm a relative would suffer. Thus, making this determination even more challenging.

4.4 *The President's Commission* Standard #4

To satisfy the fourth standard[325], once a relative has been identified, this standard requires physicians only to disclose information necessary for the patient relative to know for diagnosis and treatment. Therefore, in this case, the relative would only need to be warned that they have a genetic predisposition to ARVC. The three sons would not be informed that their mother has this genetic condition as the mother wishes not to reveal herself as the carrier. The results should only be presented to the three potentially impacted individuals, and only the necessary information

[325] Please see Appendix D

should be disclosed. By disclosing only necessary information, this will help to protect the identity of the mother.

As with the first case, the three sons may suspect that they inherited the condition from their mother. This, again, is an acceptable risk as we have evaluated the harm that will occur for both disclosure and non-disclosure. It was determined that the biological relatives would suffer greater harm (possible death) then the mother (a breach in confidentiality). It would be morally wrong not to inform the patient's three adult children of their risk of inheriting this disease because of the high likelihood and severity of harm without disclosure. Due to the high likelihood of inheritance, the serious harm, and the treatability of the disease, disclosure is necessary. In general, regardless of the patient's personal circumstances and their biological relatives, ARVC ought to be viewed as a disease that constitutes an automatic duty to warn.

There may be emotional or psychological harm experienced by the relative should they wish not to know their susceptibility to a genetic disorder. The relative may feel anxious, depressed, or other forms of psychological harm from learning their risk of a genetic disease. However, when evaluating whether to disclose the genetic information, there is a stronger argument to be made to disclose and create an honest dialogue about the relative's risk of inheriting a genetic disease. Biological relatives will only be informed if they are at serious risk and there is foreseeable harm. In this case, the patient's children have a high likelihood of inheritance and will experience serious harm (potentially death) should they carry the gene for ARVC. Disclosure will allow the three sons to undergo genetic testing, determine if they are susceptible to this disease, and seek treatment to prevent an early and avoidable death. Further, this is a treatable disease; however, it is lethal if left untreated. Therefore, non-disclosure poses the threat of serious harm and ought to be disclosed in this case. Non-disclosure would be

considered a wrong due to the lethal and treatable nature of this genetic disease. The genetic test results in this case must be disclosed.

As previously stated, it is true that the three sons may assume that it is their mother that has been diagnosed with ARVC, due to the genetic nature of this disease. However, it has been accepted that this is a justifiable risk as non-disclosure would be a wrong. The mother may experience harm by having his test results disclosed. This may include a loss of trust in health care providers or the health system as a whole, unwillingness to seek future treatment, or a future unwillingness to participate in genetic testing. However, this harm is justified as the harm to the three sons is greater and more serious than the potential harm to the father.

This standard relies on the concept of harm differently than the second and third standard. This standard requires physicians to consider harm and relies on them taking the appropriate precautions to prevent harm to either the patient or the relative. When choosing to disclose the genetic test results, we must be certain that only the necessary information for diagnosis and treatment is disclosed. The standard mandates that only appropriate third party individuals may be warned and that the patient must remain anonymous whenever possible. Privacy and confidentiality are important, and this standard ensures that only appropriate third-parties will be warned and that the patient will remain anonymous whenever possible. Ultimately, health care professionals must prevent and consider harm that may occur with the disclosure of genetic test results.

Chapter Summary

This fourth chapter applied two case studies to demonstrate the complexities of the practical application of *The President's Commission* standards due to their heavy reliance on the notion of harm. This chapter argued and established that we must determine whether disclosure without consent is a harm or a wrong and this will determine whether we may ethically breach

confidentiality. The first case utilized was a case from the United Kingdom in which a woman is suing physicians for their failure to warn her of her father's diagnosis of Huntington Disease. The second case was hypothetical. The hypothetical case focused on the genetic heart condition, arrhythmogenic right ventricular cardiomyopathy (ARVC). These two case examples were chosen as the Huntington's case demonstrated how the personal circumstances of the relative seriously impacts whether or not to disclose genetic test results. On the contrary, the ARVC case demonstrated how the severity and treatability of certain diseases and the potential serious harm to relatives overrides the duty to uphold confidentiality.

The first and second section of this chapter discussed the Huntington case and the ARVC Case in great detail and was followed by applying the current standards of disclosure. This practical application of the standards is the first step required by health care professionals to determine whether or not disclosure is ethically justifiable. The findings in these sections demonstrated that disclosure in each case is ethically justified. However, the decision of whether to disclose genetic test results was complicated by the notion of harm. The final section of this chapter discussed in detail the important distinction that must be made between a harm and a wrong in the decision-making process. This section discussed the important moral distinction between a harm and a wrong, which ultimately determines if disclosure is morally justified. To make this determination it was demonstrated how health professionals must use the current standards of disclosure and the three considerations (long-term, physical and psychological impact of disclosure or non-disclosure) to render an ethically justified decision. This section also discussed the challenges of determining the degree and probability of harm. The current situations of the relatives ought to be considered, and the potential outcome of disclosure or non-disclosure must be examined. The case examples and arguments presented throughout this

chapter strongly support that the practical application of the current standards of disclosure are complicated because of their reliance on the notion of harm.

Chapter 5: Summary and Conclusion of Findings

Section 1 Summary of Chapters

This chapter will serve as a conclusion to summarize the arguments, claims, and literature references that have been made throughout this thesis. A descriptive summary of each chapter will be provided to highlight the important arguments that have been developed. This thesis has argued that the standards developed by *The President's Commission*[326] are a good guide for health care professionals challenged by the duty to warn and patient confidentiality within the context of genetic testing. However, there are challenges when applying these standards to the decision-making process about breaching confidentiality because of their reliance on the notion of harm. Harm is complex, and when applying the standards, we must distinguish between a harmful action and a wrongful action. This distinction between a harmful action and a wrongful action must be made when practically applying the standards to avoid a mistake in our understanding of the situation. An improper understanding of harm would result in a moral dilemma as the rights of another (the patient or relative) would be infringed upon in an unjustified manner.

Chapter One's purpose was to introduce the topic of this thesis and provide sufficient background information to ensure readers had adequate knowledge to understand the subsequent chapters. Chapter One provided a detailed overview of the history and progress of genetic testing to convey the complexity of this field. This field is complex as biological relationships are at the core of genetic testing. Genetic tests reveal information about multiple individuals and in some cases, biological relatives may have a legitimate claim to access these test results if it reveals a

[326] Please refer to Appendix D

hereditary disease.[327] If a patient refuses to share their results with biological relatives, health care professionals will be confronted with an ethical dilemma between confidentiality and duty to warn. Therefore, whether or not to disclose the test results must be carefully assessed using the standards developed by *The President's Commission*.

Chapter Two focused on arguing and demonstrating that the standards of disclosure developed by *The President's Commission* are defensible against common criticisms and are a good guide for health professionals. This was achieved by presenting comprehensive responses to three potential criticisms for the current standards of disclosure of genetic information. Chapter Two used the three most common criticisms of the disclosure of genetic test results and applied them specifically to *The President's Commission* standards. The responses to these three criticisms established that the current standards are a good guide for health professionals.

Chapter Three probed the complexity of harm and discussed the challenges of practically applying the standards of disclosure because of their reliance on this principle. Feinberg's third sense of harm allows us to understand this principle and apply it to decisions regarding genetic testing as it makes the important moral distinction between a harm and a wrong. This distinction between a harm and a wrong will determine whether disclosure is morally justified and whether we may justly invade the interests of another. Additionally, I presented three considerations to provide clear guidance to health professionals to determine whether a decision is life-altering which answered the important question "where is the line between a harm and a wrong?"

Chapter Four used two case studies to demonstrate the challenges of practically applying the *President's Commission* standards' due to their reliance on the notion of harm. This chapter argued and established that we must determine whether disclosure or non-disclosure is a harm or

[327] Burnett, J W. "A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease," p. 561.

a wrong to determine whether we may ethically breach confidentiality. The first case utilized was from the United Kingdom (UK), in which a woman is suing physicians for their failure to warn her of her father's diagnosis of Huntington Disease. The second case was hypothetical and focused on the genetic heart condition, arrhythmogenic right ventricular cardiomyopathy (ARVC).

Section 2 Summary of Findings and Conclusion

Genetics has produced numerous positive benefits to the health and well-being of our society. Individuals can now determine their susceptibility to genetic conditions and thus take preventative measures and make informed decisions about their life.[328] However, these benefits were accompanied by many new and challenging obstacles for health care professionals.[329] As genetics is deeply rooted in social and biological relationships, test results do not merely reveal information about one individual. Instead, the information obtained through these test results reveals information about multiple individuals. Therefore, health professionals must balance their professional obligations towards their patients and moral obligations towards patient relatives. This thesis has argued that the standards developed by *The 1983 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research*[330] remain the current best practice standards for health care professionals challenged by the duty to warn and patient confidentiality within the context of genetic testing. However, there are challenges when practically applying these standards to the decision-making process because of their reliance on the notion of harm. Harm is complex, and when using the standards, professionals must

[328] "What Are the Benefits of Genetic Testing? - Genetics Home Reference - NIH." U.S. National Library of Medicine. National Institutes of Health, October 29, 2019. https://ghr.nlm.nih.gov/primer/testing/benefits.
[329] It is important to note that these ethical challenges have existed in genetics for decades and new challenges will continue to present themselves as science and technology continue to advance. There are many potential ways for these ethical issues to manifest themselves.
[330] "Screening and Counseling for Genetic Conditions," p. 44.

distinguish between a harmful action and a wrongful action. This thesis argued that this distinction must be made when practically applying these standards to avoid a mistake in our understanding of the situation. An improper understanding would result in a moral issue as the rights of another would be infringed upon in an unjustified manner.

This final chapter has served as a conclusion to summarize the arguments, claims, and literature references made throughout this thesis. A synopsis of each chapter was provided to highlight the important claims made throughout this paper. This thesis has established that the standards developed by *The President's Commission* are, in fact, the current best practice. However, as expressed, the main issue is the standards' reliance on the notion of harm and the complexity of harm itself. The distinction between a harmful action and a wrongful action must be established when choosing whether to breach confidentiality. Without this distinction, the result could be a moral issue because the right of another may be infringed upon in an unjustified manner. Nonetheless, regardless of the challenges in applying the standards, these standards remain the current best practice for health professionals confronted with the challenge between their professional obligations to confidentiality and their moral obligations to patient relatives.

Section 3 Discussion on Future Research, Questions and Important Conclusions Found in this Thesis

The work that has been so far in this thesis has the potential to be taken further. This thesis has acknowledged and spoken to a gap in the current bioethics literature. The existing literature developed by scholars has failed to criticize the current standards of disclosure directly. Instead, the disclosure of genetic test results has been criticized as a whole. I invite academics to critically analyze these disclosure standards and provide further criticism and feedback on the disclosure criteria. A dialogue through literature between academics can improve upon the practical application of these standards to ensure disclosure is ethical.

This thesis has brought to the surface how there is still more work and questions to be answered. First, in Chapter Three and Chapter Four, I discussed the degree and probability of harm. This thesis established that health professionals must look at both the patient and relatives' interests and current situations when determining the degree and probability of harm. This discussion was brief, and more work needs to be done in this area. In order to help guide health care professionals in evaluating the risks and probability of harm more work must be done to identify specific criteria to guide health professionals with their analysis when determining whether to disclose or withhold genetic test results. This thesis has also brought up important social questions such as, "how does disclosure impact family relationships?". While this thesis is not able to provide an answer to this question, research on this topic would be fascinating. As bioethicists, we discuss moral values and create standards and expectations, yet; we do not always see the outcome of our recommendations. A study where the outcomes of the suggestions presented throughout this thesis are discussed may help us better understand the reality of harm which is central to this thesis.

Further, it is important to note that ethical challenges have existed in genetics for decades and new challenges will continue to present themselves as science and technology advances. There are many potential ways for these ethical issues to manifest themselves. For instance, direct-to-consumer testing has continued to gain traction and interest amongst the public and will be an important area of future research. This requires further research surrounding the type of information these online genetic tests reveal. Suppose an individual wants to know about their Celtic ancestry, but their results also revealed a genetic disorder. Does the company have a duty to warn its consumers? These advances in genetic testing have occurred very recently, and future

research surrounding this area will be essential to protect the public and understand the purpose of these online platforms.[331]

The conclusions reached through my examination will be useful for those who struggle with when to disclose genetic information to family members. Those who are confronted with the challenge between their moral duty to warn patient relatives and their duty to uphold patient confidentiality (such as physicians, genetic counselors, or other health care professionals) may use the research presented in this project to help make this determination. Health care professionals can apply the presented arguments, literature references, and case examples to determine what qualifies as ethical and justifiable circumstances for disclosure. When an issue arises, which requires a decision to be made, understanding the standard's reliance on the notion of harm will lead to better and more ethically sound decisions in our health care system.

[331] Thank you to Dr. Hodgkinson for this recommendation for a future area of study in genetic testing.

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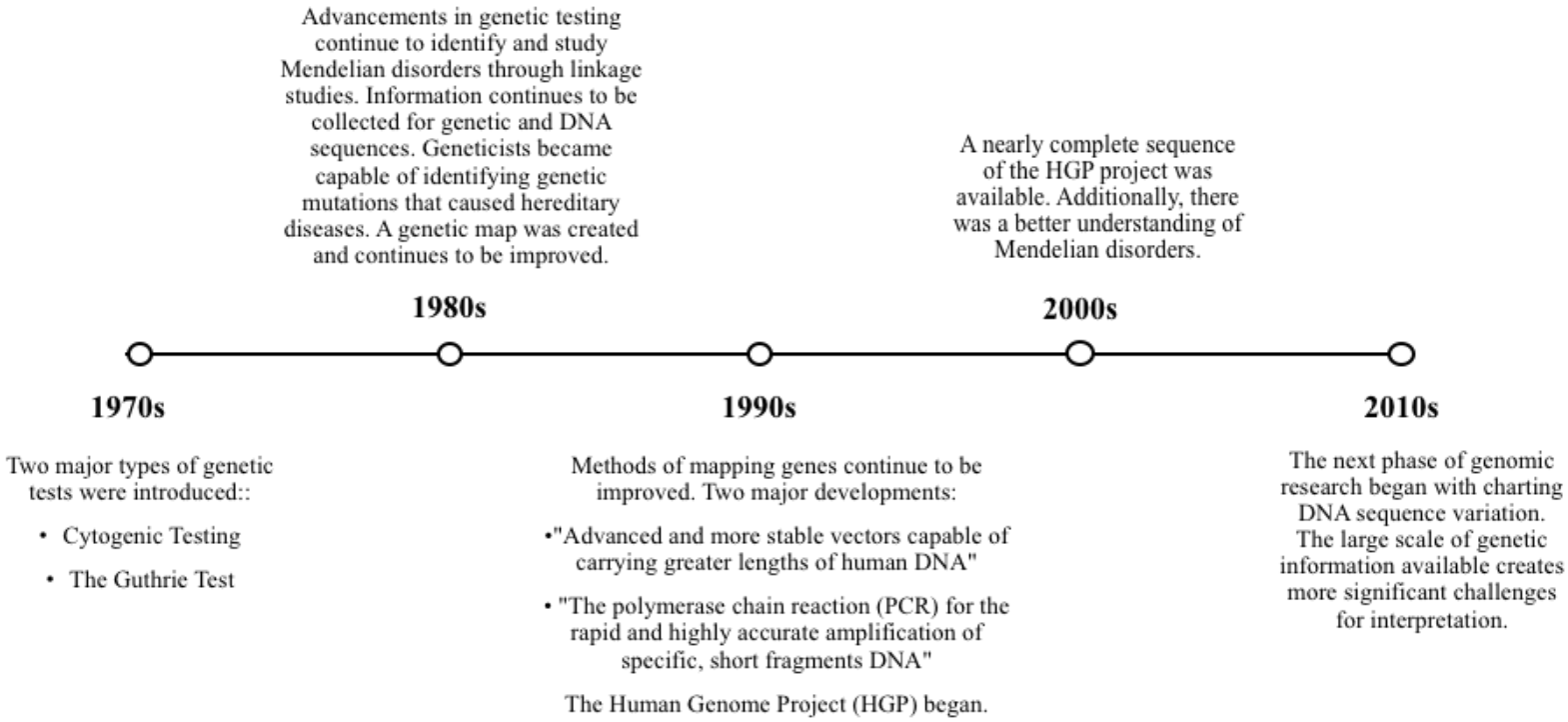
Appendix A

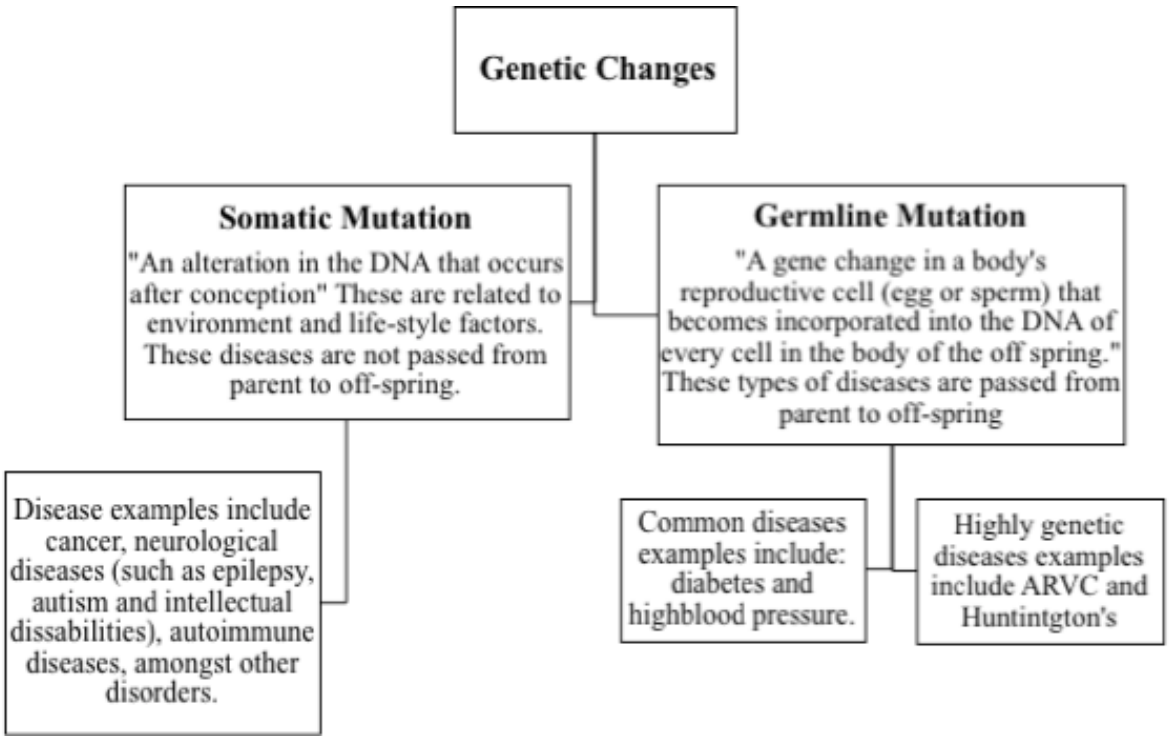
This appendix is used to demonstrate the timeline of the advancements in technology and genetic testing.[332]



[332] Diagram information and direct quotations from: Arribas-Ayllon, Michael, Sarangi, Srikant, and Clarke, Angus. Genetic Testing: Accounts of Autonomy, Responsibility and Blame. Florence: Routledge, 2011, p. 15. https://doi.org /10.1080/09687599.2014.964509.

Appendix B

This appendix demonstrates the types of genetic mutations.[333]

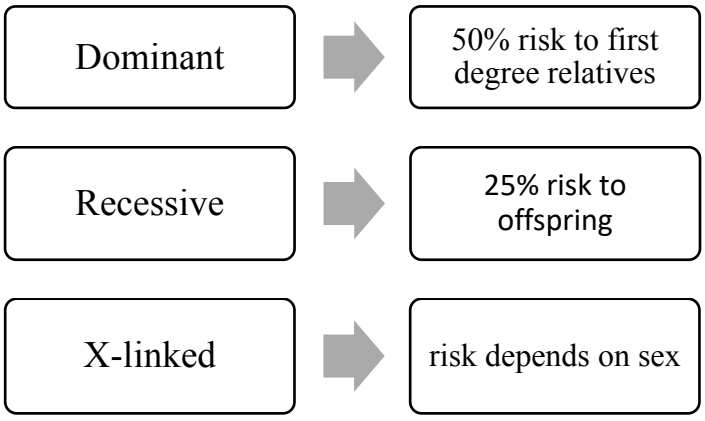


[333] Definition of "Somatic Mutations." National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer terms/def/somatic-mutation. Disease examples of somatic mutations from Li, Chun, and Scott M Williams. "Human Somatic Variation: It's Not Just for Cancer Anymore." Current genetic medicine reports 1, no. 4 (2013): 212–218., p. 213. Definition of germline mutation from "Germline Mutation." National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/germline-mutation. Thank you also to Dr. Hodgkinson for providing examples of the common diseases and highly genetic diseases of germline mutations.

Appendix C

This appendix is used to demonstrate the risk of inheritance.[334]

Risk of Inheritance



[334] Thank you to Dr. Hodgkinson for explaining the risk of inheritance.

Appendix D

The President's Commission standards of disclosure:[335]

Standard #1	reasonable efforts to elicit voluntary consent to disclosure have failed;
Standard #2	there is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm;
Standard #3	the harm that identifiable individuals would suffer would be serious; and
Standard #4	appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.

[335] "Screening and Counseling for Genetic Conditions." National Information Resource on Ethics and Human Genetics. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, February 1983., p. 4.