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My Sister's Keeper:

An Exploration of Ethical Issues

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A designer baby, as they have come to be known, is a child genetically engineered in vitro for selected traits. Currently, individuals can select gender, traits to lower the child's risk of disease, or to ensure they are a genetic match for another individual. In *My Sister's Keeper*, Kate battled leukemia for years when doctors revealed she would eventually need a bone marrow transplant. After her family members tested negative as genetic matches, other options had to be explored. Embryos were created through in vitro fertilization and screened, using preimplantation genetic diagnosis, to determine which would be a genetic match for Kate. The genetically matched embryo was implanted into Sarah's womb; and Anna was born. Within her short thirteen years of life, Anna had undergone multiple surgeries to donate blood and bone marrow to her sister.

Although it sounds like a science fiction concept, designer babes are becoming increasingly common in the world of medicine. Parents carrying genes that place their children at risk for serious disease such as sickle cell anemia, cystic fibrosis, and Fanconi anemia use preimplantation genetic diagnosis to select embryos that are not predisposed to these conditions. However, with the rapid advancement of technology, designer children selected for physical traits or attributes such as hair/eye color, height, or athleticism may shortly become a reality. Whether or not the use of this new technology is ethical is dependent on the way that individuals choose to use it. In *My Sister's Keeper* Anna's parents abused the process of preimplantation genetic diagnosis by conceiving a child whose sole purpose is to be a donor; devaluing and risking the quality of that child's life. Anna was never consulted before each procedure or given the option to refuse assuming she was willing to undergo any medical procedure to save her sister. Kate's medical needs were put at the forefront while Anna's desires and emotions fell to the wayside. This unequal treatment resulted from a parental conflict of interest. Her parent's

judgment was clouded by their concern for their oldest daughter and therefore made biased decisions. The procedures used to improve Kate's quality of life prevented Anna from living a normal childhood.

The years of pain and suffering led Anna to sue her parents for medical emancipation so she would not have to donate her kidney to Kate. As the legal battle ensued, Anna confessed Kate had asked her not to donate her kidney because she was tired of suffering and wanted to die. Despite the sisters' desire to discontinue treatment, the parents assumed responsibility in making their daughters' medical decisions. They never gave their daughters the choice to refuse procedures, which brings awareness to the importance of informed consent (Picoult, 2004). Informed consent is the basic legal-ethical principle that states health care professionals need to properly educate patients and receive permission before performing medical procedures (Purtilo, 2005, p. 210). The neglect of informed consent was due to the parents' desperation to control Kate's fate and the physicians' failure to counsel their patients. The creation of designer babies to save another sibling complicates who has the right to make decisions.

Although fictitious, *My Sister's Keeper* is based on the real-life case of Adam Nash, who like Anna, was genetically produced to be a perfect stem cell and bone marrow match for his sister. Adam has come to be known as the first savior sibling because he provided life-saving umbilical cord blood to his sister, Molly Nash, who was born with Fanconi anemia. This rare disease is characterized by damage to the bone marrow, which causes a deficiency in blood cells that can only be treated with a bone marrow or umbilical stem cell transplantation (Josefson, 2000). In present-day, informed consent is standard before a patient can be treated or participate in scientific research. However, cases involving savior siblings are the exception; considering that permission to perform procedures before and shortly after birth is impossible. In the case of

Adam Nash, his parents served as proxy and made the decision to donate Adam's cord blood. Apart from helping Molly, Adam did not benefit from the procedure. Savior siblings are in a difficult position where decisions are not made for their good but are driven by the best interests of the parents and the existing ill child (Taylor-Sands, 2013, p. 27-28)

Most commonly, preimplantation genetic diagnosis is used to select fetuses without disorders or disabilities. Not only does this discriminate against the affected embryos because it never gives them a chance at life, but ultimately it harms society by eliminating diversity (Taylor-Sands, 2013, p. 9). Utilizing preimplantation genetic diagnosis to design savior siblings is not self-indulgent or without purpose because it saves the life of an ill child. But its societal approval and regularity may progress to using selective reproduction for trivial reasons, rather than for an appropriate purpose such as improving a child's quality of life (Taylor-Sands, 2013, p. 7). The term 'eugenics' was first used in 1883 by Francis Galton "to denote the science of improving the hereditary health of society through selective breeding" (Pressel, 2013, p. 1216). Whether the selection of hair and eye color falls under the category of eugenics is open to interpretation. The progression of designer babies is unpredictable and could change the definition of human beings as they are known today (Taylor-Sands, 2013, p. 7).

The term eugenics is commonly associated with the genetic cleansing practices carried out in Nazi Germany (Taylor-Sands, 2013, p. 8). In the early 19th century, the end of World War I and the Great Depression caused mass political and economic chaos in Germany. The country was in a weak and vulnerable state, enabling Adolf Hitler to attract a large following of Germans who were desperate for change. With promises of restoring Germany and a better life, the Nazis, once unknown, rapidly rose to power (United States Holocaust Memorial Museum, n.d.). In January of 1933, Hitler was appointed chancellor, which marked the end of democracy and the

beginning of a dictatorship in Germany (United States Holocaust Memorial Museum, n.d.).

Hitler believed it was his duty to protect the blood purity of the German nation from the threat of inferior nations, and as a result, racial hygiene of the Jews became virulent during his rule (Pressel, 2003, p. 1217).

Shortly after Hitler rose to power, the process of eradicating inferior races from Germany began with the forced demotion of Jews from the medical profession. The restriction of Jewish rights continued with the passing of laws that excluded Jews from German citizenship. Then in 1933, the Sterilization Act mandated that physicians sterilize citizens who have conditions that could potentially flaw the German bloodline (Pressel, 2003, p. 1218). German physicians and medical institutions supported Nazi ideologies and assisted in eliminating all individuals who suffered from debilitating illnesses such as schizophrenia, epilepsy, and alcoholism from the German nations. The concern of the physicians was no longer providing care to patients but to rid the country of the Jews who were presumed to be a threat (Pressel, 2003, p. 1217). It was not long until the sterilization of Jews turned to killing through mass genocide and torturous medical experiments. The euthanasia program known as "T4" consisted of killing Jews, handicapped newborns and children, and adults with mental illness (Pressel, 2003, p. 1218). This then evolved to the elimination of superficial traits and individuals whom Hitler viewed as enemies. These gruesome practices continued for nearly a decade until the end of the Second World War when the crimes of the Nazis were revealed at the Nuremberg Medical Trials. The trials, which were held in Nuremberg, Germany between 1945 and 1949, brought justice to the Nazis by exposing their true identity and the magnitude of their crimes (Pressel, 2003, p. 1219).

Adolf Hitler and his following of Nazis had the misconception that their actions were achieving a greater good. They believed the necessity to purify the human race justified their

inhumane treatment and murder of millions of Jews along with the mentally and physically disabled. The Nuremberg trials served not only to punish the Nazis for these crimes, but also to set a precedent for the future treatment of humanity. During the trials, the judges set standards for the ethical treatment of participants involved in research in a document called the Nuremberg code. The Nuremberg code was revolutionary, considering that no prior documentation had ever emphasized protecting the welfare of research participants (McLean, 2004, p. 1). The code consisted of ten principles; principle one states that “the primary consideration in research is the subject’s voluntary consent which is ‘absolutely essential’” (Beauchamp, 2004, p. 1274). At the time the faults of American medical research and clinical practices seemed much less serious compared to the injustices committed by the Nazis. But the attitudes of American researchers and physicians showed similar apathy toward the well being of their research participants (Pressel, 2003, p. 1219). Prior to the Nuremberg code it was not a priority to obtain consent from research participants. The Nuremberg code transformed the relationship between researchers and their subjects and is considered the most influential document in research ethics (Beauchamp, 2004, p. 1274).

The Nuremberg Code also served as the basis in the development of new professional and governmental codes regarding human rights (Beauchamp, 2004, p. 1274). One year after the trials, in December of 1948, the United Nations’ Declaration of Human Rights was established by the General Assembly of the United Nations. This declaration is a universal standard of ethics and clearly states, “all humans are born free and equal in dignity and rights,” regardless of race, age, or disability (Paul & Elder, 2011, p. 24). During the Nazi reign, Holocaust victims were stripped of their basic human rights including right to life, liberty, and security of person. Before this declaration, the rights endowed to each human from birth were left undefined

(McLean, 2004, p. 2). Until this time, vulnerable populations, such as the poor and mentally incompetent were taken advantage of for the pursuit of knowledge through medical research in the United States (Pressel, 2003, p. 1220).

In 1966, Henry Beecher, a professor at Harvard Medical School, published an article that brought awareness to the unethical practices of American medical research. “He provided examples of 22 published research projects that risked the health or life of the subject for no therapeutic benefit but for only the potential advancement of ‘science’” (Pressel, 2003, p. 1220). Researchers viewed subjects as property with limited human rights, and therefore in almost all the studies there was no reference to subjects’ consent to participate (Pressel, 2003, p. 1220). One of the most well known experiments that violated subjects’ rights was the Tuskegee Syphilis Study. The study was held from 1932 to 1972 and was composed of 400 impoverished African American men who suffered from latent and tertiary syphilis. Its purpose was to examine the effects of untreated syphilis on longevity and health. However, participants were deceived by the researchers. They were not informed of their syphilis diagnosis, but only that they were being treated for “bad blood.” Participants were lured into the study with the offer of free health care and meals on clinic day. They were purposely never treated with penicillin, even after it was proven to be effective for treating their disease (Beauchamp, 2004, p. 1275).

Throughout the extent of the Tuskegee Syphilis study many questioned its ethics, but surprisingly the study continued. The Public Health Service reviewed the study multiple times between 1932 and 1970. However, it was not until 1972, when the study was reviewed by a U.S. Department of Health, Education, and Welfare panel, that it was terminated (Beauchamp, 2004, p. 1275). In current day, the Tuskegee Syphilis study is still quite controversial but it is most widely viewed as a violation of ethics and participant rights, especially the right to informed

consent. At the time, the focus of researchers was not on participants' well being but on the maximization of medical knowledge on syphilis. The actions of researchers were not regulated as it is today because of the lack of formal rules and guidelines. Informed consent became the focus of law and ethics in the late 1960s. This was likely due to the increased concern in human rights and equality brought about by the civil rights and women's rights movements (Beauchamp, 2004, p. 1275). Gradually, informed consent evolved to become a cornerstone of the modern-day United States health care system (Purtilo, 2005, p. 209). "Three 1972 court decisions are widely recognized as informed consent landmarks: *Canterbury v. Spence*, *Cobbs v. Grant*, and *Wilkinson v. Vesey*" (Beauchamp, 2004, p. 1275).

One of the earliest legal cases regarding informed consent was *Canterbury v. Spence*. The case involved a young man who sued his doctor after experiencing paralysis from spinal surgery. He then had to undergo additional surgery to reverse this complication. The case was established on the grounds that prior to the first surgery, his doctor never informed him of the possible risks and complications (Murphy, 1976, p. 718). The court ruled that patients have the right to make their own health care decisions and in order for them to make intelligent decisions, they must first be adequately educated and informed (Beauchamp, 2004, p. 1275). Physicians must inform patients of their diagnosis, the nature of treatment and surgery, and possible risks and alternatives (Novak, 1973, p. 386). Physicians are only allowed to omit information in emergency situations, and cases in which patients are in an unconscious state or suffering from psychological illnesses (Murphy, 1976, p. 724). *Canterbury v. Spence* standardized the practice of disclosing information so that patients are informed about what will happen to them (Purtilo, 2005, pg. 213).

Canterbury v. Spence was not the only impactful case of the 1970s. In the cases of *Cobbs v. Grant* and *Wilkinson v. Vesey*, physicians committed serious informed consent errors similar to that of *Canterbury v. Spence*. Ralph Cobbs underwent surgery due to an ulcer, and during the operation, his spleen was injured. As a result, he had to undergo a second operation for spleen removal. Before the surgery, he was informed of the risks of general anesthesia but not of the risks associated with gastrointestinal surgery (Novak, 1973, p. 385). Pertinent information regarding all complications was not disclosed. This violated his informed consent because the case clearly stated that, “the patient’s interest in information does not extend to a lengthy polysyllabic disclosure on all possible complications. A mini-course in medical science is not required; the patient is concerned with the risk of death or bodily harm and the problems of recuperation” (Cobbs, 1972). Informed consent does not require a detailed explanation of physiological processes, but patients need to be informed in laymen terms about the risk of death and other possible surgical complications (Novak, 1973, p. 393). The physician cannot choose what information to disclose and what to withhold from the patient.

In the case of *Wilkinson v. Vesey*, a patient’s skin was severely burned due to years of radiation treatment for a cancerous tumor in her chest cavity. As a result, she had to undergo extensive plastic surgery to correct the damage. She sued the physicians for failure to disclose the possible risks of radiation treatment (Goldberg, 2013). Lack of consent is not merely neglecting to inform patients and to obtain permission; it is committing an act of battery. Battery is the unlawful act of touching an individual from whom no consent was obtained, even if no harm results. The physicians in *Wilkinson v. Vesey* committed a serious crime of battery when they recommended radiation treatment to a patient who was not fully disclosed on its risks (Purtilo, 2005, p. 212). These cases condemned the physician-centered standard of disclosure,

and laid the foundation for a standard of disclosure that respects patients' rights to self-determination (Goldberg, 2013).

The increased interest in human rights and the court rulings of the 1970s played a vital role in shaping medical informed consent into what it is today. The history of informed consent is reactive as opposed to preventative; laws and regulations are only implemented after a violation has occurred. With the advancement of technologies, it is important that lawmakers, ethics boards, research conductors, and physicians anticipate and prepare to deal with potential ethical dilemmas, so that informed consent continues to evolve and protect patient rights. It is the responsibility of physicians to do what is best for the patient, doing so builds strong physician-patient relationships and allows physicians to provide exceptional care (Purtilo, 2005, p. 213). Physicians should analyze the ethics involved on a case-to-case basis using the principles of autonomy, beneficence, and nonmaleficence all of which are essential to the right of informed consent (Purtilo, 2005, p. 219)

The main ethical principle involved in informed consent is the right to autonomy. "The principle of autonomy is the capacity to have the say-so about your own well-being" (Purtilo, 2005, p. 66). Withholding information that could impact patients' decisions takes away their right to chose their own well being. Therefore, health care professionals must adequately educate patients in order for them to make well-informed decisions and provide consent (Purtilo, 2005, p. 219). Other supporting principles for informed consent are beneficence and nonmaleficence. While nonmaleficence is doing no harm, beneficence is doing good. In terms of health care, this means that physicians are obliged to do everything possible to benefit their patients and avoid actions that could harm them. Failure to counsel patients undermines their rights to self-determination due to a lack of knowledge (Purtilo, 2005, p. 220). Patients who are

not fully disclosed on their illnesses and the possible risks of treatment are vulnerable and can be easily coerced, which constitutes harm.

Young individuals are especially at risk of becoming victims of lack of informed consent. Children under 18 years old are considered to be minors and, therefore, need the consent of an adult to receive medical care. This law is intended to safeguard the well being of children. At such a young age the brain is not fully developed and they do not have the mental capacity to understand the risks and benefits of treatments (Neinstein, n.d.). Although the law protects minors in the majority of cases, it does have shortcomings. One area of concern is when parents decide to genetically design a savior sibling to donate tissues and undergo procedures to save the life of an existing child. This issue is brought to light in *My Sister's Keeper* when Anna was expected to undergo treatments that were not necessarily for her good but to benefit the health of her sister. Her parents were biased towards saving their eldest daughter's life and had what they believed was Kate's best interests in mind when they gave consent for the procedures and surgeries. However, at the end of the novel, it was revealed that Kate had asked Anna to sue her parents for medical emancipation (Picoult, 2004). As illustrated by the book, what parents choose does not always align with the wishes or best interest of their children; this is one area where informed consent falls short in protecting patient rights.

Another area in which informed consent is lacking is that it is not always properly obtained. Informed consent is mandatory before every procedure and usually involves patients signing a document that explains the treatment and its purpose (Purtilo, 2005, p. 209). These documents are often lengthy with small, illegible print that deters patients from reading them. As a result, many patients are left uninformed because they only briefly skim the document or just sign without reading at all. This is a clear violation of consent that could be prevented if

forms were designed with the participant in mind and physicians were available for face-to-face meetings to answer questions with patients. Just as in the past, issues with informed consent should constantly be examined and new laws and regulation need to be put into place to protect patients' rights and provide better quality of care. Lack of disclosure with patients is not usually intentional, but in some cases physicians' and researchers' motives neglect to inform patients for their own selfish motives.

Not only does *My Sister's Keeper*, highlight the implications that a lack of informed consent can have, it also shows that a conflict of interest can adversely affect patients who are not on the receiving end of the beneficial medical treatment. Anna's quality of life was being jeopardized because of her mother's clouded judgment. Anna's willingness to partake in these bodily and fluid transplants was never questioned because it was assumed she would be altruistic based on her close degree of genetic relatedness to Kate. Their mother never stopped to inquire about Anna or Kate's viewpoint on the situation. She was willing to do anything for her sick child, and in her mind, because they were family, all the Fitzgeralds should possess the same mentality. Sarah was so invested in her oldest daughter that she failed to see that she was neglecting her son and preventing Anna from living a normal life. Submitting Anna to medical procedures that were not intended to medically benefit her did not register as a wrongdoing to Sarah (Picoult, 2004). Because Sarah wanted to prolong Kate's life for as long as possible, in order to spend more time with her daughter, she was not able to view the situation objectively.

Sarah should not have been allowed to advocate for Anna's involvement in the transplants because of her biased thought process. She only considered the possible benefits for Kate instead of recognizing the pain and suffering it caused Anna. To Sarah, preserving Kate's life was worth the seemingly moderate inconvenience Anna experienced. Sarah's personal

involvement allowed Kate to benefit medically at Anna's expense. For these reasons, Sarah should not have been allowed to act as opposing council to Anna's lawsuit.

Conflict of interest is defined in two parts as "the circumstance of a public officeholder, business executive, or the like, whose personal interests might benefit from his or her official actions or influence" and/or "the circumstance of a person who finds that one of his or her activities, interests, etc., can be advanced only at the expense of another" (dictionary.reference.com, 2014). Situations in which a conflict of interest arises can have consequences beyond the scope of the individuals who are directly involved. Unfortunately, as in Anna's case, medical conflicts of interest often go unrecognized because the attention is focused on one aspect rather than the entire **equation**. It is not until Anna takes a stand that awareness is brought to the ethicality of compromising one individual's wellbeing for another.

My Sister's Keeper is a good example of how a conflict of interest that grew to produce negative effects could have been prevented. Conflicts of interest are one of the many things to consider before the genetic selection of "savior siblings" becomes standard practice. The use of "savior siblings" can be acceptable under limited circumstances, such as with the Nash family. Molly Nash was born with Fanconi anemia, a rare genetic disease, that typically results in leukemia by the age of 10 (Marcotty, 2010). Jack and Lisa Nash had given up on having other children because they each carried a gene for this debilitating disease and did not want to subject another child to suffering. Dr. Wagner suggested a solution that would allow them to provide Molly with a life-saving bone marrow transplant and have another child free of this condition. Adam Nash was conceived via in-vitro fertilization and genetically screened for Fanconi anemia and genetic tissue identical to Molly's (Marcotty, 2010). After his birth, his umbilical cord blood, which is usually discarded, was used to provide the bone marrow for Molly's transplant

(Marcotty, 2010). This situation is acceptable compared to Anna's because Adam's wellbeing was never compromised, and he was not a "designer baby." The Nash family did not improve the quality of life for one child while diminishing that of their other child. The use of Adam's bodily tissue stopped at birth, and his right to make decisions pertaining to his own medical care was not continuously disregarded. A conflict of interest was avoided because the value of both children was considered. They simply ensured that their next child was disease-free, rather than selecting for superficial desirable traits. The pace at which medicine advances can easily precede the guidelines determining what is acceptable or ethical. Although a fictitious story, Picoult's novel shows how important it is to have protocol and guidelines established before an issue develops. The exploration of genetic engineering is advancing at a fast pace, allowing the technology to become more accessible without complete understanding of the consequences.

With each passing day, new knowledge is acquired about the illnesses that plague humans, and hinder them from living their lives to the fullest. This knowledge is constantly being applied to configure new cures and therapies for suffering patients. With the increased options and approval of each new medication, drug companies maximize their profit exponentially. However, each drug must undergo extensive testing to prove its efficacy, and most importantly, its safety before being approved for public use. Sometimes, the protocols in place are not sufficient to protect individuals from unnecessary harm during the approval process.

This testing process is two part: pre-clinical studies and clinical trials. The pre-clinical studies test treatments that look promising on animals, to provide researchers with a baseline knowledge of how safe the new treatment is on a living creature. Because humans and animals absorb, process, and excrete substances differently, it is important to continue the testing process

to acquire further answers. After the medication clears the animal testing stage, it begins the first of five clinical trial phases. In the clinical trial, participants receive specific interventions, such as drug therapy, according to research protocols established by the investigators ("Learn About Clinical Studies," 2012). Phase zero involves acquiring participants and limited participant-exposure to the drug. In phase one, the drug or treatment is introduced to a small group of healthy volunteers to determine the drug's safety and its most frequent/serious adverse effects ("Clinical Trials," 2008; "Learn About Clinical Studies," 2012). In phases two and three it is administered to larger groups to assess the effectiveness, compare it to established treatments, and then study the effects of differing dosages ("Learn About Clinical Studies," 2012). Phase four occurs after the drug has been approved for marketing by the FDA, and is geared toward collecting data regarding the long-term effects of the medication ("Learn About Clinical Studies," 2012).

Clinical trials are supposed to serve as a safeguard by preventing hazardous substances from reaching the market ("Clinical Trials," 2008). Patients and medical providers rely on the clinical trials to guide the decision-making process by determining viable treatment options for their patients. Unfortunately though, the integrity of the clinical trials, and therefore the results, can become compromised without the knowledge of the participants and health care professionals. An example of this controversial situation occurs when researchers possess a personal stake in the company they are employed to conduct research for. Personal and financial investments in the success of a project clouds the researchers' judgment. The health of participants in the trial and quality of life for patients, who acquire the drug after it has been marketed for public use, can be endangered if the researchers do not adequately examine questionable results.

Because a researcher's involvement in a clinical trial was skewed due to his possible future financial gain, Jesse Gelsinger lost his life. Jesse was a teenager with a mild form of ornithine transcarbamylase deficiency (OTCD) who altruistically participated in a trial to help individuals with more severe cases of OTC deficiency. Ornithine transcarbamylase deficiency is a rare genetic disorder that causes ammonia to accumulate in the blood ("Ornithine Transcarbamylase Deficiency", 2006). Usually, ammonia is formed when the body breaks down proteins and the ammonia is converted to urea by ornithine transcarbamylase enzymes and then excreted from the body ("Ornithine Transcarbamylase Deficiency", 2006). In OTC deficiency, however, the Ornithine transcarbamylase enzymes are defective and the amount of ammonia in the bloodstream increases. Jesse possessed a mild form of OTC deficiency and was able to control his condition through medication and a special diet, which allowed him to live a normal life. The OTCD trial at the University of Pennsylvania aimed to deliver healthy OTC genes to each patient's liver (Obasogie, 2009). Replacing the defective genes with normal ones would eliminate the single-gene defect that was responsible for causing OTCD. The gene therapy was presented to the Gelsingers as a relatively safe procedure that appeared promising (Obasogie, 2009).

Jesse's ammonia levels skyrocketed shortly after he was injected with the replacement genes. Within a few days, Jesse was put on life support after suffering from organ failure and brain damage (Obasogie, 2009). Jesse was only eighteen when his family removed the life support. At first glance, his death appeared to be the result of an unforeseeable event. After further investigation, it became known that two monkeys had died during the pre-clinical animal testing stage. This vital information appeared on the consent form that the investigators submitted to the review board at the National Institute of Health, but was not present on the

consent forms signed by volunteers (Obasogie, 2009). Secondly, the researchers did not disclose to either the federal regulators or the volunteers that previous participants suffered from adverse reactions severe enough to have prevented the continuation of the trial if they had been reported. Lastly, it was uncovered that Dr. James Wilson, the study's lead researcher, was actually a member of the private company that he was conducting the research for (Obasogie, 2009).

Wilson held a direct financial interest in the outcome of the trial. If the trial produced a successful mechanism for delivering healthy OTC genes to the participants, Wilson's company could make millions by patenting the gene delivery system. This in itself is a conflict of interest. The decision to withhold information regarding the therapy's safety and to continue the trial process in humans was unethical. As lead researcher, it was Wilson's responsibility to protect the lives of his participants. The testing could have been extended at any point, so that the trial did not proceed to the next phase before its time. Further animal testing was essential to perfect the technique before it was introduced to human volunteers. This extended pre-clinical trial phase would cause a dilemma for Wilson because further testing costs time and money, which lowers the profit margin. As unappealing as this option is from a financial standpoint, it was a necessary decision that should have been made. Wilson allowed his involvement in the company to bias his thought-processing abilities, which resulted in an oversight that cost a teenager his life. Wilson was not objective when examining the results and deciding to continue the trial. Although the gene therapy held the potential to cure patients with severe forms of OTC deficiency, he violated his obligation as a medical practitioner to protect his patients. Jesse died as a direct result of his decision to advance the trial before its time.

The possible future benefits do not outweigh the loss of lives that occurred along the way. This thinking holds no merit because if the treatment was ineffective and dangerous, its

success on the market would be limited. Patients would not want to subject themselves to a life-threatening treatment. Once the truth became public, the gene-delivering system would not produce a profit. Wilson's judgment was clouded by his financial ties to the developing company. While the future therapeutic uses of the drug are important, researchers cannot focus so intensely on what they want to happen that it distracts from what the data is actually saying. Sadly, this example of a conflict of interest is not a single occurrence. Companies invest such substantial amounts of time, effort, and money into the development of new treatments that clinical trials can easily be affected. It is important to monitor the relationship that researchers have to the company and the study to ensure the integrity of the trial's results.

In the field of medicine, conflicts of interest are not limited to the clinical trials. Sometimes, conflicts occur when facing end of life decisions. The use of life support is controversial because, oftentimes, the appropriate time to withdraw support is unclear. It is possible for patients, even those in the most critical conditions, to make miraculous recoveries. However, the alternative is that the patient is in a persisted vegetative state and will die when life support is removed. Relatives and friends cling to the possibility that their loved one will make a miraculous recovery and life will go on as normal. The decision to terminate life support is further complicated when the patient is a child and only one parent is in favor of the termination. Unfortunately, the complexity of this situation can progress, which is the case regarding Andrew Bedner and his family.

Adam Bedner was a twenty-eight year old father who accidentally dropped his eight week old daughter, Cadence. The situation worsened when Bedner picked Cadence up by her legs, without supporting her head. Cadence began to cry, and Bedner hit her on the back of her head with his elbow (Davis, 2010). She became unresponsive and was rushed to the hospital to

be examined. Doctors documented that baby Cadence's injuries included multiple skull fractures, retinal hemorrhages, intracranial hemorrhage, multiple rib fractures, and unexplained bruises, which were so serious that she was placed in life support (O'Gorman, 2008). Upon confession, Bedner was arrested and charged with two counts of first-degree aggravated domestic assault. In court, Bedner's attorney requested that he and his client be involved with Cadence's medical decisions, rather than relinquishing all rights to Cadence's mother (O'Gorman, 2008). The dilemma: if Cadence's life support was terminated and she died, the charges against Adam Bedner could escalate to include murder.

The child had no chance of recovering, and would constantly suffer and rely on life support. For these reasons, her mother was in favor of removing life support to end her infant's suffering, but Adam disagreed with the decision in order to prevent a murder charge. The consequences he faced compromised his ability to make the appropriate decisions for his child. Rather than selecting the best option for Cadence based on her condition, Adam was influenced by the threat of an increased prison sentence. A murder charge would also hinder his future employment, housing, and relationship opportunities and prevent his potential to be successful. The decision to either prolong the agony of his daughter or sacrifice his future created a conflict of interest. Adam was too invested to be impartial. He should not be granted the privilege to contribute to Cadence's care. A precedent needs to be established, so medical care is not dictated by preventing consequences for the abuser. The treatment needs to be influenced only by the patient and centered around their needs and the best option for them.

Conflicts of interest cannot be avoided completely due to the complexity of our ever-changing medical field. However, it is important that medical institutions and research facilities prevent these situations to the best of their ability. Organizations typically implement a "Conflict

of Interest Policy" in an effort to limit these occurrences. The goal of these policies is to identify potential conflicts of interest and set guidelines to manage their presence. This will improve the internal decision-making process to discourage the manifestation of a conflicted interest.

Medical staff walk a fine line between compassion and impartiality to promote the best interest of patients, their families, employees, and practitioners. This balance can only be maintained if all parties are working toward the same goal: the health of their patients. Stanford Hospital's conflict of interest policy states that a conflict of interest arises "when there is a divergence between an individual's private interests and his/her professional obligations" and that the conflict of interest depends on the situation and not on the character of the individual" (Stanford, 2006). Acknowledging that a conflict of interest is dependent on the situation will permit the institution to be consistent in their response. Exceptions will not be made for certain individuals, which is necessary to avoid the conflict of interest and be just when administering disciplinary action. When the rules are bent, it defeats the purpose of implementing the regulation. Oftentimes, medical staff and researchers are required to sign these clauses as a stipulation of employment. This ensures that the medical professional is aware of the hospital's expectations and consequences, and reminded of their obligation to patients.

Periodically, an unprecedented conflict of interest is identified by an institution. In this case, ethics committees are utilized as another safety measure. Ethics committees consist of individuals from varied backgrounds who collaborate to consider and assist in the resolution of complicated ethical problems (American Medical Association, 1994). Although it is not an obligation to accept the recommendations of the ethics committee, their advice should receive serious consideration. The committee is constructed to be impartial and consider patients' best interests. The creation of these committees allow the event to be viewed objectively, so that care

is not sacrificed due to personal financial or emotional involvement. If new regulations are being implemented to solve an ethical issue, the hospital may conduct seminars to inform staff of the incidence and review protocol to reinforce how the event should have been addressed. All employees need to be educated in order to prevent future incidences and promote consistent handling of similar events. The consequences also need to be clear to deter individuals from ignoring the rules.

Like healthcare facilities, the medical research field also possesses committees to ensure the integrity and benefits of its work. In research, the Institutional Review Board (IRB) is assigned with protecting the welfare and rights of the people involved. Review of the research aims to prevent reoccurrences of the Tuskegee and Jesse Gelsinger studies. Approval is needed to conduct research, which will only be granted if the study meets the three principles laid out by the Belmont report (New Hanover Regional Medical Center, n.d.). To evaluate the ethicality of research proposals, the IRB needs to investigate the respect for persons, beneficence, and justice that the researchers claim to perform (New Hanover Regional Medical Center, n.d.).

Respect for persons mandates that subjects consented voluntarily and are adequately informed about the research and their rights. This principle was clearly violated in Jesse's case because information regarding the possible harm, and death of the monkeys, was withheld. Wilson was not forthcoming with key information. Beneficence, the second principle, mandates that risks are minimized and that the potential benefits to the subjects justify the risks that cannot be controlled. This was also violated for Jesse because the human participants were exposed to the risk of death before the technique was perfected in the animal testing stage. The risk of death outweighed Wilson's possible financial gain. Lastly, justice mandates that the risks and rewards produced should be available to all subsets of a community. Unlike Tuskegee, the benefits

should also be enjoyed by the individuals who faced the risks of being involved in the research. The organizations prohibit the personal stake of staff, researchers, and their families in their work. Direct investment in the success of a study compromises the trial's integrity and can endanger countless participants and patients. This highlights the necessity of IRBs: to prevent the harm of participants and consumers in the open market.

The risks that patients face while receiving medical care are countless. These risks can result from improper attainment of consent or due to a conflicted personal investment that clouds judgment. The protocol regarding informed consent and conflicts of interest have evolved significantly. Medicine is constantly improving the lives of patients, but the new technologies and procedures also complicate the ethics involved. For this reason, these ethical principles need to be examined continuously to keep up with the fast pace of medicine. Medical providers need to be aware of the implications that can arise, so that they can better prevent ethical dilemmas and provide care centered around the patient's best interest. The obligation to patients should not be forgotten, and often we fail to see how we are violating this goal. Healthcare personnel need to be objective when treating patients, so that patients do not become victims of bias. The Nuremberg Trials, Tuskegee Syphilis Study, and cases of Bedner, Nash, and Gelsinger stand as a reminder of how important it is to protect the rights of patients to prevent harm. While Jodi Picoult's novel, *My Sister's Keeper*, is not exceptional literature, it brings awareness to modern-day issues. In Picoult's novel, readers are forced to acknowledge that medicine is affecting those who sometimes are overlooked.

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