A Virtue Ethics Analysis of the Puerto Rico Birth Control Trials

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Amanda Brownlee

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

Signed: Amanda Brownlee_____

Approved: ___ Benjamin J. Laugelli _____ Date___5/5/2020_____

Benjamin J. Laugelli, Assistant Professor, Department of Engineering and Society

Introduction

Enovid, from where the colloquial nickname "The Pill" originated, was the first widely marketed hormonal birth control that was a revolutionary approach to women's reproductive health. Since the early 20th century, the island of Puerto Rico had faced years of eugenic campaigns and regulations to combat rampant poverty and overpopulation, thus its women were receptive to any methods to save money and prevent future pregnancies. These unique circumstances created the perfect location for the testing of Enovid on humans before being used in the United States, where contraception laws were strict and medical trials more regulated.

The Rio Piedras housing project in Puerto Rico (PR) is where the most extensive and most cursory trials of any pharmaceutical ever licensed by the Food and Drug Administration were conducted from 1955 until 1956 (Colton, 1992). The women who participated in the trials - about 1,500 over several years - did not know about possible side effects of pills that were up to 20x more potent than the pills used today (Colton, 1992). Literature about the unethical use of human subjects is one that has been commonplace in medical practice since the Nuremberg Code following World War 2, and this case has been no different. Controversy has come to light surrounding the questionable circumstances that surrounded these trials, with topics such as informed consent, coercion and malpractice on the part of the trial's principal investigators Gregory Pincus and John Rock, as well as accompanying population control rhetoric and misogynist research practices. While this approach is well grounded in validating the experience of the subjects and condemning the researchers in their approach to biomedical research in the name of technological advancement, it has failed to examine the very attributes for which doctors strive to fulfill. By neglecting to study how those involved in the trials failed as doctors

with respect to themselves as healers, we ignore the implications that can come from removing the humanity and ethics that surround the job of being a physician.

By analyzing the case of the Puerto Rican Birth Control trials through the lens of virtue ethics, I will examine the very attributes of character that doctors strive to embody. In this structured analysis I will be highlighting the Hippocratic virtues that should be faithfully adhered to as doctors: justice, respect and integrity. Through the absence of these qualities, the doctors failed both their patients and their vocation as healers.

Background

After the success of the preliminary Boston trials for the Pill in 1954, Harvard scientists' John Rock and Gregory Pincus were confident in their oral contraceptive. But without large-scale human trials, the drug would never receive the FDA approval necessary to bring the drug to market (Ordover, 2003). The extensive network of clinics on the island of Puerto Rico that opened following the population control initiative created the perfect environment for them to test their creation for approval. Originally a government service, the clinics had closed and women's access to contraceptive advice became increasingly dependent on the availability of contraceptive field trials like one for Enovid, which occurred outside of government clinics. While physicians on the island looked to contraceptive trials as one way to offer medical services that were otherwise unavailable, Puerto Rican women hoped that access to the trials offered them control over reproduction. Instead, the trials left them with a lack of medical attention and true commitment to reproductive health care.

Literature Review

The literature for the Enovid trials tends to focus on the factors that enabled the conditions of the trial to occur. The commonality of these examinations is their focus on how society enabled the actions used on the trial members and the implications that came from them, instead of inspecting the actions of the researchers involved and how they directly contrast against that which their profession typically encourages.

These claims are further supported with the observations made by Laura Briggs, who asserts that regardless of whether it was founded on scientific claim, political rhetoric, or religious orthodoxy, the existence of Puerto Rican women has been defined almost exclusively in terms of sexuality and reproduction. She continues by adding how these portrayals rely extensively on paradigms of victimization, rendering Puerto Rican feminism as either non-existent or always in a state of co-optation (Briggs, 2002). This was most apparent in the Feminism Movement of the US, where the limited depictions of the use of sterilization by Puerto Rican women was consistently framed simply as a matter of U.S. imperialism (Briggs, 2002). Focus on the societal factors that created deceit, colonialism and exploitation of poor women of color largely omits the morals that doctors are supposed to follow as healers.

On a similar note, there has been much controversy surrounding the approaches used in the study. This case provides a solid platform to discuss the ethics surrounding human trials in medicine. The development of birth control happened during a relatively unregulated period of scientific history. The Nuremberg Code of 1947, which established the importance of informed consent, was not legally binding. The Kefauver-Harris Drug Amendments of 1962 and the Belmont Report of 1979, which required proof of drug safety and "respect, beneficence, and justice" for human trials had not been written yet (Vijayananthan, 2008). Thus, American

researchers had no formal obligation to obtain informed consent. In fact, "The researchers believed that this would be beneficial to their study, as it would reveal whether or not these pills could be used by anyone around the world (Pendergrass et. al, 2017).

The exploitation of the researchers has been under fire in several cases, one of them coming from Harvard University, both Rock and Pincus' home institution. In his article "Ethics and Clinical Research" that vilified many of Harvard's recent scientific advances, anesthesiologist Henry K. Beecher called out experimentation that privileged the wellbeing of "patients in general" over the patients undergoing the experimentation itself. Beecher questioned whether data obtained unethically should be published (Beecher, 1966). Articles like Beecher's condemn the misuse of power dynamics and disregard for patient autonomy by analyzing the questions surrounding human treatment and ethics in the name of science. Most of this discussion is aimed at the discrepancy between a doctor's intentions and actions as a healer with respect to the patient. My analysis of the human trials in Puerto Rico will advance this argument by including an analysis of the moral character of the researchers, that way the accountability of their actions will not just be dependent on laws, but ethics themselves.

Conceptual Framework

I will use a virtue ethics framework in order to analyze the morality of the actions of Rock and Pincus in their clinical trials. Originating from the Greek philosopher Aristotle, virtue ethics is "an ethical theory that focuses on the nature of the acting person. This theory indicates which good or desirable characteristics people should have or develop to be moral" (van de Poel, 2011). Analyzing the nature of the acting person allows for raising the question of "how to live" for the medical profession, rather than what they did wrong in these specific circumstances.

According to Aristotle, an action counts as virtuous when one holds oneself in a stable equilibrium of the soul in order to choose the action knowingly and for its own sake. This stable equilibrium of the soul is what constitutes character (Sachs, n.d). This equilibrium is achieved through moral virtues, which are the "middle course between two extremes of evil" (van de Poel & Royakkers, 2011). For example, justice, the avoidance of inequitable favor or bias against certain groups, is the mean between favoritism and prejudice.

One of the advantages of virtue-based approaches is that they can explain the relationship between human motivation and ethical conduct. To possess a virtuous character, skills to define morals must be enacted when the relevant opportunity arises.

Through virtue ethics, I will be able to examine the character of the doctors by using specific virtues that are relevant to those in the biomedical realm. In "Virtues in Medical Practice" by Edmund Pellegrino et. al, others list the following virtues as integral to any medical practice:

1. fidelity to trust
2. compassion
3. Phronesis: medicines indispensable virtue
4. justice
5. fortitude
6. temperance
7. integrity
8. self-effacement
9. Intellectual Honesty
10. Humility
11. Therapeutic parsimony

While not all encompassing, these virtues provide a stable foundation to evaluate the moral character of any scientist. Virtue ethics apply to medicine by making a difference in moral analysis and in the kinds of moral choices the agent makes in concrete cases (Pellegrino et. al,

1993). Pellegrino et. al contends that virtue ethics entail differences in the degree and kind of moral behavior from what fidelity to duty may require (1993). In what follows, I will demonstrate how those running the trials showed moral deficit by failing to practice three key virtues: justice, respect and integrity.

Analysis

The methods that were implemented in the Puerto Rico Birth Control trials provide an example of moral failure not only to the trial participants but through the actions of the medical professionals running it. Demonstrating a deficiency in three virtues necessary for morally responsible medical professionals, justice, respect and integrity, shows that the actions taken in the trials were irresponsible and immoral. Clinical researchers María PérezñPinar and Luis Ayerbe claim that being a researcher is a privilege, hence if medical researchers ignore their ethical commitment, they would be ungrateful as it would be disloyal to the universal vocation to search and do the good (PérezñPinar, 2017.) The lack of moral responsibility displayed by the clinical researchers disqualifies them from their ability to earn the title of medical researcher. Below, I will demonstrate why they failed to qualify as virtuous agents by analyzing the actions of the researchers with respect to the three virtues listed above.

Justice

The clinical researchers in the trials showed a lack of justice through their continued disservice to the participants who depended on them for a reliable study. The virtue of justice is defined as a group of principles requiring appropriate distribution of benefits, risks and costs fairly (Ashcroft, Richard E., et al, 2015.) Adequate justice in the medical realm would show that a patient is due respect as a person such that the professional must always act based on that person's good. Instead, the women of Puerto Rico were chosen as a target group for the study

because Pincus knew that if he could demonstrate that the poor, uneducated, women of Puerto Rico could follow the Pill regimen, then women anywhere in the world could too. Pincus hoped that by showing that Puerto Rican women could successfully use oral contraceptives, he could quiet critics' concerns that oral contraceptives would be too "complicated" for women in developing nations and American inner cities to use (Lima, 2019). This attitude was further heightened by the physical separation between the contraceptive researchers and research subjects, who not only occupied vastly different geographic spaces but were in addition separated by factors such as class, education and language (Schoen, 2006.) The purposeful targeting of the participants displayed a predatory mentality to demote the status of one group in the name of science. Therefore, the disparity in the anticipated capacity of the trial participants showed a lack of concern for those in pain, the poor, the troubled, the oppressed, and the outcast, for which justice is especially expressed (Pellegrino et. al, 1993). The researchers chose to test the pill at the expense of the women of Puerto Rico due to a disparity of education and wealth that left that them more vulnerable. This was done with the specific intention of 'perfecting' a medication before it can be used on the "civilized" women of the United states, which demonstrates the lack of justice through the unequal regard of the two groups of women. The circumstances and practices that were organized by the researchers purposefully capitalizing on the deficiencies of the women demonstrate the lack of justice in their practice.

Respect

The clinical researchers displayed a lack of respect to the patients participating in the trial. Several factors, including the language barrier and lack of candor and information on the part of the researchers were observed during the trials. The virtue of respect is a principle requiring respect for the decision-making capacities of autonomous persons (Ashcroft, Richard

E., et al, 2015). Rules or principles need to be interpreted in context and, to do that, virtue ethicists stress that the good doctor must acquire virtues such as perceptiveness and good moral judgement to determine when these liberties are given (Kotzee, Ignatowicz, et al, 2017). To seek professional help is to trust that physicians possess the capacity to help and heal. In the investigative documentary "La Operacion", which addresses the US-imposed sterilization policies in Puerto Rico, a former trial participant recalled the following: "around 1955, a nurse came to my house to tell me about a family planning program, she went to teach at the apartments and talked about a new treatment to prevent pregnancy. Being told it is a good contraceptive, I took on an empty stomach everything was spinning, and I passed out. It turns out we didn't know that we were first in the world taking the medicine- they were experimenting with us, without us knowing what they were doing" (Anna Garcia, 1982). These women did not know that they were the first in the world to be taking these pills, nor were they aware that the researchers were experimenting with them without their consent. The scientists were performing an experiment, giving untested medicine to a subject, without the participants fully comprehending the fact they are testing a substance whose affects have not been documented yet. The researcher's scheme led to women agreeing to potentially hurt themselves through the side effects of the developing pill. They were not fully briefed on the details of the pill, and there were denied the right to choose whether to take a potentially harmful medicine. In fact, by claiming the pill as a good contraceptive, the researchers further mislead the women by instilling unjustified trust in the product. When the women voiced their valid concerns, they were mislabeled as psychosomatic and the trial continued, completely disregarding the women's expectation that as healers, their voices would be taken into consideration.

In view of these actions, it is important to address the concept of autonomy, which lies within the encompassing umbrella of respect. Autonomy is defined as freedom from external constraint and the presence of critical mental capacities such as understanding, intending, and voluntary decision-making capacity" (Beauchamp & Childress, 2001). It is a concept that has been discussed thoroughly since ethics in clinical trials became a topic of interest in the mid-20th century starting with the Nuremberg Code (1949) and the Helsinki Declaration (1964).

The principle of respect for autonomy requires both respectful treatment in disclosing information and actions that foster autonomous decision making. More specifically, respect for autonomy obligates professionals in health care and research involving human subjects to disclose information, to probe for and ensure understanding and voluntariness, and to foster adequate decision making (Beauchamp & Childress, 2001). This is where the clinical researchers failed as virtuous agents. Many of the trial participants were not fluent in English, and many were illiterate. This proved as an advantage in the researcher's eyes, as the researchers believed that this would be beneficial to their study, as it would reveal whether these pills could be used by anyone around the world (Briggs, 2002). While the women participating in the trial thought the trial acted as an opportunity for liberation, as they were informed that they were being given a pill free of charge to prevent pregnancies, it was actually a form of population control and a social experiment all together. Margret Sanger, a vital proponent of feminism and key stakeholder who funded the trials, went as far to say, " I consider that the world and almost our civilization for the next twenty-five years is going to depend on a simple, cheap, safe contraceptive to be used in poverty stricken slums, jungles, and among the most ignorant of people" (Schoen, 2006.) The respect and dignity that the trial participants should have received as patients was corrupted by the classist and economical ideologies of those controlling the

study. Several factors including the language barrier, false advertisement, and withholding of information display the egregious violation of respect performed by the researchers. By prioritizing the outcome of the technology, as opposed to its safety and viability, the researchers failed to demonstrate respect for their patients.

Concerns about what to do when informed consent is compromised raises the issue of who should be held responsible, as the patient's ability to assess medical details should be determined by the physician. This suggests that attention should be given to the doctor as the person who is in control (Dresser, 2009.) Many medical ethicists therefore feel comfortable with a more impersonal style of ethics, preferring to understand ethical responsibility in terms of legal contracts and agreed upon rules (Drane, 1995.) By this explanation, the researchers had every right to conduct the study in the manner they chose because they chose the most efficient and economical method of action to get a viable product to market, which was what the medical researchers were tasked to do in the first place.

Still, this approach fails to consider the fact that as members of the biomedical community, they owed respect to the women who were willing to participate in the name of science. While physicians on the island looked to contraceptive trials as one way to offer medical services that were otherwise unavailable, Puerto Rican women found that access to the trials offered them control over reproduction. However, it did so without providing them with real medical attention and a true commitment to reproductive health care, instead serving as a temporary solution that might have met physicians' and women's short term interests but left larger structural problems of health care access unsolved(Schoen, 2006). By deploying questionable methods to recruit and retain women into the study, as well as disregarding concerns that were brought to the researchers' intentions, those in charge made decisions not

conducive to a medical professional. Therefore, by displaying a lack of respect to their patients, they fail as virtuous agents.

Integrity

Defined as "the quality of possessing and steadfastly adhering to high moral principles and professional standards, as outlined by professional organizations, research institutions and, when relevant, the government and public", integrity is a subject that can be considered with both professional and moral principles by both raising questions and leaving clear guidance on what researchers should do (Steneck, 2006). The virtue of integrity was sacrificed in the name of churning out a new technology to American society. To demonstrate their gross negligence to integrity, I must detail how the researchers lacked accountability in their actions during the trial.

The original dose of the pill is three times stronger than the highest dose prescribed today. The effects of high doses of osteogenic birth-control are now understood, but the effects on Puerto Rican women had not been studied nor accounted for. The pill's side effects included nausea, bloating, weight gain, depression, loss of libido, severe mood changes (López, 2008). Blood clotting also became a major problem with women participating in the trial and is currently the suspected cause of death for the three deaths that occurred in the subjects while the trials were being conducted. However, it took over a decade for official recognition that there was a link between blood clotting and the use of the drug, leading to multiple deaths within the trial itself (López, 2008).

Patient advocates Edris Rice-Way and Penny Satterthwaite, who were Puerto Rican physicians who supervised the pill trials, negotiated with Pincus and GD Searle and Company in an attempt to minimize the pills side effect. Satterthwaite reported that a ten-milligram dose of the pill Enovid caused too many side reactions to be acceptable. Satterthwaite reported repeatedly that she was " a little alarmed by the marked changes" she saw in the cervixes of these

women who have been taking the pills (Schoen, 2006). There were many side effects and problems appearing with the patients as a result of the study, yet it was only patient advocates who voiced concerns about the condition of the patients. Knowing that the side effects were not "officially" known until modern studies is suspicious, considering the fact that there was a study where these very side effects were reported but not officially documented in the 1950s, which goes to show that the women's concerns were never reported in an official capacity.

Instead Pincus downplayed their concerns, contending that Puerto Rican women's complaints were largely psychosomatic and result of their emotional super activity. Both Rice-Way and Satterthwaite insisted that their warnings were valid and recommended that the pill should not continue to be used further (Schoen, 2006.) However, lead investigators Pincus and Rock felt that problems such as bloating and nausea were minor compared to the potential contraceptive benefits of the drug. Confident in the safety of the Pill, Pincus and Rock took no action to assess the root cause of the side effects. Therefore, in 1957, the US Food and Drug Administration (FDA) authorized the marketing of the steroids as specified for miscarriage and certain menstrual disorders. Finally, in 1960, the FDA licensed the first oral contraceptive (Enovid) for sale as a contraceptive agent in the mainland United States of America. Instead of listening to the reports of the physicians and taking action through the halting or changing of the trial, the head researchers chose to ignore, or disregard the feedback of other professionals. They then proceeded to finish the study without reporting the medicine's problems to the FDA that way it would be approved.

It is not unreasonable to suppose that investigators, for fear of losing long-term research support, might consciously or unconsciously withhold information about a commercially promising discovery. However, when serious misconduct occurs, it reflects a break-down in the

moral values of that community that should be supportive of scientific integrity and censorious of moral lapses that damage the whole purpose of research (Pellegrino et. al, 1993.) In the case of the Puerto Rico birth control trials, those in charge knowingly withheld, or disregarded relevant information regarding the safety of the participants. Therefore, it can be argued that the virtue-based approach provides a better account of the role of scientific leadership in promoting research integrity. Three women died while participating in the trials, yet no investigation was conducted to see if Enovid had caused the young women's deaths. Whether the three women died may not be correlated, but the lack of compassion shown by disregard for the health of the participants at the expense of finding a solution is appalling. Integrity requires physicians to maintain an exquisite awareness of the physical condition of the patient (to assess the outcome) and the values of patients or their surrogates (to assess the quality of those outcomes measured against the patient's values) (Pellegrino et. al, 1993). To knowingly ignore the problematic aspects of the trial displays an apathetic character and questionable medical intent, therefore lacking the virtue of integrity.

Conclusion

Despite the substantial positive effect of the pill, its history is marked by a lack of consent, full disclosure, true informed choice, and of clinically relevant research regarding risk. I have argued that by failing to consider the lack of morals that being a biomedical researcher entails, a severe injustice to the scientific realm is perpetrated. Technology cannot be innovated at the expense of fellow humans, and through the ethical analysis of the lack of virtues that the researchers possessed, I exposed the dangerous effects on both the people affected and scientific research itself.

While there are several opinions on how to reach optimal solutions to best serve society, it can be surmised that a dedication to virtues provide an avenue to keep biomedical professionals on track with what their job's main goal should be: healing. To be a commendable medical researcher, the pursuit of knowledge should be completed while adhering to virtues of a medical professional. From grievous misconduct that was performed, to the gross misplacement of patients' trust, the absence of virtues in medical practice enables technology to be innovated at the cost of safety and altruism. To better dedicate themselves to their profession, biomedical researchers must practice justice, respect and integrity to correctly, and effectively deploy technology to society.

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