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Fourteen

THE NEW VULNERABILITIES RAISED BY BIOMEDICAL RESEARCH

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1. Introduction

The ethical question of biomedical research on human beings for therapeutic purposes is one of the first crucial and most discussed issues in bioethics.[1] Researchers whose work involves human experimentation know that they will have to present their research objectives and the respective processes involved to ethics committees for scrutiny. In this chapter, I will examine factors that triggered this now common situation and the stages of its development. I will also discuss the current proliferation of new vulnerabilities brought about by new biomedical powers, and I propose paths for reflection and action to meet the present challenges.

2. From the Necessity for Human Experimentation to the Pressing Need for Ethical Reflection

The experimental method began to be applied to the study of man in the Renaissance period. Yet only in the nineteenth century did human experimentation became indispensable for the progress of science, for the improvement of clinical practice and for modern medicine, which evolved from art to science and is now inexorably experimental.

In the aftermath of World War II, ethical reflection on human experimentation led us to the recognition that knowledge is not an absolute value and that progress does not necessarily lead to good. Science should not be the sole creator of its own design. Instead, the interests of science must be subordinate to those of society. We need to establish ethical guidelines and policy regulations for scientific development and research.

A. From Discovery of Experimental Method to Human Experimentation

The notion of experimentation arose in the Renaissance and was further developed and refined during the period of modern rationalism. A more strict definition evolved within the spirit of contemporary positivism.

During the first phase, experimentation consisted of the appreciation of facts, in observation, in the verification of ideas, and in questioning or refuting some orthodox truths. In short, experimentation related experience to reason.

The second phase involved building the experimental method in four defining steps: observation, formulation of hypotheses, verification of laws, and determination of laws. Science no longer coincided with philosophy. It no longer consisted of thought about reality but it became empirical reality translated into thought. The third phase was the expansion of experimentation to all reality, resulting in the multiplication and development of sciences. Medical experimentation was born, and focused, systematic, and controlled experimentation on healthy human beings replaced the observation of corpses and other forms of clinical experimentation that characterized the earlier phases.

The third is the level of experimentation on human beings in the strict sense. It has arisen because of the irrepressible evolution of experimentation, justified and vindicated by the acquisition of the status of science, which has become associated with the endeavor to promote the good of man. We can define the specificity or the essential character of human experimentation in scientific and human terms. From the scientific point of view, the specificity of experimentation stems from three defining characteristics: the studies have a random design, the evaluation is double blind, and investigators compare the results with the effects of placebo substances or measures, or, preferably, to the effects of the drug commonly or previously used in the situation in question. From the human point of view, the specificity stems from the difficulty of maintaining the subject status of human beings who become objects of experimentation.

Because human beings have intrinsic, unconditional value, respect for human dignity dictates that we must not allow research to reduce human subjects to mere objects. While continuing to promote experimentation on human beings as an excellent means of obtaining benefits for humanity—to enhance the common good—we are challenged to preserve the dignity of each human subject involved in research—to preserve the individual good.

B. Phases of Evolution in Human Experimentation

We can divide the analysis of the recent history of human experimentation into two main periods of development, each of which comprises two stages. The first phase of experimentation on human beings, spanning the mid-nineteenth century through the end of World War II, a phase of discovery and implementation, saw the emergence of benefits entailed by the application of the experimental method to man, and the implementation of innovations into practice.

We can subdivide this century of progress into two sub-stages, which I call naïve innocence and uncurbed enthusiasm. Naïve innocence characterized the origins of human experimentation. Researchers worked alone, personally financed the research, and the subjects of experimentation were individual patients that the researchers aimed to treat. The researchers respected the deontological rules of beneficence and nonmaleficence, which in the era of prescientific medicine were not strictly applied. The doctor-researchers sought to promote the well-being of individuals without being able to predict the exact consequences of their experimental actions. The stage of uncurbed enthusiasm built on the still shaky knowledge achieved during the stage of naïve innocence. Researchers began to seek collaboration and to obtain a small degree of financial support. The number of experimental subjects increased, and the subjects were often anonymous. During this time, the main goal of researchers was the acquisition of knowledge. As experimentation resulted in more knowledge and researchers' enthusiasm increased, their awareness of the interests of the individual diminished, overshadowed by the so-called greater good of science or knowledge.

From "experimentation in trust" (to paraphrase Edmund Pellegrino and David C. Thomasma),[2] confined to the doctor-patient relationship and practiced on the researchers and their families, there was a move to "mass experimentation," applied to prisoners, orphans, mental patients, the aged, and soldiers. There was a growing conviction that the mass approach is justified by the absolute value of knowledge and the intrinsic goodness of progress.

Following these two phases, we see a clear transition from valuing the good of the individual to a concern for the common good. To cite an extreme example of this change in focus, we can consider the testimony of Nazi doctors on trial at Nuremberg. They claimed that they had not violated the Hippocratic principle of beneficence because they had always acted in pursuit of the common good of the German people.

In reaction to horrors imposed on human individuals in the name of the common good, the second period of human experimentation, a period of reassessment and regulation, saw a reassessment of the risks and benefits of experimentation and of the regulation of its practice. This period began after World War II, and it has continued to the present, with some transformations, which divide the period into two stages: a protectionist stage and an apparently contrary vindicatory stage.

During the protectionist stage, experimentation on human beings continued to develop, furthered by teams of researchers frequently financed by the state. At the same time, we saw a proliferation of ethical norms and bioethical institutions that assess the ethical legitimacy of projects and safeguard the interests of the subjects of experimentation. Experimentation on human beings

continued, but society imposed legal regulations on its procedures, developed ethical standards governing its practice, and controlled its financing. To prevent the violation of human dignity, society took steps to respect the primacy of the individual and the individual good over common good.

Now another stage is evolving, and together with the first, it defines the present situation. I have called it vindicatory to emphasize the uniqueness of the present movement in its consideration of minorities previously excluded from clinical trials, who now demand inclusion, and common citizens, healthy or sick, who claim the right to act as subjects of experimentation. Biomedical experimentation continues, increasingly performed by multidisciplinary teams of researchers. The projects have ever-increasing private financial backing, especially from multinational pharmaceutical companies with an unquestioning demand for lucrative returns that outweighs other ends. Pressure to safeguard the well-being of individuals and the constant need to update ethical norms has shaped new guidelines. Unfortunately, these guidelines have become increasingly legal and political in nature, and are at imminent risk of losing sight of their original ethical justification. This is the stage of experimentation *à la carte*, or on individual demand, developed alongside supervised experimentation, in which scientists select human subjects.

In its loss of naivety and in its creation of protective measures, the vindicatory stage bears witness to our efforts to surpass the negative side effects of experimentation.

C. Ethical Reflection upon Human Experimentation: From the Advent of Bioethics to the New Challenges

In the nineteenth century, a patient, confined in a charity hospital, was poor, ignorant, and profoundly vulnerable to any suggestion made by a prestigious, wise doctor. In the first half of the twentieth century, we confined abandoned orphans, mental patients, senile elderly patients, prisoners, and soldiers in institutions, bereft of their individual interests for the sake of the common good, vulnerable to those upon whom they depended. Since World War II, the individual, healthy or sick, who has agreed to participate in clinical trials, has become vulnerable to the professional standing of the researcher and the quality of the investigation.

Bioethics originated within a North American geo-cultural context, spurred by human dramas caused by experimentation. It has since been the protagonist of a new, true humanism for the "technological age" (to paraphrase Hans Jonas),[3] striving to guarantee the respect for the dignity and integrity of the subject of experimentation. The goal has been to protect vulnerable populations in two ways, by defending (negative sense) and by promoting (positive sense) individual rationality, liberty, and autonomy, through the enforced obligation to obtain informed consent.

Today, researchers in the field of human experimentation extensively promote autonomy, thanks to the numerous regulations in bioethics, biolaw, and biopolitics for the protection of individual self-determination and of individuals with diminished competence. Nevertheless, I believe vulnerabilities are multiplying without our noticing. Since this happens under the cloak of presumed autonomy, the process has become increasingly difficult to detect. Consequently, it has become increasingly difficult to protect individuals. These perplexities define our challenge for the future.

3. A Reassessment of Vulnerability in the Context of Human Experimentation

A. The Notion of Vulnerability

Vulnerability as a term has recently entered our lexicon of common morality. Texts addressing biomedical ethics frequently use the term. Of Latin origin, the stem *vulnus* means wound. Vulnerability expresses a susceptibility to being wounded, implying a fragility of the being that the term qualifies.

Emmanuel Lévinas and Jonas were the first to draw philosophical attention to the notion of vulnerability in the 1970s. Only later, in the 1990s, did the notion of vulnerability become common in bioethical thought.

In *L'Humanisme de l'Autre Homme* (*Humanism of the Other*), Emmanuel Lévinas defines vulnerability as subjectivity.[4] For Lévinas, alterity, or the other, always comes before subjectivity, or before the I. Therefore the I, depending on the other, is always in relation to the other and this relation implies vulnerability: "The I, from head to foot, right to the marrow, is vulnerable."[5] In this way, vulnerability entered the vocabulary of philosophy as an intrinsic characteristic of human beings, a condition of humanity.

Jonas, in *Das Prinzip Verantwortung* (*The Imperative of Responsibility*), also draws attention to the relevance of the philosophical meaning of "vulnerability," broadening its reality to the whole of nature and specifying its meaning as the perishable character of that which exists. Humankind is not only perishable and therefore vulnerable, but its members also have the power to harm other beings, including other humans, in their vulnerability, and so it becomes a duty, implied by power, to answer for the vulnerability of others.

Having established the relation between "power" and "duty," Jonas' vulnerability gains a positive ethical meaning, that is, it determines an effective obligation: that of defending and protecting, caring for and taking responsibility for those who are vulnerable. In Jonas, "vulnerability" is basically "concern, recognized as duty," it is responsibility before a vulnerability which, when threatened, becomes the object of care.[6]

This aspect is especially important insofar as it shows how vulnerability, as a condition of our humanity, acquires a different nature in each of the two philosophical universes: imminently descriptive in Lévinas and structurally prescriptive in Jonas. Jonas' vulnerability has a normative dimension that guarantees its necessary operative character in the ambit of an ethic applied to biomedicine.

The notion of "vulnerability," recently introduced into bioethical reflection, is understood in its broad and general sense of a universal condition of humanity, drawing attention to our all being vulnerable beings, and, in its restricted and operative or normative sense, to the duty to care for those threatened by power. In the specific field of bioethics, that power belongs to biomedicine and is accentuated in the realm of human experimentation.

Within this context, the principle of vulnerability prescribes the duty to protect people in relation to the possible threats of biomedicine. "Vulnerability" is understood in its interrelation with "power" and "duty," in an indissoluble combination.

The specificity of the bioethical acceptance of "vulnerability" lies in its being understood in two levels—broad and restricted—and in the interrelation between "power" and "duty." Vulnerability is identified in this point of intersection and it demands protection.

B. Power and Vulnerability: The "New Powers" and the "New Vulnerabilities"

Biomedicine has emerged with therapeutic, economic, and social powers during this present vindicatory phase of human experimentation. Of these, only therapeutic power, which emerged when human experimentation became scientific, corresponds to the original aim of human experimentation. Therapeutic power lies in the ability to obtain precise knowledge and to produce effective means for the cure or control of illnesses. Bearing in mind its recognizably good purpose, therapeutic power is ethically legitimate and should be developed through the strict fulfillment of the principle of beneficence (the obligation to do good), combined with that of nonmaleficence (the obligation to avoid harm), and in the subordination of that power to the interest of man.

The increase of therapeutic power results in part from and at the same time requires a growing number of subjects for experimentation. The traditional recruitment from amongst the patients by a particular doctor, service, or institution, can no longer meet the demand—and, besides, it raises delicate ethical questions concerning the dependence of the patient-subject upon the doctor-researcher.

As a result, attention has turned toward encouraging the participation of volunteers. Bioethicists have advanced the idea, with limited success, that a moral obligation exists for individuals to serve as subjects for experimentation for the sake of the scientific and social good from which each of us may benefit in our lives. At the level of applied research, conditions make participation appealing. Participants often enjoy easy access to the best health services available, which is a valuable asset for the economically underprivileged sectors of society and for people who suffer from ill health and frequently seek health care. In the final stage of clinical trials, the therapeutic aspects of the experimental procedure may be superior to those of standard procedures, which is an invaluable benefit for chronically or terminally ill patients.

A paradigmatic case of the new vulnerabilities arising from new therapeutic powers is that of Jesse Gelsinger, in the United States, in 1999. Gelsinger, an eighteen-year-old male, suffered from a mild form of Ornithene Transcarbamylase Deficiency (OTC), a rare liver disease caused by a genetic defect. Most newborns suffering from OTC die within hours after birth, but Gelsinger's symptoms were successfully controlled by drugs and diet.

Gelsinger participated voluntarily in a gene therapy trial, which was an extremely promising technique investigated since the 1980s, but which failed to live up to expectations. The innovative trial aimed to inject a vector—a modified cold virus containing the missing gene—into the blood stream, despite previous knowledge that the vector, toxic administered in high dosages, had caused the death of baboons during animal experimentation. Gelsinger's trial was the first case in which gene therapy was tested on relatively healthy people. The National Institute of Health (NIH) and the Federal Food and Drug Administration (FDA) approved the trial although some geneticists considered it too risky for use in human beings, and the researchers responsible for the study did follow the approved protocol. But Jesse Gelsinger died four days after receiving the vector. That trial, along with the entire North-American program for gene therapy, was immediately suspended pending investigation.

To think that voluntary experimentation subjects, who are administered what we believe is a benefit after granting informed consent, are not vulnerable, is a mistake. Researchers' optimism made Gelsinger vulnerable. The expectations of alternative therapies, the availability of free health services, or of swift and free access to them, make people vulnerable. As therapeutic power progresses and offers greater benefits, it also creates conditions for the appearance of new vulnerabilities, when, reasonably or not, it makes promises that might not be fulfilled. These new vulnerabilities emerge at the international, social, and especially the individual level.

At the international level, developed countries create new vulnerabilities when they export therapeutic power without considering the specific conditions of its application in underdeveloped countries. For example, the prevention of the transmission of HIV by discouraging breastfeeding exposes the newborn to other possibly more predictable and fatal dangers. At the social level, we create new vulnerabilities when a population is subjected to diagnostic methods when no effective corresponding treatment exists. Genetic screening (for example, testing for falciform anemia in Afro-Americans) and the

creation of stocks of DNA categorized by ethnic group exposes populations to potential new sources of discrimination.

At the individual level, patients for whom standard treatment offers no help vindicate therapeutic power from any source that promises hope—from fortunetellers to alternative medicine to the clinical trials underway, which sometimes recruit subjects via the Internet. The patients look for treatment for any ill from which they suffer—from hypochondria to terminal diseases that cause them to wish for a painless death. Sometimes, desperate and without other acceptable sources of comfort, they might resort to renting a room in which they will practice euthanasia. At the individual level, therapeutic power can become overwhelming and aggravate human vulnerabilities that include fear of illness, pain and suffering, death, and principally, lack of hope.

Evoking the principle of beneficence is not sufficient to morally legitimize the therapeutic power of biomedicine. Beneficence fails to protect humankind from the fascination that such power holds and which makes human beings vulnerable.

The economic power of biomedicine, unlike therapeutic power, has only recently emerged and immediately raises suspicions about its ethical acceptability. This economic power arises from the evolution of sources of financial support for research—personal, public, and later private—which has resulted in biomedical research becoming a financially viable activity.

Economic power is ethically legitimate and even praiseworthy if it complies with the principle of justice in the equal treatment of all. Today biomedical research requires heavy investments that surpass the possible financing capabilities of most gross national products.

As a result, we have seen a trend toward privatization in modern research. Biomedical research has transitioned from being conducted in universities, laboratories, and other state centers to being conducted in mega-companies, which have been created from merging pharmaceutical and biotechnological companies. The process has significant implications at the individual level. These include the growing anonymity of researchers and a consequent erosion of responsibility, and the involvement of scientists in the financial sphere, until recently unheard of. At the collective level, society has suffered a growing loss of control over the pursuits of science.

Because the economic powers financing research require profit to continue to finance more research, sponsors typically direct investigations toward predictably profitable paths. They can hold a reasonable expectation of profit only if they direct research to the needs of the richest countries and richest people. Powerful marketing campaigns support this course of action, which sometimes creates the need for the goods produced to guarantee their consumption.

In this context, Craig Venter's Celera Genomics program is paradigmatic at multiple levels. It illustrates the progressive control of private interests over public activities powered by profit, which frequently develop on the fringe of

the most urgent and global human needs. At the same time the development creates new human vulnerabilities by commodifying the human genome.

Researchers have been mapping and sequencing the human genome in the United States since 1987. The genome project had a predicted span of twenty-five years, with public financing from the Department of Energy and the NIH. Over time, the project extended to different countries, and the Human Genome Organization (HUGO) was put in charge of coordinating the international project. Meanwhile, some private enterprises sought to support the project, especially Craig Venter's Celera Genomics that, in 1998, claimed it would sequence the human genome within three years, ahead of all other competitors. At the same time, Venter announced that his company would not immediately make public the sequences they identified.

The interest of private enterprises in the human genome mapping research extraordinarily accelerated the project. At the same time, because the private financial sponsors worked to retain exclusivity on the intellectual property in the interest of making sizable profits from the patenting of DNA and its subsequent commercialization, the sponsors erected barriers to the free circulation of information. Their actions undermined the original aim of the project, which was to improve understanding of the universal genetic heritage of humanity.

Despite polemics having arisen from this issue, in 1998, the European Union adopted a directive that permits patenting in the field of biotechnology as long as the genes or gene sequences have an industrial application and use of the technology does not threaten human dignity. This was a compromise between ethical demands and economic requirements so as not to deter investment in biotechnological industries and allowing research in this field to continue.

This is not to say that economically powerful sponsors of biomedical research contemplate only crucial research or that they represent an elite pursuing financial gain, or that they lessen human needs. Presently we are experiencing a "medicalization" of human life. We seek to find a response to every human ill in health services—from simple discontent by resorting to a drug, to particular limitations such as infertility by turning to medically assisted fertilization. This state of affairs bears witness to the economic power wielded at the level of the individual. Accentuating needs increases vulnerabilities and economic power develops from the vulnerabilities it creates: from the wish for total health and well-being to ambition for absolute perfection and the desire for beauty.

Economic power also influences states of affairs at the social and international level when the means to combat disease exist but become financially inaccessible. When a community or population is unable to obtain primary health care, such as vaccination or the treatment of those infected with HIV, due to financial limitations, we consider them more vulnerable than if the means of treatment did not exist at all.

To invoke the plural principle of justice—from the libertarian model (advocates rights to social and economic liberty) to the equalitarian model (advocates equal access to the good in life that the common person values)—is not sufficient to morally legitimize the economic power of biomedicine. That principle fails to protect persons from the economic power's need for profit, and this makes them vulnerable.

Social power is the most recent of biomedical powers, evolving from therapeutic and economic power, and reinforcing them. Subtle, though no less influential, social power derives from the ability to gain people's trust from the success it achieves and to mobilize society by pursuing the future goals it claims it can reach. This power, by involving society in the objectives of science, is ethically legitimate and recommendable. It should protect individual autonomy in the sense that it should safeguard the primacy of human well-being against the exclusive interest of society or of science.

Social power sometimes extends beyond the boundaries in which its application is beneficial. The media often exaggerates achievements in the field of biomedicine, causing unrealistic expectations among the public. Bearing in mind that biomedicine benefits from publicity and that this publicity is as widespread as the predictable impact of the news, we should not be surprised that the publicity is often sensationalistic. This void sensationalism is always misleading, promotes the false belief that nothing is impossible for biomedicine, and creates a myth of life free from suffering, of absolute health, or genetic perfection. The sensationalism *per se* exploits another aspect of human vulnerability, the imagination of each individual.

A case in point is a commercial advertisement that employed a computer-enhanced image of Christopher Reeve, the paraplegic American actor who portrayed the mythical superman in the cinema, walking. Televised during the American football Superbowl in 2000, Reeve appeared to get up from his chair and approach a stage where he joined other beneficiaries of biomedical research. The impact of the image was so great that many paralyzed people who viewed the image believed that Reeve had been cured. They envisaged a cure for themselves.

Christopher Reeve became paraplegic after a horse riding accident in 1995. After that, Reeve initiated the lifestyle he maintained until his death in 2004: giving lectures, participating in academic sessions, sports programs, and television talk shows, writing books, and making public service advertisements. His goals were to promote the quality of life of physically disabled individuals and to raise funds to finance spinal cord injury research. The image of Reeve walking was intended to spur the imagination of people who, inspired by the hope that such a recovery is possible, would then donate to the cause.

Social power also generates new vulnerabilities at the social, individual, and international levels. On the international level, social power is operative in the classification of regions of the world according to their unfavorable general or specific health conditions. Where health risks are considered high, officials advise against travel to these regions. For example, the bird flu crisis has caused huge economic problems, especially in Asian countries.

Exaggerated claims about what biomedicine can accomplish causes individuals to hope that biomedicine will satisfy their every need and desire, and results in the conviction that biomedical action is always beneficial. For example, the Iranian conjoined twins, Laleh and Ladan Bijani, were the subjects of the first-ever attempt to separate adult craniopagus twins. They died on 8 July 2003 very shortly after unsuccessful surgery in Singapore. While many people applauded the medical team's efforts, others raised questions about whether or not the procedure should have been attempted. Can we not ask if these twins were victims of the social power of biomedicine?

The collective level is where the effects of this power are most visible in the growing demand for the benefits promised by biomedicine. Health associations acting as lobbyists, in the syndicalization of illness, favor those who have the greatest vindicatory power and aggravate the vulnerability of the rest. The lobby for the HIV patients is far more powerful than that for the manifoldly more numerous malaria patients; so the bulk of financing evidently goes to the first group.

To evoke the principle of autonomy is not enough to legitimize the social power of biomedicine because it does not protect people from the illusions it creates and that make them vulnerable.

4. Conclusions: The Shortcomings of an "Ethic of Rights" and the Vindication of an "Ethics of Duty"

Biomedical research on human beings for therapeutic ends has always been motivated by some good. The new powers achieved by biomedicine also contribute in diverse ways to some good. Traditionally, beneficence aimed at individual good, but it did not avoid the violation of human dignity and integrity that the promotion of autonomy sought to ensure, in the preservation of the interests of the individual.

Today, in the globalized world in which new powers are developing, the good of the individual can no longer be sustained aside the common good, nor does autonomy appear to be capable of preventing the proliferation of new vulnerabilities. Autonomy tends to leave individuals to their heightened individualism, removing responsibility from the other, hidden behind the legalism of the fulfillment of established norms. But a person is a being in relation and it is in the relation itself that the vulnerability of each individual unveils and the care of the other is put into practice.

We must move away from an individualist perspective, structured by the philosophy of rights that has determined the hegemony of autonomy in the

obligation to respect individual integrity, to a perspective of relation, to be structured by a philosophy of duties built on the obligation to protect the vulnerability of all by adopting attitudes of care and responsibility. The voice of the power of each individual expresses the individualist perspective; the perspective of relation is expressed in terms of one's duty in relation to others.

Today, therapeutic, economic, and social powers create new vulnerabilities. We need to reduce the effects of these powers. We can reduce these effects by complementing the traditional ethical principles with a principle of vulnerability. By enforcing an obligation to protect vulnerable persons, this will move us decisively from a logic of power to a logic of duty, and help our essential ethical relatedness to become fulfilled.

ACKNOWLEDGMENT

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NOTES

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