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COMMENTARY ON "THE 'PROJECT OF MORAL BIOENHANCEMENT' IN THE EUROPEAN LEGAL SYSTEM. ETHICALLY CONTROVERSIAL AND LEGALLY HIGHLY QUESTIONABLE" by Silvia Salardi

Abstract: The author investigates the concept of Moral Bioenhancement and the ethical-legal debate on the topic, with specific attention paid to regulations in the European context, the distinction between healthy individuals, unpatients, and patients, and the physician-patient relationship. She also asks the question whether the MB project is compatible with the current legal framework or not.

COMMENT

The most uncontroversial definition of Bioenhancement (MB) is given by Allen Buchanan: «a biomedical enhancement is a deliberate intervention, applying biomedical science, which aims to improve an existing capacity that most or all normal human beings typically have, or to create a new capacity, by acting directly on the body or brain». In particular, there can be a physical enhancement, where healthy individuals use modern biomedical techniques in order to enhance certain physical aspects of their body, and a moral enhancement, which refers to the use of biomedical practices to either ameliorate cognitive capabilities such as memory or concentration, or to modify attitudes or moods. The author focuses on moral bioenhancement, and in particular on that enhancement obtainable through the use of pharmaceutical substances, since they are very widespread and easily accessible by the public via web and the most realistic method, at the current scientific state of the art, to achieve enhancement – where the notion of enhancement is «a non-therapeutic intervention on healthy individuals».

The first relevant point of debate brought up in the paper is whether the project of MB should be transformed into a regulation in the current European legal system. Those who agree with the idea of pursuing Moral Bioenhancement – like Persson and Savulescu - say that it is imperative to do so, so that humanity can avoid disasters such as the global warming or the use of weapons of mass destruction. Thus, according to them, there should be a moral and a legal obligation to pursue it since it would eliminate human limits that put at risk the humankind itself – they defined this eventuality the *«ultimate harm»*.

Another problem raised by the author is the current state of the legal tools which regulate the use of pharmaceuticals in two different situations: while patients have regulations concerning the consumption of such substances, healthy individuals lack a specific set of rules protecting them should they choose to use them. This situation derives from the fact that while patients have always needed pharmaceuticals, up until recent years there has not been the need for healthy individuals to have regulations in this field. In the context of Moral Bioenhancement, however, the target public is, potentially, the totality of the population, and currently there is not the appropriate set of legal tools



to deal with this new phenomenon. Thus, healthy people are not covered, in the legal field, by specific rules that can protect them when it comes to the use of cognitive enhancers, with the risk that they may have to acquire all information they need elsewhere. As a consequence, the risk is that people do not receive adequate information to make a valid and autonomous choice: without a proper regulation, those who have interests in selling products on a large scale (like pharmaceutical companies and other economically driven actors) could spread incomplete or misleading information about the possible risks of the consumption of these substances for enhancement purposes.

A further problem is the current state of the art on the clinical studies on the subject: «the current studies on enhancement have been carried out on small samples, rarely more than 50 subjects, which limits their power [...]» (Farah, 2011). The major problem in this case would be that a regulation on enhancers would transform this practice into a mass experimentation without any control. However, there is not a complete lack of regulation, as data protection regulations and general principles of national and international law can also be applied to certain aspects of the project of MB.

The regulation concerning the physician-patient relationship is, instead, more complete and specific: there have been various cases and court decisions that provide a correct application of these rules, in particular on the crucial matter of informed consent. The right to informed consent is clearly stated in Article 3 of the European Chart of Fundamental Rights: in the therapeutic field, there are legal duties that must be followed to provide patients with clear and understandable information so that they can give their complete informed consent. These legal duties are necessary, because they aim at giving «relevant understanding, to avoid forms of manipulations, and to respect persons' rights» (Beauchamp and Childress, 2013). Moreover, since 1996 the boundary between patients and healthy individuals has become more and more blurred: the wide spreading of genetic testing, and in particular of predictive genetic tests, has had, as a consequence, the elaboration of a new category of people, the so-called unpatients. They are people with multifactorial genetic mutations causing a higher risk of developing genetic mental disorders or expressing features of personality like aggressivity or low self-esteem; even though they are healthy when they undergo the testing, they are more in danger of becoming patients than the general population, and therefore they are, potentially, the perfect target for moral bioenhancers. To rule administration of treatments in case of unpatients has always been problematic: would the use of pharmaceutical substances be considered as treatment, or would it be enhancement? Unlike healthy individuals, the category of unpatients is protected by the law, specifically by the physician-patient relationship. This relationship starts with the genetic counselling before taking the test, and continues after its results, when doctors can guide the individuals into choosing the best possible solution for their conditions. In particular, in the legal context, there have been many tools regulating the matter of genetic testing - an example is the International Declaration on Human Genetic Data of 2003 – and the problem of the protection of personal data (which is particularly delicate for the unpatients, given their high risk condition and the fact that the result of their genetic testing may also affect their family).

In addition to the abovementioned topics, the paper also deals with the implications that the use of Moral Bioenhancement may have for Human Rights, in particular for the rights to equality and non-discrimination. Moral Bioenhancement would allow people to use substances that eliminate the "bad"



traits of one's personality and develop their best traits, supposedly turning themselves into a better person. But the subject raises many questions: who is authorized to classify traits as "good" or "bad", as traits that must be eliminated or enhanced? What are the criteria for choosing one trait to the detriment of another? What goal should be set? Which justification is given on the choice of the preservation of certain features and the elimination of others? The author introduces examples of theories developed during the history, from the theory of Lombroso and Ferri, who tried to give a scientific definition of criminal behavior and introduced concepts of "social dangerousness", to Ferguson and Beaver who talk about the «betterment of society». She also reflects on the concept of Human Nature, underlining the difficulty of finding a clear definition and the risks if it is used in a misleading way. As a matter of fact, the project of Moral Bioenhancement is strictly related to the Human Nature, and consequently to the rights of equality and non-discrimination. There is not a clear definition of Human Nature as it is something that has evolved over time and depends deeply on the set of values and morals of a particular area or population. While it is unanimous that certain behaviors are morally reprehensible and should be eliminated, the range of personality traits and actions are much more nuanced than the black-and-white vision of "good" and "bad": the socio-cultural environment in which an individual grows up, the beliefs of the person itself and external events can give to the same behavior different connotations. The author of the paper underlines how the theories about Moral Bioenhancement should not focus on the research of a "Super Human Nature", on a series of markers that define it, because otherwise we would have chosen what should be human and not what de facto is. Furthermore, there is the real danger of the classification of people into certain categories and the subsequent discrimination of these groups, thus affecting the fundamental rights to non-discrimination and equality. The risk of classifying individuals into categories would not be consistent with how the current legal framework interprets the principle of equality: the European system, instead, focuses on the «equal entitlement to the same fundamental rights» (Ferrajoli, 2007) and the protection of these rights. The principle of equality, from a legal point of view, does not mean that everyone is equal, but that everyone is different and for this they must be treated equally. A legal obligation to Moral Bioenhancement and a definite set of markers to describe the Human Nature would disrupt this definition of the principle of equality.

From a legal point of view, the author investigates on the possibility of a change of the current set of legal tools offering the example of *unpatients*, whose protection is derived, with slight modifications, from the one given to the patients. She recognizes the difficulties of such a change in the current legal context but stresses out how the protection of healthy individuals in relation to Moral Bioenhancement should not be based solely on the interpretation of the right to health and self-determination. The new regulations should include rules on the transparency of information provided about the use of pharmaceutical substances for enhancing purposes and on the economic interests of those who sell it, but they would also focus on the criteria of the choice of "good" and "bad" traits and of who is entitled to choose them. This would involve an interpretation of the current European society, and a definition of Human Nature based on those results. Such definition, however, should not be set on limited markers of identity: not only would this search for a "Super Human Nature" be



unrealistic, but it would also be dangerous. As a matter of fact, it could potentially cause new forms of discrimination based on the differences between the individual and the definition of "Super Human Nature". Instead, the author suggests other matters that needs to be addressed: for example, principle of precaution should play a leading role in both the current and the future situation, as well as anticipatory models and specific rules on transparency of the information. She offers the example of the field of clinical trials, in which such principles have become the basis of the regulations, and quotes the European Regulation n.536/2016: «In a clinical trial the rights, safety, dignity and well-being of subjects should be protected and the data generated should be reliable and robust. The interests of the subjects should always take priority over the interests». Thus, the fundamental rights, including the rights to safety and dignity, have to be hierarchically superior to every scientific and economic interest (the economic interest in particular is quite strong in the enhancement field), and the information provided, mainly on the short and long term risks of the substances and on the current state of the art, should be made as available and accessible as possible.

The problems and the possible solutions delineated by the author deal with practical aspects of Moral Bioenhancement. In particular, from a legal point of view, the absence of specific rules that protect healthy individuals may expose them to unnecessary dangers, from errors in the dosage and the lack of information about the benefits and the risks in the short and long term, to active manipulation of data from those actors who have scientific and economic interests. For this reason, the instauration of some sort of physician-patient relationship should be considered even in the case of healthy people who decide to use enhancers, since the medical professionals could be the best figures people could refer to when talking about pharmaceuticals. Furthermore, the doctor would know the medical history of the person and can guide him/her while choosing whether to use enhancers or not, what type of enhancers to use, and allow him/her to give a fully informed consent. In case of creation of rules on the subject, the legislator should refer, as the author said, to the principle of precaution and to the rules on clinical trial.

Advocates of Moral Bioehnancement, who consider that MB should not be solely a moral obligation but also a legal obligation, should take into consideration the deep effect it would have on the fundamental principles and on the hierarchy of the interests. The prevention of the "ultimate harm" should not be the reason for taking enhancers, but the respect of the dignity, the self-determination and the psychophysical well-being of the individual should. In case bioenhancers to modify both cognitive and personality features should become mandatory, "we would deprive ourselves of our freedom and hence, to some degree, of an important element of our human existence» (Rakić, 2014). Rakić in particular refers to freedom as *free will*, as something different from other types of freedom that have been limited, to certain extent, by the state: free will is what compels us to act morally, and imposing a certain behavior or morality would both violate fundamental principles of human rights and doesn't make us morally superior, since there is an obligation. Another consequence would be facing the risk of considering people who do not align with the idea we will inevitably make of Human Nature as "less human" and thus more likely to be discriminated. On the other hand, leaving a legal vacuum on this subject would be dangerous, whether we do so to disincentivize MB or to leave it to the free choice of the individual. In this way, we would put at risk all those people who would use it,



because they would be subjected to the economic interests of the actors who sell the pharmaceutical substances and they would not be protected from the violation of their rights.

For this reason, an intermediate solution must be followed, if we want to allow people to make free and informed choice on the matter. A specific regulation should be provided on the subject, in particular on the way people can access these substances and on the matter of complete information and transparency. As a consequence, the concept of physician-patient relationship should be modified to also include healthy individuals who wish to ask for guidance or simply for information to their doctor. As for the form of regulations, they should impose hard limits on certain practices that could grossly violate fundamental human rights, but at the same time they should leave the freedom of choice on the individual in respect of the pluralistic view of society. In this way, people who are interested in this new form of technology can make use of it in a protected discipline, and those who are not interested can freely choose not to make use of it. Furthermore, court decisions and other instruments like recommendations, protocols and legal doctrine should also contribute to the shaping of appropriate tools to deal with this new phenomenon. In this way, the hard core given by the law could be completed with agile instruments, which are able to keep up with the quick evolution of scientific technology.

In conclusion, even though technologies are quickly progressing, challenging the shape of our society and modifying the concept of what is considered human, there is still the hard core of Human Rights that has to be protected in such a delicate matter, as a violation or a limitation of them could endanger many people. The governments should, instead, focus on the protection of these rights in consideration of the advancing of MB, and guarantee truthfulness of information surrounding the commercial interests of the actors involved, the benefit and the risks of the practices and the state of the current art, but should leave the ultimate decision to the individual.

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