Destined to be super human? Moral Bioenhancement and its legal viability

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ABSTRACT: Moral bioenhancement is strictly related to the notion of Human Enhancement. In general terms, the proposal fosters interventions by means of pharmaceutical and non-pharmaceutical tools into the human mind to make individuals become morally better. In order to understand the ethical-legal implications of this proposal, the paper will try to answer, amongst others, the following questions: Is identification of the target group of the proposal easy today? Is the traditional distinction between healthy individuals and patients so clear? What may be the implications of one's personality?

KEYWORDS: Moral bioenhancement; bioethics; biolaw; moral technologies; human enhancement

SOMMARIO: 1. Introduction -2. Definition and contextualization -3. Healthy people as the target group of moral bioenhancement: some critical remarks -4. The role of institutions in fostering moral bioenhancement -5. Destined to be super human? Some open basic questions about the project of moral bioenhancement.

1. Introduction

o talk about moral bioenhancement (MB) means to tackle ethical-legal questions of a different nature. These questions are very complex and require an in-depth inquiry into many fields of knowledge ranging from neuroscience to genetics, psychology, ethics, law and so forth. The debate began some decades ago and, in its earliest times, was mainly restricted to exchange of ideas among moral philosophers and bioethicists primarily within the academic environment. Over time, however, MB has been developed into a more detailed proposal termed 'project of MB'. The main input to development of MB as a 'project' can be traced back to the most enthusiastic promoters of MB, namely Julian Savulescu and Ingmar Persson.¹

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¹ See I. PERSSON, J. SAVULESCU, The perils of cognitive enhancement and the urgent imperative to enhance the moral character of humanity, in Journal of Applied Philosophy, 25, 2008, pp. 162-177; Unfit for the future? Human nature, scientific progress, and the need for moral enhancement, in J. SAVULESCU, R. TER MEULEN, and G. KAHANE (edited by), Enhancing human capacities, Oxford, 2011, pp. 486-500; Unfit for the future: The need for moral enhancement right: The desirability of moral bioenhancement, in Bioethics, 27, 2013, pp. 124-131.

They claim that there is a moral obligation to MB for diminishing global threats like wars and therefore to keep the conditions for a peaceful coexistence at the global level. Their original proposal envisages a society where there is an institutional implementation of MB to be applied society-wide. Their radical proposal has been discussed for decades. No agreement on the basic aspects of it has been achieved at the ethical level, and the following questions are still open: who operates the selection of traits and features of personality? What traits, impulses or instincts should be enhanced or conversely eliminated?

Despite the lack of agreement on these fundamental questions, the core idea of their thesis remains one of the pillars, albeit sometimes unwittingly, of the whole discussion about MB as a 'project'. And a testament to this is represented by the increase both in publications regarding this specific topic² and in the institutional interest at the EU level in this matter.³

This increasing interest should seriously be acknowledged: first, because so much has been written and said on MB that it may seem almost like presumptive vanity to pursue the topic any further as the risk is to become repetitive; and secondly, because the spectrum of the questions arising by MB is so broad that again the risk is to deal with the issues superficially and to give an excessively thumbnail sketch. These concerns are not exaggerated as scientific advances and technological innovation speed up exponentially, and the implications of such an acceleration is, to a quite great extent, unpredictable not only in terms of potentiality and invasiveness but also of public true understanding. However, for the purposes of this paper I cannot deal with all the ethical-legal questions arising from the project of MB. Instead, I will focus on some aspects that I think are still worthy of note. Thus, what I will do is first to define MB and put it in the context of a process started in the second half of the past century and termed 'medicalization of society'. In so doing, I will be able to approach the matter from a specific angle, that is, the relationship of the assumed target category of bioenhancing techniques (healthy individuals) with other relevant categories (patients, 'unpatients') that may or may not be target groups of MB.

The questions that will guide through my line of reasoning are: Is identification of the target group of MB easy today? Is the traditional distinction between healthy individuals and patients so clear? What about 'unpatients'? What legal protection do healthy individuals find in the current legal framework in Europe in case of use and administration of drugs for enhancing purposes? What may be the implications of MB for the right to self-determination and free construction of one's personality?

I will deal with the topic from a biolaw perspective trying to relate ethical questions with legal ones. The aim is to test the consistency of the project of MB with the current European legal framework. Eventually, I will briefly discuss what is going on behind the scenes of the project of MB, that is, what

² Recently, an entire issue of *The American Journal of Bioethics* 2014 (Vol. 14, issue 4) was dedicated to the 'project' of MB from different points of view.

³ Many projects have been dealing with the topic of Human Enhancement with particular attention paid to moral bioenhancement, see for instance, the EPOCH project (Ethics in Public Policy Making: the Case of Human Enhancement) whose final report is available at <u>http://cordis.europa.eu/result/rcn/153896 en.html</u> (last accessed July 25, 2017); the 2009 Human Enhancement Study (IP/A/STOA/FWC/2005-28/SC35, 41 & 45) by the Directorate General for Internal Policies, European Parliament; the Nerri project see <u>http://www.nerri.eu</u>, just to mention a few. And others have been financed under various EU projects like Jean Monnet and so forth.

I will term 'going back to the basics' of MB as a project. It is indeed undeniable that a specific moral stance about human nature is shaping the discourse of MB: are we destined to be super human?

2. Definition and contextualization

What is MB? If you are reading this paper and dealing with this topic, the chances are good that you live in a society where technology and science are one of the main drivers of sociocultural development, and that you have, at various points in your life, come to very much depend on what they offer you. As Jasanoff and colleagues put it: «Science and technology not only improve lives but shape our expectations, and eventually our experiences, of how lives ought to be lived. In these respects, science and technology govern lives as surely as law does, empowering some forms of life and making them natural while others, by comparison, come to seem deficient or unnatural».⁴

These short remarks are instructive in reminding us of the specific context in which the discourse about MB takes place, and consequently of a general and widespread misunderstanding about contemporary enhancing tools and devices.

Indeed, the general way of misunderstanding them is to compare these techniques with 'traditional' practices of enhancement like education, training, practice and so forth.⁵ But these kinds of enhancement are not discussed in ethics literature today. Despite the lack of a neutral and all-encompassing definition, the notion of enhancement that is being debated in ethics literature is a quite precise one: it is limited to biomedical and biotechnological interventions on the human body and mind, which aim at improving or creating capacities by acting directly on the body or brain.⁶ The general term for this is Human Enhancement (HE).

The notion of MB is strictly related to HE as above depicted, but with a specific and peculiar aim: MB focuses on the possibility of enhancing human morality by biomedical and biotechnological means. Thus, MB as a specific notion of HE emerged from and is embedded in the scientific progress of certain nations, in certain periods, above all Western countries in the post-war era. As John Harris puts it in his book entitled *How to be good. The possibility of moral enhancement:* «Human enhancement has become one of the key areas of contemporary science and innovation and focus of concerns about the responsible and ethical application of science».⁷

In this framework, MB expands the frontiers of enhancement far beyond physical and cognitive enhancement as discussed in enhancement ethics literature till recently.⁸

I suggest that, to a great extent, this kind of expansion can be traced back to a phenomenon termed 'medicalization of society' by American social scientists like Irving K. Zola and Peter Conrad between

⁴ S. JASANOFF, J. B. HURLBUT, K. SAHA, *CRISPR Democracy. Gene Editing and the Need for Inclusive Deliberation*, in *Issues in Science and Technology*, 32, 2015, pp. 25-32, at p. 26.

⁵ See the case of administration of psycho-stimulants in children for a clear analysis of what could be ordinary moral enhancement and what is not as well investigated by M. GALLETTI, *Forme di miglioramento morale. L'uso di farmaci psico-stimolanti tra terapia e miglioramento,* in *Bioetica,* 4, 2016, pp.1-22.

⁶ Allen Buchanan defines HE as «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», see A. BUCHANAN, *Beyond Humanity*, Oxford, 2011, p. 11.

⁷ J. HARRIS, *How to be good. The possibility of moral enhancement*, Oxford, 2016, p. 7.

⁸ J. HARRIS, *op.cit.*, pp.7-8.

the 1960s and the 1970s. In general terms, medicalization has been defined as «a process whereby more and more of everyday life has come under medical dominion, influence and supervision».⁹ Thus, by and large, medicalization is a process by which nonmedical problems become defined and treated as medical problems, usually in terms of illness or disorders. In the early stages of the debate, this process was strongly associated with medical dominance, namely with 'extension of medicine's jurisdiction over 'normal' life events and experiences. However, it soon became clear that not only this process is 'bidirectional' «in the sense that there can be both medicalization and demedicalization»¹⁰, but it is also very complex in relation to both the accounts of agency shaping it and to the phenomena involved in it. As for the accounts of agency shaping the process of medicalization, in its earlier stages physicians were assumed to be the key factor to medicalization. And admittedly, the medical approach for sure contributed to medicalization by reclassifying both 'normal' life events such as aging and birth and some recognized social problems and deviance from 'normal' or 'bad' to 'sick'.¹¹ Nevertheless, over time, other forces have begun to play a key role in increasing, instead of decreasing, medicalization, for instance: the decrease of public's tolerance of mild symptoms,¹² social movements, and patient organizations.¹³ Although some of these forces are more powerful in specific geographical areas like the USA, one should not overlook their role in the European context as well.¹⁴ This is also true for more recent agents like corporate entities of a different kind as, for instance, on the one side, pharmaceutical industries, and, on the other, consumers. These two entities, albeit very different in terms of interests and expectations, have become main agents for medicalization of society as well as for the extension of the concept of medicalization to mean also non-strictly therapeutic techniques like biomedical enhancement.

As is indeed well-known in the debate about human enhancement, there is a close relationship between therapy and enhancement as the boundary between them is transient.¹⁵ And I suggest that, to a great extent, this close relationship depends on the process of medicalization. In other words, HE and consequently MB by means of biomedical tools flow from this phenomenon. Indeed, biomedical interventions and advances approved for one treatment pave the way for use as enhancements for any kind of self-improvement or self-shaping.

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⁹ I.K. ZOLA, *Socio-Medical Inquiries*, Philadelphia, 1983, p. 295.

¹⁰ P. CONRAD, *The Medicalization of Society. On the Transformation of Human Conditions into Treatable Disorders*, Baltimore, 2007, p. 7.

¹¹ K. BALLARD, M. A. ELSTON, *Medicalization: A Multi-dimensional Concept*, in *Social Theory & Health*, 3, 2005, pp. 228-241.

¹² See A. BARSKY, J.F. BOROS, Somatization and Medicalization in the Era of Managed Care, in Journal of the American Medical Association, 274, 1995, pp. 1931-1934.

¹³ D.H. BROOM and R.V. WOODWARD, *Medicalization Reconsidered: Toward a Collaborative Approach to Care*, in *Sociology of Health and Illness*, 18, 1996, pp. 357-378.

¹⁴ As Peter Conrad highlights: «Medicalization is prevalent in the United States, but it is increasingly an international phenomenon. This is partly the result of the expanding hegemony of western biomedicine, but it is facilitated by multinational drug companies and the global reach of mass media and the Internet». See on this point of P. CONRAD, *The Shifting Engines of Medicalization*, in *Journal of Health and Social Behaviour*, 46, 2005, pp. 3-14, at p. 11.

¹⁵ The question whether preventative measures like vaccines are therapy or enhancement is still a very telling example. But the question is also debated in relation to the distinction between 'cosmetic' and 'therapeutic' procedures as the boundary again is fluid and uncertain.

As Nikolas Rose points out: «Life now appears to be open to shaping and reshaping at the molecular level: by precisely calculated interventions that prevent something happening, alter the way something happens, make something new happen in the cellular processes themselves. As the distinction between treatment and enhancement, between the natural and the prosthetic so inescapable, these normativities appear open to alteration. Once one has witnessed the effects of psychiatric drugs in reconfiguring the thresholds, norms, volatilities of the affects, of cognition, of the will, it no longer seems possible to imagine a self not open to modification in this way.»¹⁶ The almost undisputed social acceptance of and quest for enhancement techniques on the part of the public is, in my opinion, very facilitated by its being 'felt' and 'experienced' as something that is 'medical' in its origin, which means it is strictly associated with values like safety, trust, welfare, scientific evidence and so forth.

And of course, the strict connection between the two realms as kinds of 'medicalized solution' is interesting for entities promoting this phenomenon like pharmaceutical industries. As a matter of fact, to increase the diffusion of MB by means of pharmaceutical tools could be very fruitful in economic terms if the target group is that huge as the category of healthy individuals is. Moreover, this extension beyond the therapeutic realm is also intriguing from the consumers' perspective, as today many people are interested in using drugs or other devices and tools for enhancing purposes rather than therapeutic ones.¹⁷ The reasons for this are manifold: competitiveness, low self-esteem, the neverending quest for happiness and so forth. But among all the possible reasons there is one that I think plays a very important role, that is, the great deal of publicity surrounding the use as enhancers of devices and drugs originally developed for therapeutic purposes as just referred to. Indeed, the strict connection between therapy and enhancement has been widely exploited¹⁸ in media communication of scientific and technological discoveries to the public. How?

In newspapers and media in general, any scientific and technological advance for therapeutic purposes is immediately promoted for enhancing purposes. And I think this is deeply influencing public perception of the opportunities offered by science and technology and is playing a major role in fostering the process of medicalization.

The main problem concerning the role of media is that they present every single scientific and technological progress has having immediate possibility of implementation on a large-scale.

It follows that not only do people are misinformed about the variety of enhancers concretely being marketed and available, but they are also victim of the mystique surrounding the potentialities of very different enhancing techniques.

And here I come to the second aspect I mentioned earlier in relation to the process of medicalization: the variety of phenomena that this notion can cover. As observed, in the early formulations of medi-

¹⁶ N. ROSE, *The Politics of Life Itself*, in *Theory, Culture & Society*, 18, 2001, pp. 1-30, at pp. 16-17.

¹⁷ As testified by the Report of the Nuffield Council on Bioethics concerning *Cosmetic procedures: ethical issues*, released in 2017 we are faced with "neoliberal notions of the self", by which it is meant: «the sense of a moral imperative for individuals to work upon themselves [...] Commentators have identified the emergence of the 'enterprising self' who needs to be, and is exhorted to be, responsible not only for improving themselves [...] but for continuous self-monitoring and self-evaluation», at p. 15.

¹⁸ For instance, I just mention here some recent articles in Italian newspapers M. MONTI, C. A. REDI, *Umanità geneticamente modificata*, in *Corriere della Sera*, August 28, 2016; A. LONGO, *Umano-Postumano*, in *L'Espresso*, August 28, 2016; M. BOERCI, *Invecchiare*, in *Il Sole 24Ore How to spend it*, October, 2016; M. MORELLO, *DNA 2.0*, in *Panorama CON*, November, 2016.

calization, this was viewed as a process that was increasingly translating normal life events into medically supervised ones (childbirth and menopause, for instance) or shifting social problems such as deviance from the moral realm to the medical one.¹⁹ Thus, in those early approaches, medicalization was restricted to therapeutic interventions. But this is no longer the case today. Right because movers for the process are of a different kind, ranging from corporate entities with economic and financial interests in enhancing biomedical techniques to individuals playing a role as rights-bearers²⁰ and consumers, medicalization has extended its meaning to include biomedical interventions without a malady.²¹ This implies that we will witness an expansion of medicalization as new engines are involved in the process like, for instance, promotion of genetic tests.

As a matter of fact, advances in genetics are becoming one of the main contributing factors implicated in medicalization as well as in bioenhancement.²² Despite the category of enhancers of the mind for 'moral' purposes encompasses pharmaceutical tools like drugs and non-pharmaceutical enhancers like brain stimulation and implantable brain chips, gene therapy is one of the most appealing as its potential market is enormous. Although its potentiality has not been fully translated into reality, it is being increasingly and widely publicized as directly usable without much attention to the realistic expectations of the actual benefits and limitations of its enhancing power. This is a risk for many enhancers of the mind, both pharmaceutical and non-pharmaceutical.²³ However, gene therapy is particularly exposed to these kinds of peril.²⁴

Since genetics has indeed become one of the main drivers of the (bio)medicalization process of normal human experience, the tendency has been to broaden diagnostic and treatment boundaries to include in the 'disease' category people with milder manifestations of pathology and lower levels of risk, and to progressively expand treatments in healthier populations. The publicity of the potential uses of genetic discoveries runs faster than the process that allows science to achieve sound evidence in this field. Currently, there is no sufficient shared sound scientific evidence of the enhancing

¹⁹ See on this point P. CONRAD, J.W. SCHNEIDER, *Deviance and Medicalization: from Badness to Sickness*, Philadelphia, 1992.

²⁰ Self-shaping by means of biomedical interventions could be viewed as a means to exercise the right to selfdetermination and free construction of one's personality.

²¹ There are many cases exemplifying this trend, see P. CONRAD, *The Medicalization of Society*, cit., specifically chapter four; and of the same author *The Shifting Engines of Medicalization*, cit.

²² There are many and different uses of genetic advances for enhancing purposes, in sport, for instance, genetic testing and gene therapy play a multifaceted role in both selecting athletes and in proposing modification of DNA to develop athletic talent. See for instance S. BREITBACH, S. TUG, P. SIMON, *Conventional and Genetic Talent Identification in Sports: Will Recent Developments Trace Talent?* in *Sports Med*, 44, 2014, pp. 1489-1503; R. TUCKER, M. COLLINS, *What makes champions? A review of the relative contribution of genes and training to sport-ing success*, in *Br J Sports Med*, 46, 2012, pp. 555-561; M. UNAL, D.O. UNAL, *Gene Doping in Sports*, in *Sports Med*, 34, 2004, 6: 357-362.

²³ See M.J. FARAH, *The unknowns of cognitive enhancement*, in *Science*, 350, 2015, pp. 379-380.

²⁴ Consider in this sense the ongoing heated debate on human genome editing by means of the recent technique CRISPR-Cas9. Many institutional reports have dealt with this topic in the current year, see, for instance, amongst others, the Italian Report by the Comitato Nazionale per la Bioetica, *L'editing genetico e la tecnica Crispr-Cas9: considerazioni etiche,* February 23, 2017; National Academies of Science, Engineering, Medicine, *Genome Editing. Science Ethics and Governance*, 2017.

potentiality of genetics.²⁵ Moreover, the depiction of genetics to which the public has been exposed for decades, that is, genetics as the context in which we find certain and ultimate answers to how we are and/or should be, cannot be underestimated.²⁶ Genetics has indeed received unprecedented exposure in the popular media. And this has contributed to portraying one's genetic make-up as a near absolute determinant of health or life success and the like. As Peter Conrad has observed: «The message that biomedical enhancements impart is that individuals are dissatisfied with their current condition, whether it be height, breast size, or performance. Dealing with this dissatisfaction through biomedical means, however, may be seen as a profoundly individual approach [...] biomedical enhancements are inherently conservative strategies: they change the individual rather than deal with the social standard or expectation in a more collective manner».²⁷

In the light of the previous considerations, and given that there are multifaceted possibilities to bioenhance the mind for moral purposes, the following remarks about MB as a 'project' will be made against the background of specific cognitive enhancers, i.e., drugs. This because drugs are the most realistic options for MB to be discussed as a 'project' from a legal perspective, due not only to their large-scale diffusion and easy availability amidst the target public, i.e., healthy individuals, but also to the existence of a clear legal framework ruling their use and administration.

3. Healthy people as the target group of moral bioenhancement: some critical remarks

Every discussion about MB as a 'project' as referred to earlier has come to imply that this is carried out society-wide and that its target group are healthy individuals. First, the project of MB should be society wide, otherwise, as Robert Sparrow underlines,²⁸ the egalitarian ideals inspiring western societies would be doomed to fail.²⁹ And of course, secondly, it targets healthy individuals as enhancement is not therapy as it has different scopes like amelioration of existing abilities and creation of new ones.³⁰ If we base our reasoning on these premises, a first, perhaps redundant, consideration is that the project of MB does not concern and include patients.

²⁵ See D. MELZER and R. ZIMMERMANN, *Genetics and medicalization*, in *BMJ*, 324, 2002, pp. 863-864. The authors maintain that: «Genetics tests for markers that may not result in symptoms for half a century or more could be new examples of a process of premature medicalization-of attaching the "disease" label before it has been established that prevention or treatment is clearly beneficial», p. 863.

²⁶ See for all P. ROCHE, G. ANNAS, *DNA Testing, Banking and Genetic Privacy, N Engl. J. Med.*, 355, 2006, pp. 545-546.

²⁷ P. CONRAD, *The medicalization of society*, cit., p. 94.

²⁸ R. SPARROW, *Egalitarianism and Moral Bioenhancement*, in *The American Journal of Bioethics*, 14, 2014, pp. 20-28.

²⁹ Of a different opinion, for instance, Peter Conrad who maintains that: «The key to the notion of enhancement, however, is that only some are enhanced. There is no edge if the attribute is universal», see P. CONRAD, *The medicalization of society*, cit., p. 89. I agree with Conrad's position whenever cognitive or physical enhancement is at stake. However, I disagree with this view when bioenhancement is for moral purposes, that is, to increase moral standards. In this case, the more universal is moral bioenhancement, the more likely moral progress becomes effective.

³⁰ At the institutional level in Europe this distinction still works as testified by amongst others, the 2007 Report entitled *Genetics and Human Behaviour*. *The Ethical Context* by the Nuffield Council on Bioethics; the 2011 Report entitled *L''amélioration' de l'humain par des substances pharmacologiques* by the Swiss National Commis-

To identify the target group is important to avoid basic and trivial misunderstandings in the debate. Is it a simple task? Unfortunately, I do not think so. Indeed, who are healthy individuals? A first consideration concerning this category is that it is not so monolithic as it could seem at a first glance. The category can indeed include not only adults but also children and young people. And of course, access to enhancement techniques for moral purposes should be carefully evaluated in case of young people and children. It should be paid particular attention to the question of whether there are good reasons why the available techniques could not be delayed until adulthood and the shaping of their morality could not follow most 'traditional', not or less controversial ways. To discuss these relevant issues would broaden the horizons of this paper beyond its scope, that is why I will limit the current discussion to a peculiar and critical aspect, that is, healthy individuals as the target group of MB. The above posed question 'who are healthy individuals?' does indeed not have a clear-cut answer because the traditional distinction between patients and healthy individuals -being the former a person who is receiving medical treatment for a diagnosed illness or disorder, and the latter someone having good health and not likely to become ill/sick-³¹ has been brought into question by the emergence of a new category relevant both in medical and nonmedical terms.³² I am referring to the category termed 'unpatients' in 1996.³³ This category is associated with changes and transformations in the biomedical field brought about by the diffusion of discoveries in genetic science, in particular of predictive genetic tests for physiological or psychological risk markers. 'Unpatients' are neither patients nor healthy individuals. They carry a gene mutation that potentially puts them at risk, though they do not manifest symptoms of illness. They are 'at risk' of possibly developing a given disease. In other words, they are implicated in the process of probably 'becoming ill'³⁴, so they become 'medicalized' through processes as surveillance, screening, and routine measurements of health indicators.³⁵

sion; the 2013 Report entitled *Neuroscienze e potenziamento cognitivo farmacologico: profili bioetici* by the Italian National Committee on Bioethics; the 2009 *Human Enhancement Study* by the European Parliament (IP/A/STOA/FWC/2005-28/SC35, 41&45).

³¹ These are the standard definitions of the terms 'patient' and 'healthy' to be found in the Oxford Advanced Learner's Dictionary, 2010.

³² In nonmedical terms this category is relevant in relation to cases of social and cultural discrimination.

³³ A.R. JONSEN, S.J. DURFY, W. BURKE, A.G. MOTULSKY, *The Advent of the Unpatients*, in *Nature Med.*, 2, 1996, pp. 622-624. See for some comments and remarks concerning this specific category S. SALARDI, *Ethical and legal implications of interventions on 'unpatients': therapeutic v. non-therapeutic treatments*, in *BioLaw Journal- Rivista di BioDiritto*, 1, 2014, pp. 133-144.

³⁴ A. PETERSEN, *Risk, Governance, and the New Public Health*, in A. PETERSEN and R. BUNTON (edited by), *Foucault, Health, and Medicine*, New York, 1997, pp. 189-223.

³⁵ Some authors have suggested considering risk factors and self-surveillance as key processes of biomedicalization, which is the term they propose for renaming 'medicalization'. In their view, biomedicalization refers to: «increasingly complex, multisited, multidirectional processes of medicalization that today are being both extended and reconstituted through the emergent social forms and practices of a highly and increasingly technoscientific biomedicine», see A.E. CLARKE, L. MAMO, J.R. FISHMAN, J.K. SHIM, J. R. FOSKET, *Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine,* in *American Sociological Review*, 68, 2003, pp. 161-194, at p. 162. Peter Conrad has underlined that the authors' arguments have many virtues, but 'biomedicalization' is: «a much broader concept than medicalization and emphasizes a more extensive set of changes than is usually meant by medicalization», see P. CONRAD, *The medicalization of society,* cit., p. 14.

To see why this new category is problematic for identification of the target group of MB, we should try to answer the following question: how do we draw the line between healthy individuals and 'unpatients'?

On a fundamental level, genetic science is indeed forcing a re-examination of the concept of normality and health, as the category of 'unpatients' reminds us of the fact that everyone is potentially ill. Until an individual undergoes genetic testing of a predictive nature, she may assume to be healthy. Paradoxically, what makes the difference between healthy individuals and 'unpatients' is just the decision of undergoing a risk assessment or genetic testing.

Thus, it has become sometimes, if not very often, difficult to say at what point along a continuum healthy individuals become patients. This has of course implications of a different kind. By and large, as the category of 'unpatients' is strictly connected with taking preventive actions, one of the vexed issue is to determine which of the preventive measures 'unpatients' need should be covered by national health care systems, and here criteria such as appropriateness based on reasonable evidence of efficacy have been considered useful to guide the decision-making process. As regards the specific project of MB the existence of this new category forces us to reconsider the question of the target group. 'Unpatients' may indeed become the favoured target group of MB. As recent scientific studies carried out by insurance companies in Germany³⁶ have shown individuals prone to emotional instability, low self-esteem, and low psychological conditions are most likely to use cognitive enhancers. This could mean that those carrying a genetic predisposition to a given genetic disorder or to specific features of personality may be more willing to use cognitive enhancers to improve their condition also for moral purposes than those who do not have the same predisposition. And many ethical-legal questions arise in this case: when 'unpatients' use cognitive enhancers, are they just enhancing themselves to become 'better' or are they treating themselves therapeutically? Could they obtain equal psychological results with other traditional methods as healthy individuals can? Who should pay for these treatments?

Many of these questions are related to the fundamental distinction between therapy and enhancement and will receive adequate answers only when the transient boundary between them will be cleared up. In the meanwhile, I suggest focusing on the traditional distinction between patients and healthy individuals to test the legal viability of the project of MB in the European system. This inquiry will allow to also analyse the role of institutions in this matter.

If we consider the current legal framework in Europe in relation to interventions by means of drugs and use of drugs for therapeutic or enhancing purposes we are faced with a very different legal scenario. And this has major implications for the category of patients or healthy individuals.

Differently from patients, whose rights to health, self-determination, non-discrimination and equality has been well defined and guaranteed by the legal rules established for the physician-patient relationship, the category of healthy individuals (which I limit to adults only), which, in my opinion, deserves at least the same guarantees of safety, efficacy, information, transparency and so on, suffers from a 'legal uncertainty', albeit not from a 'legal vacuum'. The fact is that the current legal framework is not conceived to rule administration of drugs to healthy individuals with the purpose of MB.

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³⁶ D. LOSCH, Neuroenhancement am Arbeitsplatz, in Zentralblatt für Arbeitsmedizin, Arbeitsschutz und Ergonomie, 65, 2015, pp. 229-231.

There are strict rules concerning the therapeutic administration of drugs or clinical trials.

These rules are provided to protect patients from arbitrary administration of drugs and arbitrary participation in clinical trials. These rules have been designed to protect individual's health, selfdetermination, equality and non-discrimination, and they were, no doubt, intended to balance the different and conflicting interests at stake. One paradigmatic example is represented by the recent European Regulation n. 536/2014, which states in its first recital: "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 all other interests".

If one takes this mandate seriously, one cannot promote MB by means of pharmaceuticals in healthy individuals without duly imposing that the same strict conditions are met: these being, guarantee of a detailed information process, informed consent, data protection,³⁷ risk/benefit assessment and the like. Precisely because protection of health and self-determination is fundamental in the legal system, healthy individuals must not run the risk of being involved in surreptitious "mass experimentations".³⁸ Of course, large-scale trials of enhancers for healthy individuals would require enormous investments. And pharmaceutical industries may be interested in finding short cuts to their products. However, the search for rapid and easy economic gain cannot be a valid reason for a surreptitious 'mass experimentation' of the new bioenhancing techniques beyond any ethical-legal control. At least the following basic conditions have therefore to be met: 1) a fair communication/information process concerning risks and benefits of pharmaceuticals; 2) availability of competent or medical supervision in case of possible side effects, questions regarding dosage and the likes; 3) truthful information and transparency regarding commercial interests in the large-scale diffusion of pharmaceuticals beyond therapeutic purposes; 4) state of the art of scientific evidence. And this because no biological agent powerful enough to achieve major changes in body or mind is likely to be entirely safe or without side effects.

4. The role of institutions in fostering moral bioenhancement

If we understand the project of MB as a society-wide program, we implicitly acknowledge that institutions have a role to play in its implementation. What role? In Savulescu's and Persson's thesis, MB is imposed by institutions. Is this solution the best and adequate way to deal with MB? Is it viable in the European legal framework based on fundamental rights?

To deal with the institutional implementation of MB in the current European legal scenario means to address very different questions at different level of discourse. In order to investigate these aspects, I need to clarify that it is not my intent to stigmatize MB itself. My concerns are not about the individual use of bioehancing techniques, they are about the proposal of MB becoming moral mandatory as

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³⁷ How dangerous for individual's privacy new technological advances may be is clarified by A. FARANO, *Mind detection e protezione dei dati neurogenetici. Alcune riflessioni sulla privacy mentale*, in *Diritto, Economia e Tec-nologie della Privacy*, 3, 2014, pp. 433-447.

³⁸ M.J. FARAH, *The unknowns of cognitive enhancement, op.cit.*, as the author underlines: «[t]he majority of the studies on enhancement effectiveness have been carried out on small samples, rarely more than 50 subjects, which limits their power» at p. 380.

a society-wide program, and about the translation of individuals' propensity to self-shaping into legal obligations.

I am aware of the fact that each new technology brings a crop of exaggerated claims, but the main problem is that «the appeal of medical 'snake oils' is an enduring **a**ttribute of human gullibility»,³⁹ not of science and technology. And although to transform the proposal of a moral obligation into a legally binding one may perhaps not be so easy, the public and institutional interest in these issues cannot be underestimated as so many projects dealing with this matter have been discussed and implemented at the EU level.

To understand what could be the best way to legally approach MB requires framing the discussion within the 'narrative of self-shaping': techniques and practices that people use to freely construct their personality. This approach to MB allows to put it within particular discursive arrangements: on the one side, this view associates the new enhancing techniques with the conception of innovations and biomedical interventions as 'technologies of the self', forms of self-governance that people apply to themselves following Michel Foucault's understanding of moral technologies;⁴⁰ on the other side, this way of conceiving MB is consistent with the current legal interpretation of the right to self-determination and the correlated right to the free construction of one's personality.

As is well-known, self-determination and free construction of one's personality are key rights of postwar constitutions in Europe and have been stated as essential rights also in the European Charter of Fundamental Rights. They are strictly intertwined, as Stefano Rodotà has deftly illuminated: «Selfdetermination is [...] identified with the life plan pursued by the person concerned [...] for it is governed by the uninterrupted exercise of sovereignty, enabling that free construction of personality which we find enshrined at the outset of our own constitution as well as in others».⁴¹

Following this perspective, new bioenhancing techniques should not be conceived as an alternative to other more traditional enhancing practices like training, education and so on. They should be conceived as an ameliorative adjunct to them if proven safe and effective on the long-term. In other words, these new technologies of the self may be a further tool to be used by individuals to exercise their self-determination. And this because, self-determination plays an essential role in this narrative of self-shaping and precisely from a legal viewpoint. Legally speaking, self-determination has not a descriptive meaning. It is not merely synonymous with freedom of access to what science and technology makes available in the absence of a clear legal prohibition or permission. It is expression of the more radical and deeper process as referred to by Rodotà. This process does not take place by itself. In order to let it start and develop, many contributing factors are needed. In other words, we are not born 'autonomous', but to become an autonomous person, who can act autonomously, requires a proactive attitude on the part of 'others' at different stages of our lives and in different circumstances, i.e., on the part of those who have a competence in a field we are not familiar with. This proactive attitude implies the attempt to 'instill' relevant understanding of the issue at stake in that

³⁹ See D. MELZER and R. ZIMMERMANN, *Genetics and medicalization*, cit.

⁴⁰ M. FOUCAULT, *Technologies of the Self*, L.H MARTIN, H. GUTMAN, and P.H. HUTTON (edited by), Massachusetts, 1988. See also N. ROSE, *Governing the soul: the shaping of the private self*, London, 1999.

⁴¹ S. RODOTÀ, *Editorial*, in *Salute e Società*, 3, 2012, pp. 1-4, at p. 11; on the role of the self-determination principle in bioethical terms see also P. BORSELLINO, *Bioetica tra 'morali' e diritto*, Milano, 2009.

given situation to avoid forms of manipulation and let the person acquire at least a basic expertise in what is necessary for her autonomous decision in that given circumstance.

This is particularly important in the discussion of the role that institutions should play in promoting and controlling MB. As a matter of fact, to decide to use cognitive bioenhancers for moral purposes requires that an individual clearly understands the possible risks and benefits of this decision, and this kind of information ought to be provided by serious, reliable, and competent institutional sources. But eventually, the final decision whether and how to improve oneself should remain a personal choice.

Thus, what institutions should do is to proactively contribute to developing individual selfdetermination by creating conditions for building up individual capacities for autonomous choice and action.⁴² This implies guarantee of transparency, widespread and accurate information about risks and benefits of cognitive enhancers, state of the art of scientific advances, and commercial and economic interests hiding behind the project of MB. In this perspective, it will be clear that European institutions endorse science as one of the main drivers of human freedom,⁴³ instead of being complicit in encouraging the use of scientific and technological advances in a specious and deceptive way.

This solution is also compliant with the European conception of the relationship between science and society. In this relationship, increasing public participation in scientific and technological progress has become a central pillar of scientific development itself. In this respect, to adopt the 'analytic-deliberative model' could be a good way to build a true 'democratic society of knowledge' as this «presumes that, in democracies, the process of understanding risk requires constant revisiting, through deliberation, of the risks framed and the questions asked. Reframed questions in turn lay the ground for meaningful further analysis and keep publics engaged in the process of governance».⁴⁴

The antidote to the imposition of MB at the institutional level lies in remaining anchored in the selfdetermination principle as referred to earlier and in the necessary contribution of institutions to its development. This is the only way for individuals to remain sceptical and level headed in an increasingly 'medicalized' world.

There is another relevant reason, in my opinion, for understanding the role of institutions as just referred to: institutions should seriously investigate the social dimension of the increasing phenomenon of enhancing practices of the mind and the body. By 'social dimension' I mean that institutions should look for the sociocultural 'causes' that contribute to fostering the quest for very invasive interventions on the self, instead of remaining focused solely on the individual. A serious sociocultural investigation could form the basis for a balanced legal framework concerning HE and consequently MB.

⁴² This goal could also be achieved by revisiting the list of fundamental rights to include new rights able to protect individuals from possible negative effects of neuroscientific progress, on this point see the popular paper by M. IENCA, R. ANDORNO, *Towards new human rights in the age of neuroscience and neurotechnology*, in *Life Sciences, Society and Policy*, 13, 2017, pp. 1-27. They suggest introducing the right to cognitive liberty, the right to mental privacy, the right to mental integrity, and the right to psychological continuity to effectively protect individuals in their private and intimate sphere.

⁴³ In Popper's view, see K. POPPER, *Scienza e Filosofia*, Torino, 2000.

⁴⁴ S. JASANOFF et. Al, *CRISPR Democracy, op.cit.,* p. 31. See also M. TALLACCHINI, *Dalla "scienza come democrazia" alle "società democratiche della conoscenza",* in *Notizie di Politeia,* 126, 2017, pp. 6-15.

If institutions do not accomplish this task in the short-term, the risk is to fail to perceive larger patterns of the phenomenon whose understanding may be useful to avoid courses of actions with uncertain or even harmful outcomes for the single individual and for society. Without this further step, our knowledge of this very modern phenomenon with ancient roots will remain piecemeal and kaleidoscopic. The implication of such a further step is that we will be able to grasp the direct effects of MB from the society's perspective or in other words, from the group perspective as an aggregation of morally enhanced individuals.

In sum, to frame the proposal of MB within the opportunities that science offers to individuals and that should be constantly evaluated in terms of feasibility and utility, and not as a society-wide project institutionally imposed, reduces the risk of imposing a reductionist view on human intelligence. It reduces the risk of imposing an 'institutional' view on human nature, which, though rarely discussed by advocates of MB, may surreptitiously hide behind the proposal of MB. As a matter of fact, «a particular moral stance about human nature and notions of embodiment, enhancement, and morality are at play in shaping the discourse».⁴⁵

5. Destined to be super human? Some open basic questions about the project of moral bioenhancement

A society, which institutionally implements the project of MB as a society-wide program, should have found a clear answer to the following questions, which are the very *basics* of this project: what are the relevant traits that once enhanced in healthy individuals would contribute to the betterment of society? Who does select? According to what view of Human Nature (HN)?

As for the selection of traits and features of personality that could contribute to making people morally better, there is currently no shared agreement on what should be enhanced, either from an ethical-legal perspective or from a scientific one. First, from an ethical-legal perspective, no question is more difficult to be answered as it requires an agreement both on what is 'moral' in MB and on what is 'human' in H.N. These are vexed issues that were critically approached. in the legal sphere by authors like Hans Kelsen. He especially denounced the attempts to ground law in the nature of human beings following an all-embracing conception of H.N.⁴⁶ The project of MB also risks hiding an allembracing version of H.N., i.e., Super human nature.

If that is indeed the goal, the final condition to be achieved is perfection of society, not only individual betterment. This would imply that in a perfect society, there is no room left for the individual as a decision-maker. In this perspective, the individual will no longer be allowed to have the 'freedom to

⁴⁵ F. JOTTERAND, *Questioning the Moral Enhancement Project*, in *The American Journal of Bioethics*, 14, 2014, pp. 1-3, at p. 2.

⁴⁶ H. KELSEN, *What is justice? Justice, Law and Politics in the Mirror of Science*, Berkeley, 1957. Prior to Kelsen, acute philosophers like John Stuart Mill had denounced the risks related to the misuse of concepts like H.N. Mill wrote that «"NATURE", "natural", and the group of words derived from them, or allied to them in Etymology [...] are the most copious sources of false taste, false philosophy, false morality, and even bad law», see J.S. MILL, *Nature, The Utility of Religion and Theism*, London, 1904, p. 7.

fall'⁴⁷ as this would be inimical to achievement of moral perfection. Translated in legal terms, this will bring into question the contemporary conception of *law as a choosing system* «in which individuals can find out, in general terms at least, the costs they have to pay if they act in certain ways.»⁴⁸ In other words, a system where we can «predict and plan the future course of our lives within the coercive framework of the law».⁴⁹ Following this conception of law the individual can decide whether 'to fall or not', all things considered. This approach would no longer be tenable in a society where individuals are just a means to perfection of society. In such a scenario, old concepts like 'social defence', 'social dangerousness', and 'absolute social responsibility' would probably regain a key role in defining the relationship between individuals and society.⁵⁰

To develop an awareness of the fact that in the project of MB a specific stance about human nature is at play is useful to draw public and institutional attention to the perils of a holistic approach to H.N. as the sum of selected biological characteristics and to morality as something fix and that humans are not able to shape.

Secondly, even from a scientific point of view, it is not clear what traits and features of personality could be selected for the project of MB to become coherent and society-wide applicable. The reasons for this are many, but I think that the main hindrance to a clear-cut solution in this context is the target group of the project, i.e., healthy individuals. The fact is that we are not treating individuals with a specific diagnosed psychological disorder for which the cure could be specific and precisely focused: for instance, to enhance empathy while limiting aggressive attitudes -as could be the case for sociopaths. Rather, bioenhancing interventions according to the project of MB aim at acting upon the personality of 'healthy' individuals, and there is no shared agreement and understanding of what is the role of the constitutive tension between opposite instincts, impulses, feelings, and attitudes in individuals in healthy conditions. In the general discussion about the project of MB, an 'attitude' that is very popular and that according to many deserves being enhanced is empathy. Despite the general favour being shown for empathy and the rhetoric in literature, there is no scientific evidence that a society with all members possessing this attitude to great or absolute extent would be morally better. As Paul Bloom has recently underlined, empathy is not always the best moral guide in all realms of life.⁵¹

The constitutive relationship between the opposite features, traits, feeling etc. that make up the personality of a healthy individual has been at the centre of earlier philosophical debates without a de-

⁴⁹ H.L.A. HART, *Punishment and Responsibility*, cit., p. 181.

⁴⁷ As John Harris has repeatedly observed Milton's conception of the freedom to fall is very important. In his book entitled *Paradise Lost*, we indeed find in Harris' opinion «many of the most cogent reasons for suspicion as to the viability of moral enhancement as coherent project, not least because of the harm done by existing methods of moral enhancement to the possibility of human freedom as God, Milton and John Stuart Mill understood that idea» see J. HARRIS, *How to be good*? cit., p. X.

⁴⁸ H.L.A. HART, Punishment and Responsibility. Essays in the Philosophy of law, Oxford, 1968, p. 44.

⁵⁰ These notions can be traced back to the XIX century Italian Positivist Criminal School. Cesare Lombroso and Enrico Ferri, leading exponents of the criminal positivist approach, attempted to ground measurement and quantification of criminal behavior in scientific objectivity and proposed to reconsider foundation of penal law on concepts like 'social defence' and 'social dangerousness'.

⁵¹ P. BLOOM, Against Empathy. The Case of Rational Compassion, New York, 2016.

finitive say on the issue.⁵² And what is indisputable is that the relationship between rational and irrational realm, voluntary and involuntary actions, still produces an endless stream of discourse. In this stream, we should include the project of MB. In so doing, we will be able to frame some everlasting problems. In fact, after almost two centuries, we are faced with questions that forward-looking thinkers like the Italian philosopher Mario Calderoni had addressed long ago. The author suggested that, to some extent in line with Bloom's theory, «the presence of a bad feeling or the lack of a good feeling do not alter the measure of the individual responsibility».⁵³

This is the *practical* problem of responsibility, which in turn represents the *practical* problem of a project like MB. Here some questions to which I do not yet know the answers: is this project able to definitively answer the vexed questions about the limits of responsibility? Isn't it re-proposing a deterministic view? Is the project of MB hiding the search for peculiar and presumptively stable determiners of identity useful to ground policies of exclusion of specific groups of individuals who do not fit into the model?

On a fundamental level, going back to the basics of MB is helpful in revealing the risks of deterministic overtones. In order to avoid these outcomes, institutions should take a step back and not impose MB. Instead, they ought to lay down the normative framework in which people can find clear criteria to be used for helping them to make a decision whether to opt for the new bioenhancing techniques or not. At the same time, institutions ought to investigate external 'causes' contributing to the increasingly growing quest for (very) invasive self-shaping techniques in order to find possible remedies for what seems to be the *Leitmotiv* of our age, that is, the excessive dissatisfaction with one's own interior and exterior image.

⁵² I just mention the paradigmatic debate on freewill and determinism that exploded in second half of the XIX century between libertarians and determinists.

⁵³ M. CALDERONI, *I postulati della scienza positiva ed il diritto penale*, in *Scritti di Mario Calderoni*, Firenze, 1924, pp. 33-168, at p. 110, translation by the author of this paper.