## SPECIAL ARTICLE ΕΙΔΙΚΟ ΑΡΘΡΟ

## Enhancement, medical liability, and the reforms needed in the Greek legal framework An initial theoretical approach

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Medical interventions may be justified when a malady is identified in the patient. The primary aim of medicine is the use of biotechnology for therapeutic purposes. When no medically recognizable health problem can be diagnosed, intervention is not "medically necessary" but it might be considered as a form of enhancement. Although professionals from other fields are needed to provide the relevant technical expertise, physicians will continue to play a crucial role in the use of the enhancement biotechnology on individual human beings. In the future, healthcare professionals will be called upon to handle patients with no disease or obvious bodily malformation. The Greek legal framework of medical liability has been designed based on the traditional aims of medicine and on the established ways in which medicine is practised. This article presents an assessment of the way this new approach to medical intervention will influence medical liability theory and a proposal of possible doctrinal reforms.

## **1. INTRODUCTION**

The launching of new forms of treatment constitutes a promising use of biotechnology, as these therapies most closely conform to the clinical ends of medicine.<sup>7</sup> Many diseases still need to be tackled effectively, and scientific research to establish innovative forms of treatment constitutes a legitimate and desirable individual and social good.<sup>7</sup> In such cases, physicians function in their traditional role as *healers* and, thus, they have a moral and *legal* obligation to stay *informed* and *educated* in the use of the new technologies and to base their actions on the most recent findings of the medical science.<sup>7</sup>

Although in the context of the traditional objectives of medicine the primary intent of the use of biotechnology is to treat physical or mental disease, as a result of technological advancement and improved biomedical expertise Western medicine has *exceeded* the traditional role of healing and is entering the field of human enhancement.<sup>2</sup> Battling disease has been established as the fundamental aim of medicine for centuries, but biotechnology now makes it possible to enhance human features.<sup>3</sup> Novel biotechnologies, closely associated with recently developed technologies for disease treatment, could lead to the improvement of

ARCHIVES OF HELLENIC MEDICINE 2016, 33(5):689–698 ΑΡΧΕΙΑ ΕΛΛΗΝΙΚΗΣ ΙΑΤΡΙΚΗΣ 2016, 33(5):689–698

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Βιοενίσχυση, ιατρική ευθύνη και οι απαραίτητες μεταρρυθμίσεις του ελληνικού νομικού πλαισίου: Μια αρχική θεωρητική προσέγγιση

Περίληψη στο τέλος του άρθρου

### Key words

Enhancement Malpractice Medical liability Theory

> Submitted 19.12.2015 Accepted 30.12.2015

otherwise "healthy" human beings.<sup>2</sup> From the already widespread use of cosmetic surgery to the selective potential of pre-implantation genetic diagnosis, medicine is *gradually* developing *the power* and the *potential* to enhance human life at its most fundamental biological level.<sup>2</sup> As healing gives way to enhancing, the precise definitions of *health* and *disease* become problematic and more complex, and this is reflected in questions with respect to the goal of medicine.<sup>2</sup>

Before entering the core issues of this topic, a definition of enhancement must be provided. Enhancement consists of "biomedical interventions that are used to improve human form or functioning beyond what is necessary to restore or sustain health".<sup>4</sup> This broad definition has significant implications<sup>4</sup> and this particular definition apparently *restricts* the term to *biomedical* interventions and, specifically, to interventions, which make *biological* changes in human bodies and brains, using *pharmaceutical*, *surgical*, or *genetic* techniques.<sup>5</sup>

This definition serves the purposes of this paper effectively, as it relates to those interventions for which the involvement of doctors in their implementation will inevitably be required. Specifically, physicians have the necessary technical knowledge and expertise to put enhancement biotechnologies into practice. The role physicians inescapably play whenever medical knowledge is used to regain health, and to go beyond what is required to regain health, should not be underestimated.<sup>1</sup> Specialists in other fields are necessary for the realization of the promises of biotechnology (to provide the basic technical knowledge and expertise on which bioenhancement will be based), but the actual use of this technology with individual human beings undoubtedly depends on physicians.<sup>1</sup> In addition, with the use of common methods such as surgical techniques and pharmaceuticals to accomplish control of human form and function, some types of enhancement are becoming a more familiar phenomenon.6,7 Such interventions are: (a) Cosmetic surgery and the use of biosynthetic growth hormone to increase stature;<sup>8</sup> (b) "blood doping" and steroid use to improve athletic endurance and strength;<sup>9</sup> (c) psychopharmaceutical treatment for increasing memory, elevating mood, and improving cognitive capacities,<sup>10,11</sup> and (d) (currently almost entirely hypothetical) genetic and neurological manipulations to increase the human life span.<sup>5,12</sup>

Human enhancement is evidently about applying science and technologies to *expand* human capacities.<sup>6</sup> Developments in fields as diverse as sports medicine, surgery, stem cell research, gene therapy, pharmaceuticals, cybernetics, prosthetics, nanotechnology, and computer science may all contribute to enhancement.<sup>6</sup>

It thus becomes apparent why the line between therapy (or restoration) and enhancement constitutes an ongoing debate in the context of human enhancement.<sup>6</sup> The relevant literature focuses primarily on the ethics and morality of enhancement, and less on the criteria that qualify a procedure as an enhancement.<sup>13</sup> Various scholars have debated the issue of whether a distinction between therapy and enhancement is valid, but the placement of that distinction has not yet been satisfactorily addressed.<sup>14-16</sup> The dividing line is often faint and subjective (as it is closely associated with abstract notions such as health, disease and normality) and, thus, the task of accurately placing it becomes daunting.<sup>6</sup>

Depending on the specific context and individual experience, what is considered *average* or *normal* may vary.<sup>6</sup> Medicine is considered to be the route by which a person might normalize a defective feature, such as sight.<sup>6</sup> Surgery to remove cataracts and the use of corrective eyewear are two examples of medical applications of technology.<sup>6</sup> Laser *in-situ* keratomileusis (LASIK) eye surgery is a treatment that can improve vision for people who previously used eyeglasses or contact lenses.<sup>6</sup> It can also improve vision in individuals beyond the "normal" 20/20, as in the highly publicized surgery performed on the famous golf player, Tiger Woods.<sup>6</sup> This illustrates the complex and subjective character of the relevant debate. Because of the complexity of the topic the focus here will be on the possible *legal*, rather than philosophical or bioethical, implications of the distinction between medical treatment and enhancement.

# 1.1. Therapy/enhancement distinction: A discussion with significant legal implications

Taking into account the fact that the theory of medical liability is based on the traditional healing aims of medicine, the classification of a medical procedure as treatment or enhancement will have an impact on the way a potential adverse event will be handled legally.

Although the bulk of the enhancement literature focuses on thought experiments set in the future, it is based on a set of significant debates regarding how health care should be defined today.<sup>5</sup> The distinction between using biomedical tools to combat disease and attempting to use them to enhance human characteristics acquires increased *significance* as it can provide practical guidance on many issues, including the limits of *physicians' obligations*.<sup>8</sup> Since intrinsic to these obligations is the obligation of the doctor to follow the rules and standards of medical science and the medical profession, it is obvious that the therapy/enhancement distinction is related to the liability of clinicians.

In practice, the line between treatment and enhancement could theoretically constitute the upper boundary of professional obligations.<sup>5</sup> For example, the concept of *futile* treatment shows the limits of a doctor's obligations, when further intervention cannot achieve any therapeutic goals. Similarly, it could be claimed that enhancement interventions fall outside health care's proper domain by going "beyond therapy", in pursuit of other, non-medical, goals.<sup>5</sup> This could mean that patients have no right to demand such services from health professionals and that those who do provide them might bear the burden of justification for making "medically unnecessary" interventions.<sup>5</sup> Consequently, if professional obligations of physicians were to be reconsidered, the protection of patients' rights with respect to enhancement could be open to question.

It is apparent that the enhancement/therapy distinction has not only descriptive, but also *normative* significance.<sup>5</sup> Taking into consideration that identifying a procedure as either therapeutic or enhancing might have legal implications (healthcare coverage, medical liability issues, patients' rights, professional obligations), it is essential to know where the boundary lies for "going further".<sup>5</sup> The fact that enhancement is by definition and description an improvement in personal welfare makes it more difficult to find the boundary, in order to place a specific enhancement inside or outside of sanctioned interventions.<sup>5</sup> For a field dedicated to securing improved welfare for its patients, the fact that enhancements may be very similar to the other improvements that health care tries to achieve, makes it difficult to determine when an intervention goes beyond the normative limit that the distinction aims at marking.<sup>5</sup>

## 2. AN INITIAL APPROACH TO ENHANCEMENT AND GREEK MEDICAL LIABILITY THEORY: CORE DOCTRINAL CONCEPTS RECONSIDERED?

Although the literature on the topic of enhancement is extensive the relevant discussions focus solely on the philosophical and bioethical aspects.<sup>17,18</sup> More practical issues such as compensation and medical liability have not yet attracted adequate attention. This is justifiable, given that consensus has not been reached on the ethics and morality of human enhancement, let alone on the prospect of its wide application. Here what is an essentially ethical topic will be approached from a different perspective.

Specifically, the compatibility of enhancement with traditional notions of the Greek medical liability theory will be assessed. Such assessment presupposes the legitimate application and the wide acceptance and use of enhancement procedures by the medical community. Some may claim that it is too early to enter into such a purely legal and entirely hypothetical discussion, since many outstanding issues still need to be tackled concerning enhancement. A long road obviously lies ahead before the actual implementation of enhancement procedures in everyday medical practice, but as sooner or later enhancement will become routine practice in modern medicine, legal theory should be proactive and the relevant doctrinal challenges need to be considered in advance.

In the context of doctor-patient interactions for the provision of professional services liability issues (such as medical malpractice, informed consent, etc.) often arise, and the same will apply with enhancement. Adverse events are an integral part of the practice of medicine, and errors and complications will no doubt occur during the provision of enhancement services. At present, human enhancement is in its early stages and the research and practical experience with its procedures is extremely limited.

This analysis focuses on those areas and concepts

of legal theory that were based on the traditional ways in which medicine was practised and on the traditional concepts of medical science (therapeutic aims, notions of health, patient, disease, normality, etc.). These areas are likely to pose doctrinal challenges, due to their incompatibility with the special characteristics of enhancement. Doctrinal solutions are proposed that could contribute to the incorporation of enhancement procedures into the concepts of medical liability theory. The analysis covers three core topics: the definition of medical procedure, the legitimacy of the medical procedure and the concept of medical malpractice.

## 2.1. The definition of medical procedures

Presuming that enhancement procedures were to be performed in Greece, the definition of medical procedure established by article 1, paragraph 1 of the Code of Medical Ethics (law no. 3418/2005) would certainly constitute a major source of concern. According to the Code, medical procedure is considered to be: *Any procedure, which, through the use of any scientific method, aims at the prevention, diagnosis, therapy and restoration of the individual's health.* Paragraph 2 adds that medical procedures are also considered those which have research features, on the essential condition that they focus on more precise diagnosis and the restoration or improvement of people's health, and the development of medical science.

The above definition appears to include only therapeutic medical procedures and it is unduly restrictive, given the wide scope that a code of medical ethics must encompass.<sup>19</sup> In other words, non-therapeutic procedures appear to be excluded, when exactly the opposite would be necessary for other provisions of the same code, related to non-therapeutic procedures such as cosmetic surgery and medically assisted reproduction (article 11, paragraph 3 and article 31).<sup>19</sup> The relevant report of the Scientific Service of the Greek Parliament,<sup>20</sup> which was published before the enactment of the Code, underlined that the particular definition did not include medical procedures, which, albeit performed by physicians, do not have a therapeutic aim, such as abortion, sterilization, cosmetic surgery, etc. The report also pointed out that the adoption of the particular definition would hinder the application of the Code's provisions to both the aforementioned procedures<sup>20</sup> and non-therapeutic medical procedures in general. Accordingly, taking into account that most enhancement procedures are and will be regarded as non-therapeutic, the provisions of the Code may not apply to enhancement. Consequently, it is highly likely that there will be no safeguards concerning

patient safety and patients' rights during the provision of enhancement services, if these are provided outside the protective framework of the Code, and, in the meantime, relevant legal reform is not instituted. A broader definition should thus be established, in order for the provisions of the Code to apply to both procedures without therapeutic aim (which are currently being performed) and to enhancement procedures in the future.

Enhancement procedures for preventive purposes could raise interesting questions. As Pellegrino has observed, some ends, such as the desire for healthy children, are understandable, and if their means do not dehumanize their subjects, they might be considered as legitimate ends of medicine, particularly *preventive* medicine.<sup>1</sup> Hence, such procedures may serve the *traditional* aims of medicine and, as part of preventive medicine, fall within the scope of the Code's definition.

On the other hand, article 2 of the Code states that the practice of medicine aims at maintaining, improving and restoring the physical, mental and spiritual health of the individual, and at relief from pain. Whether this particular provision leaves room for enhancement procedures, under the reference to spiritual health (for example a person could seek enhancement services because he feels uneasy with himself, which has a negative impact on his spirit and attitude) is clearly an open question, is subject to interpretation of the law.

## 2.2. The legitimacy of the doctor's intervention

A key doctrinal question regarding enhancement is related to the *legitimacy* of the doctor's *intervention* in the patient's *bodily integrity* and *health*. According to legal theory, the legitimacy of a medical procedure conducted by a physician should be confused with neither its *unsuccessful outcome* nor the potential, from a medical point of view, *fault* of the procedure;<sup>19</sup> in other words, legitimacy has nothing to do with the *evaluation* or the *outcome* of the process.<sup>19</sup>

A medical procedure, therefore, needs to be legitimate *in the first place*, regardless of whether it is *successful* (actually curing the patient) or whether a medical error occurs.<sup>19</sup> The *requirements* of legitimacy (set by the legal theory) are: (a) The *therapeutic* objective of the procedure, and (b) the patient's *consent*.<sup>19</sup>

A medical procedure which is, by its very nature and purpose, considered *medically necessary* and is an appropriate option based on the particular patient's *best interests* (namely a therapeutic medical procedure), constitutes in itself neither an unlawful bodily injury nor a violation of the patient's right to self-determination regarding his(her) body and health.<sup>21</sup> Hence, *therapeutic* medical procedures are *in principle lawful* and their potential unlawfulness cannot be based on their effect on the body or the health, *but* on the fulfillment of other legal requirements (medical error or lack of informed consent).<sup>19</sup>

Non-therapeutic medical procedures are those procedures which intervene with the bodily integrity and the health, are conducted by a physician in the exercise of his(her) professional activity and have no therapeutic objective.<sup>19</sup> According to the prevailing opinion in theory, they are considered in principle unlawful violations of the bodily integrity and health and their legitimacy is essentially dependent on other requirements, specifically on their incorporation in law (see abortion under specific circumstances set by the law) and or the consent of the patient.<sup>19</sup> Consent is considered to legitimize the, in principle, unlawful procedure, when the aforementioned violations do not contradict the notion of morality, which according to the theory is considered an unwritten source of law (see article 281 of the Greek Civil Code). The notion of morality (according to the definition of the Professor I. Spyridakis) consists of the prevailing perceptions of the average prudent person as to what behavior is appropriate and meets the requirements of social ethics. The notion of morality is not fixed, but changes over time, as is the case with social ethics. Nevertheless, consent does not legitimize a violation that seriously harms or puts an individual at risk, when this is not counterbalanced by an expected benefit.<sup>22-25</sup> It is apparent that, since the medical necessity and therapeutic nature of enhancement are open to question, the lawfulness of the relevant procedures (especially interventional procedures) will be equally questionable.

Specifically, enhancement procedures could be deemed in principle unlawful, with the relevant legal ramifications. Their lawfulness, then, would depend on either their regulation or the patient's consent. For example, pre-implantation genetic diagnosis has been regulated (article 10 of the law no. 3305/2005 "Application of medically assisted reproduction") and is permitted under specific conditions set by the law (consent of the persons concerned and permission of the National Authority of Medically Assisted Reproduction).

Regarding the *consent* requirement, as a result of the aforementioned association between consent, the notion of *morality* and the harm/risk-benefit balance, the relevant discussion might return to the moral and ethical assessment of enhancement procedures and to the treatment/ enhancement debate, with the diversity of views on the topic leading to a theoretical impasse.

# 2.3. Medical liability theory and the concept of medical malpractice

The basic pieces of legislation to which both legal theory and case law refer are the laws 1565/1939 and 3418/2005. Here the focus will be on the latter, since the former is an obsolete piece of legislation, which cannot meet the demands of today's medicine, let alone the unique characteristics of enhancement procedures. The law of 2005, albeit closer to the way in which modern medicine is practised, will not provide effective solutions with respect to enhancement. The situation is even worse, since the incomplete and fragmentary character of special legislation has led legal theory to search for solutions in the general provisions of civil liability (contract and tort law),<sup>19</sup> which in many cases have proved ineffective in resolving the complex doctrinal issues of medical law.

## 2.3.1. Medical liability comprises a "battle" between conflicting goals

The major doctrinal issues in this particular area have been based on conflicting objectives which needed to be harmonized, and on specific parameters that required careful consideration. Specifically, although *de facto*, the patient is already at a disadvantage due to his(her) *vulnerability* (burden of disease) and lack of relevant knowledge and expertise as a consumer<sup>26</sup> of services.<sup>21</sup> The doctor, also, needs increased protection (from medical defense for example), because of the inherent risk of medical procedures, the social dimensions of the medical profession and the need to safeguard scientific freedom.<sup>21</sup>

The above parameters and objectives do not apply to enhancement. Most recipients of enhancement services will not have the characteristics of the average patient and, thus, the *burden of disease/vulnerability* parameter will be irrelevant in many cases.

Equally irrelevant will be the need for increased protection of physicians from medical defense and the need to safeguard scientific freedom, because the provision of services by enhancement specialists will constitute a conscious professional choice and career path.

Obviously, the various different formative factors and objectives will probably lead to different doctrinal solutions. Although it would not be feasible to formulate specific solutions, an initial attempt can be made to state certain parameters that underlie the development of the legal theory of enhancement.

Firstly, in most (if not all) cases the service will be

demanded by the individual, as is the case regarding any commercialized service. Secondly, in light of the above and since most enhancement services will, at least initially, be provided by the private sector, the individuals seeking these services will present strong consumer features, differing from patients in the traditional sense of the term. Hence, there can be no question of a burden of disease (at least based on the current meaning of disease). Thirdly, the non-therapeutic aim of enhancement might increase the responsibility of the doctors and limit the need to protect them or their scientific freedom, and the reasons for the protective treatment of physicians by the law mentioned above cease to apply. Fourthly, in traditional medicine, the common objective of the fiduciary doctor-patient relationship is cure from disease,<sup>19</sup> a goal not applicable to the notion and aims of human enhancement. In other words, the doctor-patient relationship needs to be redefined, in order for its new goal (enhancement of a human

trait) to be reflected. There is no doubt that this will induce fundamental doctrinal changes regarding medical liability, which was designed to serve the traditional doctor-patient relationship model.

## 2.3.2. The concept of medical malpractice

2.3.2.1. Unsuccessful medical procedure, therapeutic risk and the physician's obligations. According to legal theory, the doctor's obligations, which arise either from the law or from the unwritten duty of care (unwritten rules of care), do not extend to a guarantee of the success of the medical procedure, namely the cure of the patient and absence of complications.<sup>19</sup>

The physician's liability can be grounded on the violation of a professional obligation. Medical malpractice and violation of the duty to inform the patient and obtain consent before any medical procedure<sup>19</sup> are the principal legal bases of medical liability. Here the focus will be on the former, which will pose significant doctrinal challenges regarding enhancement procedures.

The relevant discussion starts with the notion of the *unsuccessful* medical procedure. Based on its *result*, the unsuccessful medical procedure is the procedure which harmed the patient either because it failed to cure him(her) (with resulting deterioration in health) or because it caused him(her) further damage, irrespective of the result of the treatment, due to side-effects or complications.

The unsuccessful medical procedure is related to the notion of *therapeutic risk*. In the broad sense, the therapeutic risk includes any *damage*, which is caused to the *patient* 

and is causally linked to a medical procedure, and, in its strict sense, includes only the *accidental damages*, namely those which are not caused by the doctor's malpractice.

According to the relevant theory, medical liability is a matter of distribution of damages; a matter of distribution of the therapeutic risk between the doctor and the patient.<sup>19</sup> From a theoretical point of view, on the one hand, it is necessary to adequately determine that part of the therapeutic risk can be attributed to the doctor (due to malpractice).<sup>19</sup> On the other hand, the issue of the *sensu stricto* therapeutic risk (i.e., accidental damage) needs to be considered, and whether this should be attributed entirely to the patient, or to the doctor or society (insurance companies, etc.).<sup>19</sup> In general, medical liability primarily focuses on the assessment of that part of the risk which is attributable to the doctor.<sup>19</sup>

Firstly, it should be noted that regardless of whether there is a medical treatment contract or the patient receives public health care services, the basic *obligation* of the physician is *the provision of medical care*, namely the execution of a medical procedure to maintain or restore the health of the patient to a satisfactory level, at the same time avoiding disproportionate exposure to risk or inconvenience.<sup>19</sup> Moreover, doctors owe the patient not normal but *increased diligence*, and this derives from both the inherent risk and the effect of medical procedures on the patient's personality.<sup>19</sup>

Based on the prevailing view, the physician's obligations, regardless of the private or public nature of the services, are *obligations of means*, and there is *no obligation of result*.<sup>19</sup> The doctor must show professional conduct that is consistent with specific standards without necessarily having to achieve a specific therapeutic result, and is liable only when he(she) violates his(her) legal or contractual obligations.<sup>19</sup>

Because of the special features and complexity of human nature, the finite nature of the human body, the inherent risk and possible complications of most medical procedures<sup>27</sup> and the fact that the medical profession acts with good intent and aims at the welfare of the patient, it would be unfair and irrational to be so strict as to accuse physicians and holding them liable for not achieving a specific result; a result, which, in many cases might have been beyond control, even if the physicians had shown the utmost care, attention and diligence.<sup>27</sup> Could such justification lead to the equal protection of physicians in the context of enhancement services? Would such an approach be compatible with the nature of enhancement? Although a clear answer cannot be given at present, an initial approach will be attempted, based on the ways in

which legal theory has handled the topic of non-therapeutic procedures currently performed by physicians.

According to a part of the legal theory, for some medical procedures that have no therapeutic character, the doctor should be considered responsible for guaranteeing the *successful outcome*.<sup>27</sup> Specifically, it is claimed that concerning procedures such as cosmetic surgery, abortion, sterilization, etc., an *obligation of result* must be established and the non-occurrence of the expected/desired outcome can give rise to a liability claim.<sup>27</sup> In practice, it should be noted that cosmetic surgery performed not for corrective purposes but to increase (perceived) attractiveness, has grown in popularity.<sup>29</sup>

This could throw light on the way enhancement procedures could be treated by medical liability theory, but many issues remain open to question. Would the establishment of an obligation of result for the doctors practising enhancement be an effective solution? Could the doctor be considered responsible for guaranteeing the successful outcome of the procedure? And if yes, how would the success or failure of the enhancement procedure be defined and assessed? Is it feasible to establish objective criteria to evaluate the outcome of the procedure, as is the case for "traditional" therapeutic medicine (through medical books, medical literature, clinical guidelines, clinical protocols, etc.), given that the development and formulation of similar sources of scientific documentation would require years of research and practical experience with enhancement procedures? Could a failure to enhance be deemed an unsuccessful medical procedure and lead to the imputation of fault and liability to the physician, even though it might leave the individual in his(her) previous normal state of health (instead of helping him(her) surpass the limits of human nature)? These questions reflect only some of the theoretical issues which could arise from the interaction of enhancement and medical liability.

2.3.2.2. Medical malpractice. The concept of medical malpractice is a key concept of the medical liability theory. From a doctrinal point of view, it is the fundamental criterion for the fair and rational distribution of the *therapeutic* risk between the *doctor* and the *patient*.<sup>19</sup>

*Medical malpractice* is the professional conduct of physicians which does *not* conform with the degree of diligence/care imposed by the standards of the medical profession and necessary to the particular case. This usually happens because the doctor has not followed his(her) professional standards or has violated the rules of medical science and art (*leges artis*).<sup>21</sup> According to the prevailing theory of private law,<sup>22-25</sup> the judgment of unlawfulness is

based on the *conduct* of the doctor. As described below, this theory will probably be incompatible with the notion of enhancement.

2.3.2.3. Medical malpractice as an illegal act. (a) The unlawfulness of medical malpractice is primarily established on the violation of the rules of medical practice and the medical professional standards. It is based firstly on the general duty of care and safety, taking into consideration the assumption of the patient's treatment by the doctor, the patient's vulnerability and the inherent risk of the specific medical procedure.<sup>19</sup> It is apparent that the assumption of an enhancement procedure by the physician and the inherent risk of the process (since the interventional enhancement procedures will inevitably have an impact on the individual's physical integrity and health), would also establish the duty of care and safety on the part of the doctor. The vulnerability parameter, however, would hardly be applicable concerning enhancement procedures for the reasons explained in the earlier sections of this paper.

Secondly it is based on the specific provisions of the laws 1565/1939 and 3418/2005. Although these provisions do not include an explicit definition of medical malpractice, they specify the physician's professional obligations and the rules of good professional conduct.<sup>19</sup> In particular, article 3, paragraph 3 of the law 3418/2005 established objective criteria for the evaluation of the doctor's conduct and the subsequent establishment or rejection of medical malpractice. According to paragraph 2 of the article, doctors should act based on (a) their education during the undergraduate studies, their practice towards the medical specialty and their on-going medical education, (b) the experience and skills they acquire in the context of their practice, and (c) evidence-based medicine. Furthermore, according to paragraph 3 of the article, the physician must conform to the generally accepted rules and methods of medical science, as they have been formed based on the results of modern applied scientific research. Each doctor has the right to *choose* the treatment method which he(she) believes significantly outperforms another, with reference to the particular patient, and based on the modern rules of medical science, and avoid using methods for which there is insufficient scientific evidence. It is evident that these criteria are hardly compatible with enhancement, as they presuppose long-term theoretical and clinical academic research and practical experience, which the currently developing area of enhancement does not yet supply.

2.3.2.4. The clarification of the medical malpractice concept: The "average prudent doctor" and the "particular patient". (a) *The average prudent doctor*. The prevailing criterion for evaluation of the physician's conduct is the *average prudent doctor*; namely, the doctor who follows the rules of medical science (*leges artis*). According to this approach, a doctor's conduct is negligent which violates the generally accepted rules (article 3, paragraph 3) or does not meet the requirements of the most recent findings of medical science.<sup>19</sup>

The notion of the average prudent doctor would probably be inapplicable with respect to enhancement procedures, especially during the first years of their application. The particular concept presupposes a large number of doctors practising a specific medical specialty, and that the majority of them uses a certain procedure and that some kind of customary practice and professional consensus has been established in the specific scientific area. Concerning newly developed biomedical procedures such as enhancement, it is evident that the (inextricably associated with the concept of the average prudent doctor) notions of professional consensus and customary practice cannot be established, as they require prolonged research and practical experience. (b) The interests of the particular patient. Another approach, grounded in the provisions of the law 3418/2005, focuses on the interests of the particular patient.<sup>19</sup> Article 3, paragraph 3 includes the particular patient in the criteria based on which the doctor chooses the treatment method. Despite its theoretical attractiveness, this approach, due to its excessive subjectivity, could create legal uncertainty and provide ineffective solutions to the complex doctrinal issues of enhancement. If the interests of the particular patient were to be established as the basic criterion for the assessment of the physician's conduct, this would essentially return to the therapy/enhancement debate and to the highly subjective definitions of disease, normal health, etc., with the relevant discussion, due to the diversity of views, culminating in a deadlock.

### **3. CONCLUSIONS**

It is evident that it is too early for firm doctrinal conclusions to be reached regarding the interaction of enhancement and medical liability. Crucial issues concerning human enhancement must be settled before the relevant procedures start being used by physicians and before the first claims reach the courts. It is essential, however, that before the relevant cases reach the courts the legal profession has reflected upon, discussed and solved the key doctrinal issues.

Given that the established legal notions are too narrow to adapt to the realities of enhancement, it is obvious that their reformulation is necessary. Whether this could be achieved through a reform of the law 3418/2005, or through establishing a code of enhancement ethics (based on which the professional conduct of the physicians who practice enhancement procedures will be evaluated) is a question which cannot be answered at present.

It is beyond doubt that further research and practical experience with enhancement procedures are necessary both to discover what constitutes effective and safe practice and to assess the "grey" areas of the field. The redefinition of basic concepts such as patient, disease, health, etc., is equally significant and this will certainly be affected by many factors, such as the increasing medicalization of human conditions.

With respect to the principles governing medical liability theory concerning enhancement procedures, these would probably include a redistribution of the therapeutic risk. Some of the features of enhancement which would inescapably have an impact on this redistribution are the following: The intense consumer culture of those receiving enhancement services, the on-demand, and nearly always private, nature of the services and their inevitable commercialization (as with cosmetic surgery during recent decades). Although already patients today are increasingly being considered and treated as consumers (see the Greek law 2251/1994 about consumer protection; according to the prevailing view in legal theory, patients fall within the definition of consumers), this will become more pronounced regarding enhancement services, because of the absence of medical necessity and the innate human pursuit for beauty and physical health.

As a general comment, it could be argued that a type of shared doctor-patient responsibility would be necessary. In this way the conflicting aims/interests of both sides could be efficiently reflected and the necessary balance between them could be achieved, from the social, legal and political perspectives. On the one hand, the professional discretion and freedom of the physicians to perform enhancement procedures (based on their belief in the value of the procedure or induced by the financial reward) should be balanced with the need for more stringent legal treatment when an adverse event occurs. The establishment of an obligation of result on the part of the doctor who does not achieve the desired/expected outcome for the patient-consumer, could be one option. On the other hand, the freedom of choice of those "patients" who can afford to enhance themselves and let a physician affect their bodily integrity and health should be balanced with the lack of compelling medical necessity and clear benefits for their health, in most cases, of enhancement. Hence, individuals should bear their own share of the therapeutic risk (regarding, for example, *accidents* not caused by the doctor's malpractice).

Regarding the possibility of introducing a new Code of Medical Ethics, the background of the introduction of the current law (3418/2005) could serve as a useful example. Despite its ethical nature, the law 3418/2005 has acquired a significant role in medical liability theory, by establishing the physician's obligations, providing specific criteria based on which the doctor's professional conduct can be evaluated in particular cases, and, hence, clarifying the inherently vague notions of tort law.

Due to the scientific and social changes during the decades that followed the establishment of the first Code of Medical Ethics (Royal Decree of 25.5/6.7 1955), it became essential that a new legal framework be developed; a framework, which could respond more effectively to the latest developments of medical science.<sup>30</sup> It was necessary for the new code to include the new scientific developments as whole chapters.<sup>30</sup> The 1955 law had been based on a framework of medical practice that was outdated, from both a technological and a social perspective.<sup>30</sup> The rise of educational and living standards, technological progress and the alterations in the way medicine was practised, necessitated the reform.<sup>30</sup> The new Code included chapters for the advertisement of physicians on the web, human assisted reproduction, abortion, organ transplantation and the protection of the genetic identity.<sup>30</sup> Accordingly, a special chapter or chapters could be added regarding enhancement (stating, for example, the physician's professional obligations concerning enhancement), if the future developments in medicine necessitate the introduction of such provisions.

Such a reform of the Code would have both an ethical foundation and legal implications. It would set the requirements of the physicians' appropriate professional conduct regarding enhancement, state the criteria based on which that conduct will be deemed as professional or not, clearly formulate physicians' obligations and define good medical practice, thus having an impact on medical liability.

The objective here was to pose questions, raise concerns and prepare the ground for future discussion on the topic. Rather than reaching precarious conclusions, this paper approached an entirely hypothetical topic from a doctrinal perspective. The issues examined should be reassessed more effectively by leading academics and scholars in the field, when (and if) enhancement procedures, such as genetic engineering, stem cell research, etc., start becoming a reality in medical practice. The aim was to inspire the legal community to *reflect* on doctrinal questions regarding

liability and enhancement – questions that are of great importance but do not yet allow final answers.

# ΠΕΡΙΛΗΨΗ

## Βιοενίσχυση, ιατρική ευθύνη και οι απαραίτητες μεταρρυθμίσεις του ελληνικού νομικού πλαισίου: Μια αρχική θεωρητική προσέγγιση

#### Α. ΠΑΝΑΓΙΩΤΟΥ

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#### Αρχεία Ελληνικής Ιατρικής 2016, 33(5):689–698

Οι ιατρικές παρεμβάσεις δικαιολογούνται γενικά, όταν μια νόσος διαγιγνώσκεται στον ασθενή. Πρωταρχικός σκοπός της ιατρικής επιστήμης είναι η χρήση της βιοτεχνολογίας για θεραπευτικούς σκοπούς. Αν απουσιάζει κάποιο ιατρικά αναγνωρίσιμο πρόβλημα υγείας, η ιατρική παρέμβαση δεν είναι πάντοτε αναγκαία από ιατρικής σκοπιάς και μπορεί να χαρακτηριστεί ως βιοενίσχυση. Παρά το γεγονός ότι επαγγελματίες άλλων επιστημονικών πεδίων είναι απαραίτητοι για την παροχή εξειδικευμένων τεχνικών γνώσεων, οι ιατροί θα συνεχίσουν να διαδραματίζουν καίριο ρόλο για τη χρήση της βιοτεχνολογίας σε μεμονωμένα άτομα. Συνεπώς, οι επαγγελματίες υγείας θα κληθούν μελλοντικά να αναλάβουν (με σκοπό τη βιοενίσχυση) ασθενείς χωρίς συγκεκριμένη νόσο ή εμφανή σωματική δυσλειτουργία. Το ελληνικό νομικό πλαίσιο της ιατρικής ευθύνης βασίζεται στους παραδοσιακούς σκοπούς της ιατρικής επιστήμης και στον καθιερωμένο τρόπο άσκησής της. Στο παρόν άρθρο γίνεται προσπάθεια αφ' ενός αξιολόγησης του τρόπου με τον οποίο αυτή η νέα προσέγγιση για την ιατρική παρέμβαση θα επηρεάσει τη θεωρία της ιατρικής ευθύνης και αφ' ετέρου πρότασης πιθανών δογματικών αλλαγών.

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Λέξεις ευρετηρίου: Βιοενίσχυση, Θεωρία, Ιατρική ευθύνη, Σφάλμα

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