Legal Arguments in Favour of and Against Neuroenhancement by Means of Brain Organoids

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11.1 Introduction

In essence, enhancement can be understood as a biomedical intervention in the physiological constitution of humans that is aimed at improving their abilities and characteristics and thus—for example, with regard to physical stamina or attractiveness, cognitive abilities or behavioural attributes—goes beyond the restoration and preservation of their health.[1] The commonly discussed forms of enhancement include plastic/cosmetic surgery, sports doping and genetic enhancement. Even this short list makes it clear that it is often impossible to draw a clear distinction between medically indicated therapies on the one hand and non-indicated enhancement on the other. For example, it is possible to understand a cosmetic operation that is exclusively due to aesthetic considerations as enhancement, whereas the same measure as a result of an accident, for example, can be understood as a medical treatment. If, however, on the occasion of a medically indicated treatment, not only the original constitution of the patient is restored, but "on occasion" an "improvement" is brought about, the classification is much more difficult.

A look at the current developments in the so-called St. Nicholas jurisprudence (Nikolaus-Rechtsprechung) in Germany is an example of the fact that a case-by-case consideration is required in this regard, taking into account all circumstances that are relevant for the respective individual case. In its famous decision of 6 December 2005, the Federal Constitutional Court stated that under certain

[1] Fuchs et al. (2002); Runkel and Heinemann (2010), p. 211.

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conditions, policyholders have a claim against the statutory health insurance for the assumption of treatment costs even if the treatment method in question is not established:

> It is not compatible with Art. 2 (1) of the Basic Law ("Grundgesetz") in conjunction with the constitutional principle of the welfare state to subject the individual (...) to compulsory insurance in the statutory health insurance and to legally promise the necessary treatment of illnesses for his contributions, which are based on his economic capacity, but on the other hand, if he suffers from a life-threatening or even regularly fatal illness for which there are no conventional medical methods of treatment, to exclude him from the provision of a certain method of treatment by the health insurance and to refer him to financing of the treatment outside the statutory health insurance. In this case, however, the other treatment method chosen by the insured person must promise a not entirely unlikely prospect of cure or at least a noticeable positive effect on the course of the disease, based on circumstantial evidence. (…) (A non-acceptance of the payments) in the extreme situation of a life-threatening illness is also not compatible with the state's duty to protect life under Article 2 (2) sentence 1 of the Basic Law. If the state takes responsibility for the life and physical integrity of the insured person with the system of statutory health insurance, preventive care in cases of a life-threatening or regularly fatal illness belongs, under the conditions mentioned, to the core area of the obligation to provide benefits and the minimum care required by Article 2 (2) sentence 1 of the Basic Law (...). In such cases, the social courts called upon by the insured person in the case of dispute have to examine, if necessary with expert assistance, whether there are serious indications for the treatment undertaken or intended by the doctor after conscientious professional assessment of a not entirely remote success of the cure or even only of a noticeable positive effect on the course of the disease in the concrete individual case (...).[2]

In consequence of the Nikolaus decision, an extraordinarily lively case law[3] has unfolded, which, surprisingly, in an extremely large number of cases concerns a constellation that hardly anyone would have previously attributed to a "danger to life due to illness". This refers to liposuction, i.e., a procedure in which fat cells are removed from certain areas under the skin using cannulas. Although liposuction is usually performed as a cosmetic operation, it is also increasingly performed for illness-related reasons in the case of the so-called lipedema. The borderline is therefore extremely difficult to draw and only becomes easier in the present example when liposuctioned fat is used for "modelling" the body by means of fat transfers.[4]

The aforementioned definition of "enhancement" is therefore extremely helpful, but must not lead to the false assumption that a generalised or schematic view of the topic is possible. Having mentioned this, the discussion on the so-called neuroenhancement will be presented in the following, before a specific examination of the challenges of enhancement through brain organoids takes place on this basis.

[2] Federal Constitutional Court (2005), p. 25 et seq.

[3] Deister (2016), p. 337; Deister (2017), p. 61; Eichberger (2019), p. 217; Kunte and Kostroman (2014), p. 610.

[4] The "Brazilian butt lift", for example, but also the modelling of the so-called washboard bellies in men are well known and have received a lot of media attention. On this: Tiryaki (2016).

11.2 Neuroenhancement

In the course of the general "boom" in neuroscience,[5] the so-called neuroenhancement also became the focus of interest about ten years ago. It has been known for some time that many psychotropic substances lead to an enhancement of cognitive abilities not only in sick people but potentially also in healthy users. However, the formerly massive side effects have been significantly reduced in the meantime,[6] which has led to considerable, medically non-indicated use.[7] In this respect, it is sometimes argued that neuroenhancement always takes place in a non-medical context.[8] As the questions of differentiation presented in the introduction should have shown, such a clear-cut classification is in fact not possible.

Two of the best known (and most controversial) psychotropic drugs that directly affect the neurological system are methylphenidates (brand names: Ritalin, Medikinet) and Modafinil (Vigil). While Ritalin is mainly used for attention deficit hyperactivity disorder (ADHD), Modafinil (Vigil) is a drug for the treatment of narcolepsy and belongs to a group of psychostimulant drugs. Both methylphenidates and Modafinil (Vigil) are increasingly propagated resp. misused as "brain doping" or "brain boosters" due to their wakefulness-keeping and concentration-promoting effect. Consumers also expect to improve their cognitive performance by taking them before exams or at work. The sales of the corresponding preparations have increased more than tenfold within a few years, so that there is a certain indication for a considerable amount of off-label use and, in the case of purchase via internet sources, also considerable use without any prescription.

11.2.1 Constitutional Framework

With regard to neuroenhancement, legal problems arise both at the level of the constitutional order and in various contexts of statutory law. To understand the constitutional implications, it is crucial to first become aware of the different dimensions of fundamental rights. While the fundamental rights guarantees (dignity, life, science, profession, property, etc.) laid down in the Basic Law are conceived in their "classical" function as defensive rights and thus aim to prohibit the state from violating individual positions, objective value decisions can also be inferred from fundamental rights. This objective effect of fundamental rights means that the state powers—legislative, judiciary and executive—must always act "in the light of fundamental rights" when exercising their activities. In this context, it may also be the case that the state's (for example, the court's) assessment of a matter concerns the dispute between private individuals and that this private legal relationship must also

[5] On this: Spranger (2009a, b), p. 1033 et seq.

[6] Kipper (2010), p. 189.

[7] See Sect. 11.2.2.

[8] So, for example: Kern (2019), § 6 recital 23.

be settled "in the light of fundamental rights"; this is then referred to as the "indirect horizontal effect" ("mittelbare Drittwirkung") of fundamental rights.

With regard to neuroenhancement, it is therefore true that the state, when dealing with distortions of competition arising from neuroenhancement, for example, must act against the backdrop of the principle of equal treatment laid down in Article 3 (1) of the German Basic Law (GG). However, it is difficult to draw the line between this and other forms of "enhancement" of cognitive abilities. To put it exaggeratedly: Why should the state regulate or even ban neuroenhancers if strong coffee, nicotine, guaraná products, energy drinks, meditation or methods with a placebo effect, or the so-called brain boosters remain completely unregulated before exams or in other contexts?[9] In the context of an examination situation, for example, the performance of the test as such is not affected by the use of the substances mentioned in all of the above-mentioned examples. Rather, it is exclusively a matter of compensating for upstream or accompanying deficits that are usually not included in the examination assessment. (Neuro-)enhancers therefore do not impart any higher insights and certainly no additional knowledge, but at best improve the recall or presentation of knowledge acquired elsewhere. Wisdom, reasoning and judgement thus remain unimpaired. The scope for state intervention is reduced not insignificantly by this circumstance.

However, certain special features arise in oral examinations: here, the form of verbal presentation as well as aspects of appearance, quick-wittedness and responsiveness as "key qualifications" are recognised as playing a not insignificant role and also significantly influencing the assessment, so that from a constitutional point of view, there would probably be a sufficient starting point for corresponding regulations. Nevertheless, the problem of differentiation from performance enhancement by other, culturally more accepted substances remains. The declaratory approach of describing energy drinks, etc. as more or less unproblematic "softhancers"[10] is in this respect merely of a semantic nature and cannot convince in this generality as an empirically unsupported demarcation.

Furthermore, the question of the detectability of a corresponding intake (with special consideration of examination candidates who have a medical indication for the corresponding medication) would have to be clarified. In this respect, there are not inconsiderable difficulties: Such tests would have to take place immediately before the corresponding examinations and would have to be measured not only against the standard of general personal right or—with regard to the generated data—against the right to informational self-determination, but—in the case of the necessity of a physical intervention (blood or hair sample)—also against the right to physical integrity. In addition, as in competitive sports, there would probably be evasion scenarios that would raise the question of the efficiency of an examination-related "doping test".

[9] On this point of view, which on closer examination is not so easy to invalidate, also: Schiess Rütimann (2016), p. 191.

[10] Like that: Scientific Services of the German Bundestag (2018).

A more viable approach for regulating neuroenhancement thus turns out to be another dimension of fundamental rights, which is addressed under the umbrella term of the "state's duty to protect". According to settled case law of the Federal Constitutional Court, the state must not only refrain from any interference with the rights of its citizens, but must rather "actively protect these rights". Such a duty to protect is recognised in particular with regard to the right to life and physical integrity under Article 2 (2) of the Basic Law. If—which seems to be disputed at present[11]—the non-indicated use of neuroenhancers entails health risks or has an increased addiction potential, a practical starting point for state regulation from the point of view of a state duty to protect would undoubtedly exist.[12] It seems worth mentioning here that the health risks with regard to potential third party dangers also include possible increases in aggression or forms of reduced ability to control (overestimation of self, development of manias or psychoses).

11.2.2 Considerations at the Sub-constitutional Level

At the level of statutory law, the legal findings are comparatively sparse: the instruments of narcotics and medicinal products law are only capable of normatively limiting psychopharmacological "improvement" to a minimum degree. The decisive factor here is the fact that the meaning and purpose of these regulations point in very specific directions: Methylphenidate is listed in Annex III to Sec. 1 (1) of the German Narcotics Act ("Betäubungsmittelgesetz", BtMG) and is therefore considered a marketable and prescribable narcotic. Modafinil (Vigil) is part of Annex 1 to Sec. 1 (1) of the Regulation on the Prescription of Medicinal Products ("Verordnung über die Verschreibungspflicht von Arzneimitteln", AMVV) and may therefore only be dispensed in the presence of a medical or dental prescription. Both the BtMG and the AMVV have an effect on the question of the marketability of a product, but do not say anything about how actions are to be evaluated that are carried out while taking preparations that were obtained in disregard of the corresponding restrictions. This clarification is particularly important because the institutionally hardly controllable procurement of corresponding active substances via the internet—also taking into account the distribution of placebos—apparently "works". The law on medicinal products and narcotics is therefore de lege lata hardly suited to absorb the broad effect of neuroenhancement that is of interest here. Legislative intervention is required here in the event that specific neuroenhancement substances are developed in which a clear performance-enhancing effect is accompanied by the absence of adverse effects for the healthy organism.[13]

However, study and examination regulations have not yet been designed to counteract the use of (possibly) performance-enhancing substances.[14]

[11] Scientific Services of the German Bundestag (2018).

[12] Lindner (2010), p. 467.

[13] Volkmer (2019), Preliminary remarks on the AntiDoping Act, recital 18.

[14] Schiess Rütimann (2016), p. 183; Bublitz (2010), p. 306 et seq.

Possible effects at the workplace—for example, in the form of indirect pressure on employees to use such drugs to improve their performance—are at first glance as difficult to grasp as in the context of examinations. The dimension that the problem of "brain doping" has reached in the meantime is made clear by the current relevant DAK health report from 2015, according to which it must be assumed, including the number of unreported cases, that 12% of employees in Germany take prescription drugs to increase their performance at work.[15] The permanent nature of many employment relationships—in contrast to the more selective or temporary exam situations—makes it seem necessary for the legislator to take action if there is a risk of health disadvantages for the person concerned. The circumstance of a possible distortion of competition in the workplace, on the other hand, is hardly suitable to justify a legislative duty to act, for the reasons already mentioned.

If, against this background, the legislature were to decide in favour of sectoral or more comprehensive regulation, it would have to act—as already explained—in the light of fundamental rights. In doing so, in addition to the aforementioned guarantees in Art. 2 (2) and Art. 3 (1) of the Basic Law, it would also have to include in its decision-making, for example, the freedom of occupation (Art. 12 (1) of the Basic Law) of the manufacturing companies in particular or the freedom of research (Art. 5 (3)(1) of the Basic Law) of the neuroscientists working in this field. In this context, any form of (self-)regulation should take into account three fundamental areas of conflicts in the neuroenhancement discussion: the risk of possible steering of the discussion by industry interests,[16] the problem of partly false and suggestive citation of scientific studies on consumption behaviour even within the scientific expert discussion,[17] and the danger of the self-fulfilling prophecy of increased consumption of corresponding preparations due to increased media reporting.[18]

11.3 Specifics of Neuroenhancement Using Brain Organoids

The specific challenges of research on and with brain organoids are scarcely legally established[19] and characterised mainly by bioethics.[20] Questions as diverse as a possible consciousness of brain organoids,[21] the creation of human–animal chimeras,[22] patients' rights,[23] the brain death criterion[24] or the possible reduction of animal

[15] DAK (2015).

[16] Lieb (2010).

[17] Schleim (2010), p. 182 et seq.

[18] DAK (2009), p. 86.

[19] Lavazza and Pizzetti (2020); initial legal considerations can also be found at Molnár-Gábor (2020), p. 237 et seq.; Taupitz (2020), p. 212 et seq.

[20] Besides, this corresponds to the classical role of bioethics; for that: Spranger (2010), p. 31 et seq.

[21] Kaulen (2018), Lavazza and Pizzetti (2020), and Koplin and Savulescu (2019), p. 760.

[22] Chen et al. (2019), p. 462 et seq.; Loike (2018).

[23] Farahany et al. (2018), p. 429 et seq.

[24] Id.

experiments[25] are discussed. If and insofar as the term enhancement is used in the respective publications, it is only in relation to the possible improvement of animal brains by human brain organoids.[26] Thus, the question of possible enhancement through the use of brain organoids has not yet been visibly addressed. On the one hand, this silence could be due to the fact that no enhancement potential whatsoever can be attributed to organoid technology. On the other hand, there is also the theoretical possibility that there are no specifics with regard to brain organoids that would give cause for discussion beyond the general neuroenhancement debate. In detail:

The transplantation of organoids or organoid-derived cells in cell replacement and regenerative therapy is already being discussed as a future clinical application.[27] Transplants from the patient's own (autologous) as well as from foreign (allogenic) material are conceivable. Through the additional use of genetic engineering methods, disease-causing mutations could also be corrected in this respect in order to differentiate healthy organoids for transplantation.[28] The mere use in cell replacement and regenerative therapy thus already raises the questions of differentiation yet described in the introduction with regard to medically indicated therapy on the one hand and non-indicated enhancement or therapeutic overcompensation on the other. The combination of organoid technology with genetic engineering methods further increases the options for applications that could be subsumed under the term enhancement. It can thus be considered certain that brain organoids and their fields of application must also be discussed with a view to possible enhancement.

However, it is more difficult to answer the question of whether the conceivable risks here differ from those that determine the general (neuro-)enhancement discussion. Unlike psychopharmacological neuroenhancement, enhancement by means of brain organoids would be characterised by the fact that no chemical substances act "from the outside", but that more or less integral components of the human body then perform "improving" functions. It seems that such enhancement would also surpass the quality of the areas of application of bionic components.[29] Comparable uses, however, would be those that would be possible in the field of human genetics, especially with the use of genome editing technologies.

As an interim result, it can be stated that enhancement by means of brain organoids is possible, but currently no unique feature of such a form of enhancement is recognisable. From a normative point of view, such a unique feature also does not result from the fact that the brain—as is sufficiently known from the brain death debate—is "not an organ like any other", not only in the perception of most people. From a legal policy point of view, it would nevertheless be conceivable for the

[25] Bredenoord et al. (2017); see also: Tierversuche verstehen – Eine Informationsinitiative der Wissenschaft (2021).

[26] Chen et al. (2019), p. 462 et seq.; see also Schicktanz (2020), p. 201.

[27] Bartfeld (2020), p. 16 et seq.

[28] Id.

[29] About this: Spranger (2009a), p. 206 et seq.

legislature to make use of the leeway available to it and regulate or even prohibit the "optimising" use of the corresponding technology.

The constitutional parameters already mentioned in the introduction would be of particular relevance in this respect. The risks associated with organoid transplantation would have to be considered above all in the light of the state's duty to protect under Article 2 (2)(1) of the Basic Law. Depending on the focus of the debate, however, the duty to protect human dignity (Article 1(1) of the Basic Law) should also be taken into account. State restrictions planned on this basis would then have to be harmonised with conflicting fundamental rights, since the desire for "self-optimisation" also enjoys constitutional protection in the first instance, as does the implementation of this desire by the corresponding professional groups. Relevant here would be, above all, the general right of personality (Art. 2 (1) in conjunction with Art. 1 (1) of the Basic Law),[30] freedom of occupation (Art. 12 (1) of the Basic Law), freedom of science (Art. 5 (3) (1) of the Basic Law), general freedom of action (Art. 2 (1) of the Basic Law) and the equal treatment clause (Art. 3 (1) of the Basic Law).

Should there be a need on the part of the state to intervene in a regulatory manner due to the identified enhancement potentials, the aforementioned constitutional parameters would have to be brought to an appropriate balance. The necessity of such a balance does not mean that a state ban would be out of the question. Rather, even a ban implemented under criminal law can be "softly formulated", for example by means of exceptions. Whether a criminal prohibition of neuroenhancement by using brain organoids to protect a "right to mental self-determination" could be implemented in the Criminal Code[31] seems questionable, not so much with regard to the objective of such a request,[32] but rather from the point of view of legislative technique: The technical background, the potential areas of application, the diversity of the rights and interests affected, but also the linkage with other sub-areas of law[33] would, in the case of legislative action, speak more in favour of drafting a specific "anti-enhancement law". Certain parallels can be drawn here with sports doping, which has been regulated since 2015 by the Act against Doping in Sport (German Anti-Doping Act, "Anti-Dopinggesetz"—AntiDopG).[34]

The Anti-Doping Act explicitly serves to tackle the use of doping substances and doping methods in sport in order to protect the health of athletes, to ensure fairness and equal opportunities in sporting competitions and thus contributes to maintaining

[30] Albers (2016), p. 195 et seq.

[31] In general about neuroenhancement already Merkel (2009), pp. 950–951. Critically on this Volkmer (2019), Preliminary remarks on the AntiDoping Act, recital 18. Further: Beck (2016), p. 117 et seq.

[32] The question of whether such a procedure would protect the right described or, conversely, violate it, does not need to be examined further in this context.

[33] In this context data protection law is particularly relevant.

[34] From December 10, 2015 (BGBl. I p. 2210), last amended by Article 1 of the Regulation of July 3, 2020 (BGBl. I p. 1547).

the integrity of sport.[35] It goes without saying that the rules of the Anti-Doping Act cannot be directly transferred to the constellation of neuroenhancement that is of interest in this case, so that fundamental objections against the Anti-Doping Act,[36] that have been raised in the literature, do not need to be discussed further in this case. What is decisive for drawing a parallel here is rather the fact that in the case of an "anti-enhancement law", the intention of the legislator is likely to be comparable. Here, as there, the health of those affected and aspects of fairness and equal opportunities are at the centre of interest. Whether it would also be necessary—analogous to the integrity of sport[37]—to address "mental integrity" would ultimately be left to the assessment of the legislator. In general, it may be pointed out that the use of established or legally tangible categories always benefits the practical implementation of laws, so that conversely, too vague constructs should be avoided.

Conversely, the inadequacies that experience has shown to be associated with such a ban should be viewed critically. Apart from the differentiation between therapeutic application on the one hand and applications for the purpose of enhancement on the other, which must be guaranteed, problems of proof would arise despite the invasiveness of the necessary interventions.[38] Above all, however, it must be warned against overestimating the behavioural control effect of legal regulations. Even in the case of a sanctioned ban of the respective techniques, a sufficiently large incentive among potential interested parties leads to the development of evasion or circumvention strategies. Of course, such phenomena are just as little opposed to the enactment of legal obligations as they are to legal policy making.

11.4 Summary

Every form of enhancement requires an interdisciplinary approach: in addition to dealing with the scientific-medical foundations (and possibilities), there is also a debate on ethical legitimacy (for example, with regard to aspects of equal opportunities, personal authenticity or the moral status of the human condition). To a considerable extent, though, the law is also called upon, which—with the exception of a few prominent areas such as sports doping—has failed to fulfil its function in this respect so far.

The so-called neuroenhancement raises not only medical and ethical but also numerous legal problems. While any distortions of competition—for example, at school, at universities or at the workplace—are difficult to grasp from a legal point of view, possible health risks for the user represent a more suitable starting point for state measures. So far, the legislator has not prepared any specific regulations in this area, also against the background of the uncertain empirical starting position. If the

[35] § 1 AntiDopG.

[36] About that: Heger (2018), p. 61 et seq.; Lutz (2016), p. 21 et seq.; Winkler (2019), p. 14 et seq.

[37] About that: Dittrich (2017), p. 189 et seq.; Jansen (2017), p. 600 et seq.

[38] In this way about the psychopharmacological enhancement: Schiess Rütimann (2016), p. 199 et seq.

legislature wants to take action here, the various fundamental rights affected (Art. 2 (1) GG in conjunction with Art. 1 (1) of the Basic Law, Art. 12 (1) of the Basic Law, Art. 5 (3)(1) of the Basic Law, Art. 3 (1) of the Basic Law, Art. 2 (1) of the Basic Law) must be brought to an appropriate balance. In principle, it would also be possible to prohibit neuroenhancement in general or specifically in the form of the use of brain organoids. In this respect, the Anti-Doping Act could serve as a regulatory model. In the case of such a legal regulation, not inconsiderable challenges for law enforcement would have be to be expected. However, even a law suffering from certain enforcement deficits would still have a signal effect in terms of legal policy and society.

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