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Human Enhancement

INTERIM REPORT: Shifting Boundaries, Changing Concepts, and the Governance of Human Enhancement (Results of Two Expert Meetings)

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The project is being carried out by the Institute of Technology Assessment, Research centre Karlsruhe and the Rathenau Institute, as members of the ETAG Group.

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1. Introduction

After reviewing the state of the art in human enhancement technology and discussing human enhancement as an issue in policy, academic and for the public, the first deliverable ended with some questions to be answered. These questions formed the starting point for the organisation of the two expert meetings. The present report provides a documentation of the meetings, which includes the documents distributed to the participants, the list of participants, and reports on the course and outcome of discussions.

The first expert meeting was held in Brussels on Thursday September 18, 2008. This meeting was entitled: *Shifting Boundaries, Changing Concepts: The Challenges of Human Enhancement to Social, (Dis-) Ability, Medical and Ethical Frameworks*. The meeting focussed on how human enhancement (HE) may change, or is actually changing, notions as "(dis-) ability", "normalcy", "therapy", "perfectibility", "impairment", "ableism", and related social en ethical frameworks and policies. The participants discussed some of the more philosophical and social questions which were raised in the last chapter of Deliverable 1. Before the meeting, all participants received a document in which influential positions on HE were compiled. This document also included an overview of the relevant results from Deliverable 1 and questions to be discussed in Brussels. During the meeting there was a rich discussion, which was not just limited to the questions listed in advance.

On Friday, October 17, 2008 a second expert meeting was held in The Hague. This meeting was organised on the basis of the first deliverable and the first expert meeting. The goal of this expert meeting was to discuss the governance of HE with stakeholders. The broad range of HE technologies was limited to two cases, pre-implantation genetic diagnosis (PGD) and deep brain stimulation (DBS), which were thought to be helpful in shedding light on the collective of HE technologies. All participants received a document in advance which provided information about HE, the STOA project, the meeting, and the questions to be discussed. In the morning, there were two sessions: one on PGD and the other on DBS, while the afternoon session was plenary and tried to translate the specific problems of regulating HE into a general perspective.

These two expert meetings and the first deliverable will form the input of the next phase of this project. In the third and final phase the results of both meetings and the first deliverable will be the input for a workshop to be held in the European Parliament on Tuesday February 24, 2009. A document which summarises the main findings so far and preliminary policy recommendations will be prepared for this workshop, and will be sent to Members of the European Parliament in early February 2009. Some of these results and policy recommendations are already sketched in the chapter Conclusions of the Expert Meetings in this deliverable.

2. Shifting Boundaries, Changing Concepts (Expert Meeting I)

Full Title

Shifting Boundaries, Changing Concepts: The Challenges of Human Enhancement to Social, (Dis-)Ability, Medical and Ethical Frameworks

Place and Date

Brussels (Office of the Helmholtz Association of German Research Centres), Thursday, September 18, 11.30-16.30

2.1 Material for Discussion

Under the title "Human Enhancement: Is there anything at stake and, if so, what?" the project team compiled some material for discussion, which included an overview of notable positions in the debate on HE (Ch. 2.1.1), some preliminary results of the project concerning the definition of HE and the state-of-the-art in relevant fields of R&D (Ch. 2.1.2), and a list of questions for discussion (Ch. 2.1.3)

2.1.1 Positions in the debate on HE

In the following, we want to sketch main positions in the debate on HE and briefly characterise the discourse in the US and the EU.

USA

In military research and in political activities on nanotechnology, a policy discourse on the enhancement of human performance started already in the 1990s. The most visible research policy players were the Department of Defense's "Defense Advanced Research Projects Agency" (DARPA) and the so-called "NBIC initiative" (NBIC: nano-bio-info-cogno) which is a "semi-official" US initiative on converging technologies (CT), started by the National Science Foundation (NSF) and the Department of Commerce (DoC) in 2001 (initially with the support of DARPA, NASA and other public and private players).

In the following, we give some examples for positions on HE in the US.

A DARPA official in 2003 wrote: "We are entering an era of unprecedented human advancement in which Darwinian principles of evolution may begin to show signs of artificial self-acceleration. (...) Granted, this requires revolutionary scientific leaps, but we should no longer consider ourselves in a position to discount these possibilities as mere science fiction." The aim is "to extend the cognitive abilities of humans, in essence helping us to be smarter and more efficient by developing technologies to augment human cognition." There are "three basic methods of augmenting the human condition" of which "(a)s a species we have already implemented two (…) with varying degrees of success" (namely "extending the body (…) through the use of clothing, hand tools, vehicles, and weapons" and "extending perception with eyeglasses, telescopes, and, more recently, with hearing aids, cameras, electron microscopes, night-vision goggles, and now retinal and cochlear implants"). However, it has

"only been within the past decade that the technologies needed to extend human cognition have emerged. Augmenting cognitive functions such as perception, comprehension, insight, and memory overtly transcend the traditional boundaries of the slowly evolving human mind and body ("development of new computational systems and working in cooperation with these powerful systems")

Another DARPA official said in an interview in 2005: "Soldiers having no physical, physiological, or cognitive limitations will be key to survival and operational dominance in the future. ... Imagine if soldiers could communicate by thought alone. And contemplate a world in which learning is as easy as eating, and the replacement of damaged body parts as convenient as a fast-food drive-thru. As impossible as these visions sound … we are talking about science action, not science fiction."

The key figures of the NBIC Initiative (Mihail Roco and William Bainbridge) wrote in 2002: "(T)he human body will be more durable, healthy, energetic, easier to repair, and resistant to many kinds of stress, biological threats, and aging processes". Advances in nanoconvergence will enhance sensory and cognitive capabilities (also "for defense purposes") and enable "brain to brain interaction". Humanity might then become something "like a single, distributed and interconnected 'brain'" or a "networked society of billions of human beings".

NSF's and NBIC initiative's Roco wrote in 2004: "One of the objectives of NBIC is maintaining and enhancing the everyday human performance. This may include improving sensorial capacity when aging, increasing group work productivity through better communication, and using implant devices and neuromorphic human-machine interfaces. We see a future where we will focus on improving human performance rather than improving technology and the machines themselves. (…) We plan to replace parts of our bodies with artificial materials and devices. However, I am not saying that we will turn humans into robots."

The US President's Council on Bioethics (PCB) wrote in 2003: "Not everyone agrees that this prophesied new world will be better than our own. Some suspect it could rather resemble the humanly diminished world portrayed in Aldous Huxley's novel Brave New World, whose technologically enhanced inhabitants live cheerfully, without disappointment or regret, 'enjoying' flat, empty lives devoid of love and longing, filled with only trivial pursuits and shallow attachments." Taking up these "semi-futuristic prospects may seem a waste of public attention", but "it is important to open up this subject for public discussion." It bears on "the nature and meaning of human freedom and flourishing. It faces squarely the alleged threat of dehumanization as well as the alleged promise of 'superhumanization' (…) and it is far from being simply futuristic: current trends make clear how the push 'beyond therapy' and 'toward perfection and happiness' is already upon us", in "uses of cosmetic surgery, performance-enhancing drugs, and mood- or attention-altering agents."

In the following, we provide a very brief summary of preliminary results of our research about the positions and activities on HE in the US.

Agencies (such as DARPA and NASA) and the NBIC initiative (which both have the task to deal with, promote or fund highly visionary R&D endeavours) contributed decisively to the new debate on HE. They shaped this debate (which has a tendency to become a debate on S&T in general: "converging sciences and technologies") by promoting techno-futurist visions, including transhumanist ones. Several cultural and, in particular, religious conservatives have reacted rather strongly and critically to some visions of HE.

The heyday of the political debate on HE were the mid-2000s, since then DARPA and other policy actors have lessened their HE rhetoric or replaced it altogether by a rhetorical focus on prosthetics and therapy. On the other hand, the latest publications and activities (until 2006/2007) of the NBIC initiative and its key players have become more and more "transhumanised", with organised transhumanists playing an important role. However, the original goal of the NBIC initiative, to become a successor of the National Nanotechnology Initiative, has not been realised. HE has been a focal point of the work of the President's Council on Bioethics so far (also with regard to human dignity).

European Union

The EU reacted to the new debate on HE (as opposed to the older debates on genetics etc.) largely within the framework of activities on "converging technologies" (CT) and nanotechnology. The EU High Level Expert Group "Foresighting the New Technology Wave" on CT was established explicitly as a reaction to the challenging ideas and visions of the NBIC initiative in the US. The topic of HE has, for example, also attracted some attention within the Ethics staff of DG Research, leading recently, to the inclusion of the topic in an EC recommendation concerning responsible nano research.

In the following, we give some examples for positions of the European Commission and of its advisors and of researchers that were funded by the EU.

In 2008, the European Commission has proposed a code of conduct for responsible nanosciences and nanotechnologies research, in which it is stated under the title "Prohibition, restrictions or limitations" that "nanosciences and nanotechnologies research organisations should not undertake research aiming for non-therapeutic enhancement of human beings leading to addiction or solely for the illicit enhancement of the performance of the human body"

In a working paper, written in 2006 in preparation of FP7 by Future and Emerging Technologies (FET) of the DG Information Society and Media, one can learn that the "convergence between the bio-, nano-, info- and cognitive sciences will enable major advances toward realising the Lisbon agenda." While this would "be most clear in the health sector", the EU may also fund "realistic efforts" to develop implementations of "human augmentation", defined as "the ICT-based enhancement of human capabilities." Out of the "confluence between closely interacting networks of increasingly sophisticated devices, the creation of new immersive experiences, the natural interaction with ICT systems and the mingling of living and non-living ICT technologies", a "progressive extension of human performances (…) is likely to emerge".

In its final report of 2004, the EU High Level Expert Group "Foresighting the New Technology Wave" on Converging Technologies stated that some proponents of CT advocate and pursue an engineering of the mind by physically altering or enhancing the human brain or an engineering of the body. In contrast, the group argued that CT should be dedicated to engineering for the mind (improvements of the cognitive environment) and for the body. However, either way, humans may end up surrendering more and more of their freedom and responsibility to a mechanical world that acts for them. Some CT visions imagine "cognitive enhancements while underestimating the complexity of cognitive processes. CT research must therefore include a study of current limits", also to avoid "bad public investments". The

prospects of CT for human enhancement appear to be the most sensitive to public debate. Alternatively, "the distinction between therapeutic prosthetics and the business of human enhancement" could be maintained, sticking to the "emphasis on non-tradable goods" in Lisbon Agenda. One has to ask "how neutral or socially coercive is the decision of individuals to gain an advantage for themselves or their children through artificial enhancement? Inversely, when entire environments are engineered to structure human action, do individuals have a legally and socially protected choice to opt out?" Particularly troubling and internationally destabilising are technologies for the enhancements of soldiers' bodies, for remote manipulation of soldiers' minds, and other military applications. In the future, business could "market consumer spin-offs of military developments and thus prepare the ground for enhancement technologies and other controversial applications." Some prosthetic and therapeutic aids may be developed "with intended spin-off applications for military, entertainment, and general enhancement uses".

In its Opinion No. 20 on ICT implants, the European Group on Ethics (EGE) stated in 2005 that the "borderline between repairing and enhancing" is not strict, although there are "clear examples of both applications". The general point is made by the EGE "that non-medical applications of ICT implants are a potential threat to human dignity and democratic society." Therefore, such applications "should respect in all circumstances the principles of informed consent and proportionality and, whenever aiming at surveillance purposes, they should comply with special rules." Access to ICT implants for enhancement should be used only to "bring children or adults into the 'normal' range for the population, if they so wish and give their informed consent, or, to improve health prospects (e.g. to enhance the immune system to be resistant to HIV)." Certain uses of ICT implants should be banned, for example, "implants used for changing the identity, memory, self perception and perception of others or for enhancing one's own capabilities in order to dominate others." By referring to Habeas Corpus and in terms of a constructive critique of informational reductionism, the EGE weighed the self-transformative nature of human beings and their use of technologies against the risks of the human body being perceived as totally controllable and malleable raw material. In its Opinion No. 21 on nanomedicine (2006), the EGE asks how we can preserve the plurality of life-styles and avoid the transformation of the medical system into a mere service system for whatever desire individuals may have. Moreover, the EGE argues that maintaining the distinction between medical and non-medical uses is important with respect to European research funding policies, because non-medical research funding of nanomedicine may not be advocated as easily as research funding within the medical sphere. The EGE proposes that enhancement technologies should not be given priority. Health care concerns "must be met first".

In the final report of the EU-funded FP6 project CONTECS on CT (published in 2008), it was stated that "(t)he analysis of the visions and the state of the art research in the overlapping fields of Nano, Bio, Info and Cogno has shown that convergence is indeed under way in various fields." However, the analysis had also "shown that visions and the state of the art research are considerably distant from each other" and "the gap is especially wide in the two human enhancement fields, namely the Brain/Neuro enhancement and the Physical enhancement and Biomedicine areas." One reason for this finding might be "that in the enhancement fields, there are more disciplines, methods and approaches to be combined than in the other fields. Here, the need for interdisciplinary research and technology development co-operation is very high."

The EU-funded European Robotics Research Network asked in 2007: "What is the rate of the ethics of functional compensation or repair vs. enhancement? This issue is especially notable regarding the problem of augmentation: In some cases a technology is regarded as a way of compensating for some function that is lacking compared to the majority of humans; in other cases, the same technology might be considered an enhancement over and above that which the majority of humans have. Are there cases where such enhancement should be considered unethical? Are there cases where a particular technology itself should be considered unacceptable even though it has potential for compensation as well as enhancement?"

The EU-funded FP6 project ENHANCE organised a conference in 2007 in which the following positions and questions came to the fore: It was emphasised that the area of cognitive enhancement is a broad one and that the distinction between treatment and enhancement is far from clear. Some project members stressed the importance of seeing cognitive enhancement in a wider perspective, not be limited to drugs or genetic engineering. Another project member argued that the Internet is a kind of enhancer that is potentially a much more challenging factor for the concept of human nature than the perspectives in other types of cognitive enhancers. Relevant questions discussed were: Does enhancement increase happiness? Does enhancement raises problems of authenticity? Is there a concept of human nature at stake? What role does the concept of welfare play in this context? What is the goal of medicine? “Mood” is different from the other areas the project is dealing with. One participant argued that there is a whole semantic jungle around mood enhancers: One would like to be fitter, smarter and live longer, but mood enhancement is about feeling happier. But the problem is that feeling bad is not necessarily always bad and something that should be avoided. Our feelings and mood makes us who we are, mood is not merely instrumental for one’s life pursuit, but an integral part of one’s self. Mood enhancement might cause a feeling of alienation: is one still author of one’s actions? In the HE context in general, the distinctions between disorders and diseases and normality are very blurred and furthermore, it is, for example, not self-evident that eliminating bad feelings is good for our life.

In 2006, the European Parliament (EP) emphasised the need to respect high ethical principles in nanotechnology research and welcomed planned reviews on issues such as non-therapeutic human enhancement. The EP expected the reviews to be public and to include a thorough analysis of nanomedicine. In a STOA report on CT in 2006 (authored by staff of the ETAG partners viwTA and Rathenau Institute) it was stated that the "perspective of human enhancement has initiated a worldwide debate about basic questions concerning human nature." The authors asked: "Are we heading for a post-human future in which our bodies and minds will merge with computer power? Should we actively strive for such a future, or actively oppose it? If so, what does this mean for public innovation policies? How does the wider public think and feel about these issues and how to involve citizens into this fundamental discussion? What role should policy makers and politicians play in this discussion?"

In the following, we provide a very brief summary of preliminary results of our research on positions in the EU discourse about HE: While advisors to the European Commission and pertinent projects of accompanying research have discussed in detail the perspective of HE and related technologies, official political statements on the topic of HE are still rare and, taken together, appear to be conceptually inconsistent and in need of clarification. Moreover, different members of staff of the EC frame the issue differently, and there is no consistent use of the perspective or of a single concept of HE in EU policy. In general, one can say that the

politico-ethical discourse on HE in Europe is rather diverse, including pro-enhancement positions as well as more or less sceptical ones. Possibly, the inconsistencies in the emerging HE policy reflect this diversity.

Others

In documents of UNESCO advisors or staff, it was argued that issues related to prospects of enhancement of the human body are, for example, the questions "what is a genuine part of the body?" and "what is an enhancement and who defines it?" It was proposed that UNESCO could initiate "the application of the bioethical principles adopted in the Universal Declaration on Bioethics and Human Rights to the area of nanomedicine." The discussions on "post-humanism" were characterised as a distraction in the debate on nanotechnology. It was noted that in this debate, a variety of proposed uses for nanotechnology to enhance, repair, replace, or augment human characteristics are introduced. Such enhancements run the gamut from nanoscale sensors that might be added to the retina that improve sight to cochlear implants that improve hearing to performance enhancement technologies for athletes to new forms of plastic surgery. Discussions of "posthumanism" would assume that the ethical dilemmas that nanotechnology will create await us in the future and that we must prepare for them, whereas they are in fact issues that already face us today, such as performance enhancing drugs in sports, genetic screening for human characteristics, or privacy concerns over the handling of information technologies that we carry on our bodies. If anything, nanotechnology should provide an occasion to renew our focus on these concerns and try to achieve real answers to both present and future issues of this sort. This would include, most importantly, the promotion of uses for nanotechnology that help solve the most pressing needs for the greatest number of people.

The NGO ETC group which is an influential voice in the discourse on biotechnologies and nanotechnologies for quite a while now, wrote in 2006: "While relatively few will be able to afford the full enhancement package, some enhancements enabled by CT will become more and more pervasive and 'naturalized' until they are viewed as necessary corrections in the way that eyeglasses are today. At the same time, there will be a corporate push to define and broaden the scope of treatable “health conditions” – often under the guise of 'raising public awareness' – in order to create or expand markets for newly-available enhancements. The practice of promoting illness in order to create markets for treatment is called disease-mongering. Certain personality traits (e.g., shyness), physical traits (e.g., “average” strength or height), cognitive traits (e.g., “normal” intelligence) will be deemed undesirable and correctable (and gradually unacceptable, not to be tolerated). The line between enhancement and therapy – already blurry – will be completely obliterated." The debate "should focus on how or if to protect those who do not currently meet the 'human' standard – and those who will not meet a revised standard in our technologically-enhanced future." Most enhancements "are welcomed into society as much-needed cures or treatments benefiting a population identified as ill or disabled. A few are developed for particular 'well' populations with specialized needs, such as soldiers in combat. Though enhancements are ostensibly intended for limited consumption, the usual pattern is that use increases dramatically soon after introduction, beyond the population that first justified the enhancements’ development. When that happens, there are real-world consequences that society has not fully anticipated."

James Hughes, a transhumanist activist and bioethicist, wrote in 2006 that transhumanism is "based on the premise that the human species in its current form does not represent the end of our development but rather a comparatively early phase." The "core idea is that people should be guaranteed the right, and work toward full access for everyone, for human enhancement technologies, technologies which are being opposed because they make us more than human."

John Harris, a British bioethicist, argued in 2007 that if "not only are enhancements obviously good for us, but that good can be obtained with safety, then not only should people be entitled to access those goods for themselves and those for whom they care, but they clearly have moral reasons, perhaps amounting to an obligation, to do so." Therefore, in his opinion, enhancements "are a moral duty." Many of those who oppose enhancement would "wish us to accept the world as it is, to accept our limitations, even to take pride in them and rejoice them." In his view, "there is a moral obligation to participate in medical and science research more generally in certain contexts, and the argument concerning the obligation to participate in research should be compelling for anyone who believes that there is a moral obligation to help others, and / or moral obligation to be just and do one's share. Enhancements being both necessarily good and often very significant goods indeed share importantly in this obligation. Little can be said to those whose morality is so impoverished that they do not accept either of these two obligations. Research (…) is a necessary part of enhancement; it requires commensurate support and endorsement."

On the other hand, The World Association for Christian Communication of the World Council of Churches wrote in 2006: "Perhaps the greatest arrogance to be confronted is any claim to 'perfect' all life and in particular the human species. This irreverence denies the sacred relationship between creator and creatures. It ignores the vulnerability and finiteness of life. It opens the door for new divisions in human community that go far beyond the past and present experiences of racism, sexism, ableism and other deeply entrenched denials of human dignity. The commodification of human life in pre-natal diagnostics, some forms of research cloning and stem cell research as well as enhancement techniques must now increasingly be faced by churches and the wider public. Yet, even these are trumped by the dreams of so called transhumanists. Their vision of constant perfection of human beings beyond the boundaries of the species entails a nightmare not only for people with disabilities, but ultimately for all people."

2.1.2 HE and the state-of-the-art in relevant fields of R&D

The project team's preliminary definition of HE

Preliminarily, we have defined "human enhancement" as a modification aimed at improvement of individual human performance and brought about by science-based or technology-based interventions in the human body. This working definition includes "strong", "second-stage" forms of human enhancement with long-term effective or permanent results as well as "temporary" enhancements such as in drug use. Because it does not relate to a definition of health, this is a non-medical concept of human enhancement. The aim to improve individual human performance is conceived independently from any goals to restore a human being to a predefined normal physical or psychological condition. Improvements of human performance which are based on interventions in the human body, but do not lead to

super-human, above-average or average human performance are therefore also seen as human enhancement.

We have distinguished, however, between "super-human" performance and "species-untypical" abilities. Super-human performance can be defined as any performance which is vastly better than the best human performance ever known (such as sprinting as fast as a cheetah). Species-untypical abilities are abilities which do not naturally occur in humans (such as flying). Moreover, we prefer the view that exoprostheses and any other body-external assistive devices which are almost continuously in use are functional elements of human corporeality, regardless of their non-biological character, and thereby enhance human performance in a way that is more similar to human enhancement than to the ordinary use of artefacts. At least insofar they give their users species-untypical abilities or allow for super-human performance, they deserve attention in this context.

In this perspective, one can already identify a broad range of R&D projects which are relevant in the context of HE. On the one hand, there are psychopharmacological R&D and the pertinent, and often rather visionary, projects funded by DARPA and other US agencies, which include "second-stage" enhancement visions (e.g. in the area of brain-machine interfaces) and which were sometimes explicitly dedicated to the purpose of HE. On the other hand, there are several EU-funded projects which are relevant in the HE context, such as various projects on new prosthetics and man-machine interfaces. A member of DG Research's staff has already argued that these projects may enable a "new way of seeing, touching, sensing and moving" and might lead "to a new perspective for man to think or re-think himself and his nature."

Some results concerning the state-of-the-art in HET

Maybe due to the contentious character of the HE issue, R&D projects are rather seldom labelled as HE projects. (A member of DG Research staff, for example, has stated in a 2006 interview with Ineke Malsch that "normally the EU Framework Programmes de facto do not finance human enhancement but give funding to treating illnesses").

However, there appears to be a broad consensus which kinds of R&D endeavours are most relevant from a HE perspective and with regard to the assessment of the state-of-art in HET.

On a general level, one could point out that efficient human enhancement (in the sense of our working definition in section III.1 of this document) or other ways of improving human performance are only widespread in such more or less established fields as prosthetics, psychopharmacology and neuro-technologies. In these fields one can observe some tendencies which are of particular interest in the overall HE context, such as (a) the development of more and more sophisticated and efficient leg, arm and hand prostheses, which could even render possible super-human performance and species-untypical abilities for their users, (b) the widespread "dual use" of pharmaceuticals, and (c) the growing importance of neuro-technologies which can or could also improve the physical performance of people suffering from diseases. And the whole area of brain-machine interface R&D appears to open prospects of new ways of man-technology interaction.

There is broad consensus that HE, in a certain sense and to a certain degree, already exists in psychopharmacology. However, enhancements caused by some drugs are short-lived and minimal at best. Moreover, and probably even more important, there is the question what can be deemed an enhancement in this context: Does, for example, the ability to stay awake "unnaturally" long constitute an enhancement even if, for example, some elements of cognitive performance or emotional well-being are impaired? Would certain interventions to restore or delete memories be enhancements, or rather the opposite? And, more fundamentally, how do certain notions of "improved performance" in a civilian or military context relate to notions of a good life, of self-realisation, individual freedom etc.? One could argue that cognitive enhancement which appears to be the main area of interest of transhumanists and of other promoters of human enhancement, is still largely limited to certain functions, and with regard to most of them the results of interventions are inconsistent and, all in all, rather meagre. This is even more the case with those mood-altering interventions that leading transhumanists and pro-enhancement ethicists would wish to use for so-called "virtue" or "paradise engineering".

Besides the various applications and visions of biology-based enhancement (genetic, nutritional etc.), there are two tendencies in physical enhancement which may deserve more attention in the HE context: (a) the development of more and more sophisticated limb prostheses, and (b) the recent developments in neuro-prosthetics which have to seen against the background of progress in brain-machine-interfaces and assistive technologies in general. While the latter already helps to fuel the more visionary debate on second-stage enhancements, prosthetic technologies are, at least outside the military context, often underexposed in the debate on HE. There are two tendencies in the field of limb prostheses which appear to be of utmost importance in the HE context and, in particular, with regard to the central concepts of ability/disability: On the one hand, prostheses for daily use become more sophisticated in terms of their integration of advanced CT. On the other hand sporting prostheses are so advanced that the boundaries between Olympic and Paralympic sports get blurred. Such developments have to be seen in the context of the also expanding R&D in the field of exo-skeletons and similar devices which are to give humans super-human levels of strength and endurance. Some of today's prostheses can allow for super-human performance and species-untypical abilities, and highly efficient neuro-prosthetic limbs might be feasible in the rather near future. R&D that is funded also by the EU or in member states demonstrate that arm, leg and hand prostheses become more and more not only functional equivalents to biological limbs, but also more like them in terms of usability, appearance and sensual perceptions. All such prostheses might in principle be designed to allow for extra functions, including species-untypical ones. Several neuro-technologies are actually improving the physical performance of people suffering from diseases, or have the potential to do so in the near future. However, a comparison of the result of present applications with what is possible for a healthy person exposes a considerable discrepancy, a discrepancy that is eclipsed by the nature of media reporting or by U.S. policy-makers who use a strategy of hype and hope and therefore talk about the prospects of "the deaf to hear" and "the blind to see". On the other hand, most pertinent studies and experts agree that the man-machine-interrelations might be fundamentally changed in the foreseeable future. (Such tendencies have been discussed, often in a more speculative vein and under the labels man-machine-hybrids and cyborgs, for quite a while now.) A human capability to "see" infrared is an example for a rather realistic vision of

an enhancement that amounts to the creation of species-untypical abilities. Even the direct use of computer memory functions by humans appears to be possible in principle, however not feasible in the near future. A very promising, but still experimental field of R&D is the use of invasive or non-invasive brain-computer interfaces (BCI) by paraplegics or locked-in patients. Such technologies, which might create more and more means of a kind of direct communications of brains and computers, are also of particular interest in the military research context, with, for example, DARPA funding several cutting-edge research projects in this field.

2.1.3 Questions for Discussion

The project team also compiled a list of questions for discussion, which it deemed most relevant for the further project work or for EU policy:

(1) How do you assess the state-of-the-art in HET (science fiction, technology in the making, or already science action?), also specified with regard to various fields of HET?

(2) What would be the chances and risks of an increased use of any or a specific HE perspective in EU policy contexts (useful? dangerous? a hype?)?

(3) With notions of "HE" recently included in policy documents, what could be a proper definition of HE for policy purposes?

(4) To which extent, if at all, should EU policy-makers, medicine and ethicists stick to the distinction between therapy and enhancement, also with regard to social, medical and individual needs?

(5) Should (and, if so, how could) the notions of "disability", "ability", "ableism", "health", "normalcy" readjusted with regard to the topic of HE?

(6) In case you accept a notion of "disability" which accentuates social barriers and discrimination rather than corporeality, how do you perceive, and how would you conceptualise, the new tendencies in limb prostheses and physical HET in general (in particular with regard to new "ability divides", the "transhumanisation of ableism", and health policy)? How do you judge, in particular, our definition of HE with regard to disability politics and health and disability policy?

(7) Which European or Western traditions of thought might be conducive and which might be impeding to the development and acceptance of HET? (Some "candidates" are: Nietzsche's overman; the New Man of utopianism, socialism, communism etc.; eugenics; perfectibility in enlightenment thought; liberal and emancipative values; imago Dei; utilitarianism; ableism; postmodernism; techno-visionary thought; feminism; ecological thinking; romanticism)

(8) Do you see a need for any new restrictions with regard to HET, and which ethical and legal frameworks need a re-evaluation in light of the HE perspective?

(9) Which lines or fields of HE-related R&D would you recommend for increased funding?

(10) Which specific role do you see for the European Parliament within the HE context?

2.2 Participants

The covered fields of ethical and social-scientific expertise included, inter alia, research into HE, neuroethics (pharmaceutics as well as implants), technology-oriented disability and ableism studies, nanotechnology, biotechnology, synthetic biology and other converging technologies as well as the related policy issues.

The following experts took part:

Prof. Dr. Rafael Capurro

(European Group on Ethics, Stuttgart Media University, and Steinbeis-Transfer-Institut of Information Ethics)

Christopher Coenen

(Project team, ITAS)

Dr. Arianna Ferrari

(Technical University of Darmstadt, Institute of Philosophy)

Ineke Malsch

(Malsch TechnoValuation, Utrecht)

Dr. Ursula Naue

(University of Vienna, Institute of Political Science)

Dr. Michael Rader

(Project team, ITAS)

Dr. An Ravelingien

(Ghent University, Dept. Philosophy and Moral Sciences)

Mirjam Schuijff, MA

(Project team, Rathenau Institute)

Dr.ir. Martijntje Smits

(Project team, Rathenau Institute)

Prof. Dr. Gregor Wolbring

(University of Calgary)

2.3 Report

The meeting was intended to stimulate a discussion between ethicists, other humanists and social scientists working on science and technology developments related to the issue of human enhancement (HE). Some of the participants additionally have a background in natural sciences. During the meeting, it was, on the one hand, discussed how the perspective of HE may change or is actually changing such notions as "(dis)ability", "normalcy", "therapy", "perfectibility", "impairment" and "ableism", and the related social and ethical frameworks and policies. On the other hand, the prospects of the HE perspective and of HET in the European context were explored, also in comparison with the North American context. Another question was how to link conceptual with policy issues.

It was expected that the contributions of the invited experts shed light on the shifting of boundaries and the transformation of concepts that come along with the rising ethical, social and political interest in the perspective of HE and with new research and development (R&D) in human enhancement technologies (HET). The invited experts were also asked for comments on the preliminary research results of the ETAG project team (see above) and for statements on policy issues related to HE in the European context.

The meeting was structured in the following way: It started with a general statement by each participant on the topic of HE, its conceptualisation, its ethical, social and political implications, and the state of the art in selected HET. Afterwards all experts were invited to comment on these statements. This was followed by a round of questions and answers on all aspects mentioned in the list of "Further Questions" above which deal with the broader ethical and social issues raised by the perspective of HE. The results of these rounds of discussion were taken as basis for statements and discussions on policy issues related to HE. Finally, overarching questions of science and technology governance and foresight were discussed with regard to the European context and the issue of HE.

2.3.1 Results of the meeting

There was consensus that with regard to HE the central question is: What are the targets and goals of enhancements?

Broadly speaking, this relates to societal and political guiding visions and to ideological factors, anthropological concepts and fundamentals values which shape science- and technology-relates debates and activities and may lead to shifts in the definitions of such notions as health, (dis)ability, impairment, normalcy, and therapy.

Guiding visions

Genetic enhancement by way of germline engineering was discussed as an extreme option for HE, which has been banned in France, Germany and other European and non-European countries already in the 1990s. Taking this example and referring to the pertinent bioethical debates since the 1980s, the experts considered broader ethical and societal aspects of the issue of HE.

One expert proposed as basic categories of analysis the distinctions between, on the one hand, individual and species enhancements, and, on the other hand, between reversible and irreversible enhancements. Accordingly, the ban on genetic enhancement by way of germline engineering can be justified by reference to human dignity (metaphysical reason) and for the pragmatic reason that the consequences of modifications are not foreseeable, but at the same time may affect the human species as a whole.

In this context, the usefulness and limits of animal models were discussed. Referring to the vision to enhance animals, brought forward by some proponents of radical HE, several experts questioned whether animal models will ever be useful in the HE context due to the subjective qualities of many enhancements.

With regard to the prospects of a species enhancement, also some societal implications were discussed: The vision of a society, for example, in which all children are born after in-vitro fertilisation was deemed highly unrealistic by several experts. However, another expert pointed out that it is far from clear that germline engineering is as inconsistent with other cultural traditions as it is with European traditions.

It became clear that there is, at least with regard to the broader and more visionary aspects of HE, a differentiation to be made between the enhancement of the species, with its eugenicist overtones, and the enhancement of individuals. Leaving aside the question of the feasibility of genetic enhancements of the species, there was consensus that an enhancement of the species is not suited as a guiding vision, for historical, pragmatic and metaphysical reasons.

Turning to such new or envisioned "second-stage enhancements" (George Khushf) by means of human-technology interfaces (such as neuroelectric implants), the experts discussed the competing visions that have been expressed in the debates on such individual enhancements. It was pointed out that proponents of HE, in particular, focus on actual and future means of cognitive enhancement as a royal way to solve a variety of personal and societal problems. Referring to the NBIC initiative on converging technologies in the US, the experts discussed North American visions of a highly competitive "enhancement society" and of using HET to maintain US superiority, also relating this topic to the Lisbon Agenda.

While the experts did neither concur in their assessments of the state of the art in the pertinent HET nor in their views on the relevance of the NBIC initiative in the US, there was broad consensus that such visions might be conducive to a specific political shaping of the ongoing and emerging developments in second-stage HET. An alternative guiding vision for the development of HET, better suited to the European context, could be the improvement of, at

the same time, individual well-being and social cohesion. This vision was approved by all experts.

However, in the discussion of societal visions and specific HET it also became clear that various challenges are raised by the perspective of HE: Firstly, it was pointed out that the discourse on HET often displays a technocratic and scientistic stance towards societal and individual problems, promising technological fixes and fading out social relations. Secondly, it was discussed how anthropological concepts and views on human corporeality shape the debate on and the goals of HE. Thirdly, the experts discussed to what extent highly speculative visions of HET, coupled with specific ideological framings of the debate, may have an impact on research policy and other policy areas.

Shaping technology and society

Focusing on the example of so-called mood or emotional enhancement, the experts discussed the relations between social and individual factors in HE. One expert argued that HE could be contextualised within a medical framework in which all interventions are conceptualised as measures to help individuals to cope with society. Accordingly, when individuals suffer emotionally, due to, for example, their general shyness, their discontent with their body, or their nervousness in certain situations (e.g. stage-fright), we should not make an artificial distinction between therapy and enhancement, but approve any effective measure to relieve their suffering as a help to cope with society.

Other experts disagreed and pointed out that (i) such an approach would further the problematic tendency of a medicalisation of social problems, that (ii) in health policy, as in any policy field, we have to set priorities and that clearly therapeutic interventions should be prioritised, and that (iii), in a framework shaped by a radical perspective of HE, the social "duty" to confirm to a norm would become a duty to fix yourself to the norm by technological means. While among these experts there was disagreement whether it would make sense to draw a line between therapy and enhancement, they concurred that such boundaries are shifting and that, for example, the road to an enhancement society could be paved by a further medicalisation of social problems and individual needs.

It was pointed out that some radical proponents of HE not only argue, from a perspective of species enhancement, that there is a general "duty to enhance" oneself, but also characterise certain bodily structures as deficient and reduce "disability" to a problem that can only be solved by interventionist technological fixes. Such a "sad view of the human body", as one expert called it, was characterised as being based on problematic notions of normalcy. Moreover, it was argued that, in the informational paradigm, the human body is also reduced to data, while the complex interrelations of bodily and psychological processes are faded out.

Nevertheless, there was broad consensus that recent progress in brain research, neurotechnologies and other fields of R&D clearly demonstrates that there is potentially a new quality of interventions into the human mind and body. In this context, it was referred to Kant's distinction between a physiological anthropology, based on a scientific understanding and manipulation of the brain (which Kant in his times characterised as fruitless) and a pragmatic anthropology, based on knowledge about the social sphere, the world, and human

behaviour. Now we appear to be on the verge of the realisation of such a physiological anthropology, insofar there are at least new means to manipulate brain activities. Accordingly, even extreme visions, such as the NBIC initiative's vision of a new social technology based on new neurotechnologies and other converging technologies, deserve attention.

There was broad consensus among the experts that second-stage enhancements, particularly those based on new human-technology interfaces, should be assessed with a view on possible shifts in power relations. It was pointed out that the persistent paradigm of control and domination of nature in Western culture, when "applied" to "human nature", might negatively affect certain European values, as the ones expressed in the idea of Man created in the image of God or in the concepts of human dignity and autonomy. While the "intuitive" rejection of interventions which go "under the skin" might often be to the point, the fundamental question appears to be how such HET might create new options for social and even remote control as well as manipulation of human beings.

Hypes and hopes in research policy and the need for alternatives

Referring to the widespread critique of the highly speculative features of the debate and some political activities on HE, the experts discussed the impacts of visions, far-reaching expectations and grandiose promises on research policy and society. Fields such as stem cell research, cancer and Alzheimer research, nanotechnology, and artificial intelligence were characterised as strongly influenced by strategies of hype and hope.

It was pointed out that there appears to be a vicious circle, with policy actors eager for scientific and technological breakthroughs with high societal impacts and scientists making exaggerated promises.

In ethical, societal and political discourses, the speculative "if's" are not innocent, because they may serve to shape S&T in certain directions. The technocratic and scientistic speculations, in particular, appear to be conducive to the fading out of any risks which are not health or environmental risks.

Social risks, such as the ones related to shifts in power relations or the pathologisation of more and more bodily or mental traits, are peripheral to the discourse, which is reflected in the funding of "accompanying", ethical and social-scientific research on new technologies. In the view of several experts, the discussions and publicly funded research projects on HET still too often focus on very visionary aspects and ignore or belittle ongoing developments in HE-related pharmaceutical research, neurotechnologies, and prosthetics. On the other hand, far-ranging visions have to be taken into account, because they can shape societal and technological futures.

Several experts also emphasised that the discourse on HE is strongly influenced by an uncritical "faith in science" and that alternative visions of the future and proposals to solve societal problems are largely absent or neglected. When focusing on individual enhancements by technological means, we may fade out such low-tech or no-tech measures such as an improvement of school meals or creation of information- and knowledge-rich learning environments. Moreover, the general public is confronted, as a bystander, with some specific

imaginations in the modus of "hype and hope" only because they are ventilated by policy actors or members of the technoscientific elite. So, there is a need for alternative imaginations and societal visions related to S&T and more public participation.

In a similar vein, it was argued that an improvement of infrastructures should, in principle, be prior to the funding of individual HET, so that people with special needs, including the growing population of elderly people, can choose how to realise their "social functioning". Again, it was stressed by several experts that the (necessarily vague) distinction between therapy and enhancement should be maintained for pragmatic reasons in a health policy context.

Changing concepts

However, it was also pointed out that, in particular in "ageing societies", there are strong tendencies to redefine what is "natural" or "normal" and that, as long as there will be no consequent modernisation of infrastructures, many people will look for new artefacts or even individual enhancements of their bodies to secure their place in society. Here we have to take into account societal changes which have, for example, profoundly altered the social roles and images of young and old people.

Moreover, one has to keep in mind that one and the same intervention may for one person be an enhancement and for another person a therapy. There was broad consensus among the experts that the notions of health, well-being and disability have to be adjusted accordingly, taking into account conceptualisations which are well established in some political and social discourses, but still not in the socio-political mainstream.

Some experts argued for making a distinction between therapeutic and non-therapeutic enhancements. The ambiguity of established concepts becomes evident when we think of a person born without arms, but healthy and not impaired, who receives new prosthetics arms which may in the future allow for a performance superior to the performance with natural arms and may include species-untypical functions.

One expert argued that the root of many societal problems and of the conceptual vagueness in the debate on HE may be the ideology of ableism in which preferences for certain abilities serve to discriminate social groups. It was argued that it is necessary to create a society in which the broadest variety of individual needs is taken into account, so that individual enhancements are a matter of real choice and do not become, step by step, socially mandatory.

2.3.2 Policy issues and options

While the meeting focused on broader ethical and societal aspects of HE as well as on conceptual issues, the experts were also invited to make comments and proposals on policy issues and options.

In the following, we list some of these statements, starting with the consensual ones.

Consensual

(1) If a perspective or concept of HE is used in a policy context, it is of fundamental importance to identify as precisely as possible the targets and the overarching goals of HE.

(2) A perspective of HE might be applied to a wide range of new or emerging science and technology fields and their related guiding visions (such as in nano- and regenerative medicine), even if these fields have hitherto partly been ignored in the recent debates on HE because of their explicitly medical character.

(3) When it comes to regulatory questions, specific applications (and not technologies) should be targeted, possibly supplemented by the definition of general principles for pertinent research funding and policy, or even by some general bans (for example in the military context).

(4) Given their potentially disruptive effects on society, it is all the more important that the governance of HET starts early, includes all stakeholders and allows for public participation.

(5) There is need for a guiding vision for the further development of research and technologies which are relevant in the HE context and such a guiding vision should be based on a societal perspective which focuses on social cohesion and distributive justice as frameworks of individual choice.

(6) In research and technology policies, the vicious circle of promises and expectations should be cut in which excessive visions more and more shape science-policy interactions, with the general public as astonished bystander.

(7) Broadly speaking, in a policy context the perspective of HE should be focused on ongoing and emerging developments, also in more or less explicitly therapeutic contexts (such as the use of drugs like Ritalin and Viagra, or the development of more and more sophisticated prosthetics), and not on far-ranging visions. However, some policy problems may already arise today from anticipations that are not realistic yet, such as in the case of transhumanist and other pro-enhancement activists who attempt to get private or even public funding for highly visionary research.

(8) In case, that there will be a consensus in the future that certain forms of HE, which are generally accepted to be safe and in line with European fundamental values, should be a matter of individual choice, there will be an even more urgent need to adjust all relevant technological and social infrastructures and processes to the broadest variety of individual needs, so that no individual is pressured to opt for HET. However, in a policy context, there are also some good reasons (such as the shiftiness of the distinction between therapy and enhancement, the proximity to eugenicist ideals, or the strong transhumanist influence in the discourse on HE) to avoid the coupling of the concept of HE with individual choice altogether.

Controversial or uncommented by other experts

(1)For pragmatic reasons, the boundary between therapeutic and non-therapeutic interventions should be maintained.

(2) In the policy context and elsewhere, we should distinguish between therapeutic and non-therapeutic interventions into the human body.

(3) Policy-makers should now act on the issue of mood enhancement (or "modulation of affective functioning"), considering, for example, the introduction of quality-of-life assessments in medical trials and a revision of drug policies.

(4) Research on the potentially disruptive effects of HET from historical and broader scholarly perspectives should be more strongly funded, including research on anthropological concepts and European traditions of techno-visionary thought.

(5) The rise of the HE perspective is based on the overall fetishisation of competitiveness, so the latter should be questioned as core element of guiding visions, also in the EU context.

(6) EU research funding should be problem-driven and not focused on technological multi-purpose developments.

(7) Given that concepts of HE are already used in the European policy context (such as in the code of conduct for nano R&D), there is a need to clarify and consistently define and use the notion of HE in this context, taking into account the full spectrum of stakeholders and by means of public participation.

2.3.3 Preliminary conclusions

The discussion exemplified that with the perspective of HE, as long as it not rashly narrowed to certain concepts and as long as its highly problematic aspects (such as the proximity to eugenicist ideologies) are not faded out, new light can be shed on recent developments in S&T and society and their interrelations.

Obviously, the new HET and the related visions aggravate the tension between, on the one hand, established views of health, therapy, disability, normalcy and impairment and, on the other hand, more complex or encompassing conceptualisations of the relationships between individual well-being, equitable social structures and technoscientific innovations.

Given that the concept of HE, which is already an established (and actually a "fashionable") topic in ethical research, is slowly penetrating policy discourses, one could argue that there is a need for a politically viable notion of HE. If so, there are good pragmatic reasons to maintain the distinction between therapy and enhancement in a health policy context, but from a societal as well as from research policy perspective the distinction between therapeutic and non-therapeutic enhancements may be more viable.

Such pragmatic and political questions appear to be most urgent, but the perspective of HE is also a challenge for a variety of European traditions of thoughts and fundamental values. While the societal discourse on new and emerging technologies should in no way be reduced to the issue of HE, the perspective of HE may prompt a re-evaluation of the interrelations of S&T, society and the individual in the European context. If only some of the visions of second-stage HET are realised in the future, there will be a growing need for equitable social structures and, in particular, for sociotechnical infrastructures in which the diversity of individual needs and social demands are taken into account.

3. The Governance of Human Enhancement (Expert Meeting II)

Full title

The Governance of Human Enhancement: Exploring Regulatory Gaps and Wastelands

Date and place

17th of October 2008, Den Hague

3.1 Material for Discussion

The second meeting aimed at exploring and deliberating policy options for human enhancement technologies in the context of European R&D on human enhancement technologies. Two chapters of Deliverable 1 of the project, on pre-implantation genetic diagnosis (PGD) and deep brain stimulation (DBS), and the following introductory text served as material for discussion.

Introductory note: Framing governance issues

> "Contemporary medical technologies do not merely seek to cure diseases, but to control and manage vital processes of the body and mind" (Nikolas Rose, 2007)
>
> "Normally the EU Framework Programmes do facto do not finance human enhancement but give funding to treating illnesses" (A member of DG Research Staff, 2006)
>
> "One of the perverse effects of the failure of the current medical framework to recognize the legitimacy and potential of enhancement medicine is the trend towards medicalization and pathologization of an increasing range of conditions that were previously regarded as part of the normal spectrum. This disease-focused model is increasingly inadequate for an era in which many people will be using medical treatments for enhancing purposes." (Nick Bostrom, 2008)

Medicine aims at treating illness and abnormalities. Today however we observe a variety of technological and social trends that indicate a decline of this obvious assumption. In a broad range of technical and medical disciplines 'healthy' bodily functions are 'improved', in the absence of obvious medical needs. Advancements in scientific fields as genetics, neuroscience, pharmacology, and man-machine interaction promise to enable enhancements of essential functions and conditions such as memory, cognition, hearing, sight, mood, life-expectancy, behaviour, sleep, endurance, fitness. Visionaries claim new horizons in social domains such as prosthetics, military and sports. Meanwhile new needs are created and new standards for normality are constructed, often at a remarkable pace. A practice like cosmetic surgery, that only shortly ago was considered to be "physically risky, morally doubtful,

prohibitively expensive and socially embarrassing" has been embraced largely by an eager public. (Aitkenhead 2006) There is a multi-billion dollar market for enhancement drugs. Ritalin and IVF, medicalising some types of unconcentrated behaviour and infertility, are broadly accepted without considerable controversies.

It is hard to depict what exactly is new about this phenomenon that we call 'human enhancement'. Some claim that it denotes a radical change, either in a positive or in a negative way. Yet humans have always tried to improve their environmental and bodily conditions. The biological body has since long changed from a natural given that was taken for granted into a resource and a malleable object. New at least in human enhancement developments is the rapidly expanding scale of possibilities. New as well is the focus on improving the individual body by technological interventions. Genetic therapy, pills and brain implants go deeply beneath the skin, as opposed to traditional biopolitical instruments such as education and training programmes. They aim at improving the individual according to individual preferences, unlike, for example, traditional vaccination campaigns or laying out drainage systems, aiming at improving health conditions of a population. It seems new that enhancement has become an explicit task, and not just a possible side-effect of medical treatment. A remarkable and relatively new phenomenon is the apparently wide public willingness to adopt enhancing possibilities that (irreversibly) change the body.

Expectations, promises, concerns and fears about the future of Human Enhancement Technologies (HET) are manifold. Yet in contrast to the reservoir of promises and concerns , scarce knowledge is available about its factual consequences for social practices, cultural norms, cultural images, individual health, environment, health insurance systems, relations between citizens and doctors, solidarity with the disabled, social justice, etcetera. This is not due to a lack of effort to gain this knowledge, but due to the highly uncertain nature of future knowledge on the course of socio-technical developments itself. Undeniably, first stage human enhancements like IVF, PGD and Ritalin are socially embedded and practiced: they are here to stay. Yet it is quite uncertain what course other second stage enhancements will take, like genetic interventions (such as gene doping and germ line engineering) and ICT implants. Their "socio-technological dynamics", that is, the way technological advancements will be linked to social practices and cultural norms, is highly unpredictable.

This concept of a complex, largely unpredictable 'dynamics 'of future developments is our first assumption for our expert meeting. It means that our reflections are necessarily of a speculative character. It also means that we do not take for granted the visionary dreams by transhumanists and the pessimist nightmares by bioconservatives, on, for example, the coming of designer babies. There is need to search for middle ground positions in the debate. And moreover, there is a need for a public arena in which the normative issues involved can be discussed.

Broadening the decision making on Human Enhancement Technologies

Our study departs from a second assumption as well: social and ethical consequences of these new technologies, possible directions and normative choices should be anticipated from an early stage on, in order to broaden the process of decision-making. This assumption is rooted in the tradition of Technology Assessment (TA). A basic thought of TA is that new technologies will have desired and undesired, expected and unexpected consequences for society. Its factual consequences will go beyond dreams and fears that are projected on

technological improvements in advance. There will be winners and losers, and there will be effects on health, welfare and environment. Further, existing social practices will be threatened and challenged and normative dilemmas will arise. New needs are created and new patterns of autonomy and dependence will arise.

Technological developments of the past have shown that new technology can radically change our lives and practices. However, choices on its course are often made implicitly or by groups that are most involved, like by patients and doctors, leaving out others that will be touched by its practice. This of course is an unwanted situation: since we assume that citizens should have some control over the external powers that determine their lives. Like other external powers and trends, technology should be controlled and steered in a democratic way. As technology assessors we encourage a broad anticipation and reflection on social, ethical and political impacts on technology, involving a broad range of perspectives, in order broaden the decision-making on human enhancement technologies. What kind of social consequences should be either aimed for or avoided and how? In what directions should the funding of research be steered? How can the process of decision-making be improved all along?

Two cases: DBS and PGD

What new dilemmas and questions arise in the context of Human Enhancement Technologies that should be taken up either by national governments or by the European government? This is the big question that forms the background of our expert meeting. Yet we think we cannot solve that question by focusing on the whole package of current and future Human Enhancement Technologies at once. We like to work bottom-up.

Our approach in this expert meeting therefore is a case-by case one. We will not focus on the full range of human enhancement technologies and their social and political impacts, but we like to focus on two specific developments and their future regulation:

(1) Mood enhancement: Deep Brain Implementation (DBS) – the electrical stimulation of brain area's by implanted electrodes.

(2) Genetic enhancement: Pre-implantation Genetic Diagnosis (PGD) – selecting an embryo for having or lacking a specific gene that codes for a specific disease or property.

These cases are described in Deliverable 1 of the project..

We have chosen for DBS and PGD for several reasons. Both represent technologies that are already applied in medical practices and that at the same time contain highly visionary and controversial aspects. They represent two distinctive areas in HET, that is brain machine interaction and genetics. They are also distinctive in the sense that the one (PGD) is much more embedded in social and regulative frameworks than the other (DBS).

The aim of the expert meeting: Exploring regulatory gaps and wastelands

In the cases of PGD and DBS there is neither lack of regulation, nor lack of debate. Current regulation however is bound to their limited medical practices, though their long-term impacts probably will transgress the medical domain. It is exactly these "" regulative gaps" that we want to track down.

Our cases show that outside the current regulatory domains “regulatory wastelands” can be observed. The use of Ritalin for example is controlled within the medical domain, but its use is uncontrolled outside the medical domain. This tendency for extending the user options also characterizes the other cases. In the case of PGD, we observed the trend of a widening of the allowed indication of its use. We also observed the trend of medical tourism by potential parents living in countries that do not permit PGD on the genes the parents search for.

We concluded that it is important to study these “regulatory wastelands” in more detail.

Case by case questions (DBS and PGD)

(1) Do you agree on our sketch of the characteristics and trends of the case? Can you add to this sketch?

(2) Which moral and politically relevant issues (with regard to Research Policy and Health Policy) come to the fore when considering the case? Do you agree on our inventory? Which elements are missing?

(3) Will current regulative institutions do in order to weigh and address these issues? If so, why? Or do we possibly need other, or extra regulative mechanisms and institutions? Which regulatory gaps and wastelands do you observe with regard to the case?

(4) Where are possibilities for interventions by governments? Where should Europe be in control? What should be left to the market? What should be left to nation states? Regarding risk and health assessment, what risks for health should be further regulated? Regarding research policy assessment, should research in human enhancement be steered and if so, what directions in research should be encouraged, what directions should be discouraged? How should the research agenda of Europe be influenced? Regarding vision assessment: how can potential stakeholder preferences be articulated within these developments?

(5) On what issues should Europe formulate a broad Human Enhancement policy?

3.2 Participants

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Professor Dr. Frans Brom

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Christopher Coenen

(Project Team, ITAS)

Professor dr. Damiaan Denys

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Gaston Dorren

(Reporter expert meeting)

Professor Dr. Helmut Dubiel

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3.3. Report

What new dilemmas and questions arise in the context of human enhancement technologies that should be taken up either by national governments or by the European government? This was the main question that formed the background of the meeting.

The meeting focused on two specific technologies that seem to have human enhancement potential: deep brain stimulation (DBS), which may in the future be used to enhance people's moods, and pre-implantation genetic diagnosis (PGD), which might be applied with a view to selecting embryos that possess certain desirable traits.

3.3.1 Introduction

Martijntje Smits of the project team gave the following introduction to the meeting.

The term human enhancement, which is normative rather than descriptive, encompasses a wide range of technologies and applications with these common characteristics:

(1) Their locus is in the body.

(2) They start out as medical therapies, but then go beyond healing.

(3) Their development is not state-led, but bottom-up, with individual self-determination as one of their key drivers.

(4) They enjoy a considerable degree of public acceptance.

(5) They are applied both within and without the medical domain.

As a new group of technologies, human enhancement poses three familiar questions:

(1) What health risks do the novel technologies cause?

(2) How accessible will the new technologies be, and how will their introduction affect solidarity?

(3) Will the new technologies be affordable for society as a whole?

But beyond these, human enhancement technologies force us to face three more issues:

(1) Shifting moral and cultural boundaries.

(2) Shifting responsibilities, with free choice coming under social pressure in areas where it hasn't been so far.

(4) The question of what makes a good life: should we accept or overcome our human vulnerability?

How do we address these collective issues?

Regulatory arrangements have already been created for, or extended to, some aspects of human enhancement. Others, however, exist in a 'regulatory wasteland', partly populated by

conscientious researchers and physicians, partly by cowboys. Developments taking place in these 'wild places' tend to be labelled in an exclusively negative way. However, we can also look upon them as social experiments. Nonetheless, it is an urgent question if current institutional arrangements are sufficient to address the issues.

The participants are invited to discuss the following questions:

(1) Which are the main drivers of the trend towards human enhancement?

(2) Which moral and political issues arise?

(3) Are there regulatory gaps?

(4) Do we need further politic intervention?

(5) What sort of initiative should the European Union take, if any?

These are discussed first in two working groups, on deep brain stimulation (DBS) and preimplantation genetic diagnosis (PGD) respectively, and then in a plenary session, with a view to 'transcending' the cases.

3.3.2 PGD as a potential enhancement technology (Session)

Preimplantation genetic diagnosis is often presented as a mere add-on to IVF. The experts of the PGD working group feel this to be a misrepresentation. The very fact that embryos are selected brings in new moral issues, Williams argues, as a choice has to be made.

Knoers points out that PGD was developed as an alternative to prenatal diagnosis (PND), the advantage being that no abortion is needed to prevent the birth of a severely handicapped child. The claim that PGS (pre implantation genetic screening) serves to enhance the success rate of IVF is incorrect. Williams says: "The actual data show it doesn't help." She adds that some centres still wield this argument in order to promote PGS to patients. Knoers is happy to report that this is not the Dutch practice: "The possibility is mentioned, but it is not offered as the best option."

How likely is it for PGD to develop into an enhancement technology? Several facts argue against this.

For one, PGD requires IVF, which is an invasive treatment. "It is complex and risky and no fun at all," as Hennen puts it. "The invasiveness is comparable to an abortion," Knoers says. "For one thing, the woman has to be hormonally activated." PGD is also disempowering: instead of being in charge of their own reproduction, couples come to depend on the medical profession. These factors make it unlikely that large numbers of fertile couples would ever turn to PGD for reproduction. This is underlined by the fact that even IVF clients do not routinely use all that PGD has to offer. In the UK, PGD treatments are counted in hundreds, not thousands. And in the months since the Dutch controversy over screening embryos for a familial breast cancer gene in the Maastricht academic medical centre, such screening has taken place five times, all told.

While the invasiveness of PGD is often underestimated, Knoers thinks its potential for human enhancement is generally much overestimated. "We will come to better understand the links

between genes and characteristics such as intelligence, but never to the same degree we understand the monogenetic disorders that PGD has targeted so far. It's intrinsically impossible, as environmental effects will be much more relevant here." Hennen believes that media reports foster a belief in 'genetic determinism' that is scientifically outdated.

All present agree that by far the most effective way of having an intelligent child is the time-honoured 'technique' of choosing an intelligent partner. PGD will never even rival it. The famous 'designer baby' – a beloved cliché since the 1970s – is most unlikely to be brought about by PGD.

3.3.3. DBS as a potential enhancement technology (Session)

Even though deep brain stimulation is past its experimental stage and has now been applied to tens of thousands of Parkinson's disease patients worldwide, it is still "the last option", as Maarouf says. "If it is possible to treat patients with medicines instead of DBS, that is the thing to do," he adds, speaking as a surgeon who is "happy to help people by means of DBS to improve their life." The operation is not a simple one, though: "DBS requires 8 hours of surgery."

What makes DBS an ultimate remedy is the serious drawbacks for the patients involved, as Gabriëls points out. Some of the patients feel their life has not even improved. In others, DBS simply doesn't work. She feels that media reports tend to overlook this, and even Internet forums where patients discuss their experiences overemphasise the successes.

Dubiel, who has first-hand experience of DBS as a method of alleviating the symptoms of Parkinson's, feels that, on balance, he is better off now than 5 years ago, before he had the device. He has experienced serious problems though, some of them entirely unexpected both to him and to physicians. One unexpected setback is that he finds it easier to talk with the stimulator off, but when he turns it back on, walking is more difficult than before. Another downside is the eeriness of the experience: "The reaction to the brain stimulus is a totally new condition, unrelated to any 'story about myself' and impossible to share with people without DBS." In all, he finds it extremely difficult to weigh up DBS's advantages against its disadvantages.

Gabriëls points out that even though strictly speaking DBS is a reversible technology – the device can be switched off – in a more profound way, it isn't, because the 'eerie' experience that Dubiel referred to can never be 'reversed' in the sense of erased. This sheds a sobering light on the much-touted reversibility.

While it is agreed that DBS is a valuable technique for Parkinson's patients, there is considerable doubt about its experimental use as a treatment for depression. DBS can undoubtedly have a mood-enhancing effect. But as Denys points out, "enhancing someone's mood is not the same as treating their depression." And Gabriëls, a psychiatrist, observes that "not being depressed does not imply happiness. In fact, some of the people I've treated for a major depression had been ill for so long that they were not happy at all when they finally had the clarity to realise what a mess their daily life had become." Maarouf is equally reserved: "Psychiatric cases are complicated. Can we really improve the life of these patients by using DBS?"

On a practical note, Stoutmeijer points out that treating such a widespread affliction as depression with DBS would entail huge costs. She also expects ethical issues to arise, since depression has a strong social component. Denys puts the discussion in perspective with a sobering figure: so far, only 50 people worldwide have received DBS for psychiatric purposes.

3.3.4 What is human enhancement?

The discussions about PGD and DBS both led all present to realise that enhancement is not as straightforward a concept as it may seem. For one thing, many seeming enhancements prove to come at a cost. Gabriëls warns that memory enhancement, which is thought to be a potential effect of DBS, might in the longer run turn against the person, in that they may not evolve their natural learning capacity to the degree they might otherwise have. She also stresses that DBS has only been used on people with a severe condition. The effects of DBS on a healthy person are unknown.

Landeweerd, too, points out that some enhancements and 'disenhancements' may turn out to be communicating vessels. There is some evidence that a constantly improved mood may affect a person's cognitive skills; heightened intelligence may lower their social capabilities. Moreover, even unpleasant experiences can be useful, ter Meulen points out: "Nobody likes to feel guilty, but this emotion has great social value in making people conscientious." Deleting it, by whatever technological means, might be an enhancement from a short-term, individual perspective, but definitely not from a longer-term, social perspective.

The difference between therapy and enhancement can be extremely subtle. Blume gives the example of growth hormones: "In a short child, born to short parents, these would amount to enhancement, whereas the treatment would be a mere therapy if the child's parents are of average height." This is not to say that the difference should be done away with. Denys for one feels it is important to retain it, as does Schermer, both for medical and policy reasons. Ter Meulen on the other hand is "bothered" by the distinction, "the enormous watershed" as he calls it: "A lot of what is going on in the medical realm is really enhancement, especially when it comes to afflictions such as depression."

Might 'human enhancement' be a misnomer? Blume feels it is: "All technology is enhancement." Coenen agrees a more neutral term would be better, as "it would be less overshadowed by Superman fantasies". As a first suggestion, he offers 'personality-changing techniques'.

3.3.5 What drives human enhancement?

Human enhancement techniques enter our lives by the medical route. They first alleviate or cure some condition, thus legitimising their existence. Only afterwards do other applications arise which might be termed enhancement. Or they might not, for by redefining perceived human imperfections as medical problems, the use of a technique may be labelled therapeutic after all. This mechanism is called medicalisation. As Landeweerd sums it up: "All except normalcy is a medical problem. And our definition of normalcy has become ever narrower."

Left unchecked, medicalisation can get to a point that would have been considered preposterous at an earlier stage. Stoutmeijer gives an example: “The Dutch Medicine Evaluation Board (CBG) recently discussed whether a Botox treatment should be recognised as a legitimate therapy for depression in people who feel their condition is caused by their wrinkles.” Denys ironically offers an alternative treatment: “Why not send the depressed person on a holiday to Turkey?” Blume is not surprised: “Cosmetic surgery can easily be, and often is, justified by citing the patient’s psychological suffering.”

Once a technique is generally considered to be a therapy, new ‘drivers’ emerge. Media framing is one. Since reports tend be to long on impressively successful cases and possible future developments, but short on failures and psychological cost for the patient, media consumers get an overoptimistic idea of what therapies can achieve. And that is just reporting; marketing does its bit to convince potential clients (and physicians) of the technological wonders whose time has come or that are just around the corner.

All the information – some of it good, much of it not so good – has turned patients into very critical medical clients. “Some patients are very demanding,” Gabriëls says. “They will put physicians under pressure to ‘give them the chip’, i.e. DBS, even if the diagnosis does not indicate the treatment.”

This attitude can be seen as an excessive side effect of the strong, widely shared ideology of patient autonomy, which is in turn part of Western individualism. “In the case of human enhancement, this individualism is particularly strong,” Asscher believes. “I think it is related to the historical eugenics trauma. That explains the strong qualms about selection you see in Europeans. As soon as you discuss what might be beneficial or not to the whole of society, you rub many people the wrong way.”

Related to this, our society is obsessed with choice. “As soon as there is a choice,” Landeweerd says, “the whole paradigm shifts and we feel everything should be chosen. The disappearance of ‘fate’ as something that just happens to occur puts severe pressure on the question of how to deal with life. At the same time, we underestimate how burdensome all these different options are.”

Or maybe we just consider that ‘burden of choice’ as the price to pay for making the best of our lives. Blume quotes sociologists “who suspect that medicalisation is attractive to us because our society has become more competitive and more fragmented, with weaker social networks.”

Once a technique has become a matter of routine, the opposite problem may arise: patients are no longer offered a neutral choice, but may be subtly channelled to accept what is being offered. For example, “Pregnant mothers in the UK often have to justify their decision when they decline prenatal screening,” Williams says. There is agreement that pregnancy counsellors should be non-directive on this issue, and Knoers feels that, in the Netherlands at least, they are.

Hennen mentions another case of subtle pressure, with legal undertones: “Some doctors want women who refuse a test to sign a declaration to that effect, so as to pre-empt ‘wrongful life’ claims.”

3.3.6 Is there a slippery slope?

Does all of this mean that medical technology and especially its enhancement effects have such an unstoppable momentum that they will lead society down a slippery moral slope? “If you start enhancing humans your message is that human beings as they are now are in fact a mistake”, Denys argues. And Gabriëls adds, “Moreover, you put people under pressure who do not want to be enhanced, but who feel they might need to in order to remain competitive.”

“The slippery slope argument is seldom a strong one,” Asscher asserts against this. “The first step generally doesn’t imply the next.” And “the argument assumes a specific direction, which is not necessarily correct,” Landeweerd adds in support. “I hope you’re right,” Hennen voices his doubt.

Yet, it would be false to think that patients are turning out in droves to benefit from every conceivable novelty, as the limited numbers of people choosing for PGD show. Also, people refusing technological options do not seem to be ostracised: Knoers points out that a great number of people prefer not to have their unborn child tested for Down syndrome, even though such prenatal screening has been possible for many years.

At the same time, it is expected that the number of conditions that can be detected through PGD will increase. Many of these will be less serious than cystic fibrosis or Duchenne’s disease, to name two typical targets of today’s screening. Even familial breast cancer, for which screening is now allowed in the UK and the Netherlands, has a mortality of well under 100%. There is no obvious percentage that justifies or fails to justify PGD. In other cases, mortality is not even the issue. Knoers mentions non-hereditary mental retardation, some forms of which will soon be eligible for embryo screening.

Williams contributes yet another complication: it is possible to identify and select out embryos carrying a recessive gene coding for a disease, even though this individual will not express it, i.e. will not itself have the disease. Such a decision would effectively impact not only on this individual, but also on future offspring. Should parents be offered that choice, or is that sliding down the slippery slope? “Not necessarily,” Knoers replies. “I do think it would have to be quite a serious condition. I feel it would not be warranted with, say, haemophilia.”

3.3.7 The case-by-case approach

‘Human enhancement’ is a catchall term for very dissimilar technologies and even future possibilities. The closer one looks at any single technology, the more diverse its promises and risks turn out to be. As Landeweerd puts it, “There’s quite a difference between somebody aged thirty who dreams of enhancement for cycling uphill faster and parents who wish to determine what their children will be like through PGD.”

Also, the fine line between therapy and enhancement will have to be drawn differently, case by case, for each enhancement technology, Blume believes. So differently in fact, that he feels ‘enhancement’ is hardly a meaningful category – “for policy-makers, it will be a red herring.” Still, with a case-by-case approach, a difficult question will be to define what a case is. “Is ART (artificial reproductive technology) a case? Is PGD one? Or is every particular gene you screen for a case? If you define ‘a case’ narrowly, then with every new technology, there’s new regulation needed.” Or should PGD, alternatively, be considered as a part of the wider case of genetic testing, as Hennen suggests?

3.3.8 The medical tourism problem

Some countries, such as Belgium, the UK and the Netherlands, are more liberal in their admission of certain new medical technologies than others, such as Germany, Austria and Ireland. Other technologies, some of them experimental, may not be controversial, but require so much investment in expertise and equipment that hospitals in some countries prefer not (yet) to acquire them.

One consequence of this is that patients have to travel from one country to another for treatment. Sometimes they are referred to a centre of expertise abroad by their own local health system. Probably more often, they try their luck elsewhere on their own accord. “In Cologne, we have quite a few foreign patients, from Europe and from the Arab world,” Maarouf says. “These are people who can afford the expensive treatment.”

This ‘medical tourism’ is not unproblematic. “I dislike it,” ter Meulen says. “Who’s going to pay for it if the patients don’t have the means? And who is going to do the aftercare when they get back home, far away from Cologne or wherever they were treated?”

Gabriëls remembers a telling case: “A Belgian neurosurgeon had operated on an African Parkinson’s patient. But when the battery of the patient’s brain stimulator ran out, nobody in his country could replace it, and he was as miserable as he was before.” Yet, she doesn’t object to medical tourism in principle. “The patient’s local health system should do the aftercare. The expertise centre where the surgery takes place should teach medical centres elsewhere how to do that.” The follow-up usually requires much less sophisticated skills than the initial surgery.

3.3.9 Regulation: introductory remarks

What sort of regulation is needed for human enhancement technologies (regardless of whether PGD and DBS potentially are such technologies)? Policy-makers have to strike a balance between two somewhat contradictory objectives, Asscher thinks: “Of course, you want the regulation to be effective and enforceable. At the same, you want it to be flexible enough as to allow for future technological developments. I think the way forward is to have little ‘hard law’ and on top of that a licensing system that deals with all the specific cases.”

Hennen sees a risk with such a legal case-by-case approach, however: “With every new development, patients will immediately clamour for swift application. The burden of proof then rests with the authorities; they have to explain why it may not be a good idea to put this new technology to practice. France has dealt with PGD in a different way. French law states that this technology can only be used to prevent ‘serious diseases’, or words to that effect. It is then up to the patient, or rather to the parents, to prove that a particular condition meets that requirement. Of course, you still get discussion, and there should be, but this law creates different dynamics from a case-by-case approach.”

3.3.10 Who should regulate what?

In the case of technologies with a human enhancement potential, there is a role for professional self-regulation. Gabriëls explains how the major centres of expertise in Europe

and the United States concerning DBS have co-operated to write common guidelines. Similarly, doctors in the UK and the Netherlands perform PGD under an agreed set of principles. For each new case, they establish an advisory committee.

Yet, there is general agreement that self-regulation can only do so much, and not only because the reimbursement issue has to be solved by other actors, particularly national governments and insurance companies. For one thing, self-regulation won't stop the 'cowboys', i.e. the practitioners who will cater to a patient's every wish as long as there is money to be made. "They do not care for the respect of their colleagues working in public hospitals," Denys says. This practice is common in cosmetic surgery, but could easily spill over into other 'medical industries'. Stoutmeijer feels that there is no point in banning private clinics for, say, DBS, as she believes this will merely lead to illegal practices. "I think peer pressure is much more effective than legislation." "I know these people," Denys replies, "and I doubt it." Dubiel feels the same way, and adds: "If you want to regulate these practices, you will have to be quite exact and specific."

Denys has other reasons to look to the state for regulation, over and beyond professional self-regulation. "What if a doctor routinely does DBS and after a while things start going wrong? For instance, it turns out there is a surge in suicides among patients? There will be public outcry, of course. I want public regulation to protect the doctors." Ter Meulen and Gabriëls argue similarly.

What political arena should we turn to in order "to politicise the big issues", Smits asks, the ones that go beyond the nitty-gritty work of regulating particular cases; issues concerning no less than the direction of society. Hennen would like to appeal to parliaments to take these up. "Among other roles, parliaments should be the liaisons between policy-making and the public. By discussing the issues, they can clarify what is at stake."

Another part of the answer to Smits's question comes in a short discussion about regulation as a concept. "The word always seems to point to the government,' Stoutmeijer says. "Therefore I would prefer a different term, since I feel we [i.e. the Ministry of Public Health] are not the only relevant regulator." It is generally agreed that the government is not the only actor responsible for regulation. Therefore, helpful alternatives such as 'governance' and even 'organisational trajectory' are offered, as these would express more clearly that all stakeholders are to be involved in the process.

Returning to Smits's question about politicising the big issues, Schermer suggests "what is really needed is raising public opinion. Of course, regulation is a good thing for practical matters, but for the major questions like 'where should society be heading' regulation is just no option."

3.3.11 Specific issues to be regulated

In the course of the discussion, a series of regulatory gaps and wastelands are identified, where rules are needed. These include the following:

Trans-boundary medical care

Under what conditions should citizens of one country get their medical costs reimbursed if they travel to another country for medical treatment? Asscher feels this question is one for the

EU, especially as “it is practical and not as value-laden as many others. I feel the 27 member states should be able to come to agreement.”

Moving from cost to care, it is recommended that centres of medical expertise which serve a large geographical area should train staff elsewhere, so that patients will receive adequate follow-up treatment not too far away from their homes.

Practical requirements

Treatments should be organised according to specific requirements. “For instance, it should be compulsory to have at least a neurosurgeon and a psychiatrist to handle a case,” Denys says. “These two should work together and communicate properly. They should follow a particular education programme where the surgeon learns to implant the electrode correctly and the psychiatrist learns to assess this particular group of patients. All of that should be regulated.”

Registration

Gabriëls is convinced that “there are clinics that do not follow up on their DBS patients, and consequently do not report any problems that might pop up some time after the operation.” She would like to see a “central registry where physicians would report on each and every one of these patients.” Such a registry would facilitate a structured build-up of experience that is now lacking.

Orphan technology

Some medicines are effective for treating such small groups of patients that companies cannot make a profit on marketing these so-called orphan medicines. This is probably equally true for certain applications of DBS, Schermer points out. European regulation should make sure these applications become available even though they are not profitable in economic terms.

Specialisation

According to Maarouf, patients will be better off if fewer hospitals offer highly complicated treatments. “In Germany some 30 medical centres offer DBS treatments,” he says. “This means that some surgeons have very few DBS patients each year, which is risky, for it is a truism that the more experienced surgeons operate more safely.” Specialisation is therefore an objective that regulators should seek to achieve.

Suffering

There is much to be said for the conventional approach of defining conditions under which it is appropriate to perform a certain kind of procedure, Blume feels, adding, however, “that this should be coupled with a valid claim that the treatment targets a patient’s suffering. We shouldn’t just assume that, or ask the patient; we should look for some sort of proof.” “The concept if suffering is important,” ter Meulen agrees. “Maybe it should be left to committees made up of both professionals patients to discuss it.”

New domains

Human enhancement technologies are likely to be used in the military and maybe other non-medical domains, according to Gabriëls. Since these do not fall under medical regulations, special regulations are needed.

3.3.12 Challenges for regulation

National differences

An important obstacle, as with so many European regulation issues, is the member-states' variety in both their values and their institutions; their health care systems, in this case. Of course, European regulators have enormous experience in making arrangements that somehow allow for institutional differences. As for the value gap, ter Meulen points out that the British have a somewhat more gung-ho attitude to human enhancement than the slightly more wary continent. Still, he feels common ground can be found, based on shared values such as justice and solidarity.

Serendipity

The case of DBS clearly shows how new treatments with enhancement potential are stumbled upon in the course of standard therapeutic treatments, Schermer points out. While it is possible to regulate research projects, serendipitous discoveries cannot, by definition, be ruled out by whatever law or regulation. "And is natural for scientists to want to follow up on their interesting findings." It is up to the medical-ethical committees, who already watch over DBS research, to look closely into whether such fundamental further research is justified.

Non-compliance

There is a twofold risk of rules not being observed: within the system, and outside it. Blume remembers how the Dutch Health Council recommended that the number of centres of expertise for cochlear implants be extended from two to four. But since all academic hospitals wanted to be among those two additional centres, every one of them started doing these implants, without waiting for government permission. A year later, the minister could only acknowledge that she was incapable of regulating which hospitals should be centres of expertise for this technology.

The risk of non-compliance outside the system, which refers to the 'cowboys' mentioned earlier on, is of a different order. It will lead to unequal access to expensive treatments (though some participants take a more pragmatic view on this than most others) and may have spectacularly unsuccessful results.

Prompted by the latter risk, chairman Brom asks poignantly, "Do we really need to stop stupid people with too much money from buying ineffective dangerous things?" the 'ineffective dangerous things' being unproven medical or even enhancement treatments. Schermer describes these potential treatment consumers as "very rich and very bored. Some may even

want to try out DBS, and not all physicians will be ethical enough to deny them the experience."

After some discussion about Brom's question, the prevailing view seems to be that for the sake of consumer protection, an attempt should be made to regulate all practitioners, including those outside the public medical system. Some participants add to this that such regulation also protects the ethical professionals against the reputation damage the 'cowboys' could do to novel therapies.

Acceptance of constraints

Apart from non-compliance by the professionals, there is also a risk of non-acceptance by the public. Blume wonders, "What constraints on our free choice do we accept?" Apart from the invasiveness of many techniques, which could be considered an inherent constraint, there is the obvious cost factor: not all treatments are affordable for a public health insurance system. (Though some expensive treatments, such as selecting against embryos with genes coding for disorders, may in the long run be cost-effective, Asscher points out.) But is society capable of imposing constraints on individual choice for the good of the collective? Patients' claims, or parents' claims in the case of PGD, predominate in discussions on any medical progress, which makes it very difficult to impose constraints. The historical eugenics trauma adds to this.

Yet, certain constraints on what we can purchase might be both sensible and acceptable, Blume thinks. He draws a parallel with organ transplantation. While this is an almost universally accepted technology, most people draw a line at selling and buying organs. So, in principle, we do not feel that every technology that saves a person without harming anyone else is morally acceptable.

3.3.13 Conclusions

At the end of the day, Smits summarises the results of the meeting. Two core questions passed the table.

Firstly, what is the added value of the HE concept when reflecting issues of regulation and EU policy? In the discussion, she observed a peculiar contradiction on the fruitfulness of the umbrella term 'human enhancement' for addressing social issues. In terms of the cases, HE did not appear as the most fruitful concept when discussing moral issues that arise at the level of the case. At that level, designer babies and mood enhancement do not make any sense. In other cases however, such as Ritalin, we see that enhancements have become a reality. But at the same time we agreed that there are big issues that transcend the level of the cases, such as medicalization, equity, changing norms about normalcy, what kind of society do we want. When we discuss the specific cases, it appears to be difficult to get these broad, cultural and moral issues into view. We are in danger of loosing sight of those broader issues if we focus on the cases only and dismiss the overarching concept of human enhancement. If so, how do we keep the big questions in vision?

The second question is, which regulatory wastelands are there to be remarked, and what should be done about them? Smits likes to distinguish two types of wastelands. There is one type that emerges when discussing the cases: we talked about the uneven accessibility of the

techniques, their risks, medical tourism, the agenda setting and funding of research, the relationship between professional and political standards – should not the professional standards be informed by public discussion?

The other wasteland seems to be the lack of political arenas where we can politicize the big questions and abridge the gap between public opinions and the views of practitioners . How can we encourage those bridges, what kind of instruments are there? Leo Hennen suggested to found a multidisciplinary working group on HE and the requirement of reflection on social issues in research funding (like in the funding programme on nanotechnology). These seem to be fruitful directions. Smits thinks we should further explore these type of instruments.

4. General Conclusions of the Project Team

Both expert meetings demonstrated that a broad, but specific perspective of HE can help to better understand a wide range of developments in ongoing and emerging R&D and their interrelations with society.

4.1 The perspective of HE and conceptual issues

Concerning our definition of HE – defined as any "*modification aimed at improvement of individual human performance and brought about by science-based or technology-based interventions in the human body*") –, we found

(i) that the renouncement of a clear distinction between "therapy" and "enhancement" does justice to an equitable and critical understanding of such notions as "(dis)ability", "normalcy" etc., but raises problems when it comes to issues such as distributive justice and priorities in the health system,

(ii) that it is crucial to emphasise that modifications which aim at improvement of individual human performance are not necessarily improvements from every normative perspective,

(iii) that a concept of "HE" that includes traditional, physically non-invasive means for the progress of humanity (such as education) is too broad to be relevant at all, and

(iv) that for historical, pragmatic and metaphysical reasons the "enhancement" of the human species is not suited as a guiding vision.

However, this still leaves one with the question of how to handle the social and political consequences of individual demands for HET, a question that is all the more intractable considering the widely different views on the topic in Europe. In any case, it appears to be necessary to take into account the highly problematic aspects of the whole notion of "human enhancement", such as the proximity to eugenicist ideologies.

Given that the concept of HE, which is already an established (and actually a "fashionable") topic in ethical and other academic research, is slowly penetrating policy discourses, one has to decide whether the problematic notion of "human enhancement" should be used in a political and legally relevant context at all. If this option is taken, one has furthermore to decide whether the distinction between therapy and enhancement (which is, for example, important in a health policy context) should be made or whether from a societal as well as from research policy perspective the distinction between therapeutic and non-therapeutic enhancements may be more viable.

Such pragmatic and political questions appear to be most urgent, but the perspective of HE may also prompt a revaluation of the interrelations of S&T, society and the individual in the European context. If only some of the visions of second-stage HET are realised in the future, there will be a growing need for equitable social structures and, in particular, for sociotechnical infrastructures in which the diversity of individual needs and social demands are taken into account.

4.2 What is the added value of the HE concept for European policies?

When it comes to issues of regulation and EU policy, we first have to ask: What is the added value of the HE concept for European policies? In the case of applications such as PGD or DBS, where even the ideologues of HE do not claim to see any kind of non-therapeutic enhancement, "human enhancement" does not appear to be a fruitful concept when discussing ethical issues. However, in other cases, such as certain pharmaceutical interventions, some kinds of enhancements have already become a reality. Moreover, there are overarching issues that transcend the level of the cases, such as the tendency of medicalisation, changing norms of normalcy, ability etc., or the question of distributive justice. Both, the "big questions" as well as the problems in certain fields of R&D, are in need of political answers and some kind of political action.

In sum, participants of both expert meetings agreed that HE is a real phenomenon, although it is not always, if at all, useful to label technologies or cases as "HET" or "HE". However, through all of the case, similar or the same questions that transcend the individual cases can be recognised. These questions connect the cases to the meta- or trend-level of HE. The transcending questions are so far unanswered. The big, unanswered questions deal, for example, with our common understanding of normalcy, happiness, and solidarity.

As with any other social trend, policy-makers should monitor and try to grasp what is going on in society with regard to HE, so that, if necessary, a policy to respond to or prevent problems can be undertaken in due time. They should also be in a position to assess whether or not a reaction from the European or national Parliaments is necessary. In the following, we give some reasons why we feel the EU should respond to the developing HET and present some ideas for action and with regard to strategic options.

4.3 Why should the EU address the topic of HET?

To a certain extent, HET are already being developed and used today. They potentially have a huge impact on society, but the main questions are related to the health care systems which are regulated on the micro-level (and per case) by the member states. At the moment, there is no unity in the regulations across the EU, because every country forms its own regulation. Given the European Internal Market (especially the free movement of people and the freedom to provide services) and the new directive on cross-border health care that is being made, this means that the national health care systems will be put under pressure to allow what is allowed elsewhere, or that people will travel to another country to be "treated" or "enhanced". This will force up health care systems costs. It also puts strains on solidarity if such "treatments" or "enhancements" will only be accessible for the rich.

Moreover, the EU is already funding a lot of research on possible HET, some of which could lead to undesirable consequences. Such R&D should not be uncritically funded, and the role of far-reaching promises and expectations, which have created a kind of vicious circle in research policy, should be discussed more intensively. Guidelines are needed and criteria on what to fund and what not. Research proposals need to serve socially desirable goals, and this also requires, as participants of both expert meetings emphasised, a broad (European) deliberation and reflection on the regulation of possible HET and on the fundamental normative and societal aspects. At the moment, we do not even have a clear picture of how Europeans think about "human enhancement", although surveys that were undertaken in the

US have shown that not only in the US, but also, to a lesser degree, in some European states the rejection of HET is widespread (which is, for example, contributing to some "public image" problems of the nano-sciences and technologies).

4.4 A proposal concerning the form of a European approach

As we have argued above, there is a complicated relation between the meta-level of "human enhancement" and its instances (the technologies). At the moment, there is no "dialogic space" in which the cases can be connected to the trend and questions can be addressed. Such a dialogic space should be created, on the basis of a critical notion of "HE" which is also taking into account its problematic aspects. What is necessary is some form of intermediary agent to formulate and analyse the trend, assess the moral and social questions for the EU connected to it, and provide output or feedback in the form of a general or broad normative HE framework.

Such an intermediary agent could be set up by the European Commission in the form of a working-group, consisting of different kinds of experts. Social, ethical, technological, natural-scientific, medical, and policy expertise should be involved in the group, which would also need to reflect European cultural diversity, i.e. would have to involve perspectives from different countries.

Involvement of the European Parliament in the ethical reflection and preparation of policies would be preferable in order to strengthen the intermediate and public role of the working group. This could be achieved by participation of MEPs in the working group. The parliament could moreover also decide to set up a temporary committee as it may regard the issue of HE to be of major strategic importance for steering of S&T on the European level.

The working group or committee would discuss questions, issues, and regulations regarding the cases of actual and potential single HE-Technologies as well as the questions, issues and regulations concerning the overarching trend in S&T in order to formulate a normative framework for HE. This framework should help to:

- define the limits within which each country can regulate HE to its own insights;
- prevent undesirable effects of HET within member states and the EU;
- prevent inequalities in health care between European countries;
- prepare the ground for a policy on funding of HE research.

4.5 Strategic options for a European approach

One can roughly distinguish between five strategies to regulate HET: (i) a total ban of any technology that alters "human nature", (ii) a laissez-faire approach, (iii) a qualified pro-enhancement approach, (iv) a qualified restrictive approach, and (v) a systematic case-by-case approach.

In our view, which was confirmed by the participants of the two expert meetings, the first two strategies are neither desirable nor realistic: HET are already in the process of development or used, and a total ban appears to be neither feasible nor, even if based on a rather strict definition of HE, wholly eligible. Moreover, such a ban could not be based on the contentious notion of "human nature". A laissez-faire approach is also not desirable, because some HET

could have unwanted consequences if not properly regulated and some appear to be problematic in principle (such as enhancements in the military context with its duties and hierarchies). And there already exists a competitive pressure to use enhancing drugs and technologies, a tendency which needs to be countered, also by means of established, or even new, regulatory measures to protect the rights and quality of life of people who do not want or cannot afford such enhancements.

So, it needs to be decided whether HET should be regulated in the EU by a qualified pro-enhancement approach, a qualified restrictive approach, or a systematic case-by-case approach. Because actual and potential HET as well as the very idea of "human enhancement" challenge some widely held European values and reinforce others, the whole spectrum of European cultural diversity has to be taken into account in such forthcoming deliberations. In any of the three strategies, the deliberations could be supported by the use of state-of-the-art tools for public deliberation and participation, by rigorous examinations of the ethical, social and cultural aspects of the perspective of HE, and by a series of surveys to learn more about the European public opinion on the various facets of the issue. In the next paragraphs, the three remaining regulative strategies are briefly illustrated.

In a *qualified pro-enhancement approach*, EU policy would explicitly fund R&D in (non-therapeutic) HET, while preserving all applicable elements of existing ethical frameworks and, as a matter of course, respecting the fundamental European values. In such a strategy, EU policy would try to stimulate a societal dialogue on HET about how risk-averse we really have to be and how open we should be to innovations which might run counter to more traditional value systems. A revaluation of the concept of "informed consent" in the HET context might be another goal. And initiatives to stimulate discussions about deregulation in areas such as drug and doping policies or in the field of reproductive technologies could be another element of this strategy.

A *qualified restrictive approach* would ask whether proposed HET solutions to social and individual problems really do have an added value when compared to non-technological ones and whether funding priorities should be changed accordingly. Moreover, the precautionary principle would be applied as systematically and comprehensively as possible, because, in this view, individual enhancements should never be allowed to threaten the social fabric and fundamental cultural values. The ideologies (such as ableism) and the social prejudices underlying the recent trends towards HE would be subject to further scrutiny and critical examination. Some kinds of R&D or interventions might be banned altogether, such as HET in the military field.

In a *systematic case-by-case approach*, the perspective of HE would be taken into account in all cases of technology- or science-based interventions into the human body which aim at improvement of individual human performance. Any decision whether such an intervention should be allowed or whether relevant R&D should be funded, would be subject to a process which includes, first of all, those directly affected by such interventions and their organisations and, secondly, "culturally representative" expertise from all relevant fields and disciplines.

In both expert meetings, a lot of time was devoted to discussing how HE should be regulated and by whom. The great majority of invited experts tended to prefer a combination of a systematic case-by-case approach and a restrictive approach. Accordingly, a tailor-made, case-by-case approach was seen as valuable for the individual cases, but the experts also

thought that there needs to be regulation on the meta-level as well. According to them, it is probably best if the policies, at least for now, express a reserved attitude towards HE, and the EU could play an important role in the process of stimulating, organising and establishing regulations of HE.

In the first deliverable of this project, human enhancement technologies and debates surrounding them were described and analysed. In this second deliverable, we presented and analysed the results of two expert meetings that were organized by the project team. The third deliverable will be the background paper for the workshop, to be held in the European Parliament in February 2009. For this next deliverable, we will build further on the results of the project so far and will also explore the policy options in more detail.