

Autonomy and justice in neuroethics of cognitive enhancement

An approved thesis presented to the Faculty of Humanities of the
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by

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To Aleksandra

„...though I would not deny that such elements can be misconceived,
I believe the idea of a realistic utopia is essential.“ (Rawls 2002, p. 6)

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List of abbreviations:

AC	– alternating current
ADHD	– attention deficit hyperactivity disorder
AMPA	– α -Amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid
BMA	– British medical association
BCI	– brain-computer interface
CE	– cognitive enhancement
CED	– cognition enhancement drug
CHADD	– children and adults with attention deficit disorder
CNS	– central nervous system
CREB	– cAMP (cyclic adenosine monophosphate) response element-binding protein
DA	– dopamine
DAT	– dopamine transporter
DBS	– deep brain stimulation
DC	– direct current
DEA	– US drug enforcement agency
DSM	– Diagnostic and Statistical Manual of Mental Disorders
EMA	– European medicines agency
ECT	– electro-convulsive therapy
EDM	– economic disincentives model
EU	– European Union
FDA	– US food and drug administration
GABA	– γ -Aminobutyric acid
IRB	– internal review board
LTP	– long-term potentiation
MAO	– monoamine oxidase
MCDHS	– multi-criteria drug harm scale
MD	– medical doctor
NA	– noradrenaline
NIH	– US national institutes of health
NMDA	– N-Methyl-D-aspartic acid
RACE	– regulatory authority for cognitive enhancement
RT	– reaction time
rTMS	– repetitive transcranial magnetic stimulation
TBS	– theta burst stimulation
tDCS	– transcranial direct current stimulation
TMS	– transcranial magnetic stimulation
UN	– United Nations
UK	– United Kingdom
US	– United States

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For good or bad, my articles are usually initial attempts to outline and work out ideas – attempts that have matured with the help of anonymous peer reviewers, and evolved by the feedback I got after the articles are published from friends, colleagues and complete strangers by the time they were incorporated into the dissertation. A number of papers are thus part of this project - I have employed parts of them at various points in the dissertation. They have always undergone significant changes as I keep finding ways to say more or to better explain something the constraints of space disallow in an article. The papers which are most important for this dissertation are “Principles of Justice as the Basis for Public Policy on Psychopharmacological Cognitive Enhancement”, (*Law, Innovation and Technology*); “Toward a Legitimate Public Policy on Cognition-Enhancement Drugs” (*American Journal of Bioethics – Neuroscience*); “Cognitive Enhancement, Rational Choice and Justification” (*Neuroethics*); “Prohibition or Coffee-shops: Regulation of Amphetamine and Methylphenidate for Enhancement Use by Healthy Adults” (*American Journal of Bioethics*); “Autonomy in Neuroethics: Political and not Metaphysical” (*American Journal of Bioethics – Neuroscience*); “Response to Open Peer Commentaries on Prohibition or Coffee-shops: Regulation of Amphetamine and Methylphenidate for Enhancement Use by Healthy Adults” (*American Journal of Bioethics*); and “What is Cognitive Enhancement?,” (in *Cognitive Enhancement*, edited by Shira Knafo and Cesar Venero) (The full list references can be found in the bibliography).

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by Veljko Dubljević

Chair: Prof. Dr. Catrin Misselhorn

Major: Neuroethics and Philosophy of neuroscience and technology

A great number of existing, emerging and hypothetical technologies offers the possibility of neuroenhancement of human beings, promising (or threatening) to drastically change the lives of citizens. Among them are so called „smart drugs” - psychopharmacological interventions that allegedly boost brain power, and „neuroprosthesis“ - electromagnetic interventions in the brain in the form of interface with computers or even artificial means of augmenting cognition, new brain stimulation technologies that combat pain and control mental focus, and even highly sophisticated neuroimplants with special sensory input or electro-mechanical output.

The debate on enhancement in neuroethics, the field of applied ethics analyzing the social, legal and ethical challenges of these technologies, had been sidetracked to a metaphysical argument about human nature. Most arguments against enhancement tend to concentrate on the issue of authenticity or what it means to live according to human nature. The pro-enhancement arguments are broadly utilitarian, and furthered by the claim that human brains are no more than tools among other tools of cognition, and even that human beings are “natural born cyborgs”. The issue of distributive justice has been evoked on both sides, although without specific content to the conception of justice that should be applied. The questions of what implications does neuroenhancement have for individual and especially to political autonomy are so far rather left unanswered.

This dissertation conducts an in-depth case by case analysis of existing and emerging cognitive neuroenhancement technologies while extending and applying Rawls' concept of autonomy and conception of distributive justice, in order to formulate a distinct approach in neuroethics that would be political and not metaphysical. The primary objective of this

research is to contribute toward answering the question: *What public policies would be legitimate and effective in the context of use of cognitive enhancement drugs and devices by healthy adults in a democratic society?*

More specifically, the dissertation extends and applies Rawls's principles of justice and autonomy by confronting their normative requirement with contemporary empirical findings that might challenge or even undermine them. Then, sufficiently updated Rawlsian notions of autonomy and justice are used in a case-by-case analysis of existing pharmaceutical (Modafinil, Methylphenidate and Amphetamines) cognitive enhancement technologies. In the case-by-case analysis, by drawing on empirical findings on safety and efficacy, long term effects and prevalence, arguments for and against the use of a given technology are discussed and a corresponding policy approaches and models analyzed. The appropriate approach (discourage use) and model (economic disincentives model) are specified and further analyzed in the context of existing legal regulation (including international treaties) of stimulant drugs.

The principles, approach and model are then also applied in a case-by-case analysis of existing electro-magnetic (transcranial magnetic stimulation and transcranial direct current stimulation) cognitive enhancement technologies. The differences between the regulatory framework in stimulant drugs and devices are analyzed, along with currently available evidence on safety and efficacy and danger profiles, before tentative conclusions about policy are made.

The analysis of particular cases is then tested against general objections to a Rawlsian framework, and more specific objections to the Rawlsian idea of public reason. Finally, concrete objections to the policy proposals and conclusions in specific cases of existing pharmacological and electro-magnetic cognitive enhancement technologies are reviewed and refuted.

Zusammenfassung der Dissertation

**Autonomie und Gerechtigkeit in der neuroethischen Auseinandersetzung um
Kognitionsverbesserung**

Von Veljko Dubljević

Lehrstuhl: Prof. Dr. Catrin Misselhorn

**Forschungsfokus: Neuroethik und Philosophie der Neurowissenschaft und
Technologie**

Ein breites Spektrum bestehender, aufkommender und möglicher Neurotechnologien ermöglichen menschliches „Enhancement“. Sie versprechen (oder drohen) das Leben der Bürger drastisch zu verändern. Zu diesen Technologien gehören Medikamente zur Steigerung der Gehirnleistung, Neuroimplantate für Computerschnittstellen, künstliche Behelfsmittel zur Kognitionsverbesserung, neue Gehirnstimulationstechniken um Leiden zu mindern oder Stimmungen zu kontrollieren und Hochleistungsprothesen, um (einen) speziellen sensorischen Input bzw. mechanischen Output zu ermöglichen.

Die Debatte um Enhancement wurde in der Neuroethik – der Bereich der angewandten Ethik, der gesellschaftliche, rechtliche und ethische Herausforderungen dieser Technologien analysiert – stark durch metaphysische Annahmen über die menschliche Natur beeinflusst. Die meisten Argumente gegen Enhancement konzentrieren sich auf Fragen nach Authentizität und einem der menschlichen Natur entsprechenden Leben. Die Argumente für Enhancement dagegen sind im Allgemeinen utilitaristisch und stützen sich auf die Annahme, dass das menschliche Gehirn nur eines von mehreren kognitiven Werkzeugen sei und Menschen im Grunde „natural born cyborgs“ wären. Zwar wurde dabei die distributive Gerechtigkeit von beiden Seiten thematisiert, jedoch nicht der spezifische Gehalt der Gerechtigkeitskonzeption, die hier angewandt werden sollte. Fragen nach den Wirkungen von Neuroenhancement auf die individuelle und politische Autonomie blieben bisher unbeantwortet.

Im Rahmen dieser Dissertation ist eine eingehende Fall-zu-Fall-Analyse bestehender und aufkommender Neuroenhancement-Technologien verfolgt worden. Dabei wurde die Rawls'sche Theorie von Autonomie und Verteilungsgerechtigkeit angewendet, um einen neuroethischen Ansatz zu formulieren, der politisch und nicht metaphysisch ist. Das Ziel dieser Forschungsarbeit war es, einen Beitrag zur Beantwortung der Frage zu leisten: *An welchen grundlegenden Moralprinzipien sollten sich Gesetzgeber und Bürger in einer*

demokratischen Gesellschaft in Bezug auf Neuro-Enhancement orientieren?

Die Disseration hat dabei insbesondere die Rawls'schen Prinzipien der Gerechtigkeit und (dessen Konzept von) Autonomie analysiert und angewandt. Dabei wurde deren normativer Gehalt mit neuen empirischen Ergebnissen konfrontiert, welche diese nicht nur herausfordern sondern sogar untergraben könnte. Daraufhin wurden hinreichend überarbeitete Rawls'sche Prinzipien der Autonomie und Gerechtigkeit in einer Einzelfallanalyse herangezogen und auf bestehende pharmazeutische (Modafinil, Methylphenidat und Amphetamine) Technologien zur kognitiven Verbesserung angewandt. In dieser Analyse wurde durch Bezugnahme auf empirische Ergebnisse zur Sicherheit und Wirksamkeit, sowie der langfristigen Wirkungen und Prävalenz, Argumente für und gegen den Einsatz der jeweiligen Technologie(n) diskutiert und entsprechende Möglichkeiten der Regulierung sowie Modelle thematisiert. Ein Ansatz zur Regulierung („discourage use“) und ein angemessenes Modell („economic disincentives model“) wurden formuliert und vor dem Hintergrund bestehender gesetzlicher Regelungen (einschließlich internationale Verträge) von Stimulanzien analysiert.

Prinzipien, Ansatz und Modell wurden in einer Einzelfallanalyse, namentlich der kognitiven Verbesserung mittels bestehender elektromagnetischer Technologien (transkranielle Magnetstimulation und die transkranielle Gleichstromstimulation) angewandt. Die Unterschiede zwischen der bestehenden gesetzlichen Regelungen von stimulierenden Medikamenten und Geräten werden gemeinsam mit verfügbaren Daten zur Sicherheit, Wirksamkeit und Gefahrenprofile analysiert und vorläufige Schlussfolgerungen zur Frage der Regulierung formuliert.

Die Analyse von Einzelfällen wurde gegen grundlegende Einwände gegen die Rawls'sche Theorie geprüft, insbesondere gegen die Kritik an Rawls' Idee des öffentlichen Vernunftgebrauchs. Schlussendlich wurden spezifische Einwände gegen die vorgebrachten politischen Vorschläge diskutiert und Schlussfolgerungen bezüglich bestehender Technologien zur pharmakologischen und elektromagnetischen kognitiven Verbesserung wurden gezogen.

1. INTRODUCTION

Human beings have used technology since the dawn of civilization. Although there is no doubt that humans use technology exactly while it enhances their performance, the extended notion of technological enhancement of *human beings* has generated a lot of resistance and a heated discussion (Ashcroft 2003). For many people, human beings themselves should be “off limits” in the quest for enhancement of performance, as they are not merely tools or means. The distinction between therapy and enhancement is usually part of the arguments for or against allowing technological intervention in the human body or mind, as many people feels that some interventions may be morally permissible or even required in case they are administered as a therapy, but not so in “normal” levels of functioning (Selgelid 2007).

Recently, however, with the developments in neuroscience and emergence of the so-called “second-stage” enhancement technologies (Khushf 2005; STOA 2009), the boundaries between therapy and enhancement are blurred. Namely, a wide range of existing, emerging and visionary technologies offers the possibility of restoring and then surpassing „normal” functioning levels of human beings. Even before have some forms of therapy been used as enhancements, but the „second stage” enhancements create the possibility of “super-human” performance, and even enable “species-atypical” abilities. Some of the examples given in the literature illustrate this point with shocking clarity – for example, a blind person with a neural/video interface could have the options of upgrading to night-vision, infrared or ultraviolet (see STOA 2009). Among powerful neuroenhancements mentioned in the literature are drugs that boost brain power, neuroimplants that could provide interface with computers or even artificial means of augmenting cognition, new brain stimulation technologies to alleviate suffering and control mood, and highly sophisticated prosthetic applications that may provide specialized sensory input or mechanical output (STOA 2009).

According to Khushf (2005, 2008), the second stage enhancements alter the approach to disability. There has been a shift to maximizing function, whereas in older disabilities research, there was an interest in restoring typical human function and mimicking “normality”. The fact that new technologies are multifunctional, i.e. once the technology is introduced many other functions are enabled (or could be in the future, at a relatively low cost), means that the initial “treatment” becomes an early experiment in the transformation of human body.

As the case of „first stage” enhancements shows, not all people have qualms about using medical and technological interventions on themselves in order to be (or at least appear to be)

„superior” to others and this creates significant social pressure. Contrary to the case of genetic enhancement of unborn individuals, the individuals and organizations (industry and the military) that push for the use of neuroenhancement technologies do have a claim that any interference by society needs to be justified. The ethical analysis of these enhancement technologies is highly relevant, while they are promising or threatening (depending on the comprehensive worldview to which one subscribes) to drastically change the lives of citizens in all societies. The sheer number of worldviews that conflict (potentially very strongly) on this matter and the urgency of social regulation for the issue of neuroenhancement, has made some authors conclude that *neuropolicy* will be the major source of political and economic conflict in the decades to come, while some even think that it would surpass the ferocity of the conflict over means of production in the previous century (Hughes 2006; Lynch 2006).

But to what extent is this discussion based on science fiction and science fact? Since most discussions on this topic start with fictional scenarios and thought experiments, in order to critically appraise the literature, the justifiability of these scenarios needs to be assessed. Since some ethicists confront readers with highly unlikely events, which are not happening in the present, this could be justified only if the scenarios are at least likely to happen in the future, or they serve the purpose of dissociating between relevant aspects of “the case”, which would facilitate moral judgment.

Let’s start with delineating the relevant topic and establishing what mode of discourse on the subject would be appropriate. As the method of offering futuristic examples is still not evaluated as fruitful or unfruitful (for the project of ethical evaluation of cognitive enhancement), it can be tested within this discussion for its merit. Consider two fictional scenarios:

Scenario 1:

World news report: Tensions between Kazanistan and Vaziria reach the highest point ever – Kazanistan threatens with preemptive strikes on Ampakine-factories in Vaziria.

The dispute between Kazanistan and Vaziria may lead to an armed conflict. Both countries accuse each other of financial and military support to terrorist or insurgent groups. Vaziria warns that if Kazanistan continues to support groups of religious fundamentalist on Vaziri territory, there will be no option left but to prohibit religious practices in Vaziria. The

Prime-minister of Kazanistan vows to put an end to Vaziri „illicit drug trade“ and „support to inhuman terrorists“. He has issued an ultimatum to Vaziria – either they will stop the production of Ampakines and cancel their asylum policy for enhancement seekers from Kazanistan, or Kazani army and intelligence will put a stop to it with preemptive and retaliation strikes. In the meantime, the Posthuman Liberation Army of Kazanistan has taken responsibility for the recent kidnapping of several prominent religious figures in Kazanistan, and unofficial reports state that both countries could potentially produce nuclear weapons.

Scenario 2:

Encrypted transmission from: The department of recruitment and neural resources, Hegemony marine core, Military post VK-72072

Dear sub-lieutenant Pauperson,

regarding your request No. 13-56 for release from active service and issuing a permit to re-enter civilian population, we regret to inform you that your request has been denied.

According to your service and health insurance contract, any and all enhancements that were installed in your body are the property of Hegemony armed forces.

Our records show that after you have been wounded during the peacekeeping intervention in Vaziria, you have had a replacement right arm with retractable blades and built in sub-machine gun, as well as a titanium skull replacement with ventromedial prefrontal cortex inhibitor and targeting computer, video/neural interface night-vision and infra-red vision. All these enhancements are class M devices that cannot be released to the civilian population or foreign powers.

You could only be released from service if and when you have paid for the removal of all the military enhancements, are fitted with civilian replacement enhancements and found gainful employment in a civilian or mercenary corporation.

We are happy to inform you that according to your last monthly medical and neuropsychiatric evaluation, your CNS is in above-average condition, so that you could accumulate sufficient funds for such replacements within 5 years, and gain promotion to the status of lieutenant if you volunteer for a mission behind enemy lines now.

With kind regards,

Richard Bolyar, MD, MBA

Department of recruitment and neural resources, Hegemony marine core, Military post VK-72072

TAG: Be the chosen one! Be superhuman! Join us now! Gain employment, health insurance and enhancement!

-----end of transmission

These obviously fictional scenarios describe circumstances and consequences of a potential conflict between a fictional religiously ordered society from Rawls's influential book *The Law of Peoples*, and an equally fictional post-communist country Vaziria. It serves the purpose of depicting some of the worst possible ethical, social and legal issues stemming from new enhancement neurotechnologies. It also presupposes that cognitive enhancements could actually increase cognitive capacities, as opposed to merely the maintaining cognitive capacities in spite the effects of sleep-deprivation and fatigue. The moral of the story is that enhancements need to be regulated, and not just at the level of state. However, this conclusion is largely contingent on the condition that such events might occur in the future. Whether this is the case or not is still unclear at this stage, but it has to be noted that the topic has not been ignored by governments.

The questions regarding regulation of cognitive enhancement have been deemed important by relevant policy makers in the U.S. and the EU, and several studies and reports have been completed on their behalf (PCB 2003; EGE 2005; BMA 2007; CONTECS 2008; Williams & al. 2008; STOA 2009). These studies and reports offered analyses of the distinction between therapy and enhancement, and very often fictional scenarios about the impact of possible, future technologies. Whatever the merits or faults of these reports are, the use of neurotechnologies for non-medical purposes by healthy adults is currently still not (adequately) regulated in the EU and US (Greely, Sahakian, Harris, Kessler, Gazzaniga, Campbell & Farah 2008). One plausible interpretation of this fact is that the debate on (cognitive) enhancement in neuroethics has been sidetracked by arguments stemming from metaphysical, ethical and religious doctrines (that necessarily lead to reasonable disagreement) and that a discussion in terms of political arguments is necessary for legitimate public policy. A view that fictional thought experiments have decreased the perceived need for regulation could be plausible as well. An additional problem of these reports is that they considered unified solutions and approaches (such as laissez-faire and prohibition) for a

diverse class of cases.¹

Although very efficient in drawing attention to the problems that could be faced by the society, introducing fictional scenarios (utopian or dystopian) can and indeed has fueled the disagreement in the literature on cognitive neuroenhancement. I will argue that the current lack of adequate regulation of these technologies does not result from using fictional scenarios and thought experiments per se, but stems from the strong reasonable disagreement between irreconcilable comprehensive doctrines that the authors devising such scenarios endorse. I will also argue that cognitive neuroenhancement poses a real problem, and that the regulation of these technologies needs to be justified in terms of reasonable conceptions of justice.

Let's start with the assessment of reality of the problem. Imaginary worst case scenarios (or currently not yet attained effects) are not the only means available for evaluating the impact these enhancements will have on society. Based on assessments of competitiveness and on currently available technology, it could be assumed that the pressure to enhance will be most acute in the areas of space research, military, and education, but probably the most far reaching influence will come from the sphere of business.

Consider the example of logistics companies in a more or less laissez-faire market economy.² Let's say that the most profitable trucking route is 1250 km long. The run could be achieved in one day, although with considerable stress and fatigue. Without enhancement drugs, companies offer the service of transportation with the duration of 2 days, with the price including accommodation for the truck-driver. Let's say that company A decides to assume an employment policy that is preferable to truck-drivers that have no problem in using Modafinil (the medical treatment for narcolepsy) to stay alert and make the run in just one day. The company offers the service for the same price, thus gaining extra profit, but for half the duration. Company B, the chief competitor of Company A, responds by offering the "overnight express" service and accordingly gives current employees the following choice: either they will start using Modafinil in order to cope with the requirements of the job, or they will be laid off.

The effects on the market are not hard to foresee. All other logistics companies would either adopt similar policies, or go out of business. The truck-drivers would either use drugs or be out of work. Their choice is dictated by market forces completely beyond their control. Thus, enhancement technologies could have profound influence on the everyday lives of most

¹ Of course, it should be noted here first that other interpretations are possible, and secondly that the issue is not in providing an adequate description of certain decisions by policy makers, but in engaging in a discussion that will ultimately be conducive for legitimate regulation.

² An earlier version of this example has appeared in Dubljevic 2012a.

citizens, as the working day and deadline expectations will change according to the social pressure.

Having a brief sketch of possible problems helps clarify why the issue of enhancement in general and cognitive enhancement in particular does need to be regulated adequately, and not just on the level of the state. It is my firm opinion that federal laws in the US and European framework laws in the EU, and international agreements as well are needed for adequate regulation. Although that is not a matter of a philosophical discussion, but rather of democratic decision making and policy, the public debate on enhancement is a necessary condition, and it should take the fact of reasonable pluralism seriously. Accordingly, public policy on enhancement should not be based on any sectarian values or principles or a mere compromise.³

³ A compromise is perfectly acceptable in everyday politics. However, in issues that concern the basic structure of society, a consensus is needed in order to ensure social stability. See discussion on the applicability of justice in Chapter 2.2.

1.1 Argumentative goal: Beyond nonpublic reasons – public reason, autonomy and justice in neuroethics

The debate on human enhancement is not new.⁴ The issues of sports doping and cosmetic surgery are well known and discussed. These are the “first stage” enhancements and according to Khushf (2005) they seem to have modest effects on society and harms that could be studied and quantified. However, with the developments in genetics and neuroscience, and the emergence of the already mentioned “second-stage” enhancement technologies (Khushf 2005, 2008), the boundaries between therapy and enhancement are no longer seemingly self-evident. The debate concerning *genetic* enhancement has been going for quite some time, precisely because the effects are no longer modest and the harms are potentially overwhelming. It produced a number of opposing positions and strategies that have continued to influence the issue of enhancement in general and cognitive enhancement (CE) in particular.

On the one hand, there are the „hype and hope” positions associated with transhumanism and posthumanism, which share a utopian belief in the enhanced future of the superhuman race. According to these views, we could achieve the transition from humans to post-humans, create eternal bliss, happiness and pleasure, eliminate aging and greatly enhance human intellectual, physical, and psychological capacities (Campa 2008). A notable example in the context of CE is the claim that some of these goals could be achieved by investing in production of the „cheap pill that safely enhances cognition” as a substitute for „years of extra education” (Bostrom 2008a, 2008b). These extremely optimistic techno-utopian views, along with the more modest libertarian positions from the debate on genetic enhancement (Agar 2005), continue to shape the broader interests of prominent scientists and researchers (e.g. Warwick 2008).

On the other hand, there are the „gloom and doom” views that are tied to religious comprehensive doctrines and apocalyptic visions of the future. They warn against scientists „playing God”, and form the basis of some influential philosophical positions. Some of the most notable in the genetic enhancement debate are those of Fukuyama (2002) and other authors in the U.S. President's Council on Bioethics (PCB 2003). They have set the stage for the entire enhancement debate by focusing on the issue of what it means to be truly human, and what is an authentic human life, and thus sidetracked the discussion to a quarrel about

⁴ This Chapter draws on Dubljevic 2012a

moral implications of strong metaphysical positions. It could be argued that this strategy has influenced efforts by the pro-enhancement authors to prove that enhancement is the fundamental part of human nature – that we are „natural born cyborgs” (Clark 2003).

Cognitive neuroenhancements pose new challenges. On the one hand, they are enhancements of the mind, as opposed to the earlier „mindless” enhancements of the body. Also, they concern competent adults making individual choices for themselves, as opposed to the well analyzed (Habermas 2001; Buchanan & al 2000) question whether parents have the right to impose irreversible decisions on their unborn children. Moreover, CE promises (or threatens) to challenge and change the lives and work of all citizens, and not just members of certain professions (athletes, movie stars, etc.)⁵.

According to George Khushf (2005), the „second stage” enhancements would provide considerable advantage to those who obtain them. This means that in the competitive contexts of education, business and the military, the pressure to use these enhancements will grow, and the problems raised by this will become prominent and pervasive in the everyday life of all people. This view is *prima facie* plausible because history teaches us that at least drugs (for enhancement or recreational purposes) are easy to produce, administer and smuggle, and they will be produced if only there is a demand. Therefore, the cases of healthy adults using existing cognition enhancement drugs that were initially used to treat attention deficit hyperactivity disorder (ADHD), Alzheimer's and narcolepsy (Glannon 2008, Sententia 2006, Riedel 2008) should be the starting point of the analysis. Although we do not know how much of the hopes or fears about the next generation drugs would turn out to be true, proactive ethical consideration is better than after-the-fact reactive policy. Currently available drugs, such as Ritalin® (Methylphenidate), Provigil® (Modafinil), and the more controversial Adderall® (a combination of Dextroamphetamine and racemic DL-Amphetamine salts) can undoubtedly provide „Performance Maintenance”, while „Performance Enhancement” along with the safety issues still remain disputed. Performance enhancement means that healthy adults could use these drugs to achieve significantly better results, while performance maintenance means that normal levels of functioning could be maintained while effects of fatigue and sleep deprivation could be reduced (Lieb 2010).

The example of logistics companies mentioned above serves to show that serious injustices could stem from the use of enhancement technologies even if they only provide performance maintenance. Admittedly, indirect coercion is more often than not associated

⁵ There is some evidence about wide-spread use of cognition enhancement drugs among the student population, medical professionals and researchers. See Maher 2008.

with the question of autonomy⁶, but the threats of society-wide violations of equal rights and discrimination are questions of justice. Either way, the use of these drugs has potential impact for the overall society, and short-sighted paternalistic prohibition⁷ or too loose regulation based on partial views and interests could lead to disastrous consequences, apart from undermining legitimacy. That is why public policy should in any case be based on notions that could lead to a moral consensus between citizens endorsing different reasonable comprehensive doctrines.

The pharmaceutical companies have a vested interest in loosening of the regulation for selling their products, and they are gathering support for their agenda. The results of a relatively recent poll in *Nature* (Maher 2008), and the call for „responsible use of enhancements by healthy adults” from a group of influential neuroscientists and ethicists (Greely, Sahakian, Harris, Kessler, Gazzaniga, Campbell & Farah 2008) seems to indicate that pro-enhancement arguments are increasingly viewed as progressive and liberal, at least in scientific circles. In order to avoid cynical notions and presuppositions concerning public policy, the enhancement debate should be reflected upon critically. Arguments should be scrutinized and decisions based on mere ideology or non-public reasons should be publicly challenged. Thus a relevant question should be posed: Are the positions in the debate so far just expressions of hidden economic interests supported by individual and/or group preferences, or are there some genuine moral arguments and public reasons supporting legitimate claims?

As there are countless ways to lead a good life, or to be authentic, and the question of human nature leads to metaphysical quandaries, these notions cannot lead us out of reasonable disagreement.⁸ Unless a conceptual common ground could be found for a consensus, a mere

⁶ As such the issue is raised by Appel (2008), but insistence on the 40 hour work week, or legislation analogous to the way genetic testing is regulated in the U.S. would not solve the problem as presented in the introduction. Also, there are conceptual problems that need to be solved before the argument from autonomy can be leveled. See Chapter 2. 2 Coercion and Compulsion: the post-metaphysical principle of autonomy in neuroethics.

⁷ The issues with prohibition are a) that prohibitive policies are currently not effective, and b) that in some case they might not be justified. I am grateful to Thomas Potthast for constructive comments that have helped me make this point more clear. See the discussion on autonomy and prohibition in Chapter 2.3.

⁸ Good life, authenticity and human nature have been used as the basis for public policy in different societies, but the important claim here is that these approaches cannot be used as basis for a legitimate public policy in a pluralist democratic society. Doctrines of the good (ethical, religious or metaphysical) are not always openly contested and could be the basis of a self-understanding of the whole society (e.g. Islamic state policy in Iran), but in contemporary pluralist societies, the appearance of such unity in self-understanding could be achieved only with the use of coercive force (see Rawls 2005; Habermas 2004).

The notion of authenticity is burdened with ambivalence (Parens 2005) – some citizens might think that, say, smoking is an expression of their authentic selves, whereas others might be inclined to think that smoking is inauthentic as it is the result of clever marketing and peer pressure. Since the issue at stake is the use of coercive legal and political force, it would not be legitimate to base public policy on such unclear and relative (non-public) arguments. That is not to say that it is unimportant to address the issue. On the contrary, it is very important for every citizen – individually – to reach a conclusion whether using PCE (or nicotine) would undermine or reinforce their authenticity. Public decisions, on the other hand should be made according to the

compromise between different elites and powerful lobby groups would be reached that would be unstable and a source of permanent conflict. Even worse, the discussion needed for deliberative democracy could be dominated by the deadlock between those who are just swayed by the “hype and hope” promises and those who fear the “gloom and doom” threats, and this could lead to slow or non-existent regulation.

Authenticity, human nature and the good life are generally adequate criteria at the level of individual choice, but not adequate at the level of public policy. Principlism of Beauchamp and Childress (2008), with the mid-level principles of beneficence, non-maleficence, autonomy and justice shows more promise.⁹ Unfortunately, in the debates on neuroenhancement (as opposed to genetic enhancement) some influential authors in neuroethics, the interdisciplinary field analyzing the social, legal and ethical challenges of neuroscience and technology, have been downplaying the importance of justice when considering policy options for regulating CE, and have focused on utility or authenticity arguments instead.¹⁰ There could be at least four plausible reasons for such treatment of arguments based on justice. First, these authors might believe that the issue of justice leads to a reasonable disagreement as well.¹¹ Second, they might hold that justice applies only to public funds and state action, but does not concern individual choice or corporate actors.¹² Third, they might think that performance enhancement does imply questions of justice, while performance maintenance does not.¹³ Finally, the underlining belief could be that there is no sufficient difference between CE and other technologies that would warrant the importance of

impact the free use of such substances has on freedom and equality of all.

The question of human nature is likely one of the most important questions philosophy has posed and not answered to satisfaction of all. Again, it is possible that there is a *true* doctrine of what human nature is, but public policy has to make do with what is reasonable (Rawls 2005).

⁹ This assertion should not be understood as a substantive argument for principlism. The issue here is that foundationalist arguments (stemming from comprehensive doctrines) could not be invoked as basis for legitimate public policy, whereas coherentist arguments could. Whether principlism could offer the most convincing arguments or would be endorsed by citizens is an entirely different question. The point of mentioning principlism is to contrast the fact that the question of social justice is fairly standard in bioethics, but downplayed in neuroethics.

¹⁰ The list of these authors includes, but is not limited to: Lieb (2010), Levy (2007), Gazzaniga (2005), Racine (2010), Harris (2011) and Farah (2011).

¹¹ Racine (2010) seems to believe this as he considers the impact of “culture wars” and different normative approaches of libertarianism, conservatism and moderate liberalism. Although he opts for moderate liberalism, his arguments point to a compromise, and not a consensus.

¹² Gazzaniga (2005) holds this view. He explicitly states: “Off-label use of Ritalin reminds us that the unintended use and misuse of drugs is a constant. Trying to manage it, control it and legislate it will bring nothing but failure and duplicity. ... Aricept works ..., caffeine works, Ritalin works. Individuals will use such drugs or not use them, depending on their personal philosophy about enhancement. Some people are reluctant to „cheat“ with plastic surgery or balding remedies, and some are reluctant to „cheat“ using steroids.“ p. 77.

¹³ Lieb (2010) could be understood in this way, although it should be noted that he does not support enhancement.

justice for the debate.¹⁴ These arguments could be an important challenge to the approach, and so they will be dealt with in the next chapter. Let's first have a short look at the faults of the arguments that have been used in the debate in the absence of argument from justice.

The utilitarian calculus (sometimes using the arguments similar to beneficence and non-maleficence) has been successfully used to rally support for enhancement in neuroethics (e.g. Levy 2007, Harris 2011). This approach (when not kept in check by requirements of justice) is embedded in a comprehensive ethical doctrine, and it is not to be expected that all, or even a majority of citizens would be convinced with such arguments. The principle of autonomy does seem to be clear in supporting claims that any interference by society needs to be justified unless it is to be viewed as merely arbitrary and paternalistic, and thus not legitimate. Yet, the example of logistics companies above serves to show that non-existent regulation could lead to violation of autonomy and equal rights of citizens not wishing to enhance. These citizens would also have every right to claim that a society in which they are discriminated, coerced and exploited is not just.

They could appeal to the ideal of public reason they share with fellow citizens, and argue that CE is unjust because it undermines the equality of rights and liberties of citizens wishing to enhance and those that do not. Furthermore, they could claim that using CE is cheating as it violates fair equality of opportunity, and that the use of medical drugs or devices might be justified in instances of poor health but not when seeking positional advantage.¹⁵

¹⁴ Harris (2011) is explicit in endorsing such views, and a similar approach could be found in arguments presented by Levy (2007), Farah (2011) and many others. This view is the basis of the approach Savulescu (2006) endorses. Namely, he claims that although some injustices may stem from enhancement technologies, the same is true for all technology, and future benefits made possible by enhancements for all indicate that justice *requires* enhancement.

¹⁵ These arguments are framed according to Rawls's influential theory of justice. Rawls's principles of justice (in the final formulation) state that: 1. Each person has an the same indefeasible claim to a fully adequate scheme of equal basic rights and liberties, which scheme is compatible with the same scheme of liberties for all; (the equal liberty principle); and 2. Social and economic inequalities are to satisfy two conditions: first, they are to be attached to positions and offices open to all under conditions of fair equality of opportunity (the principle of fair equality of opportunity); and second, they are to be to the greatest benefit of the least advantaged members of society (the difference principle) Rawls 2001, pp. 42-43.

It should be noted here that the argument is not yet made. If truck-drivers that do not want to be forced to enhance in order to keep their jobs are to make this claim, the challenges to justice have to be answered first. However, the claim that the truckers are merely forced to be rational would not be enough to refute their claims. Economic rationality cannot be an excuse for coercing or discriminating groups of citizens (compare Rawls 1997). The argument will be more fully developed in Chapter 2.2.

1. 2. Epistemic goal: Extension of Rawls' theory of justice in the practical account of public policy on cognitive enhancement

It will be remembered that autonomy, justice, beneficence and non-maleficence as mid-level, non-foundationalist principles have a long and successful use in bioethics (Beauchamp and Childress 2008). However, the developments in neuroscience and technology have motivated approaches that put the principle of autonomy under scrutiny (Felsen & Reiner 2011), and question the applicability of social (or distributive) justice (Harris 2011) in neuroethics. In the expanding field of neuroethics, sometimes described as the bioethics of the brain (Glannon 2007), these principles have had less prominence in the debates. Utilitarian considerations (consistent with the principles of beneficence and non-maleficence), along with other issues, such as authenticity, good life and human nature have come to dominate neuroethics and especially the cognitive enhancement debate (compare Levy 2007).

I will extend and apply Rawls's principles of justice and autonomy in a case-by-case analysis of existing pharmaceutical (Modafinil, Methylphenidate and Amphetamines) and electro-magnetic (transcranial magnetic stimulation and transcranial direct current stimulation) cognitive enhancement technologies. Of course, principles of beneficence and non-maleficence are also important in the context of this analysis, but arguments based on them have been discussed more often in the literature. Thus, although all mid-level principles of bioethics (Beauchamp and Childress 2008) will be given due consideration in the cases, I expect that new insights and contribution to the field will come from the extension and application of Rawlsian principles of justice and autonomy. Given this emphasis, two general issues have to be cleared before case-by-case analysis can proceed: first the content and applicability of social justice; and second the content and applicability of autonomy.

In order to clear the first general issue, it will be remembered that there might be some good arguments against using justice, and these must not be forgotten at any time during the analysis. Thus, four reasons that some influential authors in the field of neuroethics might have for downplaying the importance of social justice will be analyzed: a) The issue of justice allegedly leads to a reasonable disagreement as well, as it is loaded with political ideology; b) Justice applies only to public funds and state action - not to individual choice or corporate actors; c) "Performance enhancement" does imply questions of justice, while "performance maintenance" does not; and d) There is no sufficient difference between cognitive enhancement and other technologies to warrant the importance of justice for the debate. Also,

I will have to suitably define demands of justice in order to proceed with the application to the cases.

In contemporary political philosophy, when defining demands of social justice one either has to start from Rawls's theory or explain at great length why not (see Nozick 1974). This assertion is as true (compare Sen 2009) as it was when Nozick first made it, so it is prudent and efficient to begin with Rawls. Of course, Rawls's principles of justice (as well as ideas of reflective equilibrium, public reason and overlapping consensus that are relevant for this research) have been the subject of many criticisms over the years. Most notably, the debate with Habermas forced Rawls to further develop or change his ideas (Dubljević 2010). Namely, Jürgen Habermas argued that the idea of public reason, as formulated by Rawls, is antidemocratic because it "fixes" the content of public reason in favor of a liberal conception of justice in advance of any actual democratic discourse between citizens (Habermas 1995). Other authors claimed, among other things, that Rawls's take on justice is too secular and that it arbitrarily or wrongly excludes the sense of justice of religious citizens (for an overview, see Larmore 2003). Rawls responded (1997) by defining minimal conditions for reasonable conceptions of justice for public reason of democratic society, and explicitly included Habermas's social-democratic approach to legitimacy, and Finnis's conservative account of natural law and natural rights. Rawls's original view will be the starting point for the general case on cognitive enhancement, while the reformulated view of justice and public reason will serve as a form of internal check.¹⁶ Of course, this analysis will serve the purpose of eliciting further discussions on what justice requires in issue of use of cognitive enhancement by healthy adults. Other reasonable conceptions of justice could and should be extended and applied in order to enrich the debate.

The starting hypothesis is that in the analysis of the cases of cognitive enhancement technologies there will be convergence on what justice requires. The application of Rawls's principles of justice (and quite likely other reasonable conceptions of justice) could explain the considered judgment of many citizens that treatments are obligatory and permissible while enhancements are not. Namely, it could be assumed that citizens view cognitive enhancement not in terms of technologies used, but in terms of social relations. Thus, unlike therapy, enhancement is viewed as not being an issue of providing basic necessities for those who are lacking, benefiting the least advantaged or restoring citizens to a position of equal opportunity. Furthermore, citizens might be concerned that the use of enhancements by healthy adults would rather maintain or increase than reduce social inequality. Moreover,

¹⁶ See Chapter 5

cognition enhancements could be viewed by citizens as being used as means for obtaining undeserved positional advantage and with the unknown long-term side-effects and/or through coercion could create additional disadvantages and needs for citizens lacking basic necessities.

The second general issue is the content and applicability of the principle of autonomy. According to Felsen & Reiner (2011), the findings of neuroscience cast doubt upon the traditionally defined capacity for autonomy of persons. That is why I will conduct a conceptual analysis of ideal-typical notions of indirect, direct and total coercion, as well as mild, severe and total compulsion. The idea is to draw on Rawls to define a political concept of autonomy that does not presuppose any metaphysical epistemic view (determinism, indeterminism or compatibilism), in order to give justification for ascribing moral responsibility.

1. 3. Research questions and the structure of the dissertation

According to Rawls (2001), political philosophy has four important tasks: (1) the practical task of clarifying and resolving conflicts; (2) the task of orienting us as citizens and then (3) reconciling us to our social and political world, and finally (4) the task of probing the limits of practicable political possibility. These tasks could be extended to the political perspective in neuroethics, and I assume that such an approach could enrich the debate on cognitive neuroenhancement. That is why in this dissertation I will start with Rawls's framework and try to work toward defining and fulfilling the political roles of neuroethics. The questions of justice and autonomy are crucial for clarifying and resolving conflicts and positional advantages potentially offered by cognitive enhancements should be carefully analyzed. The first question that needs to be answered is whether we can extend our principles of justice to orient us as citizens in the questions of neuroenhancement, or do we need to define new, radically different conceptions of justice.

There are some other, equally important questions. One of them is the question whether cognitive neuroenhancement technologies have the potential of undermining the autonomy and the formal status of free and equal citizens of democratic societies, and what policy options there are for preventing such threats. Although some (e.g. religious) citizens will be appalled with the aims of other citizens (e.g. utilitarians) in virtue of irreconcilable differences between their comprehensive doctrines, could they be reconciled to the social and political world in which legitimate policy decisions reflect public autonomy and respect the reasonable freedom of individual choice, even if this choice seems inauthentic? Is it possible to maintain the social construct of the difference between therapy and enhancement, or do we need to construct the notion of augmentation for species atypical and super-human enhancements? ¹⁷ Could a society be successful in regulating outrageous experiments and

¹⁷ Maturity is one clear example that can provide insight on what is meant by "social construct." Maturity is vague, due to the fact that it is gradual. Conceptual and empirical analysis might provide relevant insights, but the exact age at which persons are entitled to say drink, drive, vote, and freely dispose of their property is a social construct that differs from one society to another. In some societies the age is 18 for all these relevant rights (e.g. Serbia), while no amount of analysis would provide definite answers what is so drastically different between persons aged say, 17 years and 11 months, and 18 years and one day. In other countries (e.g. U.S.), the ages are 21, 16, and 18, respectively, although one might find individuals that are mature enough to vote at 16, and those that are quite immature at 21. That is not to say that this is entirely arbitrary. Societies create sharp boundaries where in reality there are merely gradual changes, but there are legitimate reasons for boundaries to be set.

The concept of therapy was taken to be fairly unproblematic for a long time, but when people realized the potential of certain technologies they started asking the question what are the conceptual differences between, say, vaccination and enhancement. That is not to say that new technologies have blurred the boundary themselves, but that the understanding has shifted from taking-for-granted to the need to explain. The notion of

practices internally and externally, or will the problems of enhancement tourism and unchecked research and human experiments in outlaw states prove to be too much of a challenge?

All these questions are preliminary issues for the primary objective of this research, and that is to make a contribution toward answering a single question: *What are the most legitimate public policies for regulating the cases of use of cognitive enhancement neuro-technologies by healthy adults in a reasonably just, though not perfect, democratic society?*

In order to answer the posed questions, the appropriate method must incorporate devices of representation for impartiality. The ideas of *public reason* and *general and wide reflective equilibrium* as construed in contemporary political philosophy (see Rawls 1999, 2005) are an appropriate starting point for the research questions, and therefore will be used.

Public reason giving is *impartial* as it involves justifying a particular position by way of reasons that people of different moral or political backgrounds could accept (or at least could not reasonably reject). Non-public reasons, by contrast, are quite partial. They involve the exercise of an individual's reason to the constrained norms and interests of some sub-set of the society as a whole, such as a business, a political party, the military or a religious community. Many arguments in the enhancement debate so far (e.g. authenticity, as well as “Playing God” and posthumanist claims) have been based exactly on partial norms and interests.

The method of reflective equilibrium is a coherence procedure for justification in several areas of inquiry, including inductive and deductive logic as well as ethics, applied ethics and political philosophy (Daniels 2011, Beauchamp and Childress 2008). In the current context, the analysis will start from the considered judgments on cognitive enhancement, and with the application of general principles of justice strive toward coherence by testing general principles against judgments about particular cases, and testing judgments about particular cases against general principles, until equilibrium is achieved .

This approach could shed some light on what justice requires in different cases of non-therapeutic uses of cognitive neuro-technologies. Also it should help in refining and clarifying the legitimate policy options for a democratic society. In the neuroenhancement debate so far, there was not much attention given to realistic policy options, and the arguments have been

augmentation would be another example of a legitimately arbitrary boundary. Enhancement technologies that are so potent as to be too dangerous for the general populace could be reserved for military uses only, or even banned even for such purposes by international treaties. They would be treated as conventional (e.g. rocket launchers) or unconventional and banned weapons (e.g. chemical weapons of mass destruction) that are certainly not legally accessible to citizens.

based on utilitarian calculus, authenticity, human nature and the good life, although the idea of public reason might exclude or amend such arguments. Nevertheless, it should be remembered that there might be valid reasons why principles of justice and autonomy have not had a prominent place in the debate. Therefore, as already mentioned, two general issues have to be cleared in the chapter on conceptual foundations before the case-by-case analysis can proceed: 1. the content and applicability of social justice; and 2. the content and applicability of autonomy.

In the case-by-case analysis, by drawing on empirical findings on safety and efficacy, long term effects and prevalence, arguments for and against the use of a given technology will be discussed and a corresponding policy will be proposed. The proponents of enhancement insist that new enhancement technologies (drugs and implants) are similar to old ones (coffee and computers), and base the argument on the appeal to the fairness of treating like cases alike. Nevertheless, policy options in a democratic society are not limited to taking no action and thus permitting any actions by the private sector as pro-enhancement authors want, or to try to ban or block the technology as opponents would like. There are also options of regulating technology so that the individual use is encouraged via government incentives or discouraged via taxation, or even to make the technology mandatory (Blank 2010). These policy options rest on the familiar distinctions in moral philosophy between actions that are a) morally required, b) morally desirable and permissible, c) morally neutral and permissible, d) bad but nevertheless still morally permissible, and e) morally impermissible. The notions of autonomy and justice are indeed crucial in this context, and the charge of unjustified paternalism is avoided only if a norm could be grounded in both these principles. The point is that fairness of treating like cases alike depends on defining sufficiently like cases.

The testing of general principles against judgments about particular cases thus starts with the application of Rawls's principles of justice. An in-depth case by case analysis of existing and emerging neuroenhancement technologies (specific disabilities they focus on initially, and further enhancement possibilities) is necessary for both testing general principles against judgments about particular cases, and testing judgments about particular cases against general principles. In this analysis, a line could be drawn between psycho-pharmacological (Modafinil, Methylphenidate and Amphetamine) and electro-magnetic (TMS and tDCS) cognitive neuroenhancements. The first type is easier to produce, administer and smuggle, so the cases of cognition enhancement drugs that were initially used to treat narcolepsy and ADHD (Riedel 2008; Glannon 2008, Lieb 2010; Metzinger & Hildt 2011) need to be carefully examined. Although there are hopes and fears about future cognition enhancing

drugs (e.g. Ampakines), due to the fact that their effects are unknown and for reasons of space, only Methylphenidate (Ritalin ®), Amphetamine (Aderall ®) and Modafinil (Provigil ®) will be analyzed.

The second type is sometimes given more space in the literature as potentially inducing drastic social changes. Typically, ethicists analyze brain stimulation technologies (Pascual-Leone & al. 2011) and invasive neuroimplants that could provide interface with computers (Maguire & McGee 1999, EGE 2005, Warwick 2008). Indeed, neuroimplants that could provide interface with computers or even artificial means of augmenting cognition are the most radical, but also seen as a strategically important enhancement technology (EGE 2005). The examples of self-experiments in the context of „Project Cyborg“ by Kevin Warwick and related experiments on animal/robot hybrids (Warwick 2008) bring to the fore not only the questions of whether the society should or has the right to limit the freedom of voluntary subjects of experiments and self-experiments with implantable (brain) chips, but also a wide range of issues concerning the rights of such enhanced or Cyborg individuals.

However, if we take *existing* cognitive enhancement devices under scrutiny, some such as invasive neuroimplants that could provide interface with computers (Maguire & McGee 1999, EGE 2005, Warwick 2008) are still at the level of hypothesis. Experimenting on human beings by implanting an artificial hippocampus (Cohen 2013) might become a pressing research ethics issue, but it is very far from being a problem for the society at large. As such a regulatory response might be warranted at the level of institutional review, but not at the level of state. However, brain stimulation technologies (Pascual-Leone & al. 2011) are much more advanced than that. Transcranial magnetic stimulation (TMS) is frequently analyzed in the literature (e.g. STOA 2009) and apparently more than 60 academic articles report use of TMS to produce performance enhancements in perceptual discrimination, motor learning, visual search and task involving attention, memory and language in healthy human subjects (see Luber and Lisanby 2013).

Nevertheless, the high costs, necessary technical knowledge (Simpson & al. 2009), and low potential for creating positional advantage makes the regulation of TMS on the level of society less urgent, so a “wait and see” strategy that is currently used in most societies might actually be appropriate. However, the in-depth analysis of available data will confirm or disconfirm this hypothesis. On the other hand, transcranial direct current stimulation (tDCS) might need to be regulated as soon as possible because of the apparent cognitive enhancement possibilities, (Dockery & al. 2009, 2011, Adey 2012) and the fact that it can be widespread, due to low costs and ease of production and use. Indeed, calls for more regulation

concerning the emergent use and marketing practices regarding tDCS (Fitz & Reiner 2013, Anonymous 2013, Bikson & al. 2013, Maslen & al. 2013) point to a conclusion that social penetration of tDCS might warrant regulation. Again, the in-depth analysis of available data will confirm or disconfirm this hypothesis.

The analysis of particular cases will then be tested against objections in order to achieve a *wide reflective equilibrium* for legitimate public policy. Namely, the conceptual analysis using the idea of public reason excludes purely utilitarian, authenticity, human nature and the good life arguments – as they are the content of irreconcilable comprehensive metaphysical, religious or ethical doctrines, and lead to strong reasonable disagreement – but it does not exclude alternate conceptions of justice. Furthermore, if such arguments are “translated” into political values, they can be very important addition to the analysis and facilitate better public policies. As it was emphasized earlier, public reason giving involves justification by way of reasons that people of different moral or political backgrounds could accept, and so the proposed public policy should be analyzed in the context of different worldviews, and not just one.

Since no single philosopher, theory or tradition has privileged access to the moral point of view, different reasonable conceptions of justice and their „devices of representation” for reaching the moral point of view with corresponding principles should be used.¹⁸ Such a procedure should insure coherence by testing different points of view against judgments about particular cases, and testing judgments about particular cases against theories, until wide reflective equilibrium on public policy concerning cognitive neuroenhancement is achieved.

It is important to note that the final stage of justification for legitimate public policy, the *general and wide reflective equilibrium*, can only be achieved by citizens themselves. This is accomplished when citizens and their representatives participate in an open discussion in the public forum, in which reasonable arguments are invoked in line with the requirements of public reason. There is no substitute for such a discussion, but careful philosophical analysis of principles of autonomy and justice applied on a case by case basis could be helpful. It could help to steer the debates on enhancement clear of irreconcilable comprehensive

¹⁸ Rawls’s idea of a “device of representation” should be explained here. Namely, he argued that different philosophers always use some kind of device for “filtering” inappropriate claims and norms of action (Rawls 2007, pp. 19-20), as say, narcissism could not be reconciled with the moral point of view. Since his primary “device of representation” – original position with the veil of ignorance – has met with reasonable disagreement by some philosophers and citizens, it is reasonable to include positions that start with reasonable devices of representation (Habermas’s conditions of ideal speech situation; Finnis’s conditions of knowledge, good will, and frankness) and principles. The point is that there are in fact positions that are reasonable and could serve, along with “justice as fairness” as the basis for “overlapping consensus”, but Rawls insists that his position is the “most reasonable” (Rawls 1997).

doctrines and to focus on the moral basis for democratic consensus instead.

Last but not least, a note on the “case-by-case” analysis should be taken into account. Namely, words “case-by-case” are used for lack of a better term – they could be misleading if it is not stated from the outset that this analysis is not a form of particularism or casuistry. Unlike Jonathan Dancy’s (see e.g., 2004) particularism which rejects principles and rules, cases are defined here more in the sense of “empirical models” - i.e., not as a single instance of use of a particular cognitive enhancer, but as a model case of a particular technology with distinct physical, social and liberty improving or constraining properties. To give an example, a particularist research agenda would dissociate from the case of one particular individual (e.g. John Doe the biochemistry researcher) that uses a particular item of cognitive enhancement technology (e.g. Modafinil) for a specific purpose (e.g. to be able to finish in time his grant proposal on a novel approach to cancer research to NIH). As opposed to that, “case analysis” (for lack of a better term) means the ethical analysis of a particular cognitive enhancement technology, in order to formulate rules and principles that could and should apply to all. Public policies, from prohibition to mandatory use rely public reasons to define rules which apply to all citizens.

To sum up, I start from the premise that the use of neurotechnologies for non-medical purposes is not adequately regulated in democratic societies. The debate on enhancement in neuroethics has been sidetracked by arguments that are unacceptable from the point of view of public reason as it is construed in contemporary political philosophy. In order to avoid decisions based on mere ideology or non-public reasons, the enhancement debate should be reflected upon critically, and considered judgments on cases of cognitive enhancement scrutinized.

Recall that authenticity, human nature and the good life are generally adequate criteria at the level of individual choice, but not adequate at the level of public policy. As there are countless ways to lead a good life, or to be authentic, and the question of human nature leads to metaphysical quandaries, these notions cannot lead out of reasonable disagreement. Unless a conceptual common ground could be found for a consensus, a mere compromise between different elites and powerful lobby groups would be reached that would be unstable and a source of permanent conflict. Even worse, the discussion needed for deliberative democracy could be dominated by the deadlock between those who are just swayed by the “hype and hope” promises and those who fear the “gloom and doom” threats, and this could lead to slow or non-existent regulation.

This research should lead to a normative elucidation of this conceptual common ground. The concrete proposals for legitimate public policy in the cases of cognitive enhancement technologies will be grounded in the most relevant conception of justice and analyzed for acceptability in view of reasonable interpretations of three influential traditions of political thought. The more general justice-based approach in neuroethics should offer a coherent account that captures the sense of justice of citizens in a democratic society. Therefore, general principles, considered judgments and policy proposals should be empirically informed and justified in the normative sense. This dissertation strives precisely toward these goals.

2. CONCEPTUAL AND METHODOLOGICAL FOUNDATIONS

2. 1. Rawls' political philosophy

Before starting with the extension of Rawls' political philosophy to the issue of regulation of cognitive enhancement neurotechnologies, what exactly is extended needs to be discussed. The sheer amount of ideas in Rawls' work, which are relevant for contemporary political philosophy, necessitates exclusion of some very important issues (e.g., civic disobedience) from the present discussion. However, the basic ideas that will be used in the extension of Rawls' theory for neuroethics in general and assessment of cognitive enhancement in particular, are shortly summarized here.¹⁹

The publication of *A theory of justice* in 1971 (Rawls 1971/1999) can be seen as a turning point in political philosophy. Rawls' "justice as fairness" has left a significant mark not only on philosophy, but has also revived the debate on issues of justice in different academic disciplines. Apparently, hardly anyone was indifferent toward this theory. On the one hand, it quickly gained an enthusiastic following, and on the other hand, it managed to generate fierce critics and alternate theories of justice that challenge one or the other aspect of his position. His philosophy thus strongly influences the contemporary discussions of social, political and economic justice, that take place in the framework of philosophy, law, political science, economics and other social disciplines (see Nozick 1974, Walzer 1983, Miller 1999, Sen 2009).

Summarizing the results of his responses to controversies that have followed his theory of justice for decades and his further conceptual research, in 1993 Rawls publishes *Political liberalism* (1993/2005), which introduces improvements and changes to his theory of justice. In fact, *Political liberalism* is a reconsideration of justice as fairness, which takes into account the issues of legitimacy and acceptability to ordinary citizens. Justice as fairness is now presented as a political conception rather than a more general comprehensive (ethical, religious or metaphysical) doctrine. Unlike his original view in *A theory of justice*, where the idea of a well-ordered society presumed stability and homogeneous value orientation of citizens, political liberalism is based on the fact of pluralism - the premise that modern

¹⁹ Due to the fact that many of these ideas will be revisited in Chapter 5, the discussion will be short and succinct.

democratic society is heterogeneous. Namely, modern society is inherently divided by a multitude of reasonable philosophical, ethical and religious doctrines which, although reasonable, are incompatible and irreconcilable, because each and every one of them aspires to be “the truth”. A well-ordered society, according to Rawls, can only be a society which is unified with the aid of a political conception of justice. Thus, justice as fairness is accepted by citizens no longer as their comprehensive belief, but as the political minimum, which forms the basis for social consensus (see Dreben 2003).

The political conception of justice as fairness allows for the "overlapping consensus" on reasonable comprehensive doctrines, i.e. it can be accepted by the various philosophical, ethical and religious doctrines that coexist in a well-ordered society. The “political” character of this conception is reflected in its agnostic attitude toward the truth of comprehensive doctrines, and inclusiveness toward all reasonable doctrines (and, conversely rejection only of doctrines that are unreasonable, even according to the very thin criterion of reasonableness – see below). Thus justice as fairness may be acceptable, and form the basis of peaceful coexistence for all citizens, whether they are religious or secular, regardless of their specific religious or ideological views.

Rawls’ overall philosophical project is dedicated to building and formulating a liberal theory of justice as a reasonably systematic and acceptable alternative to utilitarianism (see Scheffler 2003). Namely, in the twentieth century, the dominant ethical theory in Western democracies was utilitarianism (in various shapes and variants). The main reason for this pursuit is the weaknesses of utilitarian doctrine as the basis for the institutions of constitutional democracy. For Rawls, it is not the utilitarian goal of achieving the greatest overall happiness, or the greatest balance of the total satisfaction of all individuals that create problems for democracy. Problematic is the lack of limitation of state power, and the ethical mandate to trade the lives and happiness of minorities for the sake of the majority. For utilitarianism, even justice is merely a special kind of utility and a specific way of advancing the interests of the majority. Loss of rights and liberties for the minority is supposed to be justified with the gain in the wellbeing of the majority (see Rawls 1971/1999 pp. 19-30). For Rawls, this is a clear case of injustice, as no citizen should be the object of bargaining, nor a means of achieving social goals and objectives. Samuel Scheffler in his analysis of Rawls and utilitarianism (Scheffler 2003) concluded that Rawls largely agrees with utilitarianism, and that is because of these shortcomings an alternative theory, that would remove these defects, is necessary.²⁰

²⁰ Scheffler states: “Perhaps one might even say that it is precisely because he agrees with utilitarianism about so much that Rawls is determined to provide an alternative that improves upon it in the respects in which it is

Due to these weaknesses of utilitarian justification, Rawls framed his theory of justice as an example of social contract theory. The merits of the contract terminology are that it conveys the idea that the principles of justice can be conceived as principles that would be chosen by rational agents, and that this way the sense of justice can be explained and justified.

Rawls's principles of justice (in the final formulation, see Rawls 2001, pp. 42-43) state that:

1. Each person has the same inalienable claim to a fully adequate scheme of equal basic rights and liberties, which scheme is compatible with the same scheme of liberties for all (the equal liberty principle); and

2. Social and economic inequalities are to satisfy two conditions:

First, they are to be attached to positions and offices open to all under conditions of fair equality of opportunity (the principle of fair equality of opportunity); and

Second, they are to be to the greatest benefit of the least advantaged members of society (the difference principle).

Rawls originally envisioned his theory of justice as the most important part of rational choice theory, trying to ground the acceptability of principles with the interests of rational participants (see Rawls 1971/1999, pp. 123-130).²¹ The public nature of the principles of justice is guaranteed by the approval in the "original position" - a constructed environment for rational choice under uncertainty. Rawls' original position can be modeled in the following way (see Display 2.1.): Let's assume that the parties are assessing available options for the basic structure of society, which will influence the availability of certain options in the future. The veil of ignorance obscures the morally irrelevant information: social class, race, gender, etc. The options are provided by principles from social philosophy (and compared to one another) and every participant compares the outcomes for the worst case scenario. In the case of the principle of utility (which would be a prominent alternative), principles of justice outperform the best outcome for the genuinely disadvantaged, while at the same time, do not burden the advantaged by any malingering caused by free-riders.²² Clearly, rational agents that

deficient" Scheffler 2003. p. 452. Conversely, my project starts from the similar premise. Since utilitarianism has a dominant position in the debates in neuroethics, and utilitarianism has defects for a democratic resolution of the issue of cognitive enhancement, an alternative that improves upon it is necessary.

²¹ Rawls later abandoned this "comprehensive" view with the distinction between the rational and reasonable as separate capacities (see Rawls 1993/2005).

²² The same model could then be used to compare principles from other ethical traditions (e.g., intuitionism and perfectionism, see Rawls 1999, pp. 30-36 and 285-292). Due to reasons of space the modeling will not be provided here. It has to be noted that the choice of most rational principles depends on whether participants are risk-averse or not (see Harsanyi 1975 for a discussion). Namely, if participants are not risk averse, they might choose the principle of utility and hope to be advantaged – thus maximizing the maximum (since there would be no entitlements for the least advantaged). Conversely, if they are risk-averse, they would choose to maximize the

do not know their own future position would choose principles of justice as a way to maximize their outcome in case they turn out to be disadvantaged.

Display 2.1: A basic original position model

	Utility principle is chosen	Principles of justice with the difference principle are chosen
Agent is advantaged	There are no distributive entitlements for others	There are distributive entitlement by others only if the inequality does not benefit the least advantaged
Agent is disadvantaged	Agent doesn't have any distributive entitlements toward the advantaged	Agent does have a legitimate distributive claim toward the advantaged

Participants in the original position know that they have a rational plan of life, but they do not know the details of the plan, nor their specific goals and interests. Since rationality requires the ability to make effective plans on the basis of the objectives pursued, and the ability to identify and choose the means and methods for their implementation, this would mean that rationality implies good understanding of specific goals that the veil of ignorance excludes.

To overcome this problem Rawls introduced the knowledge (and expectation) of primary social goods by the participants in the original position. The primary social goods are defined as things that are assumed to be such that any rational person wants them, regardless of what their rational life plans are - universal goods necessary to implement life plans. Rawls lists several types of primary goods: rights, liberties and opportunities, income and wealth, and social bases of self-respect (see Rawls 1999, p. 54). The freedoms and opportunities are determined by the rules of basic social institutions, while the distribution of income and wealth regulate them.

Now, it has to be understood that “justice as fairness” is not a complete contract theory, because it does not extend the choice for comprehensive ethical system, i.e., the selection principle of all virtues, but only for justice. This is because Rawls differentiates between the requirements of virtue, to which a strict requirement of autonomy is applied (i.e., an individual has the autonomy to apply the virtues or not) and justice, which can be externally imposed and sanctioned.

minimum, and principles of justice with the difference principle. Rawls was drawing on empirical evidence that majority of people are risk averse, to make his argument.

Rawls considered his theory of justice as a form of a political conception that is not foundationalist, but draws on the elements present in the public political culture of democratic societies. Initially, it could also be understood as a comprehensive moral and philosophical doctrine, based in the liberal tradition. However, after a lengthy debate on the acceptability of justice as fairness, Rawls drew a distinction between comprehensive religious, moral and philosophical doctrines and concepts that are restricted to the domain of the political, and posited that his theory is a "political conception of justice."²³

Recall that political liberalism (Rawls 2005) starts from a central assumption that the diversity of reasonable comprehensive, or religious (e.g., Catholicism), metaphysical (e.g., Dialectical materialism/Marxism) and ethical (e.g., Utilitarianism) doctrines with the claim on truth is a permanent condition of the public political culture, and not a historical contingency that is soon to disappear. This has profound consequences on the issues and arguments that can be deemed convincing to citizens endorsing these opposing doctrines. Because of this "fact of pluralism" political liberalism starts with the question: "How is it possible for there to exist over time a just and stable society of free and equal citizens, who remain profoundly divided by reasonable religious, philosophical and moral doctrines?" (Rawls 2005, p. 4).

First of all, since modern society is inherently "divided", the major problem is social reconciliation. In a well-ordered society, according to Rawls, this diversity can only be reconciled by a political conception of justice that provides an "overlapping consensus" of reasonable comprehensive doctrines. Namely, comprehensive doctrines which coexist in a well-ordered society must accept a certain common denominator, if they are reasonable.

Clearly, the notion of reasonable (as opposed to merely rational) plays a major role in Rawls' position. But what is reasonable, and how does it relate to rational?

On the one hand, if the citizens of a society were only rational, and society was divided by only rational (but not reasonable) religious, philosophical and moral doctrines that aspire to be true, they would all reach the rational conclusion that it is necessary to homogenize society – by force if necessary. According to Rawls, history of religious and civil wars shows that precisely such conclusions were common. However, forcefully homogenized societies are not fair, nor stable in the long term. On the other hand, reasonable people can coexist with other reasonable citizens, as well as reasonable religious, philosophical and moral doctrines that do not require the forced homogenization of society (and are thus not unreasonable).

Further elaboration of the difference between rational and reasonable can be explained

²³ For an extended discussion on the political aspect of Rawls' theory and the relation with the idea of democracy, see: Cohen 2003. pp. 86-138.

as follows (see Rawls 2005, pp. 48-54): if people are rational, we do not know what their goals are, only that they will achieve them intelligently. If people are reasonable when working with others, we know that they are willing to manage their own behavior according to the principles on the basis of which they and others can reason in common. Furthermore, reasonable people consider the consequences of their actions for the benefit of others.

The disposition to be reasonable is not derived from the rational, nor is opposed to it, but is incompatible with selfishness, since it is related to the disposition to act morally. Rawls also notes that the difference between the rational and reasonable is also well-grounded in everyday speech. Very often for a proposal (as well as action, claim or a person) it is said that it is perfectly rational, though entirely unreasonable, even outrageous. Instead of providing a full definition of reasonableness, Rawls provides two main aspects of reasonableness: 1. willingness to propose fair terms of cooperation and to respect them if others do, and 2. willingness to recognize “the burdens of judgment” and accept the consequences burdens of judgment have for reasonable disagreement.

Namely, unlike in the natural sciences, where it is possible to reach agreement on the basis of evidence of truth of a certain claim, debates within the society frequently cannot be settled with evidence since they are about metaphysical or religious issues (which per definition cannot be settled by science, and there is no evidence to support or disconfirm them) or about comprehensive ethical worldviews which are context dependent. Therefore, it cannot be expected that some of the most important judgments will be same (i.e., that persons with full intellectual ability would come to the same conclusion after a free discussion).

Since conflicting reasonable judgments cannot all be true (although it is possible that they are all wrong), the idea of reasonableness with the burdens of judgment is of utmost importance for the democratic idea of tolerance. Thus we come to the idea that, according to Rawls, should guide free public discussion and “reasoning in common with others” – the idea of public reason.

The content of public reason is given by the principles and values of the family of political conceptions of justice that:

1. Apply to the basic political and social institutions;
2. Can be represented independently from comprehensive doctrines; and
3. Can be worked out from the fundamental ideas implicit in the public political culture of a constitutional regime (e.g. free and equal citizens, society as a fair system of cooperation).

John Rawls has postulated the thesis that the society, and every reasonable and rational

agent (individual, family, association, and even a confederation of political societies) has a way of formulating plans, ranking priorities and decision-making. The way a society does that is its reason. Not every reason is *Public reason*, as sub-society (and undemocratic) agents use *Nonpublic reason*.²⁴

Rawls reserved the authority of public reason for fundamental problems of public political culture, such as regulating voting rights, tolerating religions, positive discrimination of disadvantaged members of society, or the right to property. The ideal of public reason doesn't only regulate the public discourse on fundamental rights of citizens. It regulates their practical deliberation and actions on issues that affect the basic structure of society. Rawls made a difference between the application of public reason on citizens and public officials. Public reason is applied (or should be applied) in official forums, on legislators when addressing the parliament and representatives of the executive branch in their public actions and statements. It especially concerns judges, as they have to explain and justify their decisions and argue that they are based on their understanding of the constitution and the Law.

According to Rawls's view, it is reasonable and rational that the citizens would rely on the public conception of justice and not on the whole truth as they and their reasonable comprehensive doctrines see it. He started from the fact that the diversity of reasonable comprehensive doctrines with the claim on truth is a permanent condition of the public political culture, and not a historical contingency that is soon to disappear. This fact of pluralism is very important, as citizens have an overriding interest in adequately regulating the use of coercive political power. That is why they could agree to replace the truth claim with the claim of reasonableness, in order to achieve an "overlapping consensus".

The principle of legitimacy, as forcefully argued for by Rawls, determines that the use of political power is right and justified only when it is in accordance with the constitution and if it is reasonable to expect that its elements would be confirmed by all citizens in light of principles that are acceptable as reasonable and rational. As the use of political power must be legitimate, the moral duty of civility is imposed so that the citizens would mutually respect the differences of comprehensive doctrines. Also, while deliberating on fundamental issues, the citizens should explain that the principles and policies they argue and vote for could be supported by the political values of public reason, and not merely by non-public values provided by comprehensive doctrines.

The starting assumption was that Rawls' ideas could be useful for the debate on public

²⁴ In what follows I draw on Rawls 2005, Lecture VI. It is important to note that Public reason should be understood in the opposition to Nonpublic reason.

regulation of enhancement in general and the issue of CE in particular. I turn to such an extension of Rawls now, and the immediate problems such an extension might need to respond to.

2.2. Principles of justice as criteria for assessing cognitive enhancement of healthy adults – perspectives and counterarguments

As already mentioned in the introduction, there might be some good arguments against using justice in the argument about cognitive enhancement: 1. The issue of justice could be seen as leading to a reasonable disagreement as well, due to burdens of political ideology; 2. Justice could be limited in application only to public funds and state action - not to individual choice or corporate actors; 3. It could be argued that “Performance enhancement” does imply questions of justice, while “performance maintenance” does not; and 4. One might maintain that there is no sufficient difference between cognitive enhancement and other technologies to warrant the importance of justice for the debate. Furthermore, demands of justice need to be suitably defined in the general case before the application to individual cases of cognitive enhancement (CE).

Let’s start with the first and most important challenge²⁵ - how can we be sure that the issue of justice does not lead to a reasonable disagreement as well? Although even the idea of justice has been the basis of many political conflicts, and the history of 20th century has shown disastrous effects of clashes between libertarianism, communism and conservatism, the deadlock between conflicting political traditions has been steered to a constructive development by Rawls’s account of „Justice as Fairness” first in his *A Theory of Justice* (1999), and later in *Political liberalism* (2005). By taking ideas present in the political culture of democratic societies as a starting point, and replacing the truth claim (that is rightly present in scientific discourse and ideological in political discourse) with the claim of reasonableness, Rawls has avoided the strong reasonable disagreement of comprehensive doctrines, and offered a view of public reason that can steer the debates toward consensus, or at least a *weak* reasonable disagreement. It will be remembered that public reason giving involves justification by way of reasons that people of different moral or political backgrounds could accept. Although there are many relevant political conceptions of justice for a democratic society, and not just one, they are all grounded in the idea of citizens as free and equal. They might disagree on the *ordering* of equality and freedom as ideals of democracy, but there is agreement on the *content*. The idea of a „family of reasonable political conceptions of justice“ assumes that there can be at least a rough agreement on the sense of justice of citizens in a

²⁵ In this Chapter, I draw on Dubljevic 2012a

democratic society, and I will argue that this content of reasonable conceptions of justice in a democratic society should be the basis of legitimate regulation of CE.

Admittedly, some authors in bio-medical ethics (e.g. Gert, Culver and Clouser 2006) have questioned the applicability of *any* conception of justice in the context of adjudicating conflicting valid claims for medical assistance (e.g. in distribution of organ transplants). Fortunately, the cases of enhancement do not create such problems, as there is convergence on the practical account that justice requires that claims of citizens lacking basic needs and in desperate need of medical assistance should be answered first.

The issue of enhancement is not a micro-level problem, but rather a question of importance for the basic structure of society, and accordingly public policy on CE should be reasonable and legitimate for all citizens. If the citizens in a democratic society could agree to refrain from imposing their comprehensive doctrine (say, religious or posthumanist views) when supporting public policy, the principles of justice could and should be used to provide rationale for a general case, as well as case-by-case assessments of enhancement technologies (see the discussion of public reason in Chapter 2.1).

Several conclusions stemming from the strict application of the idea of public reason could be useful for the debate on public regulation of enhancement in general and the issue of CE in particular. First of all, neither utilitarian, nor any of the classical entrenched political positions (libertarian, communist or conservative) would be accepted at face value by the citizens in a democratic society, as arguments stemming solely from these presuppose a comprehensive doctrine and/or run afoul of one or more principles and values in public political culture. Utilitarianism is quick to sacrifice the rights of citizens so that a greater net balance of happiness could be achieved, which makes minority groups especially vulnerable.²⁶ Libertarianism does not acknowledge that basic medical needs could be a matter of justice (which makes it very appealing to corporate interest, but less appealing to citizens)²⁷, and communism and classical conservatism also do not respect intuitions of reasonable citizens endorsing different reasonable comprehensive views.

Secondly, the debate on an appropriate public policy for enhancements in general, and CE in particular should be about issues that could be the content of public reason and framed

²⁶ This is not to say that any utilitarian approach would be excluded – merely that approaches that reduce justice to utility could. For reasons of space, I will not pursue this point further than asserting that utilitarian arguments that are prominent in the debate on CE (e.g. Levy 2007, Harris 2011; etc.) could be excluded if not reformulated in a manner that takes justice and rights of citizens as free and equal seriously.

²⁷ Again, for reasons of space, I cannot pursue this point further. For a recent discussion providing arguments at a greater length about the faults of libertarianism in the context of CE, see Capps 2011.

according to reasonable conceptions of justice. Authenticity, human nature or the good life are the content of irreconcilable comprehensive metaphysical, religious or ethical doctrines, and as such can only lead to reasonable disagreement. In order to appreciate fully the faults of some strands in the enhancement debate so far, it is essential to emphasize again the importance of the idea of public reason. It should be remembered that public reason giving is *impartial* as it involves justifying a particular position by way of reasons that people of different moral or political backgrounds could accept (or at least could not reasonably reject). Appeals to the principles of justice satisfy this criterion. Non-public reason and private reason, by contrast, are quite partial. They involve the exercise of an individual's reason to the constrained norms and interests of some sub-set of the society as a whole, such as a business, a political party, the military or a religious community. Some arguments in the enhancement debate so far (e.g. authenticity, as well as “Playing God” and posthumanist claims) have been based exactly on partial norms and interests.

The questions whether enhancements could undermine equality and increase unjustified inequalities, lead to undeserved distribution of resources and rewards and/or to citizens lacking in basic necessities, should be discussed along with realistic policy options. Admittedly, some of these questions have already been posed, but the discussion so far in neuroethics (in the domain of CE) has been dominated by authenticity or utility arguments. I have noted four plausible reasons for downplaying the importance of justice while considering public policy for CE and the discussion so far was aimed at refuting the first.²⁸ This should suffice to postpone the looming threat of the first challenge, but it should be noted that only a full meta-theoretical discussion can resolve this issue sufficiently, and as such will be provided in Chapter V. For the time being, let's consider some general implications for the ethical assessment of CE and legitimate policy options, and review the implications of the other three challenges in turn.

One important implication is that the principles of justice could and should be used to establish a limited defense for the fleeting boundary between therapy and enhancement.²⁹ Of course, this boundary is a social construct as so many others, but the arbitrariness in the exact setting of age for driving, voting or drinking for example does not imply that it should not be set at all. The common claim of authors opposing enhancement (e.g. Selgelid 2007) is that treatments are obligatory and permissible while enhancements are not. The application of the

²⁸ The challenges are: 1. the issue of justice leads to a reasonable disagreement as well; 2. justice applies only to public funds and state action, 3. performance enhancement does imply questions of justice, while performance maintenance does not, and 4. there is no sufficient difference between CE and other technologies that would warrant the importance of justice.

²⁹ In what follows I draw on Dubljevic 2012b.

principles of justice can explain why this might be the case in CE, once operative definitions of using drugs and devices due to health needs and for cognitive enhancement have been offered.³⁰ Preventive, curative, rehabilitative and compensatory use of medical drugs and devices is an important part of meeting health needs (Daniels 2008). On the other hand, cognitive enhancement could be defined as *use of medical drugs and/or devices for non-health related improvement of cognition*.

Using CE is not an issue of providing basic necessities for those who are lacking, benefiting the least advantaged or restoring citizens to a position of equal opportunity and liberty, while in the case of citizens suffering from ADHD or tinnitus (using therapy prescribed by a medical doctor) it is.³¹ Furthermore, providing CE to gain positional advantage could cause erosion in the fabric of society, as people would see that medical resources are diverted into controversial enhancements, while clear cases of disease and impairment are left untreated. This means that justice could be used to draw the line between cases in which it is permissible and obligatory to provide medical drugs and devices and those that it is not. Also, this means that claims that justice *requires* enhancement (e.g. Savulescu 2006) are not very clear, and that it is highly unlikely that these claims are impartial and in accordance to public reason. Moreover, as resources are too limited to meet all needs for treatment, justice requires that we meet most important medical needs first. Only if all treatments are taken care of could any public finance for enhancements be allowed.

This can be neatly summarized with the version of the Justice Trumps Beneficence Argument:³²

Enhancement is not required by justice but only by the value or principle of beneficence;
The widespread use of enhancement would create a serious risk of injustices to citizens choosing not to enhance due to their comprehensive doctrine;
Justice trumps beneficence (when the pursuit of beneficence creates a risk of serious injustice, the avoidance of injustice should take precedence);

³⁰ It should be remembered that Rawls's principles of justice (in the final formulation) state that: 1. Each person has an the same infeasible claim to a fully adequate scheme of equal basic rights and liberties, which scheme is compatible with the same scheme of liberties for all; (the equal liberty principle); and 2. Social and economic inequalities are to satisfy two conditions: first, they are to be attached to positions and offices open to all under conditions of fair equality of opportunity (the principle of fair equality of opportunity); and second, they are to be to the greatest benefit of the least advantaged members of society (the difference principle) Rawls 2001, pp. 42-43.

³¹ In this paragraph I draw on Buchanan & al. 2000. For a more complete discussion of this issue, see pp. 119-152.

³² Buchanan & al. (2000, pp. 270-272) discuss this argument as posed by the disabilities movement, but with suitable changes, I believe that the argument could be successfully employed in this context. An earlier version of this analysis has appeared in Dubljevic 2012a.

Therefore, public funds should not be allocated to enhancement purposes, and/or measures should be taken to compensate those citizens likely to suffer injustices.

This leads us to the second reason for downplaying justice. Namely, what is non-obligatory and/or to be avoided in the context of public funding and health insurance can be permissible or impermissible for individuals or groups. Do principles of justice give any guidance in these matters? Does justice require that enhancement should be prohibited entirely? The hard cases mentioned in debates on genetic enhancement (Buchanan & al. 2000) and examples of pro-enhancement authors (e.g. Levy 2007) for currently allowed enhancements point to the need of careful consideration. If education and coffee are enhancements as well it would be absurd to arbitrarily ban any enhancements without having clear criteria.³³ The principles of justice have so far only excluded the possibility of having a legitimate claim on public funding for enhancement purposes.

But what if private companies and citizens interested in enhancement provide funding? Does not the principle of autonomy require that they be allowed to do as they please? Would it not be paternalistic to arbitrarily limit their legitimate interests? I will try to shed some light on what justice requires and to refine and clarify the policy options for a democratic society.

It will be remembered that proponents of enhancement insist that new enhancement technologies are similar to old ones, and base the argument on the appeal to the fairness of treating like cases alike. Nevertheless, policy options in a democratic society are not limited to taking no action (as is the case with coffee) and thus permitting any actions by the private sector as pro-enhancement authors want or to try to ban or block the technology (as is the case with cocaine) as opponents would like. As already mentioned there are also options of regulating technology so that the individual use is encouraged via government incentives (as is the case with higher education) or discouraged via taxation (as is the case with tobacco), or even to make the technology mandatory (as is the case with elementary education). These policy options rest on the familiar distinctions in moral philosophy between actions that are a) morally required, b) morally desirable and permissible, c) morally neutral and permissible, d) bad but nevertheless still morally permissible, and e) morally impermissible (Blank 2010). It is important to have in mind that fairness of treating like cases alike depends on defining sufficiently like cases.

Although concrete proposals for the social regulation for non-medical use of cognition

³³ Although the definition of cognitive enhancement used here excludes viewing coffee and education as enhancement, it could be imagined that some citizens might disagree with it, and insist that any improvement of cognition is enhancement.

enhancement drugs or devices for healthy adults must be made in the context of their case by case analysis (which will proceed in Chapters 3 and 4), the rationale for a general approach and starting point for that analysis must be made. The principles of justice seem to require at least that the use of CE be discouraged with taxation, fees and requirement of additional insurance, and that the funds obtained from those who seek advantage by enhancement be allocated to the least advantaged. From what is considered so far it could be surmised that even on the conceptual level enhancements in general and CE in particular are more often than not bad in the context of justice. If widespread and inadequately regulated, the use of CE by healthy adults would more likely maintain or increase than reduce social inequality (Glannon 2008). Furthermore, the use of enhancement drugs and devices could undermine equality in an additional and very important sense. Namely, although there are factual inequalities in socio-economic status of citizens, the idea of public reason presupposes that citizens are equal in their ability to formulate and revise their rational life-plans, and to have equal opportunity to do so (Rawls 1999). However, if their choice is dictated by market forces – that make it rational (in the economic sense) to pursue only one, or a limited range of options (such as to enhance) – their status as free and equal citizens is undermined. Also, according to the duty of civility, citizens that do wish to enhance should respect the wishes of their fellow citizens not to enhance and strive toward public policy that would protect the rights of all.

CE can and will be used as means for obtaining undeserved positional advantage (Adee 2012, Maher 2008), and the truckers example from the introduction serves to show that they could be used to ensure positional advantage of corporate actors as well. If students use Methylphenidate (Ritalin ®) during an exam because they are diagnosed with ADHD they are merely having a fair opportunity to compete with other students on an equal footing. However, if they use it as enhancement, they are taking a chance with the unknown long-term side-effects in order to gain positional advantage. Similarly, persons using tDCS while learning because they are diagnosed with tinnitus are merely restoring their fair equality of opportunity, while using it without a medical necessity to improve focus and concentration is motivated by possibility of gaining positional advantage. Such practices, if left unchecked, could lead to a situation in which citizens in all walks of life need to use some sort of CE to be able to compete. For example, all truck-drivers would need to use drugs in order to be able to work. Logistic companies would (indirectly) coerce truck-drivers in order to gain more profit, while truck-drivers would have to take the risks of long-term effects because they are not in the position to refuse. They are at the same time robbed of the ability to decide for themselves

whether to use enhancements or not and forced to be the ones bearing consequences of the use. In other words, with the unknown long-term side-effects and/or through coercion CE could create additional disadvantages and needs to those already lacking basic necessities. Thus, on this interpretation, discouraging use and redistribution of resources is required by the difference principle, and a policy of economic disincentives for individual and corporate use is required as a matter of basic justice.

The principle of equal liberty also shows that the current practice is unjust. Namely, access to CE for healthy adults is currently reserved to a privileged class of scientists and medical professionals, or those who are somehow related to them or deemed worthy by them. Principles of justice require as well that any medical necessities stemming from the use of enhancements are not financed from public funds, as they are the result of expensive taste (when voluntary), or are at least given the lowest priority. Moreover, the principles of justice require that the social pressure to enhance is dealt with efficiently so that no citizens are coerced to take enhancements in order not to lose their jobs. The principle of fair equality of opportunity requires that either enhancements be forbidden as a form of cheating in competitive situations (e.g. exams), or that those who do not use enhancement be somehow encouraged and compensated.

All this could be achieved by introducing economic disincentives for the use of CE - the imposition of taxes, fees and requirements of additional insurance would offset any positional advantage, while additional funds thus created could be allocated to meet basic health needs and/or to finance education.³⁴ The companies earning profits obtained from CE could be further taxed or obliged to invest extensively in the so-called orphan drugs.³⁵ Such policy would be legitimate as it is in accordance with the requirements of justice, and it does not undermine the autonomy of citizens any more than taxes on alcohol and tobacco do.

Although the requirements of justice seem to be clear, it should be remembered that in the debates on neuroenhancement some influential authors in neuroethics have been downplaying the importance of justice when considering policy options for regulating CE. The first challenge has been at least postponed, for the time being (until Chapter 5) but there are other reasons that need to be considered. It will be remembered that some (e.g. Gazzaniga

³⁴ An earlier version of this argument appeared as Dubljevic 2012b.

³⁵ When the number of individuals suffering from a particular illness or disability is too small, it is simply not profitable for pharmaceutical companies to produce drugs that might be effective. According to Rawls's difference principle (or the broader principle of need, suitably construed), production and sale of enhancement drugs and devices (that would be clearly and visibly labeled as potentially dangerous) might be allowed only if it would lead to the benefit of the least advantaged, or those in dire need.

2005) might believe that justice applies only to public funds and state action, but does not concern individual choice or corporate actors; that others (e.g. Lieb 2010) might think that performance enhancement does imply questions of justice, while performance maintenance does not; and that some (e.g. Harris 2011, Levy 2007 and Savulescu 2006) might argue that there is no sufficient difference between CE and other technologies that would warrant the importance of justice.

So, if justice only applies to public funds and state action, would the imposition of economic disincentives for CE be legitimate? Could not a *laissez-faire* approach be more legitimate? To address the claim that justice applies only to public funds and state action (the second challenge) more directly, two points should be made.

First, it is true that citizens and organizations are free to follow their interests as long as they do not harm anyone, violate anyone's rights and pay taxes. Nevertheless, if these private or partial interests are to be fulfilled at the expense of public interest and/or drastically affect the very basic structure of society (by achieving monopoly, for example), principles of justice apply with full force, and autonomy is not violated as justice is supposed to protect the autonomy and equal rights of those likely to be adversely affected. The example of plastic surgery would be a good point where justice does not apply directly because good looks have nothing to do with competence and performance. The issues of justice are indeed not urgent here.³⁶ However, the example of logistics companies from the introduction serves to show that CE could drastically change the basic structure of society (as monopolies and cartels do), and that the state intervention and regulation are justified.

The third challenge was the claim that performance enhancement does imply questions of justice, while performance maintenance does not. As Caffeine, Methylphenidate, and Modafinil provide only performance maintenance, whereas Amphetamines such as Adderall®

³⁶ Indeed, if one takes the example of say, Michael Jackson, or any other person that overdoes plastic surgery, it is even questionable whether plastic surgery has anything to do with good looks, or merely with personal dissatisfaction. Even if good looks could be correlated with performance, it could be assumed that the correlation would be limited to a relatively narrow part of society. On the other hand, empirical research from organizational psychology has undoubtedly shown that general cognitive ability predicts performance over a wide range of jobs and occupations, and hence CE has much more potential for social pressure. "The most comprehensive demonstration [of correlation between cognitive ability and performance] was a recent meta-analysis conducted by Schmidt and Hunter (1998), in which nearly 85 years of research findings on various predictors of job performance are summarized. Their analysis indicated that the corrected correlation between general cognitive ability and performance across jobs was .51—that is, over 25% of the variance in performance across jobs is due to differences in general cognitive ability. This does not take into account other factors that may impact job performance (e.g., motivation, leadership, and situational constraints), so this finding is truly impressive" (Jex 2002, p.97).

perhaps might provide performance enhancement (and are entirely prohibited in Germany, for example; see Lieb 2010), should we not treat Caffeine and other compounds equally? The example of truckers is useful yet again. Although coffee is widespread and not regulated (because the effects are well known and modest) and most truckers use it, no one is coerced to drink it directly or covertly. It is possible to be a professional driver without drinking coffee, if someone so chooses. The point is that *consumption* makes all the difference. A company employing only coffee-drinkers or vegetarians (or CE-users) would be discriminating citizens according to arbitrary criteria, limiting the freedom of citizens and therefore doing injustice. Similarly, the use of medical devices that directly manipulate the brain entails risks that no person should be coerced to take. Economic disincentives for the use CE through taxes, fees and requirements of additional insurance do not create any injustice as citizens would be allowed to use them if they so choose, and are protected from indirect coercion if they do not.

The fourth and final challenge is the claim that there is no sufficient difference between CE and other technologies that would warrant the importance of justice. According to this view, injustices do stem from the use of any technology, and some groups (e.g. the Amish) are worse off because they choose not to use certain technologies. Nevertheless, that does not give these groups any reason to invoke the issue of justice because they have freely chosen not to use them. On the other hand, the question of certain groups not being able to afford CE is out of the question, because drugs (like Modafinil) and devices (like tDCS) could be fairly cheap and should not be made more expensive with taxes. As for the truckers, haven't they already accepted the benefits of technology by driving vehicles? Why should they be allowed to invoke justice to stand in the way of progress?

I will try to answer this challenge without being drawn in to a discussion about the nature or essence of various forms of technology (or the question whether education is enhancement or technology at all). First of all, this challenge does not make the policy of imposing taxes, fees and additional insurance any less legitimate. Consider the example of vehicles: in order to use this readily available type of technology, a person must pay *fees* for a training course and pass an exam as proof of competence. Then when the vehicle is bought, *taxes* should be paid. In order to use the vehicle, an appropriate *insurance* must be taken and both the vehicle and the driver should be *registered* by a government agency. Finally, while using the vehicle, taxes on fuel, tolls and appropriate fees for regular technical *check-ups* must be paid.

Secondly, there is a considerable difference between vehicles and CE drugs. Again, *consumption* makes all the difference. Consuming CE drugs alters the brain chemistry in ways

that are not yet fully understood. Although being happy (e.g. when one gets a new car) or sad (e.g. if one crashes it) changes the brain chemistry as well, these forms of alterations are in balance with background physiological processes. Consuming drugs when neuro-physiological processes are off balance makes sense, as there is less to be lost, but when the balance is intact, it is rational to be cautious. Citizens who express concerns about the possibility to jeopardize that balance by consumption of drugs are clearly reasonable, and not merely opposed to technology. Therefore, they have every right to invoke justice if economic forces and corporate interests coerce them to consume drugs to be able to work.

But, what is the problem with using medical devices? Surely they are more like vehicles and computers, since no person is going to consume say a tDCS device. In such cases *direct manipulation of the brain* makes all the difference (pace Levy 2007). Using tDCS changes the synaptic activity in ways that are not yet fully understood. Although the safety record of TMS and tDCS is acceptable in controlled situations, they have been known to cause epileptic seizures, while long term effects are unknown. Again, using stimulation devices when neuro-physiological processes are off balance (say in case of tinnitus, applied as therapy under guidance by a medical doctor) makes sense, as there is less to be lost, but when the balance is intact, it is rational to be cautious. Citizens who express concerns about the unmonitored use of such devices are clearly reasonable. Therefore, they have every right to invoke justice to offset short-term positional advantage if economic forces and corporate interests start indirectly coercing people to use such devices in order to attain good social positions and offices.

After reviewing the objections to using justice as the criterion, the model for legitimate regulation needs to be further elaborated and some possible objections to it should be shortly reviewed as well. According to the British Medical Association Discussion Paper (BMA 2007, p. 32) there are a range of mutually non-exclusive regulatory options that could be considered incorporating aspects of prohibition, permissive regulation or a *laissez-faire*, free market approach. The examples are:

1. Prohibit the use of cognitive enhancements in healthy individuals, with penalties either for their supply or use (as with recreational drugs and techniques such as reproductive cloning);
2. Permit some methods of enhancement (such as the use of nutritional supplements and pharmaceutical products) and prohibit others (such as genetic selection and manipulation);

3. Permit the use of enhancements in some situations or for some patients but not others (for example, in explicit competitive situations their use could be prohibited or their use could be restricted to adults who are able to give consent);
4. Have a permissive system of regulation – as with assisted reproduction – where techniques are permitted under license from a regulatory body;
5. Rely on health professionals to act as “gate-keepers” of such technology subject to guidance from professional and regulatory bodies; or
6. Allow individuals to make their own decisions and leave the area completely unregulated or regulate only the claims made about the products or techniques to ensure individuals are not misled.

Our discussion above clearly excludes the laissez-faire option (No. 6), due to possible effects on the basic structure of society. Also, the first option is not sufficiently supported because it could undermine the autonomy of citizens, apart from being costly and inefficient. The second option would have to be evaluated on a case-by-case basis, but at any rate the exact way in which enhancements are permitted would need to be further elaborated.

This leaves only the options to rely on health professionals to act as “gate-keepers” and to have a system of licensing and regulation – a sort of Regulatory Authority for Cognitive Enhancements (RACE). BMA envisions a drawback of RACE: “the establishment of a statutory regulatory body is expensive, bureaucratic and involves considerable work and time from those regulated” (BMA 2007, p. 34). First of all, it is entirely unclear why a new regulatory body would need to be established. Under what I will call the Economic Disincentives Model, an already existing government agency (e.g. Ministry of Health or FDA, etc.) could offer a licensing procedure to companies that produce pharmaceuticals and medical devices. Such a policy would not be inefficient or lack legitimacy, especially if it is based on economic disincentives, and functions as an addition and not a further drain on public funding. The imposition of such a policy would ensure that all citizens could have legal access to CE, but with the imposition of taxes, fees and requirements of additional insurance, it would be less profitable for companies to “insist“ that their employees use CE.

But how would that work? Under a strictly regulated licensing procedure for pharmaceutical companies, drugs that were initially used to treat ADHD and narcolepsy could be marketed under different names (and with different quantities of the active substance) for use by healthy adults. Similarly, medical devices that offer the possibility of enhancement could be licensed for use by healthy adults. The producing companies would bear the costs of

the licensing procedure to put the drug or device on the market, and they would bear it gladly as there is considerable amount of money to be made.

An additional licensing procedure for users would be financed by those citizens interested in CE. In order to use, say, Modafinil for jet-lag or to be able to work longer, a citizen should first pay *fees* for a course about known effects and side effects, and pass an exam as proof of knowledge. Similarly, in order to use, say, a tDCS device a person would have to pay *fees* for a training course and pass an exam as proof of competence. These procedures should suffice to secure *informed* consent. In order to use CE, an appropriate additional medical *insurance* would have to be taken and the enhancement-using citizen should be *registered* by a government agency, and issued a *license* to use a specific drug or device. In effect, CE would be legal, controlled and monitored. If a citizen wanted to use, say, Modafinil, Methylphenidate, and tDCS three licenses would be needed.

The health of these citizens would be reasonably protected through self-financed obligatory annual medical tests. The privacy of registered citizens would be protected, and they would have the option to opt out from providing information on long-term effects of the use of the drug or device (and the potential complications stemming from using multiple drugs and devices) through annual medical tests that they would finance themselves. In a way, they would be willing subjects in a longitudinal study of the effects that a particular drug or device has on healthy adults. A word of caution is needed here. Requesting that all citizens that want to use enhancements provide information would be coercive and illegitimate. That is why providing information is merely set as a default, while the citizens are fully informed of that during the training course and allowed to opt out. Such an approach would not be coercive and is entirely legitimate. It could be objected here that citizens are bearing all costs, while corporate actors profiting from enhancement are off the hook and social aspects of use are forgotten. This is not the case here however. Namely, under the Economic Disincentives Model, the prices of CE would be regulated – they would contain the standard costs of production and distribution, the profit margin would be limited and an additional tax would be imposed. The companies earning profits obtained from CE could be further taxed and obliged to invest extensively in orphan drugs. The funds gained by such policy should be invested in providing medical necessities for the least well-off and the remaining funds would be allocated to finance education. Additionally, using devices and acting under the influence of CE drugs might be impermissible in certain instances such as exams.

But let's get back to the first objection to the model. It will be remembered that the British Medical Association Discussion Paper envisioned considerable drawbacks of any

“permissive” model - namely, the procedures could turn out be expensive, bureaucratic and involve considerable work and time from those regulated (BMA 2007, p. 34). However, this objection fails to undermine the model. For example, the licensing procedure for driving vehicles is bureaucratic and involves considerable time and work from those regulated, and it is still efficient and legitimate. Furthermore, it should be remembered that the economic disincentives model would function as an addition and not a further drain on public funding. This policy would efficiently and legitimately ensure that all citizens could have legal access to CE, and with the imposition of taxes, fees and requirements of additional insurance, it would offset any positional advantage from using them.

Another possible objection could be that the economic disincentives model gives more power to state agencies, and under the principle of subsidiarity, only problems that can't be resolved at lower levels should be passed on for state regulation. Couldn't medical professionals act as “gate-keepers” for CE? Wouldn't such decentralized decision-making be better?

First of all, the “gate-keeper” approach (or any derivative of option No. 5 in the BMA paper) would not be as efficient as it lacks any economic (dis)incentives for the stakeholders. But efficiency is not the only or even the most important issue here – this approach would also lack transparency and legitimacy if applied to CE. Medical doctors have the expertise to diagnose illnesses and prescribe therapy, whereas every citizen should have the right to decide for him or herself whether to use enhancements or not. The economic disincentives model is more legitimate because it excludes arbitrary decisions as the conditions under which CE can be used are publicly available and negative decisions could be publicly challenged.

One final objection could be that the economic disincentives model would not be successful as CE (at least drugs) would be available via prescription as well, so everyone would try to avoid the licensing process. Again, that does not have to be the case, as physicians would support the legitimate model by doing their job responsibly. Namely, if there is a publicly recognized procedure for obtaining these drugs, medical professionals would be less inclined to prescribe drugs if they are unsure if these are really needed. In addition, the criteria for prescription could be made strict under guidance from professional and regulatory bodies and off-label prescriptions could be discouraged.

To sum up - the Economic Disincentives Model could be the basis for a reasonable and legitimate public policy on CE. Although longitudinal studies of effects of use of specific drugs and devices need to be taken into account, this policy taken as a starting point for

regulation would ensure that all citizens could have fair equality of opportunity. Furthermore, the imposition of licensing procedures, taxes, fees and requirements of additional insurance should offset individual and collective positional advantage from using CE. The example of truckers losing their jobs from the introduction could be successfully tackled with the above policy. Economic disincentives could curb indirect coercion, and so enhancements, even if allowed would not be as widespread, or at least would not lead to as much injustice.

It can be assumed now that conceptual analysis of justice has provided valuable insights for further work. Justice is indeed applicable to the problem of public policy on CE, and an appropriate model has been determined. However, in order to apply the model to individual cases further conceptual analysis is needed. Namely, it has been assumed that amphetamines are not applicable for the Economic Disincentives Model. Their apparent addictive properties have motivated government agencies in many countries (including Germany) to entirely prohibit these drugs. However, that is not the case in the United States and Canada. The analysis of addictive properties of different drugs (and perhaps devices) is an important part of the discussion in Chapter 3 and the model might be amended accordingly. But before turning to empirical matters, there is one more conceptual point that needs to be resolved. A decision on specific cases is justified only if it is grounded in principles of justice and autonomy. Therefore, a liberal might object that Germany merely has paternalistic laws and that “liberal” countries should not prohibit use of amphetamines, because that would be coercive and counter to autonomy. Furthermore, the notion of indirect coercion, which has been used throughout needs to be specified. Namely, what is coercion? How is “indirect” coercion different from coercion proper? What is the relation between coercion and autonomy. To complicate matters further, in light of neuroscientific findings it is not clear whether autonomy is a viable principle, or whether indirect coercion is merely a fact of life in societies that are paternalistic per definition. The discussion now turns to these issues.

2.3. Coercion and compulsion: The political and not metaphysical principle of autonomy in neuroethics

The concept of autonomy as conceived traditionally in moral, legal and political (or jointly: practical) philosophy has recently come under scrutiny.³⁷ Relatively recent developments in Neuroscience have facilitated the process of revising traditional philosophical concepts informed by “Folk-psychology”, and it should be stated from the outset that the challenges produced by this process are beneficial and indeed frugal for practical philosophy (see e.g. Levy 2007, Glannon 2007). However, some of the debates concerning these challenges rest on conceptual misunderstandings that could and should be resolved in order to make way for new ethically and empirically informed insights. This Chapter is a contribution toward this goal, and these insights should provide an adequate basis for the case-by-case assessment. But what exactly are these misunderstandings?

I will argue that one of the most important misunderstandings is the conflation of the metaphysical concept of free will with the moral-political concept of autonomy. Since Benjamin Libet published the results of his experiments (Libet 1985), neuroscientific findings have given a new impetus for metaphysical debates, which have mistakenly spilled over in practical philosophy.³⁸ Some have reacted to this alleged confrontation between the scientific and ethical world-view with the claim that free will is an important illusion (e.g. Wegner 2002). Others (e.g. Greene & Cohen 2004), mistaking autonomy for free will, claimed that we need to reform the legal system due to the fact that free will (and thus responsibility) is empirically void. These claims have been largely ignored in political philosophy as the *freedom of will* debate was rightly seen as metaphysical and *liberty* in the political sense of citizens as being free and equal has been construed as post-metaphysical (Habermas 2004) or

³⁷ In what follows, I draw on an earlier version of this argument, that has been published as Dubljevic 2013a.

³⁸ I claim that they have mistakenly entered moral and political philosophy because I extend Rawls's (1974, 1985) view that practical philosophy should avoid metaphysical disputes and that the laws and policies (like most common sense judgments) largely do that. The concept of autonomy embedded in the legal and political system does not presuppose libertarianism nor compatibilism and/or determinism. Of course, there are many philosophers who willingly enter such discussions and link discussions on autonomy with discussions on free will. I am sceptical about the possibility that scientific evidence will resolve any *metaphysical* disputes, and believe that this pragmatic approach is implicitly shared by many lawyers and political theorists. My aim in this Chapter is to make the implicit pragmatic assumptions of the legal and political system more explicit. Henrik Walter (1999, Müller and Walter 2010) has expressed somewhat similar views on autonomy, but unfortunately in his work he presupposes determinism.

political and not metaphysical (Rawls 2005)³⁹.

Recently however, the notion of autonomy has been scrutinized without recourse to the sweeping claims in the manner of proponents of metaphysical determinism. After a discussion that is both ethically and empirically informed, Felsen and Reiner, in their article “How the Neuroscience of Decision Making Informs Our Conception of Autonomy” (2011) conclude that “we need to reconsider the principle of autonomy in order to align our moral values with neuroscientific findings”. Now, this has important implications for this project. Although the general approach of Felsen and Reiner is laudable, there are again some misunderstandings that should be clarified. Furthermore, although they did not link their discussion with metaphysical doctrines, it is unclear whether their definition of autonomy presupposes metaphysical commitments. Therefore, the political concept of autonomy that could serve as a basis for ascribing responsibility in practical philosophy and is implicitly assumed by the legal and political system needs to be defined. Of course, such a definition will be very valuable for the case-by-case analysis of CE.

In this Chapter I will first shortly review the argument on external influences as presented by Felsen and Reiner, and refute their claim that neuroscientific evidence renders autonomy “quixotic” (and thus supports a shift toward paternalism). Then, I will elaborate the moral-political notion of autonomy that is independent from metaphysical debates on free will. This political notion of autonomy is consistent with empirical findings (e.g. Moller & al. 2006) and it can be presupposed in ascribing moral and legal responsibility to all adult human beings that are not suffering from debilitating pathologies or subject to oppressive and constricting conditions. This approach includes an operational definition of autonomy together with the distinction between different ideal typical levels of mitigating factors for qualifying diminished autonomy. Finally, the objections to the position are refuted and the frugality of such a notion of autonomy is tested on the example of addiction. This should provide valuable insights for the empirical models in Chapters III and IV.

But let’s start with the challenge to autonomy. In their discussion on neuroscience and autonomy, Felsen and Reiner focused on empirical findings that seem to suggest that our decisions are not as free from undue external influence as the standard model of autonomy requires.⁴⁰ By quoting studies and works on “priming effects” (Tulving and Schacter 1990),

³⁹Admittedly, Habermas did recently entangle his views on moral philosophy with metaphysical doctrines. See Habermas 2007b. It should be noted though that he does no such thing in his legal and political philosophy. See Habermas 2004. However, in order to avoid confusion, I will focus on Rawls.

⁴⁰ Felsen and Reiner analyze three presuppositions of autonomy: 1. Consistency with individual’s higher-order beliefs, 2. Rationality and 3. Relative independence from external biases. They conclude that Executive control

“framing effects” (Tversky and Kahneman 1981), and “anchoring effect” (Ariely 2008) the authors claim that we are more open to covert external influences and that the standard model of autonomy cannot accommodate for these findings. Furthermore, while arguing that physicians, corporations and other actors take advantage of tactics (e.g. framing, branding) for influencing decisions, they conclude that the principle of autonomy needs to be reconsidered in the areas of medical decision making, treatment of addiction, marketing and the broad field of political philosophy. Although conclusions stemming from the data on addiction at first glance seem to be compelling, their conclusions about improbability of autonomy in medical decision-making, and expecting drastic problems in marketing and political philosophy are obviously bolder than the data appear to allow.

Let's start with the conclusion regarding political philosophy. Contrary to the assumption made by Felsen and Reiner - that autonomy presupposes constant independence from external factors - personal autonomy presupposes only the *right* to refuse some influences as undue and external to the agent and to make one's own decision.⁴¹ The agents (alone or publicly) decide which influences are due and which undue, in accordance to actual exercise of political rights. While the *ideal* of autonomy or autonomy in the maximal sense exalts the image of an agent that makes choices uninfluenced by any factor that is not rationally chosen or endorsed, the minimal or basic sense of autonomy requires only that the agent is *capable* to make major decisions on rational reflection and in accordance to his or her own long term interests, not that it is always the case (Levy 2012). Furthermore, influential accounts of autonomy in both analytical (Rawls) and continental (Habermas) political philosophy presuppose that individuals are embedded and open to the social world. Rawls (2005) postulates that citizens see themselves as fully able to reflectively endorse or reject *shared* reasonable principles, while endorsing comprehensive doctrines they might be indoctrinated into. Habermas (2004) stresses the importance of so called “public autonomy” and postulates that “private” and “public” autonomy are mutually presupposed.

How does this square with priming, framing and anchoring effects? If agents are always already constituted in private or personal autonomy through social practices and

theory and empirical findings on the role of prefrontal cortex in decision making corroborates the first, and that Somatic marker hypothesis and the notion of ecological rationality offer an important addition to the second. For reasons of space, I will not deal with their arguments that confirm the usefulness of the first two prerequisites, and will limit my analysis to the alleged neuroscientific evidence that renders autonomy “quixotic” and supports paternalism. It should be noted here that the discussion with Felsen and Reiner is not the primary motive, but merely an occasion to clarify the post-metaphysical notion of autonomy that will be used in further analysis.

⁴¹ Gaus calls this basic notion of autonomy „agency“ or „autarchy“ (see Gaus 2011, Chap. II and IV) and treats it as the fundament of morality. Although using different notions to delineate between basic and ideal autonomy might be a good idea, agency could be seen as presupposing metaphysical commitments, whereas autarchy has a connotation of irresponsible willfulness and arbitrariness, that I would like to avoid.

norms (i.e. they are citizens of a society, or at least members of a group), it is entirely consistent with their higher-order intentions to participate in group/social endeavors, accept sound advice from experts and peers, and to trust fellow human being unless there are good reasons not to. Commitment to conform to the group norm and subconscious processing of symbolic cues (e.g. priming) is entirely consistent with these views. Also, biases (e.g. framing and anchoring effects) in reasoning can be incorporated in contemporary political philosophy through the ideas of “reasonable pluralism” and “burdens of judgment”.⁴² Reasonable citizens in a democratic society tolerate different comprehensive doctrines and refrain from coercing others to accept their favorite or “anchored” views precisely because they recognize fallibility due to “burdens of judgment” or various biases. Furthermore, political autonomy - apart from enabling citizens to be seen as authors of laws which they should uphold - serves to protect citizens from abuse by agents who would be willing to manipulate them for their own ends (e.g. via lack of information or with subliminal messages). The empirical results thus confirm the assumption that humans are fundamentally fallible social creatures and explain the mechanisms of openness to the social world, which can be and sometimes are abused. Does a naturalistic framework dispute autonomy, then? No, but it might point toward means of manipulation and toward areas in which further legal protection of rights and autonomous choice is needed.

Such protections are sometimes already in place, and some might need to be instated. For instance, in the economic sphere apart from familiar rights of consumers to change their minds within a set period of time (e.g. money back guarantee), regulatory bodies might need to be formed and new laws and regulations put in force in order to prevent new „stealth marketing“ practices. This all seems to be clear.

But let us turn to the case of medical decision making. The clash between autonomy and medical paternalism is a recurrent theme in biomedical ethics (Müller and Walter 2010), and there are undoubtedly many who lament over the introduction of patient autonomy in the mainstream of medical practice. Although some positions based on findings in neurobiology of addiction (e.g. Leschner 1997) seem to discredit the possibility of respecting the autonomy of some patients (a point I will discuss at length later in this Chapter), respect for autonomy and informed consent are an important part of patient’s *rights*. It is important to note that citizens have a right not to use their rights in certain situations. For example, in many

⁴² Indeed, Gaus has done precisely that in his excellent book *The Order of Public Reason: A Theory of Freedom and Morality in a Diverse and Bounded World*. See Gaus 2011. One of the problems with this book is that it does not delineate clearly between freedom in the political and metaphysical sense, although it could be plausibly assumed that he presupposes only the political sense, but unless this is explicit it can cause misunderstanding.

democratic societies, there might be a large number of citizens who abstain from their right to vote, which is again within their political rights. Similarly, contrary to the conclusion of Felsen and Reiner that unqualified patient autonomy is unlikely (“quixotic” p. 10), and that “soft” paternalism might be the best option, autonomy and rights of patients need to be observed whether they are used or not.

Let's suppose that most physicians frame their advice of medical options according to what they consider to be best for the patient while informing the patients about their rights and that the majority of patients unquestioningly accept the physician's advice. This in no way reduces or justifies any reduction to autonomy or patient's rights since these patients have actually made an autonomous decision a) to trust a fellow human being, b) to assume, unless there is compelling evidence to the contrary, that the physician is offering an expert opinion in the best interest of the patient and not trying to manipulate patients for private ends, and c) to trust that the society, and the legal and medical system would protect their rights in case that a) and b) were mistakes. The fact that only a minority of patients is using some rights (e.g. insisting on a second opinion or refusing treatment) does not mean that their decisions are not autonomous.

But does not a naturalistic framework contradict the basis of these rights, namely free will? If free will is an illusion (Wegner 2002) shouldn't we reform the legal, political and medical system in a more utilitarian fashion (Greene & Cohen 2004) and abandon the language of rights entirely? It is important to emphasize again that the concept of autonomy is merely human self-determination and does not require full-fledged free will or any other metaphysical basis.⁴³ Apart from capacities to form long term intentions and plans and rationality that Reiner and Felsen discuss at greater length (2011, pp. 4-8), autonomy presupposes having the capacity of self-control or self-regulation, not that these are exercised all the time. Self-control can be depleted and imperfect, but empirical research points toward the conclusion that it is undoubtedly present in most adults (Baumeister & al. 1998, Moller & al. 2006, Vohs & al. 2008)⁴⁴. However, bearing in mind that a great deal of human action

⁴³Again it must be stated that many moral philosophers have been entangling autonomy with metaphysical doctrines. My claim is merely that this is not necessary and that it creates misunderstanding. Uncaused causation or any other metaphysical entanglement is neither assumed nor necessary in autonomy and responsibility (moral or legal).

⁴⁴ Vohs & al. (2008, p. 884) equate self-control and self-regulation (which is the literal translation of word autonomy) and define it as “the self exerting control to override a prepotent response, with the assumption that replacing one response with another is done to attain goals and conform to standards”. Moller & al. 2006, in their self-determination theory make the distinction between self-control (which is ego-depleting) and self-regulation (which is not). I assume that further empirical research will resolve this debate, but regardless of the merits of their definitions, these studies make it clear that the political notion of autonomy has firm support in empirical literature.

actually conforms to social, environmental, and other external factors, autonomous action needs to be spelled out more clearly. I will define voluntary or autonomous action, to which responsibility can be ascribed, in the following way:

*An agent acts autonomously when she/he: a) endorses decisions and acts in accord with internal motivational states in the absence of coercion and compulsion, and b) identifies with them, and could as a reasonable and rational person continue to do so after a period of informed critical reflection.*⁴⁵

But isn't this opening of autonomy to external factors that could be endorsed hypocritical? Aren't laws and the legal system actually already paternalistic? Doesn't the state coerce individuals all the time for their own good?

Let us start with the more precise clarification of the role coercion and compulsion play in political autonomy. All adult human beings are assumed to be responsible for states of affairs their bodies have causally initiated - and those that they did not but could have in cases of negligence - unless it can be proven that they were coerced by an outside force or compelled by an inside force *they could not endorse and incorporate in their long-term rational life-plan* after a period of informed critical reflection. Since self-control can be depleted and comes in degrees, the question of justification of intervention by society needs to be somehow qualified. For example, we presuppose that competent adults can offer resistance based on reasons (e.g. health, greater benefits at a later time) to an offer of sweet food that would determine the behavior of say children or monkeys. Even if these reasons are formulated by someone else, they are endorsed and identified with by the agent. An ideal-typical distinction of degrees of coercion and compulsion that is plausible for our everyday moral, legal and political deliberation might help put things into perspective. If we consider *coercion* – three types of external influence could be distinguished⁴⁶:

⁴⁵Walter Glannon provides important criticism to the so called argument from illusion, and offers a similar yet distinct definition that he (unfortunately) links with the compatibilist argument for free will. See Glannon 2011 and 2007 respectively. Unlike Glannon, I claim that autonomy is a political and not metaphysical concept. The concept of reasonableness might also need to be specified here. I will use reasonable throughout the text as equivalent to appealing to reasons, such as standards, values and principles that can be accepted as relevant by people who are trying to find ways of cooperating with each other on mutually acceptable terms. Compare Rawls 2005, Lecture IX, and Daniels 2008, pp. 103-142.

⁴⁶Audi (2000, p.88) made a distinction between primary and secondary coercion. The first requires a particular action such as paying a tax, whereas the second either includes the first (by e.g. spending tax payments in a way an agent finds objectionable) or is conditional - it applies to circumstances a citizen might wish to avoid (e.g. deciding not to drive and so avoid being forced to go through the process of licensing). Gaus (2011, pp. 497-508) draws on Audi in his complicated analysis of increasing costs of coercion. However, both these accounts are lacking in not addressing the real issue, namely providing a distinction that would not put, say taxation and solitary confinement (that most reasonable persons intuitively judge differently) in exactly the same category.

1. Indirect coercion (e.g. social pressure, taxation) - influences through expected utility⁴⁷;
2. Direct coercion (e.g. robbery, legal ban) – sanctions for non-compliance⁴⁸; and
3. Total coercion (e.g. force feeding, straitjacket) – exertion of physical force.

Coercive intervention of the state is justified if it *protects and respects* the autonomy of citizens.⁴⁹ Hence, total coercion is the hardest to justify, but it *can* be admissible as a reaction of society. If an individual has performed total coercion on fellow citizens, constitutes a major threat to life of others, and/or if autonomy is utterly lost due to total compulsion (see below), the state interferes and the possibility of such interference is in accordance with political autonomy.⁵⁰ If an individual is totally coerced, physical force has been exerted to cause some behavior or the body of an individual is physically constrained. In such instances, autonomy is completely lacking and hence no responsibility can be imputed.

Direct coercion diminishes autonomy in a less profound manner. However, autonomous choice is not entirely absent in cases of direct coercion, although responsibility might well be. Individuals that threaten others with force are coercing directly, and the society is certainly justified in prohibiting such actions. Legal sanctions connected with such prohibitions are also a form of direct coercion, which is in accordance with political autonomy.⁵¹ As the state laws prohibit a great deal of actions which are not directly connected to curbing direct coercion by individuals, how can they be justified on this reading? The idea of political autonomy presupposes that all citizens could as reasonable and rational persons endorse laws enacted according to democratic procedure after a period of informed critical

⁴⁷ Norman Daniels treats this type as quasi-coercion. See Daniels 2008, pp. 191-217.

⁴⁸ Nozick (1969) defined coercion in terms of a successful threat. A great deal of literature on coercion actually follows Nozick in this regard, which actually leads to absurd conclusions. Namely, on this reading, if I was threatened by a robber, but I did not succumb, but rather used force to defend myself, no coercion was involved. For a good overview of the literature and counterintuitive results of many definitions of coercion see Anderson 2010.

⁴⁹ Laws and the legal system are thus not paternalistic if they are democratic: “(T)he democratic principle states that only those statutes may claim legitimacy that can meet with the assent (Zustimmung) of all citizens in a discursive process of legislation that in turn has been legally constituted.” Habermas 2004, p. 110. That is not to say that all laws are in fact legitimate. However, in a reasonably just democratic society most (or most important) laws are.

⁵⁰ The state is not paternalistic when it assumes that basic autonomy is an inalienable right, e.g. selling oneself to slavery or choosing heroin addiction is counter to autonomy.

⁵¹ Consider the following example: The state may threaten to imprison those who threaten with physical violence, which (it could be assumed) makes it unlikely both to threaten or force others and to retain one's liberty. The possibility of a stable system of social cooperation actually depends on the existence of such laws which prohibit arbitrary (threats of) violence to others. If such a regime is in fact valuable, then the threat to incarcerate violent offenders may both reduce people's liberty with respect to one sort of action (by making threatening with violence with remaining unincarcerated unlikely), while enhancing it with respect to others (by making it possible to act freely without constant fear of violence). This example is based on Anderson's (2011) analysis on the relation between stealing and property rights.

reflection. Such laws that are based on whims of the rulers or partial interests of the elite are not legitimate, and diminish autonomy. However, legitimate laws do not. Also, both citizens that obey legitimate laws due to genuine wish to uphold the law and those who are merely avoiding sanctions are acting autonomously on this reading of autonomy. It could be argued that citizens that merely avoid sanctions are not autonomous as their decision is not “authentic”. However, the basic notion of autonomy does not presuppose authenticity – reasons for (in)action based on any kind of values or principles would suffice.⁵²

Indirect coercion (that is not unfair) does not diminish autonomy (pace Gaus), at least not in healthy adults. If societies and collective actors offer incentives or disincentives for some actions (e.g. monetary awards or fines) the autonomous choice is intact, and so responsibility for actions can be imputed.⁵³ Society can regulate all sorts of actions in this way providing that there are good reasons for such regulation and that fairness is not undermined. For example, the state can regulate potentially unhealthy commodities that are appealing (by themselves or by clever marketing) by introducing disincentives (e.g. taxes) to offset this form of indirect coercion. The rationale is that indirect, direct and total coercion by individuals and corporate actors can justify similar coercive responses by the state.⁵⁴

All this is more or less uncontroversial. However, the notion of compulsion is more demanding of clarification. After all, how do we know if an individual is compelled? Subjective report alone could not be the answer as many individuals claim they were compelled in order to avoid responsibility. Furthermore, human beings are compelled to breathe, eat and reproduce and this does not reduce responsibility in any way.⁵⁵ What does

⁵² Henrik Walter (1999) has linked autonomy with authenticity, which in my view is a grave mistake. See the discussion in the Introduction, especially Chapter I.2.

⁵³ Rawls (2005, p. 472, n) briefly discussed two types of voluntariness: rational and reasonable voluntariness. On this view, incentives and disincentives are never compromising rational voluntariness, whereas they might compromise reasonable voluntariness if the system makes it economically rational to act unfairly. This is an important point, but due to reasons of space I will not pursue it to its fullest extent. It should suffice to say that indirect coercion that “levels the playing field” and increases available options is in accordance to autonomy, whereas indirect coercion that reduces options is not.

⁵⁴ This “degrees of coercion” approach better explains our intuitions – at least better than the “lesser evil principle” (Anderson (2011) shortly discusses this principle and related difficulties. To him I owe the examples in this footnote). Namely, one of the tests for diminishing responsibility through coercion that was proposed was limiting the responsibility of someone acting under coercion if she acts in a way that minimizes the total amount of harm. So, for instance, we might deny that a person is responsible for choosing to injure another to avoid being killed, but hold her responsible if she chooses to kill someone to avoid being injured herself. Though this reading of the lesser evil principle is intuitively plausible, it is not acceptable in non-coercive contexts. For instance, we do not permit one to snatch a spare kidney from one individual to save the life of another. The “degrees of coercion” approach does a better job of explaining our intuitions because it presupposes justification through commensurability of types of coercion. It could also be useful for defining excessive use of force by law enforcement officers.

⁵⁵ Nordenfelt (2007) uses the notion of compulsion in strictly negative sense in his analysis of psychopathologies. The concept used here is broader and incorporates both compulsions that are not at all negative (such as consuming oxygen) and those that disrupt rational life-plans (such as addiction to heroin). A further point has to be made here: Nordenfelt uses the notion of compulsion also to describe internal motivations

compulsion mean in the context of autonomy, then?

The notion of compulsion presupposes internal influences that are more or less unavoidable, and it undermines autonomy only to the extent that it is not and could not be endorsed and incorporated in to a long-term rational life-plan after a period of informed critical reflection. Again, three types of compulsion could be distinguished:

1. Mild compulsion (psychological dependence, reversible);
2. Severe compulsion (physiological dependence, reversible); and
3. Total compulsion (physiological dependence, irreversible).

Let's start with total compulsion. All human beings have a total compulsion to consume oxygen. However, no reasonable and rational person is lamenting this fact, and it is fully endorsed by most, if not all human beings. Indeed, it is rational to infer that anaerobic metabolism, even though it could be possible in theory, would require major trade-offs and limit autonomous choices and rational life-plans that individuals hold dear. Therefore, this particular compulsion does not diminish autonomy or responsibility in any way. The upshot of this argument is that responsibility *could* be lacking in situations in which an individual has reacted to oxygen deprivation. The important point here is that in the everyday functioning of individuals, the possibility of rational and reasonable endorsement makes all the difference. If addiction to a certain substance constitutes total compulsion – physiological dependence that is not reversible without total coercion by an outside force (a point I will discuss at length below) - and reasonable and rational persons could not incorporate this fact in to a long term rational life plan, then autonomy is lacking.

Severe compulsions can diminish autonomy and responsibility but only if they cannot be endorsed and incorporated into a long term rational life-plan. For instance, human beings have a severe compulsion to consume solid food, but this fact does not diminish autonomous choice. It could be possible to live on fluids – even intravenously, but most people do not find this option appealing. If addiction to a certain substance constitutes direct compulsion – physiological dependence that is in some cases reversible without coercion by an outside force, and in most cases reversible with certain types of direct coercion by an outside force - and reasonable and rational persons could not incorporate this fact in to a long term rational life-plan, then autonomy is diminished, and responsibility needs to be qualified.

Mild compulsion does not diminish autonomy and responsibility. For example, human beings have a mild compulsion to reproduce, but most can employ self-control in different

of coerced individuals. I believe this only creates confusion, and should be avoided.

ways to avoid reproduction if they so choose. Similarly, many substances cause mild compulsion - psychological dependence that is in many cases reversible without coercion by an outside force, and in most if not all cases reversible with certain types of indirect and direct coercion by an outside force. Similarly to the case of coercion, the rationale is that mild, severe and total compulsion in certain cases can justify indirect, direct and total coercive responses by the state, without being paternalistic. In other words, total compulsion or total coercion could justify total coercion by society only if other means of deterrence have been exhausted. For instance, temporary solitary confinement might be justified in cases in which an individual has committed murder and is repeatedly trying to physically harm others.

The threat of severe compulsion and direct coercion could justify direct coercion by the state (with commensurable sanction). For instance, if a substance such as heroin is highly addictive and effectively precludes individuals from following and realizing a long term rational life plan, it might be legitimately prohibited and criminalized.⁵⁶ Finally, the threat of mild compulsion and indirect coercion could justify indirect coercion (again with commensurable incentives). For instance, if corporate actors use clever marketing strategies to increase sales of potentially unhealthy commodities, introduction of taxes and other economic disincentives is justified to offset the effects of indirect coercion without diminishing the autonomy of citizens.

This reading of autonomy obviously emphasizes the positive role of capacity for reasoning: formulating, revising and endorsing rational plans or intentions that extend into near and distant future. The capacity for reasoning presupposes “mental time travel” or capacity to think about past, present and future (Tulvin 2002)⁵⁷ and not merely understanding of available affordances (Gibson 1986), or reaction to external stimuli, and so distinguishes the type of beings autonomy can be ascribed to. For instance, dogs are not autonomous, whereas most human beings are. Also, autonomy assumes that an agent can practice self-control to inhibit reacting to certain affordances, if such a reaction would be unfair. For example, if a friend of mine drops her valet (without noticing) while walking in front of me in a deserted street, I as a rational creature immediately perceive an affordance to get some money with minimal effort and practically no cost for my reputation. However, as a reasonable creature I practice self-control to inhibit such impulses and inform my friend that

⁵⁶ Although heroin might seem a bad example for the types of addiction that will be discussed in the next chapter, it is fairly uncontroversial that it should be prohibited. One of the reasons for that is that there is no positional advantage in using heroin, whereas amphetamines could provide a competitive edge in the short term. Since I want this part of conceptual analysis to be as uncontroversial as possible the argument will be developed by using the “clear case” of heroin, in order to gain insights that could be used in the next chapter.

⁵⁷ This capacity is not only theoretically postulated, but also it has been empirically corroborated. See Nyberg & al. 2010

she has dropped her valet. Now, if I had ventro-medial prefrontal cortex damage that would effectively make it impossible for me to practice self-control, I might be excused even if I did keep the money, whereas if I had no such excuse I would be rightly scorned for my misdeed.

However, capacity for reasoning should not be conflated with the claim that conscious control is maintained all the time. Most decisions might well be made intuitively and/or with the aid of heuristics (Gigerenzer and Geissmaier 2011, Sunstein 2005). The long term rational life plans and intentions could actually be *automatically* (i.e. non-consciously) followed but if they *could* be endorsed after a period of informed critical reflection there is no reason to treat them as irrational or contrary to autonomy. Consider the example of religion. Most people do not question religious doctrines into which they have been indoctrinated. Nevertheless, these doctrines could be and are endorsed by rational and reasonable persons even after a period of informed critical reflection, although some people revise their commitments and change or completely abandon religious groups. This view is fairly established in political philosophy. For instance, Rawls (2005) defined voluntary (and thus autonomous) choice in terms of acceptance due to endorsed religion, which is “enough from the point of view of the political” (p. 472).

It could be objected here that this position is too vague and that it draws on an outdated model of addiction to make the case. First of all, the grades of diminishing and justificatory factors (coercion and compulsion) actually comprise a wide variety of different responses. Direct coercion of the state in the case of theft and murder is indeed different. Secondly, the “moral model of addiction” has been contested by neuroscientists and the “brain disease model” (Leshner 1997, Volkow and Li 2005) has gained considerable influence in neuroethics (See Carter and Hall 2012, Carter, Hall and Illes 2012).⁵⁸ If the political view of autonomy presupposes the moral model of addiction in the analysis of compulsion, it is suspect from the outset.

Let's start with the first objection. It is entirely correct that the types of coercion and compulsion presented actually contain a huge number of divergent cases, and that most cases actually do not conform obediently to neat categories. For instance, in some cases the sanctions of the state such as the possibility of a fine and of serving time are actually somewhere in the middle between indirect and direct coercion. However, these categories should be understood as ideal-typical, and as such they can be frugal as a starting point for a

⁵⁸ The brain disease model is at the core of Felsen's and Reiner's (2011) claim that autonomy has to be reconsidered in the context of addiction.

discussion about relevant aspects of the case at hand.

It could be further objected here that the position is still vague or too demanding, as according to these ideal-typical categories, the reactions of the state are currently illegitimate in many important cases. Namely, alcohol and tobacco can cause addiction that has severe physiological effects and could be quite a challenge for a person to deal with (Volkow and Li 2005). Indeed, most people addicted to say nicotine need substantial interference by outside factors in order to cure their condition and even if they are successful there is the danger of relapse. Thus, this could be classified as a severe compulsion, which would justify *direct* coercion of the state, similar to the policy on heroin, instead of the current policy of economic disincentives (indirect coercion). A cynic would even say that it shows how political philosophy only tries to legitimize deep seated interests of economic actors and political elites, or that it necessarily reflects morals of middle-class, middle-aged risk-averse white males. This serious extension of the first objection can only be answered together with the response to the second objection. Namely, models of addiction and legitimate policies need to be further qualified.

It has to be emphasized here that the post-metaphysical notion of autonomy presupposes neither the moral model nor the brain disease model of addiction. Both these models actually assume that autonomy is an all-or-nothing capacity, which is false. Some neuroethicists (e.g. Carter and Hall 2012, Levy 2012) have recognized this fact and have proposed the middle ground position in the context of addiction: an addict may be capable of choice and suffer from diminished autonomy at the same time. According to this position, autonomy comes in degrees and the elaboration of ideal-typical constraints serves the purpose of qualifying these degrees in the post-metaphysical notion of autonomy.

The possibility of rational and reasonable endorsement as criterion of autonomy also needs to be further elaborated in the context of addiction. To achieve this, I will further clarify the ideas of endorsable compulsion and “oscillation of preference”. Consider the example of Tommy McHugh⁵⁹: he was a heroin addict incarcerated for violent offenses, and his addiction has persisted until a cerebral hemorrhage altered his personality. After suffering damage to frontal and temporal lobes, he was effectively cured of his addiction but he developed a *compulsive* interest in painting, sculpting, and writing. Unlike his previous condition (addiction), he identifies with his current compulsions, and claims that “life is 100% better”. The idea of authenticity would lead us astray here if it was used as a criterion of evaluation in this case. Namely, there is no objective or inter-subjective criterion to determine if

⁵⁹Walter Glannon (2007, pp. 40-42) recapitulated the objective details of this case. Tommy McHugh's subjective narrative can be found on <http://www.tommymchugh.com/biography.html>

identification with a compulsion is authentic or not. However, the idea of a rational life-plan clarifies the difference in these two compulsions. Namely, addiction to heroin cannot be incorporated into a long-term rational life-plan whereas compulsive artistic interest can. One of the reasons for that is oscillation of preference (which will be explained shortly), but an additional important reason is that this addiction is so destructive and harmful, that the life of the individual in question is bound to be horrendous until the untimely end. It is important to add that rational life-plans are not a stand-alone category. For instance, while compulsively painting, sculpting and writing, Tommy McHugh is also meaningfully socially connected in various capacities. Therefore, compulsive artistic interest could be endorsed by a reasonable and rational person as it is not destructive for the person and acceptable under fair terms of social cooperation, whereas a compulsion to consume heroin could not.

In fact, heroin addicts as a result of seeking access to drugs often engage in risky, degrading and illegal activities, which is not acceptable as a rational life plan under fair terms of social cooperation. Also, they spend time and effort both in pursuit of their drugs and attempting to stop consuming the drugs. Levy (2012) calls such inconsistent behavior “oscillation of preference”. Heroin addicts oscillate between the preference to consume the drug and the preference to be free from the compulsion to use it because they are “ego depleted”. Namely, assessing rational options and inhibiting affordances and reflexive responses uses cognitive resources of self-control which could be depleted (Baumeister & al. 1998). Normally, these resources are sufficient so that healthy adult humans can plan their future actions reliably, without constant fear that they will impulsively do the opposite of the planned action.

Heroin addicts, on the other hand, cannot trust themselves sufficiently to realize long term intentions because their dopaminergic system has been “hi-jacked” (to use an expression from the brain disease model) by the substance of abuse. The effects of heroin on brain functioning are greater than those of common environmental rewards (e.g. food, sociability), and chronic heroin use produces changes in the higher cortical areas of the brain that impair the addicted individuals' self-control – the capacity to inhibit the desire to use heroin (Carter and Hall 2012). However, addicted individuals retain *some* degree of control over their drug use and *some* degree of autonomy (Carter and Hall 2012, Levy 2012). Namely, although they are severely compelled to take the drug, they are not compelled to say commit a robbery in order to get access to drugs.

The ideal typical scale could be useful in qualifying the extent of loss of autonomy and the exact action that is committed under diminished autonomy. Consider the example of

robbery: if someone is threatening a bank clerk with a weapon and demanding money, the bank clerk is certainly directly coerced. The bank clerk makes an autonomous decision that life is more worth than money and succumbs to the coercion. Responsibility might be lost, but autonomy is merely diminished, and that only if the bank clerk informed the authorities immediately after the direct coercion (i.e. threat of violence) is no longer present. This subsequent action clearly proves that the first action was not endorsed. The only cases in which autonomy is completely gone are total coercion and total compulsion. Therefore, both the moral model of addiction which claims that addicts are completely autonomous and the brain disease model that claims that addicts have no autonomy are false.

What does all this mean for the case of Tommy McHugh, or the case of tobacco regulation? First of all, Tommy McHugh's artistic compulsion is endorsable and stable. He is not suffering from oscillation of preference - in fact he can reliably plan for the future according to his long term intentions. The fact that he cannot change some of his intentions does not mean that they are not autonomous as long as he identifies with them. Similarly to this, consumption of nicotine could in fact cause severe compulsion, but unlike heroin, this compulsion (although certainly unhealthy) is not so destructive and harmful that the life of the individual in question is bound to be horrendous and short. It is important to note that addiction to nicotine does not entirely disrupt all other rational life-plans a person might have. For instance, while smoking, a person can also be meaningfully socially connected in various capacities.

It might be helpful to further unpack the argument about "endorsable compulsion" here. After all, it could be objected that arguing on the basis of autonomy to prohibit coercion of others is one thing, while using a similar argument to prohibit voluntary use of substances is quite another. Is not harm to self perfectly acceptable as long as others are not harmed in any way? And for the argument about social acceptability of heroin users, is not the stigma and coercion by society the cause of most of their suffering? It would be hypocritical to argue that heroin addicts cannot hold a job and be meaningfully connected with other people as a result of their addiction, when society scorns and marginalizes them and actively coerces them to the fringes of society and criminal activities.

Let's try to tackle this objection by reemphasizing the idea of autonomy as an inalienable right. Although certain amount of risky activities would certainly not be counter to autonomy (whereas it would be counter to autonomy to prohibit all risky activities), and smoking might be one of these, they can be dissociated from a class of "intrinsically debilitating activities" (Freeman 1999, p. 125). Selling oneself to slavery, or permanently

mutilitating one's cognitive and conative capacities can be legitimately prohibited as it can be reasonably assumed that such an option is un-endorsable after a period of critical reflection. Now a word of caution in order to fully appreciate even irrational voluntary choices, the prohibited act need not be the voluntary activity that is "intrinsically debilitating" – it could just as well be participating or providing means for another to commit an "intrinsically debilitating activity". A few examples might be helpful here. Let's say that reasonable and rational people would not endorse a system in which it was possible to sign a contract according to which debtors could be sold to slavery. However, let's say that an individual in really desperate financial circumstances does precisely that – approach an individual (or institution) and offer to sign such a contract for a sum of money. The society would only prohibit the enforcement of such a contract and punish the individual or institution that wanted to benefit from such a scheme (not the individual in desperate circumstances). Similarly, if an individual for whatever reason (extreme circumstances come to mind) does voluntarily and autonomously choose to consume heroin with full knowledge of its addictive properties and harmful physiological and social consequences, the society would be legitimate in punishing the producers and distributors of heroin, while heroin addicts might need to be treated and not punished.

To go back to the distinction between autonomy reducing properties of heroin and tobacco: since heroin addiction is un-endorsable, whereas nicotine addiction could be endorsable, direct coercion as a blanket response to nicotine use would be a failed and illegitimate social policy. In fact, since most people do not object to indirect coercion (i.e. civil regulation of safe manufacture, taxation and public use) of only potentially dangerous substances (Morse 2012), this type of response in the case of nicotine is legitimate and it does not undermine autonomy. The issue of effectiveness is distinct from the issue of legitimacy. For instance, economic incentives might be effective in treating addiction (Levy 2012), whereas certain types of direct coercion (e.g. the threat of incarceration) might be entirely ineffective. The analysis provided here has only skimmed the surface of the complex problem of addiction⁶⁰, but the goal was not to resolve this issue, but to offer a clarification of the political notion of autonomy for political philosophy and neuroethics, that would be used in the following chapters and would hopefully be useful in public discussions on public policy.

To sum up: empirical evidence does not prove that autonomy is "quixotic" (nor supports a shift toward paternalism). Priming, framing and anchoring effects merely offer

⁶⁰ For that matter, the even more complex problem of drug use and personal liberty (see De Greiff 1999) has not been dealt with at all.

insight into the social nature of humans and point to the conclusion that public and private autonomy are inseparable. Furthermore, the notion of autonomy has been mistakenly associated with the metaphysical concept of free will. Since scientific evidence is unlikely to resolve any *metaphysical* disputes, the pragmatic and political approach to autonomy - which I believe is implicitly shared by many lawyers and political theorists - needed to be spelled out. My aim in this Chapter was to make these implicit pragmatic assumptions of the legal and political system more explicit. Therefore, I have offered a political definition of autonomy: An agent acts autonomously when she/he: a) endorses decisions and acts in accord with internal motivational states in the absence of coercion and compulsion, and b) identifies with them, and could as a reasonable and rational person continue to do so after a period of informed critical reflection. To some, this notion of autonomy will be too restrictive or too thin. After all, free will and authenticity have been presupposed in so many works on autonomy. To this I can only answer that metaphysical discussions are important and indeed unavoidable for comprehensive doctrines citizens might endorse. Public policy and the legal system have to and can make do with notions that are political and not metaphysical.

In this Chapter I have clarified the ideal-typical degrees of coercion (indirect, direct and total) and compulsion (mild, severe and total) that serve the purpose of qualifying reduction of autonomy and responsibility in certain cases, and elaborating the middle ground position between the “moral” and “brain disease” model of addiction. This analysis, along with the insight from the previous Chapter will now be used in the case-by-case analysis of currently available CE technology.

3. PSYCHO-PHARMACOLOGICAL COGNITIVE ENHANCEMENTS

Having dealt with the conceptual and methodological questions, I can focus on medical drugs that can be used for enhancement of cognitive function by healthy adults. However, before starting the case-by-case analysis, several questions have to be answered:⁶¹

1. What are the relevant cases?
2. What are the relevant options?
3. What are the relevant external considerations for policy options?
4. What are the expectable future challenges that public policy might have to tackle with?

The Scenario 1 from the introduction, although being entirely fictional, gives a nice prelude to answering most of these questions.⁶² Recall that one of the disputed substances was a new class of drugs named Ampakines. So, to contribute to answering the first question, Ampakines need to be included or excluded in the case-by-case analysis. But, according to what criteria?

The most reasonable criterion is one of pragmatic possibility. Since Phase I and Phase II clinical trials have repeatedly proven that Ampakines at least in principle and on animal models might significantly improve cognitive performance, which would make them good candidates for analysis. However, only those substances for which there is sufficient data available could be analyzed, whereas those that have not yet finished all the phases of clinical trials should be excluded and relayed to future analysis.

⁶¹ In what follows, I draw on the arguments presented in Dubljevic 2014.

⁶² For the sake of the clarity of the argument, the scenario is repeated here - Scenario 1:

World news report: Tensions between Kazanistan and Vaziria reach the highest point ever – Kazanistan threatens with preemptive strikes on Ampakine-factories in Vaziria.

The dispute between Kazanistan and Vaziria may lead to an armed conflict. Both countries accuse each other of financial and military support to terrorist or insurgent groups. Vaziria warns that if Kazanistan continues to support groups of religious fundamentalist on Vaziri territory, there will be no option left but to prohibit religious practices in Vaziria. The Prime-minister of Kazanistan vows to put an end to Vaziri „illicit drug trade“ and „support to inhuman terrorists“. He has issued an ultimatum to Vaziria – either they will stop the production of Ampakines and cancel their asylum policy for enhancement seekers from Kazanistan, or Kazani army and intelligence will put a stop to it with preemptive and retaliation strikes. In the meantime, the Posthuman Liberation Army of Kazanistan has taken responsibility for the recent kidnapping of several prominent religious figures in Kazanistan, and unofficial reports state that both countries could potentially produce nuclear weapons.

The question of relevant options has not been introduced in Scenario 1 (whereas it has been partially answered in the analysis of requirement of justice), but one relevant aspect can be identified. Namely, cognition enhancement drugs (CED) have the potential of creating problems (not necessarily so drastic, but nevertheless serious) beyond boundaries of a single society, which points to the answer to the third question. Namely, societies do not implement public policies in vacuum, but are bound by various international conventions and treaties. The 1971 United Nation Convention on Psychotropic Drugs is just one example, because the regulatory framework for at least two relevant candidate drugs (Amphetamine and Methylphenidate) is explicitly laid out. This is the case precisely because such drugs could cause serious harms and even major international incidents.

The final question has to be answered, even though it is very easy to err with assessments of future problems. Some guidelines are nevertheless available. Recall that according to Rawls (2001), political philosophy has four important tasks: the practical task of clarifying and resolving conflicts, the task of orienting us and then reconciling us to our social and political world, and the task of probing the limits of practicable political possibility. Future challenges are those for which there are sufficient reasons to believe that they can cause conflicts, could substantially change our social and/or political world, and are within limits of practicable possibility. Ampakines are a perfect example of this: having proven effects on animal models, they are arguably within limits of practicable possibility. By virtue of significantly increasing cognitive function, which in the knowledge based economies of post-industrial societies is extremely important, they have the potential of both substantially changing the social (and perhaps political) world, and of creating conflicts within and between societies.

3. 1. Cognition Enhancement Drugs – general issues

Now, having given brief criteria for answering the questions, these should be applied and questions answered at least provisionally.

Ad 1. What are the relevant cases?

In the literature on CE drugs, a plethora of medications and substances is mentioned. Apart from new drugs targeting CREB, AMPA and NMDA receptors (Ampakines being the most widely known of these) medical drugs used as therapy for ADHD (e.g. Methylphenidate and Amphetamine), Narcolepsy (e.g. Modafinil), Alzheimers disease (e.g. Donepezil), and various natural preparations (e.g. Angioton-H) and herbal extracts (e.g. Khat) are analyzed. However, based on the criterion of pragmatic possibility, new drugs targeting CREB, AMPA and NMDA receptors have to be excluded from the case-by-case analysis, and relayed to Chapter 6. Also, natural or homeopathic preparations (e.g. Angioton-H)⁶³ that allegedly improve cognitive ability have to be entirely excluded due to lack of objective evidence of their efficacy. Herbal extracts will also be excluded due to lack of evidence pointing to their use actually being any problem.⁶⁴

Antidementia perhaps might be an issue in the future, but currently available drugs (such as Donepezil, Rivastigmin and Memantine) actually do not increase, but might even decrease cognitive function in healthy adults (Lieb 2010, p. 79). Therefore, the candidate CE drugs for the case-by-case analysis are reduced to Methylphenidate (e.g. Ritalin®), Amphetamine (e.g. Adderall®) and Modafinil (Provigil®).

Ad 2. What are the relevant options?

This question is harder to answer. Namely, relevant options are basically limited by the relevance of the social problem and by the efficacy of proposed solutions.⁶⁵ On the one hand, discussions on this topic have tended to focus on abstract theoretical positions while concrete

⁶³ Angioton-H, in some countries available as Vivoton-S is a homeopathic preparation that is available over the counter in certain pharmacies. Although practitioners of homeopathy claim that it increases cognitive function, there are no studies confirming any effects beyond placebo. The use of these preparations is discouraged in most countries with a ban on marketing and taxation measures which apply due to the need to protect citizens from fraud, while at the same time respecting their more metaphysical convictions.

⁶⁴ Iversen (2008) analyzes Khat, a plant traditionally chewed in the middle east, due to the chemical properties of the active substance (Cathinon), which is similar yet distinct from Amphetamine. Due to the fact that Khat consumption does not seem to be a social trend, for reasons of space herbal extracts in general will be excluded, while Khat in particular will be relayed to the “loose ends” section.

⁶⁵ An earlier version of the argument has been published as Dubljevic 2013b.

policy proposals and detailed models are scarce. On the other hand, many authors (eg. Gazzaniga 2005, Greely & al. 2008) have voiced opinions that regulation of CE drugs needs to be liberal and permissive, while others (e.g. Appel 2008, Capps 2011) have voiced concerns about the social pressure to enhance if the moderately liberal public policy that seems to be preferred (see Racine 2010, Ch. 6) is too permissive. There is no consensus in the literature on the particular approach or model of regulation that should be used, and in the analysis of requirements of justice (Chapter 2.2) the “gate-keeper” approach that has been assumed in many influential accounts (e.g. Glannon 2008, 2011; Lieb 2010, Merkel & al. 2007) has been criticized as paternalistic, illegitimate and un-transparent. One of the results of the analysis of requirements of justice was that an alternative taxation approach could be legitimate and effective, and that at least one model (the Economic Disincentives Model) could specify this liberal middle-ground position. However, the fears about social pressure and indirect coercion (that have been presupposed in the introduction with the truckers on Modafinil example)⁶⁶ are far from being proven.

There is some evidence that in certain parts of society that may well be the case (See Maher 2008). However, the relevant concern is whether CE drugs might have effects in many or all parts of society. However, apart from thought experiments, examples and very limited (almost anecdotal) empirical evidence there is little in a way of a sustained rationally constructed argument to make the case that CE drugs could cause enormous pressure to enhance. However, using the tools of rational choice theory in general and Rawls' “device of representation” - original position with the veil of ignorance - such an argument could be provided. The social pressure to enhance could be modeled as a multi-person prisoner’s dilemma. Within a Rawlsian framework, the rational choice modeling is set within the third and fourth stage of the original position. Namely, in Rawls' “Justice as Fairness” the argument for the two principles of justice occur at the first stage of the original position. At this stage the veil of ignorance is at its “thickest” , and apart from choosing the principles of justice, the

⁶⁶ For the sake of the clarity of the argument, the example is repeated here: Consider the example of logistics companies in a laissez-faire market economy. Let’s say that the most profitable trucking route is 1250 km long. The run could be achieved in one day, although with considerable stress and fatigue. Without enhancement drugs, companies offer the service of transportation with the duration of 2 days, with the price including accommodation for the truck driver. Let’s say that Company A decides to assume an employment policy that

is preferable to truck drivers that have no problem in using modafinil (the medical treatment for narcolepsy) to stay alert and make the run in just one day. The company offers the service for the same price, thus gaining extra profit, but for half the duration. Company B, the chief competitor of Company A, responds by offering the “overnight express” service and accordingly gives current employees the following choice: Either they will start using modafinil in order to cope with the requirements of the job, or they will be laid off.

The effects on the market are not hard to foresee. All other logistics companies would either adopt similar policies or go out of business. The truck drivers would either use drugs or be out of work. Their choice is dictated by market forces completely beyond their control.

parties also agree to very broad political consideration, such as the principle of just savings - to regulate how much one generation must save for future generations. Since the parties do not know which era the citizens they represent live in, it is rational for them to choose a savings principle that is fair to all generations. The issues of cognitive enhancement are too particular and concrete for this stage. After agreeing on the two principles and a principle of just savings, the parties then proceed further through the “four-stage sequence”, tailoring these general principles to the particular conditions of the society of the citizens they represent. The veil of ignorance that screens out information about society's general features is gradually thinned, and the parties use the new information to decide on progressively more determinate applications of the two principles.

At the second stage the parties are given more information about the society's political culture and economic development, and take on the task of crafting a constitution that realizes the two principles. Again, this stage is too abstract to be used for regulation of CE drugs. At the third stage the parties learn still more about the details of the society, and agree to specific laws and policies that realize the two principles within the constitutional framework decided at the second stage. This seems like the natural fit for the modeling of the case, but for the sake of the argument the entire sequence should be analyzed. At the final, fourth stage, the parties have full information about the society, and reason as judges and administrators to apply the previously-agreed laws and policies to particular cases. Since some laws concerning CE drugs could be seen as already existing, the modeling will analyze application of existing laws as well as policies that have not been used, but are merely conceptual.

Let's assume that parties in the original position are assessing available options before an important cognitively demanding test, which could influence the availability of certain options in the future. The veil of ignorance obscures much of the information, as it serves the purpose of modeling choices for a diverse class of rational agents in a competitive setting – from students to employees of a corporation. The options of each and every rational agent should be modeled as a game in which every participant is playing against all other competitors:

Display 3.1: A basic original position model on cognition enhancement drugs (CED)

	Others do not use CED	Most others use CED
Agent uses CED	Agent gains competitive advantage over others.	Agent gains no advantage, but at least suffers no disadvantage.
Agent refrains from using CED	Agent does not gain any advantage. She competes on equal footing with those that do not use CED. However, if resources are very scarce (she is competing for number one position), her chances are reduced if at least one competitor is using CED	Agent does not gain any advantage, and in fact suffers a disadvantage.

As can be seen from Display 3.1, the rational decision depends on the choices of others, and uncertainty about the use of others leads to using CED being the dominant (or most rational) choice under the circumstances. It should be noted here that this analysis (as opposed to the analysis in Chapter 2.1.) did not start with any substantive normative presuppositions. Taking CED has not been labeled as cheating nor preferable – the “original position” is at this stage neutral toward prior preferences. When prior preferences are introduced this analysis also explains the (controversial) finding of Maher (2008) that many people who would otherwise refuse to give CED to their children, would reluctantly do that if other children in the same school are using CED. The conclusion is that one CED user in a given competitive environment is enough to start the chain reaction. So far, the warnings about social pressure to enhance seem to be on the point. But what are the proposed solutions? What kinds of policies could somehow change this picture? Recall that the British Medical Association Discussion Paper (BMA 2007, pp. 33-35) proposes a range of regulatory options that branch out from the general prohibition, permissive regulation or a laissez-faire, free market types of policy. Let’s start with the analysis of these general types of policy.

Laissez-faire type of policy has some merits, but mainly it has drawbacks. Namely, although it is universal in reach (i.e. all citizens would have equal access) it is certainly not neutral – being the preferred option of the pro-enhancement group. Furthermore, it would obviously lead to the chain reaction (as can be seen in Display 1), so if the policy on CED is to be justifiable to both groups of citizens – those that want to enhance and those who would rather not - it would have to be something else.

A prohibition type of policy also has some merits, and great drawbacks. Again, it is universal in reach (i.e. ideally no one would have access), but it is not neutral – being the

preferred option of the anti-enhancement group. Furthermore, it is not clear that it would a) be effective i.e. really change the chain reaction picture, and b) that even if it could in principle be effective, that the costs associated would be worth taking. Consider first the current situation in Germany where nominally prohibition is in place: the possession and use of stimulants such as Methylphenidate (Ritalin®) without a prescription is a criminal offense which could be sanctioned by up to three years in prison (Lieb 2010, p. 100). Prescribing stimulants to healthy adults is also a criminal offense. And yet according to available data 33.4% of Methylphenidate (Ritalin®) is used off-label, while 12.6% is used without any diagnosis (DAK 2009)⁶⁷. Perhaps this ineffectiveness of prohibition could be offset with random testing procedures, since currently none are in place.

Let’s try to model this situation again, this time with a “fourth stage” original position. Let’s assume that most others do not use CED (as it is prohibited) and that there is a costly procedure of random testing for CED (similar to sports doping tests). The options should be modeled now as a game in which every agent is playing against the system:

Display 3.2: Original position on CED in a prohibitive environment

	There is no test	There is an appropriate test
Agent uses CED	Agent gains competitive advantage over others.	Agent gets caught. Depending on the sanctions she is either merely disadvantaged or severely limited in available options
Agent refrains from using CED	Agent doesn’t gain any advantage. She competes on equal footing with those that do not use CED. However, if resources are very scarce (she is competing for number one position), her chances are reduced if at least one competitor is using CED	Agent doesn’t gain any advantage. She competes on equal footing with others.

As it can be seen from Display 3.2, the rational decision depends on the chance of being caught and the severity of sanctions, which pushes the associated costs to ever higher limits. Namely, if tests could be circumvented in any way (e.g. by bringing other peoples

⁶⁷ This data, notwithstanding all the drawbacks of methodology, represents the prevalence in the general adult population in Germany. If studies that focus on population of University students in highly competitive environment in the US are taken into account, the numbers are much higher. According to the study conducted by De Santis & al. (2008) 34% of students reported using ADHD stimulants illegally. Most illegal users reported using ADHD stimulants primarily in periods of high academic stress and found them to reduce fatigue while increasing reading comprehension, interest, cognition, and memory. Furthermore, most had little information about the drug and found procurement to be both easy and stigma-free, i.e socially accepted.

clean urine samples) or if sanctions are not high enough, using CED would again be the dominant (or most rational) choice under the circumstances. Therefore, it would also most likely lead to the chain reaction of social pressure. Furthermore, the prohibition policy itself (and the rising costs associated with it) would have to be justifiable to both citizens that want to enhance and those who would rather not. At this stage the veil of ignorance is thinner, and agents are aware that there are two groups – one arguing for enhancement and the other arguing for prohibition of enhancements. However, they do not know to which group they belong. Given all this, the most rational decisions are either using enhancements or returning from the fourth stage to the third stage and analyzing other policies. Thus, it is unsurprising that many authors (e.g. Glannon 2008, Racine 2010) have concluded that a legitimate policy would have to be something else. But what other options are there?

In the permissive regulation category, the so called “gate-keeper” approach is the most prominent, since it has been assumed in many influential accounts in neuroethics (e.g. Glannon 2008, 2011, Racine 2011, Merkel & al. 2007). However, it is unclear whether such an approach would solve the problem of social pressure (or just create others) and whether it could be justified to both sides. Furthermore, the analysis of requirements of justice (Chapter III.) points to the conclusion that any model within the gate-keeper approach would be an illegitimate and inefficient policy, since it lacks transparency and economic incentives and disincentives for relevant actors. Let's try to test this claim by modeling the options in yet another original position. Let's say that the society roughly relies on health professionals to act as “gate-keepers” of CED subject to guidance from professional and regulatory bodies (compare BMA, 2007, p. 34). Agent's choice is constrained with the decision of a health professional:

Display 3.3: Original position on CED in a gate-keeper environment

	MDs of many other competitors do not prescribe CED	MDs of many other competitors prescribe CED
Agent’s MD prescribes CED	Agent gains competitive advantage over others.	Agent gains no advantage, but at least suffers no disadvantage
Agent’s MD refrains from prescribing CED	Agent doesn’t gain any advantage. She competes on equal footing with those that do not use CED. However, if resources are very scarce, her chances are reduced if at least one competitor is using CED	Agent doesn’t gain any advantage, and in fact suffers a disadvantage.

It is important to note here that the decision is made by the health professional, which reduces the autonomy of Agents whatever their preferences might be. On the one hand, if Agent's preferred personal choice is not to use CED, she does not consult her MD and is most likely disadvantaged. If Agent's preferred choice is to use CED she consults an MD. The MD makes the relevant decision: if this particular MD thinks that Agent's particular case is justified, CED will be prescribed, but if not, Agent has the option to go "doctor shopping", until she finds access to CED. Now, that could be circumvented by introducing a model with sterner regulation by the state or regulatory bodies. Perhaps Agents could be limited to only one second opinion. That might resolve the issue of widespread "doctor shopping", but then society is stuck with the issue of unfair access of already privileged members of society. Namely, under the sterner regulation model, MDs would be very careful not to overprescribe CED, while a certain amount of prescriptions would be expected and approved. But which members of society would have access to CED then? It is safe to assume that class differences might have some impact here, so the conclusion (from Chapter II.1.) that enhancements are more likely to increase or maintain social inequality seems to be on the point. Again, the most rational decisions are either using enhancements or returning from the fourth stage to the third stage and analyzing other policies.

Recall that one of the results of the analysis of requirements of justice was that an alternative taxation approach could be legitimate and effective, and that at least one model (the Economic Disincentives Model) could specify the liberal middle-ground position that would be acceptable to both citizens that wish to enhance and those who do not. However, it has not yet been demonstrated whether such an approach would solve the problem of social pressure (or just fill the budget) and whether it could pass the test of neutrality and be justified to both sides. Let's turn to the analysis of several possible models of a taxation approach type of policy and of the justificatory problem.

Discouraging use with taxation could have different forms. One possible form could be similar to tobacco regulation in say Norway.⁶⁸ The aim of government policy in Norway was to decrease an unhealthy habit which is in principle legal. From 1973, when about half the population was smoking, the percentage of use in 2010 has dropped to 19%, which is reasonably successful as policies go. This has been achieved with anti-smoking measures,

⁶⁸ In this and next paragraph I draw on information available at <http://www.euromonitor.com/tobacco-in-norway/report> Accessed on August 15th, 2012

such as heavy taxation and a ban on the visible display of tobacco products. This created a negative environment for both users and providers. These measures have been designed to create financial burdens and inconveniences for producers, providers and users. Not least, when the user finally manages to purchase the discouraged product, the package is adorned with graphic images depicting the potential health hazards associated with use. The rules and regulations in Norway appear to serve as an effective barrier and a legitimate policy of discouraging use (applied to smoking).

However, it is unclear whether such a model could be equally well suited to CED. Namely, the structure of the user population is certainly different, and so similar measures could provide different responses. Norwegians with higher levels of income and education tend to abstain from smoking or smoke less. Hard core smokers tend to start earlier, have a lower level of education, live in poorer regions of Norway and earn low incomes. The multiple-person prisoner's dilemma assumed choice related to competitive advantage, whereas tobacco use offers only health disadvantages. Therefore a similar policy that is effective in the case of tobacco use could be totally ineffective in the case of CED.

A second option could be to apply a model similar to regulation of so called "soft drugs" in the Netherlands.⁶⁹ Soft drugs such as cannabis and hallucinogenic mushrooms are legal for personal use. As a result the use of soft drugs (even in public) is not prosecuted. Sale of these drugs, although technically illegal under still valid Opium Act, is widely tolerated provided that it happens in a limited, controlled way. The legal control of sale regulates designated places (coffee shops), product (only soft drugs can be sold – not alcohol), quantity (5 grams maximum transaction), eligible users (only adults, but not limited to citizens), availability of information (no advertisement of drugs are allowed) and the political choice of local residents (the local municipality can give the order to close the coffee-shop).

Again, the original position assumed choice related to competitive advantage, whereas use of soft drugs offers only recreational benefits. Therefore, a similar policy that might be effective in this case could be totally ineffective in the case of CED. Furthermore, an additional problem of enhancement tourism might be created, with unknown complications.

A third model has been specifically designed for CE. Recall that BMA (2007) proposed a permissive system of regulation where techniques are permitted under license from a regulatory body – the Regulatory Authority for Cognitive Enhancements (RACE). This rather sketchy proposal suggests that RACE could approve use of particular CE techniques and issue guidance. From the few remarks there are on the model it could be assumed that it

⁶⁹ In this paragraph I draw on http://www.cannabisbureau.nl/en/doc/pdf/Dutch%20Opium_Act_30556.pdf Accessed on August 15th, 2012

would create financial burdens and inconveniences for producers, providers and users. However, recall that even BMA envisions drawbacks of such a model: “the establishment of a statutory regulatory body is expensive, bureaucratic and involves considerable work and time from those regulated” (BMA 2007, p.34).

Recall that the economic disincentives model (EDM) explicitly tackles with the drawbacks of RACE, and seeks to limit the costs for society, while optimizing regulatory capacities and demands of justification.⁷⁰ Although EDM is designed specifically for CE (including drugs and devices), and thus it might avoid possible problems of tobacco and coffee-shop models of regulation, again it has not been demonstrated that it would solve the problem of social pressure (or just fill the budget) and whether it could be justified to both sides. Let's turn to the preliminary analysis of effectiveness of taxation approaches and the related justificatory problem.

A possible problem with taxation approaches is that they already presuppose a normative standpoint that might be prejudicial toward citizens wishing to enhance.⁷¹ Even if there might be health costs associated with the use of CED, as was the case with tobacco use, it is not self-evident that these would be legitimate policies. This point deserves a bit of elaboration. Modern democratic societies are characterized by a plurality of different worldviews, and important positions in political theory have tried to formulate an impartial standpoint that could adjudicate between conflicting claims of such worldviews. Rawls's “Justice as Fairness” (2001) and “political liberalism” (2005) are at the forefront of these attempts, and that is why the analysis of Rawls's principles of justice in the context of CE has been used to justify the general taxation approach and the economic disincentives model. However, these principles are far from being uncontroversial.⁷² The difference principle, for

⁷⁰ For the sake of clarity of the argument, the EDM will be shortly summarized here: Under EDM an already existing government agency (e.g. FDA or Ministry of Health) would offer a licensing procedure to pharmaceutical companies to market CE drugs for healthy adults. This way all citizens could have legal access to CE, but with the imposition of taxes, fees and requirements of additional insurance, it creates financial and regulatory burdens for their use.

EDM envisions an additional licensing procedure for users - in order to use CE citizens would have to pay fees for a course about known effects and side effects, and pass an exam as proof of knowledge. Furthermore, an additional medical insurance and obligatory annual medical tests need to be taken in order to obtain (and renew) a license to use CE. Also, the prices of CE drugs would be regulated – they would contain the standard costs of production and distribution, the profit margin would be limited and an additional tax would be imposed. The companies earning profits obtained from CE would be further taxed and obliged to invest extensively in orphan drugs. The funds gained by such policy should be invested in providing medical necessities for the least well-off and the remaining funds would be allocated to finance education. Additionally, the use of CE would be impermissible in certain competitive situations such as exams.

⁷¹ Recall that the normative judgment on use of CE being bad, but nevertheless permissible, rests on the analysis of requirements of justice, and recall that the first objection to the use of normative criterion of justice (Justice leads to reasonable disagreement as well) has not yet been fully refuted, and will have to be dealt with in Chapter 5.

⁷² Recall that Rawls's principles of justice state that: 1. Each person has an the same infeasible claim to a fully

example, has come under heavy attack from almost all major political theorists from the '70's onwards (e.g. Nozick 1974, Miller 1999). If the taxation approach is based on the difference principle (and in the discussion in Chapter 2. 2. it explicitly is), then the taxation approach could be suspect from the start. Furthermore, the original position has been used by other theorists to argue for utilitarian policies and principles. However, a legitimate and effective public policy on CE could at this stage be additionally justified by yet another original position, and merely by deducing policies from one theory of justice. Namely, if a rule or policy could be presented to citizens as rational *within their own evaluative framework*, then it is justified by neutral means and this further supports conclusions deduced from substantive principles or theories.

Let's assume that Agent 1 would not like to use CE as a personal preference, whereas Agent 2 would. Their choices can again be modeled as a game in which each agent is playing against all others:

Display 3.4: Original position on CED in a taxation environment

	Regulation (some sort of taxation approach) is in place so many others do not use CED	There is no regulation and most other use CED
Agent 1 (or 2) uses CED	She gains competitive advantage, but pays the costs for it (financial and health)	She gains no advantage, but pays the costs (financial and health related)
Agent 1 (or 2) refrains from using CED	She does not gain any advantage but she does not pay health costs and advantage of competitors is not significant as they pay financial and health costs	She does not gain any advantage, and in fact she is disadvantaged, but she does not pay any health costs

Now someone could object that regulation policy would be justified only from the point of view of Agent 1, who doesn't want to use CED anyway. But that is clearly not the case. It has been assumed that Agent 2 actually wants do use CED as a matter of personal preference. She has weighed advantages and health costs and she thinks the health costs are a

adequate scheme of equal basic rights and liberties, which scheme is compatible with the same scheme of liberties for all; (the equal liberty principle); and 2. Social and economic inequalities are to satisfy two conditions: first, they are to be attached to positions and offices open to all under conditions of fair equality of opportunity (the principle of fair equality of opportunity); and second, they are to be to the greatest benefit of the least advantaged members of society (the difference principle) Rawls 2001, pp. 42-43. Although these principles have had a great deal of impact in Bioethics (see e.g. Daniels 2008), there are dissenting voices on applicability of justice to bio-medical issues (e.g. Gert, Culver and Clouser 2006).

reasonable trade-off to achieve her goals. But notice (on Display 3.4) that in case there is no regulation, Agent 2 doesn't get the advantage (which is the reason she wants to use CED in the first place) but merely endures the costs. Clearly, regulation is rational and in the best interest of both Agent 1 and 2, and actually provides a framework in which both can follow their personal preferences.

The analysis has shown that CED could in fact create considerable social pressure, and that prohibition and laissez-faire types of policy would neither be effective nor justified. A moderately liberal public policy shows more promise, but not all approaches within this type of policy would be legitimate and effective. The "gate-keeper" approach and related models could not be justified whereas approach based on taxation with suitable models might be legitimate and effective. This finally answers the second question (What relevant policy options there are?)

Ad 3. What are the relevant external considerations for policy options?

Recall that societies do not implement public policies in vacuum, but are bound by various international conventions and treaties. Thus, the analysis needs to step back from the ideal conditions of the original position and assess existing international law – as non-ideal as it might be. The 1971 United Nation Convention on Psychotropic Drugs is the most important external consideration because it laid out the regulatory framework for CED that will be analyzed in the case-by case analysis (Amphetamine and Methylphenidate). Of course, no regulatory policy or framework for regulatory policy is unchangeable, and the 1971 UN Convention recognizes several ways for change.⁷³ However, changing or opting out from international treaties should not be advised lightly, so the policy proposals in the case-by-case analysis will have to take into account the associated "international costs".

Although, all four policies (Tobacco analogy, Coffee-shop model, RACE and EDM) might be justified based on the discussion of ideal conditions so far, not all of them would be legal and legitimate, i.e. in accordance with all requirements of the UN Convention of 1971. Article 3 does state that a preparation may be exempted from the current regulatory regime if it "is compounded in such a way that it presents no, or a negligible, risk of abuse and the

⁷³ According to Articles 29 and 30 of the Convention, every country has the right to denounce the convention entirely or to propose amendments. However, this is not the only way to propose regulatory change. Namely, Article 3 Paragraph 2 explicitly states: "If a preparation containing a psychotropic substance other than a substance in Schedule I is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem, the preparation may be exempted from certain of the measures of control provided in this Convention..."

substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem” (UN 1971, p. 4). This provision will be of great importance in the case-by-case analysis (at least in cases of Methylphenidate and Amphetamine). But if the liability to abuse, and public health and social problem criteria from are met, all previously reviewed taxation approaches could be more or less appropriate (indeed rational choice modeling was not sensitive to differences between these policy options). However, the Convention requires even if a preparation is exempted that the following measures are in place: a) licenses for manufacture (Article 8); b) statistical records of quantity, date, supplier and recipient (Article 11); c) prohibition of and restrictions of export and import (Article 13); d) inspection of manufacturers, distributors and users (Article 15); e) statistical reports of use, abuse and commerce for the UN (Article 16) and f) penal provisions for illicit manufacture and trafficking in the regulated substances (Article 22).

Although they might be legitimate as a policy of an individual state for substances and drugs not regulated by international treaties, both the Tobacco analogy and the Coffee-shop model do not conform to the requirements of the Convention. Therefore, they would require the state which chooses such a policy for Methylphenidate or Amphetamine to denounce the Convention (see Article 29) or to try to impose amendments, and both options have considerable drawbacks. The proposal for a Regulatory Authority for Cognitive Enhancements (RACE), even though it is sketchy, might be construed in accordance with the Convention, and the Economic Disincentives Model (EDM) envisions all the requirements from the Convention, and thus is the most legitimate.

Ad. 4. What are the expectable future challenges that public policy on CE drugs might have to tackle with?

The analysis so far has pointed to an important issue that must be taken into account. Although it is impossible to know which of the new drugs targeting CREB, AMPA and NMDA receptors will turn out to be effective on humans, the licensing procedure of the EDM will have to be properly specified to tackle future developments. Namely, if EDM is proposed as a public policy for enhancement use of an existing medical drug, it has to be sufficiently specified to account for new medical drugs appearing on the market, and the licensing procedure cannot be reserved to specific cases. It might be useful to emphasize again that cases should not be understood in the sense of single cases that casuistry uses, but as analysis

of relevant aspects of particular substances that will lead to public policies that should be applied to all citizens, and that should be test cases or models for future developments.

Bearing all this in mind, the EDM is further specified by the following requirement: only medical drugs that have been approved as a treatment in standard clinical trials, and are currently available in the market as prescription drugs and there are independent studies confirming their safety and efficacy on healthy adults, could be candidates for the licensing procedure for CED. The additional clinical trials would be financed by the company wishing to put the drug on the “over the counter” market, but controlled by the government agency. Furthermore, all negative results (i.e. studies pointing to a conclusion that the new drug is not more effective than placebo) would have to be internationally publicly available. Bearing these criteria in mind, neither Khat, nor any alternative remedies would be eligible candidates for EDM type of regulation.

Having answered (at least provisionally) these important general questions, the case-by-case analysis can proceed.

3.2. Empirical Model I: Methylphenidate (Ritalin ®)

Despite the fact that EDM is designed specifically for CED, and thus it might avoid possible problems of other models of regulation it is unclear whether such an approach would be appropriate given the effects Methylphenidate has on the Dopaminergic pathways in human Central Nervous System (CNS). Although many authors (e.g. Iversen 2008) assume that Methylphenidate is safer than Amphetamine, even Ritalin®⁷⁴ has been “accused” for creating all sorts of physiological and social harmful effects, from addiction to maintaining racial inequality by overmedicating and pacifying youth of minorities (see e.g. Breggin 2001, Fitzgerald 2009). Therefore, known facts about Methylphenidate have to be carefully analyzed, and harms and benefits have to be weighed before concrete policy options are proposed.

Methylphenidate, which is mostly known under the brand name Ritalin is currently used around the world as a medical treatment for Attention Deficit Hyperactivity Disorder (ADHD). However, the use of this drug has been spilling over to the population of healthy adults (students suffering from ADHD frequently share or sell it to their peers)⁷⁵ and it has been challenged even in the area of therapeutic use, due to increasing rates of prescription. The controversy surrounding Methylphenidate is fueled by the fact that it is (along with Amphetamine) currently on the list of controlled substances of law-enforcement agencies all over the world. In fact, the United Nations 1971 Convention on Psychotropic Substances explicitly lists Methylphenidate as a Schedule II drug (dangerous substance with known medical uses). However, many experts (e.g. Nutt & al. 2007) argue that different (medical and illicit) drugs have been classified in Schedules haphazardly, due to historical contingencies and that the real danger profile often does not correspond with the classification.

So which of these claims are true? What is Methylphenidate used for? Methylphenidate has been used from the 1940's onwards, first as a means of increasing blood pressure, and then for increasing endurance and decreasing hunger (Bigelow 2006, p. 807). From the 1960s onward it was used to treat ADHD (then named ADD), but there are some controversial find-

⁷⁴ Although Ritalin is the most famous, a variety of formulations and (generic) brand names exist. Among these, instant release (Ritalina, Rilatine, Attenta, Medikinet, Metadate, Methylin, Penid, Rubifen and Focalin), and extended release formulas (Equasym XL; Medikinet XL; Metadate CD; Ritalin LA; Rubifen SR, Ritalin-SR; Methylin ER; Metadate ER; methylphenidate SR, Concerta; Watson methylphenidate ER; and Teva-Methylphenidate ER-C) should be distinguished due to different abuse potential. An earlier version of this argument has been published as Dubljevic 2013c.

⁷⁵ See De Santis & al. 2009

ings about populations being treated. Namely, according to some reports, students from minority populations have been overprescribed, whereas their white peers have been underrepresented in the population of users. The most drastic example is a report from 1999 according to which 1.65% of students in one South African urban area were receiving Methylphenidate, but none of these children were white (Miller 2002, p. 292). Similar reports from Great Britain and the USA (about fewer prescriptions for white students) have given face validity to claims that Methylphenidate is a means of racist policies (see Fitzgerald 2009). However, there are other reports according to which in the US Asian-American students are virtually absent in statistics for Methylphenidate use whereas African American families use Ritalin at rates one-half to one-quarter of their white socioeconomic peers (Bigelow, 2006, p. 813). Racism could not explain these discrepancies, but cultural differences could.

On the one hand, the data on the amount of methylphenidate produced and prescribed merely points to the conclusion that physicians are actually prescribing the drug for a growing multitude of minor “non-conformist” behavioral patterns (and students of various cultural backgrounds fare differently in this respect). Obviously, this is a growing trend, along with the enhancement use. Namely, the Methylphenidate production quota increased almost tenfold from 1990 to 2000 (Merkel & al. 2007, p. 355). On the other hand, *enhancement* use of Methylphenidate is correlated with university students, researchers and medical personnel (Maher 2008) – basically individuals with a higher socio-economic status, so this kind of use can hardly be characterized as a sort of outside behavioral control. But perhaps the question has to be rephrased. Instead of asking what is it used for, perhaps the right question is: what is Methylphenidate?

Simply put, Methylphenidate in all of its various formulations is a stimulant that affects the dopamine (DA) and noradrenalin (NA) receptors in the CNS.⁷⁶ Methylphenidate is a DA and NA reuptake inhibitor which basically means that it amplifies spontaneously released DA and NA in the brain. This has the effect of increasing attention and concentration of individuals, especially those that have problems with learning, such as people suffering from Attention Deficit Hyperactivity Disorder (ADHD).

Since DA and NA are important for arousal, attention and vigilance, Methylphenidate can produce the effect of higher neural activation and a state of heightened concentration, along with decreasing the effects of fatigue.

Just how effective Methylphenidate is can be seen from the following table:

⁷⁶ In what follows I draw extensively on Iversen 2008. Unless otherwise noted, this is the source of data in this Chapter. I will try to keep the discussion as understandable as possible for a generally educated non-expert reader.

Table 3.1: Effectiveness of Methylphenidate in available randomized control trials (RCT) on healthy adults

Substance (Dosage)	Number of RTCs	Sleep deprivation	Number of participants	Age	Fatigue	Vigilance/Attention	Reaction Times	Subjective assessment
Methylph. (5-40 mg)	6	No	205	18-40	N.R.	+	(-)	0/(+)
Methylph. (5-40 mg)	1	Yes	20	20-31	N.R.	N.R.	N.R.	0/(+)

Legend: N.R. = No results available, 0 = no effect, (+) weak increase, (-) weak decrease, + moderate increase; - moderate decrease; ++ strong increase; -- strong decrease. Adapted from Lieb 2010, p. 69.

As can be seen from Table 3.1., Methylphenidate has a moderate increasing effect on cognitive capacities such as attention and concentration, and a slight decreasing effect on reaction times. This means that healthy adults could use Ritalin® (and other formulas of Methylphenidate) to be able to work longer and faster. That might have been good news apart from the fact that this drug has considerable side-effects.

Apart from dry mouth, nervousness, drowsiness, insomnia, and possible adverse effects during pregnancy, Methylphenidate could cause serious cardiovascular adverse events and addiction. The most immediate adverse effect is the increase in blood pressure, which could be dangerous to individuals that suffer from high blood pressure, and may even cause sudden death. Methylphenidate is dangerous if injected directly into the bloodstream, or inhaled. Namely, the standard, oral use (in moderate quantities) of Methylphenidate is more or less safe. The drug enters the body via the intestinal tract and is gradually released into the bloodstream (while a portion of the substance gets inactivated by the liver). The drug again gradually enters the brain from the bloodstream (across the so called blood-brain barrier), and produces the desired effect. However, if administered intravenously or inhaled, the drug is no longer released slowly and it can create rapid effects (the so-called rush), euphoric effects (so-called high) and psychiatric adverse events. Methylphenidate has general short-term side-effects similar to Amphetamine (due to chemical similarity), but other than that the danger profile of Methylphenidate differs considerably, as can be seen in Table 3.2:

Table 3.2: The harm profile of Methylphenidate and Amphetamines according to the Multi-Criteria Drug Harm Scale:

	Physical harm				Dependence				Social harm			
	mean	acute	chronic	Intra-venous	mean	pleasure	Psych. Depen.	Phys. Depen.	mean	Intox.	Social	Health costs
Heroin	2.78	2.8	2.5	3.0	3.0	3.0	3.0	3.0	2.54	1.6	3.0	3.0
Cocaine	2.33	2.0	2.0	3.0	2.39	3.0	2.8	1.3	2.17	1.8	2.5	2.3
Amphetamine	1.81	1.3	1.8	2.4	1.67	2.0	1.9	1.1	1.50	1.4	1.5	1.6
Tobacco	1.24	0.9	2.9	0	2.21	2.3	2.6	1.8	1.42	0.8	1.1	2.4
Cannabis	0.99	0.9	2.1	0	1.51	1.9	1.7	0.8	1.5	1.7	1.3	1.5
Methylphenidate	1.32	1.2	1.3	1.6	1.25	1.4	1.3	1.0	0.97	1.1	0.8	1.1

Adapted from Nutt & al. 2007

The data from Table 3.2 needs to be clarified, of course. First of all, the way the data has been generated has to be explained. Experts in psychiatry, pharmacology, and addiction rated drugs on three major dimensions of harm (physical health effects, potential for dependence, and social harms) using a four-point scale, with 0 being no risk, 1 some, 2 moderate and 3 extreme risk (Nutt & al. 2007). The numbers in the table represent mean values from multiple assessments. The potential for intravenous use as a part of Physical harm profile is relevant both primarily (for achieving higher effects of acute toxicity) and for secondary harms (e.g. spreading of blood-borne viruses). Of special interest for the discussion are also categories Physical and Psychological dependence: Physical dependence involves increasing tolerance (higher dosage is needed to produce the desired effect), intense craving and withdrawal reactions when the drug use is stopped. Psychological dependence is characterized by repeated use of drug, but without tolerance or physical symptoms. Some illicit drugs along with tobacco are included in this table, because they can provide benchmarks against which the harms of Methylphenidate (and Amphetamine) can be assessed. With the knowledge of risk assessment of various other substances and models of regulation, sufficiently like cases could be defined.

However, before further defining the case of Methylphenidate, a caveat is necessary. The pharmaceutical corporation Novartis (the producer of Ritalin) has been funding various “neutral” appeals to get Methylphenidate off the list of controlled substances, so all the data has to be critically examined in order to check for bias. To provide a telling example, in year 1995 a self help group named “Children and Adults with Attention Deficit Disorder” (CHADD) started lobbying the Drug Enforcement Agency (DEA) to reclassify Methylphenidate from Schedule II to Schedule III. The question of international treaties notwithstanding, during the background check of this initiative it has become known that Novartis (at that time

named Ciba-Geigy), the only producer of Ritalin, funded the activities of CHADD with 900 000 \$ (Iversen 2006, pp. 85-86). This has unsurprisingly spurred considerable controversy. The “Citizens Commission on Human Rights” has issued a campaign to “take a stand against Ritalin”.

However, the controversy and existing bias are not bad news only. Namely, as a result of these accusations and counterinitiatives by Novartis, many specific claims made by the “anti-Ritalin” lobby (e.g. Breggin 2001) have been empirically tested. Of course, the pharmaceutical industry has a vested interest in loosening of the regulation, so the danger profile should be carefully analyzed and studies confirmed by independent researchers before any change in current prohibitive policy is allowed. However, by most accounts, the short-term benefits and cost effectiveness of Methylphenidate is well established. Unlike Amphetamine, Methylphenidate poses only modest risks (Kociancic & al. 2004). In fact, if the danger profile of Methylphenidate from Table 2 (Physical harm mean 1.32, Dependence mean 1.25 and Social harm mean 0.97) is compared to that of benchmark substances - heroin (2.78, 3.0 and 2.54), cocaine (2.33, 2.19 and 2.37), tobacco (1.24, 2.21 and 1.42) and cannabis (0.99, 1.51 and 1.50) - it seems plausible to argue that this case is more like to cases of tobacco and cannabis, and less like cases of cocaine and heroin, and should be regulated accordingly.

However, there are other aspects that might weigh in favor of prohibition. Namely, the use of Methylphenidate by the healthy could be a “gateway” to use of other illicit drugs, such as cocaine and heroin. The basic idea is that since Methylphenidate stimulates the CNS and affects the Dopaminergic pathways, its use can “open the door” to the use of “harder” drugs and so makes their use more likely. Such arguments have historically been used to argue against legalization of cannabis, although this drug is less dangerous than tobacco. The statistical correlation between cannabis use and later use of heroin and cocaine was enough to establish this more remote danger for autonomy and public health. Regardless of the merits and demerits of the “gateway” argument, according to available empirical data there is no such correlation between Methylphenidate and “hard drugs” (see Barkley & al. 2003).⁷⁷

Also, unlike tobacco, Methylphenidate does not increase the risk of developing cancer in humans (see Walitza & al. 2007)⁷⁸, so it seems that some sort of regulatory model from the

⁷⁷ Of course, bearing in mind the vested interests of both pharmaceutical industry and anti-Ritalin lobbies, such conclusions should never be based on a single study. However, Merkel & al. (2007) report that most empirical studies have the finding that Methylphenidate treatment actually decreases the risk of developing substance abuse disorders (four of these are quoted), while others have found no correlation whatsoever (again, four studies are quoted, and among them Barkley & al. 2003). According to Merkel & al. (2007) only one study has found an increased risk, but the results of this study have not been replicated, so the claim that there is no correlation that would support a “gateway” drug argument is fairly uncontroversial.

⁷⁸ Actually, Miller (2002) reports that Methylphenidate is correlated with lower than normal incidence of cancer. Therefore, the claim that Methylphenidate does not increase the risk of developing cancer in humans is fairly

taxation approaches discussed above might be appropriate. Nevertheless, there is a difference in oral use and abuse of Methylphenidate. Although moderate use enhances cognitive function, chronic abusive use can lead to tolerance and psychological dependence with varying degrees of abnormal behavior. Although extremely unlikely, Mania and Psychosis can be caused if Methylphenidate is used intravenously or inhaled (indeed, the danger of intravenous use – 1.6 in Table 2, is the reason why Physical harm mean is above 1).

However, there is a difference between various formulas of Methylphenidate. Time release technology can effectively preclude non-oral use and danger of addiction (Lieb 2010, p. 96), so extended release formulas might have a different danger profile than instant release formulas. This assertion needs to be explained: the Physical harm mean in Table 2 is calculated by adding harm of acute use (overdose), chronic use, and possibility of intravenous use and dividing with 3. For instant release Methylphenidate the Physical harm mean is 1.32, since harm factors are 1.2, 1.3 and 1.6 respectively. These numbers reflect the fact that Methylphenidate can be extracted from Ritalin capsules and injected or inhaled in order to achieve euphoric effects. The Physical harm mean of tobacco is 1.24, even though acute and chronic factors are 0.9 and 2.9. The fact that intravenous use factor is 0 significantly decreases the danger profile. Now, if the same logic is used on Methylphenidate extended release formulas, the danger profile would be 1.2, 1.3 and 0, so the Physical harm mean is 0.83. Compared to tobacco (1.24) and cannabis (0.99), Methylphenidate extended release formulas are very safe. Hence, prohibition of use by healthy adults as a form of regulation perhaps might be justified in the case of standard, instant release formulas, but not in the case of formulas for which it could be proven that they cannot be abused.

But what kind of policy would be legitimate for these “safer” formulas of Methylphenidate? Recall that any public policy proposed should be in accordance with all requirements of the UN Convention of 1971. Article 3 does state that a preparation may be exempted from the current regulatory regime if it “is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem” (UN 1971, p. 4). Since extended release formulas of Methylphenidate (e.g. Ritalin-SR) apparently cannot be recovered by readily applicable means in a quantity liable to abuse, and the preparation in fact does not give rise to a public health and social problem, this could make a taxation approach appropriate. However, recall that the Convention requires even if a preparation is exempted that the following measures are

uncontroversial.

in place: a) licenses for manufacture (Article 8); b) statistical records of quantity, date, supplier and recipient (Article 11); c) prohibition of and restrictions of export and import (Article 13); d) inspection of manufacturers, distributors and users (Article 15); e) statistical reports of use, abuse and commerce for the UN (Article 16) and f) penal provisions for illicit manufacture and trafficking in the regulated substances (Article 22).

The Economic Disincentives Model (EDM) envisions all the requirements from the Convention, and thus a licensing procedure for marketing extended release formulas of Methylphenidate could be in principle permissible. However, this licensing procedure should entail the requirement of additional studies to confirm findings on safety and efficacy, and these should be funded by the Pharma industry, but controlled and monitored by a government agency. Furthermore, as an additional means of discouraging use, a ban on the visible display of Methylphenidate based products (including a ban on marketing campaigns in the media) should be introduced. Such policy would be efficient in several regards. Namely, EDM could contribute toward a decrease in off-label prescriptions of Methylphenidate. If there is a publicly recognized procedure for obtaining Methylphenidate, medical professionals would be less inclined to prescribe it if they are unsure that it is really needed. In addition, enhancement tourism would not be a problem. Namely, only individuals with the residence on the territory of the state implementing EDM would be eligible to the licensing procedure for individuals. Furthermore, individuals using Methylphenidate without prescription or license would have to pay an extensive fine.

The knowledge course and exam individuals are required to take in order to receive the license should incorporate all known effects and side effects, as well as detailed analysis of cases of sudden death and adverse cardiovascular events related to Methylphenidate. Since Methylphenidate could be dangerous to individuals that suffer from high blood pressure and perhaps could cause addiction (if a creative way of abusing even extended release formulas is found), based on results of required medical tests. The license should not be issued or renewed to individuals in risk groups and those whose hair samples show even minute traces of illicit drugs.

The policy could be revoked or reassessed if the data on longitudinal studies (using the data from obligatory medical tests) shows considerable long-term side effects that were previously undetected. In order to safeguard privacy, all personal data should be classified and the individuals requesting a Methylphenidate license should have the option of opting out from providing data for scientific purposes. However, data use should be the default option, and

consent to such uses should be treated as tacit (by virtue of applying for a license) as long as consent is not explicitly revoked.

It could be objected here that EDM as a policy on Methylphenidate would not resolve the problem of cheating. Namely, if Methylphenidate is legally available, it seems as if there is no justification to ban its use during exams, and if it is not banned users will have clear positional advantage, and the indirect coercion will persist. That does not have to be the case, however. The issue of banning could be addressed with an example - even though driving and drinking are separately perfectly legal activities, together they are prohibited (even though not criminalized). The state might have every right to ban the use of Methylphenidate for healthy adults during state administered exams. However, that might not be necessary. Namely, positive discrimination measures (e.g. decreasing the pass score for non-licensed individuals) might be as effective. Furthermore, society might also relay such concrete decisions to private actors (e.g. private universities) to have their own more or less stringent policies on the matter. Namely, the introduction of explicit norms could lower the occurrence or spreading of CE drug use. For example, it has been shown that honor codes of Universities have an impact on expected sanctions, prevalence rates, and a greater adherence to the academic integrity policy (McCabe and Trevino 1993; McCabe et al 2001; McCabe & al. 2002). Mentioning and discussing CE drug use in the honor codes of universities and professional associations could have similar effects on the frequency of methylphenidate use, if the institution in question endorses an anti-enhancement worldview.

3.3. Empirical Model II: Amphetamine (Adderall ®)

Could the same logic (and thus EDM) be applied to the regulation of use extended release formulas of Amphetamine⁷⁹ (e.g. Adderall XR) as well? Apparently not, because the 1971 UN Convention in the Resolution II warns that Amphetamines in all forms are particularly liable to abuse.

But why is that? What are the historical reasons for such serious international regulation of Amphetamine?

Amphetamine was discovered in 1880 in Germany, but did not receive much attention until 1927, when Gordon Alles noticed the effect it has on feeling of energy and fatigue.⁸⁰ The first medical use of Amphetamine was for asthma: Benzedrine, the earliest and most basic form of Amphetamine had a beneficial influence on the peripheral nervous system, especially in the respiratory system. In 1931, the pharmaceutical company Smith, Kline, and French introduced the Benzedrine inhaler for nasal congestion. However, first Benzedrine users reported trouble sleeping when they were on the drug, which led to further research into sleep reducing effects. In 1935, drug companies were marketing Amphetamines for the treatment of narcolepsy - a rare sleep disorder characterized by daytime tiredness and sudden attacks of sleep. Early use of amphetamines in young patients with ADHD (around 1937) produced surprising results - instead of making them jittery, Amphetamine calmed many of these children and noticeably improved their concentration and performance.

This, along with an article published in *Lancet* in 1936 about the ability of Amphetamine to increase intelligence scores, has marked the start of its use as enhancement in general and cognitive enhancement in particular. Apart from a massive increase in prescriptions, Am-

⁷⁹ Amphetamines are a very diverse class of drugs. On the one hand, some Amphetamines are medical drugs with legitimate health benefits and regulated purity (e.g. Adderall, Adderall XR, Dexedrine, DextroStat). On the other hand, some Amphetamines are illicit drugs known by their street names (e.g. speed) with shifting amounts of various substances (see EMCDDA 2010). To complicate matters further, some drugs are originally medical drugs acting as *precursors* of Amphetamine (i.e. the human body metabolizes the initial substance into amphetamine). Some of these are still used as appetite suppressants (Benzphetamine, Deprenyl, Dimethylamphetamine, Fampofazone, Fencamine, Furfenorex, Selegiline; see Freye 2009, p. 135). Yet other precursors of Amphetamine (such as Fenethylline/Captagon) have been used as safer versions of Amphetamine, but have gained popularity in the underground scene, and then moved entirely into illicit traffic (see EMCDDA-Europol 2011). Furthermore, many discussions include methamphetamine and other substances in the class of amphetamines (see e.g. Freye 2009), which decreases clarity. Namely, methamphetamine has different effects and greater toxicity than amphetamine, and is not used as a CED, but only for recreational purposes. Generally, the discussion will be limited to medical drugs, named jointly Medical Amphetamines, containing the active substance Amphetamine in the strict sense with regulated purity and used for enhancement purposes by healthy adults. An earlier version of the argument provided in this chapter has been published as Dubljevic 2013c.

⁸⁰ In this paragraph I draw on Bigelow 2006.

phatamine was seen as sufficiently safe to be sold over the counter to be used without medical supervision (Bell, Lucke and Hall 2012).

During World War II, soldiers on all sides of the conflict used Amphetamine to enhance attention and endurance, and immediately after the war many individuals had trouble functioning without the drug. The “post war epidemic” effect was most pronounced in Japan, where increasing numbers of the population started using Amphetamine until the government introduced restrictive measures in '50s. At the same time, in Europe and United States Amphetamine was regarded as a “wonder drug” – an instant cure for a range of disorders (e.g. depression) and unwanted physical effects (e.g. being overweight). Amphetamine was readily available until the advent of the '60s drug generation and the appearance of “speed freaks” – individuals that injected Amphetamine intravenously in order to get high. The massive increase in drug use at that time prompted governments throughout the world to pass new anti-drug laws and regulations (e.g. the Classified Substances Act was introduced in 1970 in the US), and to start working on international treaties such as the 1971 UN Convention. This drug problem was not limited to Amphetamine, of course, but the fact that 1 in 20 Americans had a prescription for Amphetamine while at least the same number used it without prescription is telling (see Bell, Lucke Hal 2012).

However, although it might seem that the “drug generation” caused a global overreaction toward Amphetamine, its abuse potential is not only a question of historical contingency, but of empirical fact. Amphetamine differs in the effect on the CNS from Methylphenidate because they not only inhibit reuptake of DA and NA, but also inhibit monoamine oxidase (MAO) enzymes, which are vital to inactivation and breakdown of monoaminergic neurotransmitters (such as DA and NA), and also *reverses* the DAT action. In fact, the mechanism of reuptake inhibition is achieved by blocking DAT from gradually transporting used neurotransmitters back inside the pre-synaptic neuron for re-use, whereas reversal of DAT action influences a further excretion of DA and NA. This means that Amphetamine is much more effective, since apart from prolonged presence of already available DA and NA in the synaptic cleft it causes additional release (in high quantity) of these neurotransmitters.

It will be recalled that DA and NA are important for arousal, attention and vigilance, and so Amphetamine (e.g. Adderall ®) can produce the effect of higher neural activation and a state of heightened concentration, along with decreasing the effects of fatigue.

Just how effective Amphetamine is can be seen from the following table:

Table 3.3: Effectiveness of (Methylphenidate and) Amphetamine in available randomized control trials (RCT) on healthy adults

Substance (Dosage)	Number of RTCs	Sleep deprivation	Number of participants	Age	Fatigue	Vigilance/Attention	Reaction Times	Subjective assessment
Methylph. (5-40 mg)	6	No	205	18-40	N.R.	+	(-)	0/(+)
Methylph. (5-40 mg)	1	Yes	20	20-31	N.R.	N.R.	N.R.	0/(+)
Amphet. (10-20 mg)	6	No	154	18-44	(-)	++	-	+
Amphet. (20 mg)	6	Yes	331	18-36	--	++	--	0

Legend: N.R. = No results available, 0 = no effect, (+) weak increase, (-) weak decrease, + moderate increase; - moderate decrease; ++ strong increase; -- strong decrease. Adapted from Lieb 2010, pp. 69 and 73.

As can be seen from Table 3.3., both Methylphenidate (which is included for comparison) and Amphetamine have an increasing effect on cognitive capacities such as attention and concentration. However, the effects of Amphetamine are much more pronounced. Furthermore, Amphetamine has a decreasing effect on reaction times in both situations of sleep deprivation and without sleep deprivation, and (unlike Methylphenidate) Amphetamine decreases the effects of fatigue. This means that healthy adults could use Adderall to be able to work longer and faster, not only compared to people not using any drugs, but even compared to Ritalin users. This was the more or less good news. Now for the bad news: apart from the fact that side-effects are more considerable, Amphetamine causes overestimation of ability, which can be dangerous in certain situations. The decrease of effects of fatigue and hunger, coupled with the effect of overestimation of ability can even lead to death due to extreme physical exertion. For example, the British athlete Tom Simpson died during the Tour de France in 1967, in large part because he did not feel exhausted due to effects of Amphetamine (see Iversen 2006, p. 96). Furthermore, some formulas of Amphetamine are carcinogenic. For example, the digestive system converts benzphetamine (Medical Amphetamine used as appetite suppressant) into methylbenzyl nitrosamine, a substance identified as causing cancer (Miller 2002, p. 57).

But that is just the physical side of adverse effects. Recall that Amphetamine inhibits monoamine oxidase (MAO) enzymes. This influence on MAO alone increases the danger profile of Amphetamine. Namely, MAO dysfunction is correlated with a number of psychiatric and neurological disorders, such as depression, schizophrenia, substance abuse and ADHD. Hence, Amphetamines can be very effective in helping individuals with too much

MAO, and thus too little DA (as in ADHD) but cause severe psychotic episodes in people with too little MAO, and thus too much DA for too long (as in schizophrenia).

Indeed, even with oral use of larger quantities, Amphetamine can cause aggression, impulsivity, manic behavior, self-injurious behavior and psychotic episodes (Iversen 2006). The self-injurious behavior related to Amphetamine use is usually “stereotypic self-mutilation” (e.g. banging one’s head against the wall or self-biting) and not major self-mutilation (e.g. eye enucleation). Clinically defined manic behavior is sometimes virtually undistinguishable from the effects of Amphetamine: elevated mood, increased speech and energy, decreased need for sleep, hyperactivity, “racing thoughts”, impaired self-control, reckless (daredevil) behavior without thoughts about possible risks, increased libido. Also, psychotic states that can be caused by chronic Amphetamine use are virtually indistinguishable from positive symptoms of schizophrenia. During these psychotic states the perception of reality is impaired and accompanied with paranoid delusions.

But how do these adverse effects come to pass? The fact that Amphetamine reverses DAT increases both the therapeutic effects and the danger of addiction. Namely, Methylphenidate is only able to extend the time naturally occurring DA and NA remain in the synaptic cleft, whereas Amphetamine causes additional excretion of DA and NA. NA increases arousal, but also increases blood pressure, so additional quantities might cause adverse cardio-vascular events in people with high blood-pressure. Heart trouble has been attributed to several years’ abuse of the drug, and some brain damage has been noted as well (see Miller 2002, p. 107).

But these are just bodily harms stemming from years of abuse – too much DA in a couple of weeks can literally “hi-jack” volitional capacities and impair cognitive capacities of an individual. If the amount of DA increases rapidly an intoxicating effect (rush) is achieved which impairs volitional capacities and might cause aggression. If the amount of DA is steadily high, it produces pleasurable euphoric effects which can impair cognitive capacities in the short term (by intoxication) and in the long run (by causing chronic conditions of alternating capacity and incapacity). If this effect is sustained for prolonged periods of time (a week or more), then it might even produce psychiatric adverse events which are comparable to positive symptoms of schizophrenia, as mentioned above. The so-called Amphetamine Psychosis is a state of heightened emotional arousal, with frightening visual, auditory and tactile hallucinations and paranoid delusions. Persons affected can be violent and dangerous to self and others.

A mere look at the number of diagnoses related to Amphetamine is telling:

Display 3.5. Diagnoses related to Amphetamine according to DSM – IV

Code	Term
304.40	Amphetamine Dependence
305.70	Amphetamine Abuse
292.89	Amphetamine Intoxication
292.0	Amphetamine Withdrawal
292.81	Amphetamine Intoxication Delirium
292. xx	Amphetamine-Induced Psychotic Disorder
	.11 With Delusions
	.12 With Hallucinations
292.84	Amphetamine-Induced Mood Disorder
292.89	Amphetamine-Induced Anxiety Disorder
292.89	Amphetamine-Induced Sexual Dysfunction
292.89	Amphetamine-Induced Sleep Disorder
292.9	Amphetamine-Related Disorder Not Otherwise Specified (NOS)

Source: Yudko & al. 2003, p. 79.

Amphetamines are often described as having a high abuse potential, being a danger of causing “extreme psychological dependence” and “severe social disability” (Bigelow 2006, p.234). How to judge the harm potential of Amphetamine? For the sake of clarity of the argument, Table 3.2. is displayed again.

Table 3.2: The harm profile of Methylphenidate and Amphetamines according to the Multi-Criteria Drug Harm Scale:

	Physical harm				Dependence				Social harm			
	mean	acute	chronic	Intra-venous	mean	pleasure	Psych. Depen.	Phys. Depen.	mean	Intox.	Social	Health costs
Heroin	2.78	2.8	2.5	3.0	3.0	3.0	3.0	3.0	2.54	1.6	3.0	3.0
Cocaine	2.33	2.0	2.0	3.0	2.39	3.0	2.8	1.3	2.17	1.8	2.5	2.3
Amphetamine	1.81	1.3	1.8	2.4	1.67	2.0	1.9	1.1	1.50	1.4	1.5	1.6
Tobacco	1.24	0.9	2.9	0	2.21	2.3	2.6	1.8	1.42	0.8	1.1	2.4
Cannabis	0.99	0.9	2.1	0	1.51	1.9	1.7	0.8	1.5	1.7	1.3	1.5
Methylphenidate	1.32	1.2	1.3	1.6	1.25	1.4	1.3	1.0	0.97	1.1	0.8	1.1

Adapted from Nutt & al. 2007

Quantitatively, if the danger profile of Amphetamine from Table 3.2 (Physical harm mean 1.81, Dependence mean 1.67 and Social harm mean 1.50)⁸¹ is compared to that of heroin (2.78, 3.0 and 2.54), cocaine (2.33, 2.19 and 2.37), tobacco (1.24, 2.21 and 1.42) and cannabis (0.99, 1.51 and 1.50), this case is somewhere between the case of tobacco which is regulated with taxation, and cases of cocaine and heroin which are legitimately prohibited.

⁸¹ A further point needs to be explained here. Based on data from Table 3.2 it could be assumed that Amphetamines are not really addictive. However, recall that the Physical dependence rating reflects the increasing tolerance (higher dosage is needed to produce the desired effect), intense craving and withdrawal reactions when the drug use is stopped. Amphetamines do not cause withdrawal reactions, but do cause intense craving and tolerance, so the rating is 1.1. However, the fact that it can be highly pleasurable (2.0) and cause psychological dependence (1.9) make the threat of addiction very real, especially if abused.

Although, unlike heroin, Amphetamine is not likely to cause death by overdose (Singleton & al. 2009), it is a “gateway” drug for harder substances. It is sometimes described as “poor man’s cocaine” and poses a significant social problem as the most abused drug in Europe (EMCDDA-Europol 2011).

Admittedly, Amphetamines could provide great benefits if used responsibly. Indeed, that is the reason the military uses Amphetamine to this day, especially in the Air Force (one of nicknames of Amphetamine is “co-pilot”). Empirical studies have shown that Amphetamine can allow satisfactory performance by airplane pilots on continuous simulator flight duty for 64 hours straight without sleep (Miller 2002, p. 108). However, this use is certainly not without danger. In one notable “friendly fire” incident US Air Force pilots have killed Canadian soldiers in Afghanistan while under influence of Dexedrine (Dextroamphetamine).⁸² Furthermore, the threat of irresponsible use and the fact that Amphetamines are overwhelmingly abused makes a prohibitive response more appropriate. When the principle of beneficence is weighed along with the principle of non-maleficence, it is clear that the dangers of Amphetamine use clearly outweigh benefits.

However, several objections could be leveled here. Firstly, isn’t prohibitive response of the state in case of enhancement discredited in general (Greely & al. 2008, Merkel & al. 2007).⁸³ It could be surmised that the principle of autonomy weighs in favor of a permissive approach, even with Amphetamine. Namely, isn’t prohibition of a substance based on self-harm extremely paternalistic? Secondly, has not rational choice modeling in original position (in Display 3.2.) proved that a prohibitive response would be only costly and totally ineffective? In order to answer these challenges, and establish effectiveness and legitimacy of such regulation, the specific regulatory environment of Amphetamine prohibition should be modeled using tools of rational choice and the original position with the veil of ignorance, and the notion of autonomy has to be shortly discussed afterwards.

Let’s assume that Agent is contemplating whether to use Amphetamine in order to gain competitive advantage, especially since Methylphenidate is already available to at least some competitors via EDM licensing procedure. Agent’s options should be modeled again as a game in which she is playing against the system:

⁸² See Bigelow 2006, p. 238.

⁸³ The current prohibitive response of the state even on the issue of illicit drugs such as heroin seems to be discredited - see e.g. Husak 2005, 2007; Duke and Gross 1993, De Greif 1999. However, for important dissenting opinions see e.g. Wilson 2007, De Marneffe 2005. It has to be emphasized that even the dissenters agree that the current prohibition regime is too harsh and costly, especially in cases of relatively harmless drugs (e.g. cannabis).

Display 3.6: Original position on Amphetamine in a Mixed EDM/Prohibitive Environment⁸⁴

	She has a license for Methylphenidate	She skips licensing and cheats the system
Agent uses illegally acquired Amphetamine	Agent gains competitive advantage over others in single or several occasions. However, on her next medical test Amphetamine is detected in her hair, her license is revoked and her examination record for that year is put to question.	Agent gains competitive advantage over others in single or several occasions. However, since examination authorities (and peers) are aware of visible side-effects, she is caught sooner or later.
Agent uses Methylphenidate	She gains slight competitive advantage, but pays the costs for it (financial and health)	She gains slight competitive advantage. Since authorities are aware of visible side-effects, she is caught sooner or later.

By the virtue that EDM is in place for Methylphenidate, prohibitive regulation of Amphetamine is much easier. Namely, random tests are not necessary, since licensed Methylphenidate users are already paying for annual medical tests in order to renew their license. Amphetamines can be tested for easily in sweat, blood, saliva and most importantly in hair, and testing for trace evidence of drug abuse in hair would be an important part of the annual test. Bearing all this in mind, the most rational decision is to use Methylphenidate legally, with a license, and to avoid connection with the underworld and products of questionable safety and social dangers (e.g. loss of reputation, revocation of degrees, etc.).

Having established effectiveness of prohibitive regulation in the case of Amphetamine, the notion of autonomy has to be shortly discussed in order to establish legitimacy. It will be recalled that in the discussion on autonomy (Chapter 2.3.) degrees of compulsion have been defined and addiction to a substance such as Amphetamine was deemed severe compulsion. However, endorsability was named as the crucial criterion, so the key question is could Amphetamine addiction be endorsable?

It will be recalled that autonomous actions could be analyzed in terms of normal choosers who act (1) voluntarily or intentionally (volitional component), (2) with sufficient information and understanding (cognitive component), and (3) without controlling influences that would determine actions (liberty component). These controlling influences can be external (coercion) or internal (compulsion). Hence, all adult human beings are assumed to be

⁸⁴ The fact that Methylphenidate is legally available via the EDM modulates the prohibitive environment for Amphetamine. I am grateful to Catrin Misselhorn for constructive criticism that helped me make this point more clear.

responsible for states of affairs their bodies have causally initiated - and those that they did not but could have in cases of negligence - unless it can be proven that they were coerced by an outside force or compelled by an inside force *they could not endorse and incorporate in their long-term rational life-plan* after a period of informed critical reflection. Namely, criminal laws could be viewed as coercing and internalized moral code could be seen as compelling individuals, however such influences arguably could be endorsed and incorporated in a long-term rational life-plan after a period of informed critical reflection. Although coercion is an important topic for the issue of autonomy, healthy adults using CED are usually not coerced, at least not directly. However, abuse of Amphetamine and addiction have very important consequences for cognitive, volitional and at least one aspect (compulsion) of the liberty component of autonomy, and might diminish responsibility that accompanies legitimate choices by individuals.⁸⁵

So far, the discussion has managed to provide an argument based on autonomy for a type of prohibition policy (prohibition of production and sale, but not of possession and use) in the case of “hard drugs” such as heroin. However, according to available data heroin might cause permanent impairment of volitional capacities (with cognitive capacities only temporarily impaired) while Amphetamines might impair volitional capacities only temporarily, and some forms of Amphetamine such as Adderall are actually sought after in order to enhance cognitive capacities. That might point toward the conclusion that some sort of a taxation based approach is the only justifiable option. Responsible use (oral, in moderate quantities) might be ethically permissible in any case, but the danger of abuse complicates the picture here. Namely, the danger profiles have shown that abuse (e.g. non-oral use) of both Methylphenidate and Amphetamine (and even oral use of the latter) can lead to a disturbance of a whole range of cognitive, affective, sensory and volitional capacities. Furthermore, apart from permanent impairment, chronic conditions of alternating capacity and incapacity if they are likely to produce harms to others (in this case psychosis and mania) could be a legitimate ground for certain forms of prohibition (see Feinberg 1986, p. 320 f.). Bearing all this in mind, it has to be concluded that the legitimate public policy on the enhancement use of Amphetamines by healthy adults (including extended release formulas such as Adderall XR) is prohibition of production and sale.

⁸⁵ Indeed, legal representatives of US Air Force pilots who have killed Canadian soldiers in a “friendly fire” incident while under influence of Dexedrine (Dextroamphetamine) argued that Amphetamine use has diminished autonomy and responsibility of their clients. See Bigelow 2006, p. 238.

3.4. Empirical model III: Modafinil (Provigil ®)

Modafinil (Provigil), has generated a lot of attention in the academia and the media because empirical evidence indicates that it can offer enhancement of cognitive function to healthy adults (Repantis & al. 2010).⁸⁶ This drug is especially interesting because it is dissimilar to other stimulants in several important respects. First, modafinil might offer “performance enhancement” as well as “performance maintenance”. Performance enhancement means that healthy adults could use this drug to achieve significantly better results, while performance maintenance means that normal levels of functioning could be maintained while effects of fatigue and sleep deprivation could be reduced. Second, unlike the cases of older stimulants - methylphenidate and amphetamine (see Chapters 3.2. and 3.3. above), modafinil is not mentioned in relevant international treaties, and so international framework for regulation is not in place. The regulation of modafinil seems to be arbitrary and haphazard as it differs significantly from country to country. Third important difference is that modafinil was designated as an “orphan drug” since the prevalence of narcolepsy – the condition for which it was first approved - is very low (Kasselheim & al. 2012). Thus the producers of modafinil have benefited from government incentives.⁸⁷ However, the off-label use has been on the rise, along with the profits – the global market share of modafinil is more than 700 million US\$ per year (Norman & Berger 2008). This could be due to increased public perception of enhancement effects, which the manufacturer has been allegedly advertizing illegally (Department of Justice 2008). Finally, there is not enough reliable data on exact mechanisms of action (Gerrard and Malcolm 2007, Kim 2012). Although potential for abuse seems to be low (Deroche-Gamonet & al. 2002; however see Volkow & al. 2009, Mohamed 2012), long term consequences of use by healthy adults are unknown.

Even though there are articles discussing promises and perils of modafinil (e.g. Cahill 2005, Tannenbaum 2012), there is no sustained discussion of physiological, social and regulatory aspects from a comparative neuroethical perspective. This article tries to address these issues in the hope of facilitating an informed discussion and legitimate public policy that would avoid falling into the trap of common extremes - hype and hope, and gloom and doom.

⁸⁶ An earlier version of the arguments provided in this chapter appears in Dubljevic 2014b.

⁸⁷ In the United States, three operative types of incentives for orphan drugs are: 1) government subsidies for clinical trials; 2) a tax credit of half of clinical research costs; and 3) a seven years of monopoly for marketing the drug.

Modafinil, which is mostly known under the brand name Provigil, is used around the world as a medical treatment for narcolepsy, disorders of breathing during sleep (sleep apnoea) and in the treatment of sleep disorders resulting from shift-work (Ballon and Feifel 2006). A recent review of available studies has shown that non-sleep deprived volunteers may also benefit the domains of working memory, visual recognition, planning performance and executive inhibitory control (see Repantis & al. 2010). The benefits of modafinil, along with its apparent lack of obvious toxic effects or abuse liability, seem to have led to considerable ‘off-label’ and enhancement use in the educational context (AMS 2008, but see RKI 2012), in addition to its use in military settings, most notably in the United States (Caldwell & al. 1999, Estrada & al. 2012). Furthermore, there appears to be mounting anecdotal evidence about increased use in the work context, especially in cognitively demanding jobs (e.g. Kolker 2013).

Modafinil first became controversial when the pharmaceutical corporation Cephalon (the holder of orphan drug monopoly on modafinil at the time) started promoting its use for non-FDA approved conditions, such as general “excessive sleepiness” (Cahill 2005). At first, Provigil was approved to treat narcolepsy, but the label was then expanded to include treatment of sleep apnea and shift work sleep disorder. From 2001 through 2006, Cephalon allegedly promoted Provigil as a non-stimulant drug for the treatment of sleepiness, tiredness, decreased activity, lack of energy and fatigue. In 2002, the FDA sent Cephalon a letter, warning the company to cease and desist promoting Provigil off-label. Cephalon apparently ignored this warning and continued to undertake its promotional practices via a variety of techniques, such as training its sales force to disregard and/or downplay restrictions of the FDA-approved label. The effectiveness of these promotional strategies can be seen in the steady rise of the number of patients filling prescriptions for on- and off-label uses of Provigil – not only has the percentage of off-label prescriptions reached 90% (Cahill 2005), but the trend of increase is mounting yearly in absolute numbers (Kasselheim & al. 2012). Be that as it may, the activities of Cephalon resulted in a lawsuit which was settled in 2008 for 425 million US\$ (Department of Justice 2008).

Bearing all this in mind, the potential for biased conclusions in the issue of modafinil regulation for healthy adults needs to be taken into account. Since the pharmaceutical industry obviously has a vested interest in loosening of the regulation, the dangers of enhancement use of modafinil by healthy adults should be carefully analyzed and studies confirmed by independent research teams before any sort of permissive public policy can be officially adopted. Nevertheless, according to available data, the short-term benefits and cost effectiveness of modafinil for treatment of narcolepsy are well established. Unlike older

stimulants like amphetamine, modafinil poses almost negligible short-term risks. Indeed, the empirical studies conducted on healthy adults for the military recommend replacement of amphetamine with modafinil, and its use in combat missions (See Caldwell & al. 1999, Estrada & al. 2012). Furthermore, the toxicity of modafinil is very low. This is evidenced by the fact that doses of up to 1400 mg per day have not produced significant detrimental effects in patients, and although blood pressure was found to be elevated in elderly persons receiving 1000 mg per day, these effects were not clinically significant (Estrada 2012). Moreover, the risk of mortality associated with modafinil overdose seems to be close to zero as suggested by the report by Bastuji and Jouvet (1988). Namely, a female hypersomniac who attempted suicide via the acute ingestion of 4500 mg modafinil (45 times the usual single dose) suffered only tachycardia and 24 hours of nervousness, nausea, and insomnia prior to a full recovery.

But what exactly does modafinil do? How does it relate to other stimulants?

It is useful to compare modafinil to methylphenidate and amphetamine in various respects - physiological, social, and legal - in order to gain an insight into an appropriate public policy regarding its use by the healthy.

Older stimulants like amphetamine (e.g. Adderall) and methylphenidate (e.g. Ritalin) have a clear mechanism of action. It is well known that they affect the dopamine (DA) and noradrenalin (NA) receptors in the central nervous system. Recall that Methylphenidate inhibits reuptake of DA and NA, while amphetamine also inhibits monoamine oxidase (MAO) enzymes, which are vital to inactivation and breakdown of monoaminergic neurotransmitters (such as DA and NA, but also serotonin and a whole range of trace amines), and also *reverses* the DA transporter action. Consequently, amphetamine is much more effective as a stimulant, since, apart from prolonged presence of already available DA and NA in the synaptic cleft, it causes additional release (in high quantity) of these neurotransmitters (Iversen 2008). This additional release can create rapid effects (the so-called rush), euphoric effects (so-called high) and psychiatric adverse events, and a decrease in mood and energy (the so-called crash) after the initial effects wear off (see Ranish, Garofoli and Dubljević, 2013).

Contrary to the relatively clear neurobiological picture of older stimulants, the exact molecular mechanism of modafinil's action is unclear and there are several possible explanations for its effects (AMS 2008). Modafinil is thought to alter the balance of major inhibitory (GABA) and excitatory (glutamate) neurotransmitters, leading to a cascade of neurophysiological events, including the release of both histamine and orexin (Ballon & Feifel 2006). Also, stimulation effects of modafinil may be related to its weak DA reuptake inhibition properties,

which means that it also amplifies spontaneously released DA and NA in the brain and this makes its danger profile similar to that of methylphenidate. Although modafinil acts as only a weak DA reuptake inhibitor, concentrations of the drug achieved after oral dosing are quite high and sufficient to have a substantial action on DA reuptake which might explain the rare occasions of psychosis and mania connected with its use (Mariani and Hart 2005, Kanal & al. 2012). Enhancement of extracellular serotonin levels and serotonin neurotransmission is another possible molecular mechanism of its action (Kanal & al. 2012). All in all, the mechanisms underlying modafinil's neuromodulatory effects are complex and somewhat different from older stimulant drugs such as methylphenidate and amphetamine, potentially incorporating extracellular and intracellular effects (Gerrard and Malcolm 2007). Furthermore, they seem to focus on hypothalamus-based wakefulness circuits rather than overall brain activation (Ballon & Feifel 2006).

Whatever the exact mechanism of action may be, since decrease in GABA, increase in glutamate and modulation of histamine and orexin are important for arousal, and even indirect action on DA and NA influences attention and vigilance, modafinil can produce the effect of higher neural activation and a state of heightened concentration, along with decreasing the effects of fatigue.

Just how effective modafinil is can be seen from the following table:

Table 3.4.: Effectiveness of modafinil in randomized control trials (RCT) on healthy adults

Substance /Dosage	Number of RTCs	Number of participants	Age	Fatigue	Vigilance/ Attention	Reaction Times	Memory	Subjective assessment
Modafinil 100-400 mg	6	218	19-67	0/-	+	--	0/+	0/+

Legend: 0 = no effect, + weak increase, - weak decrease, - - moderate decrease; Adapted from Franke and Lieb 2010, p. 854.

The wakefulness promoting properties of modafinil are different than those of traditional stimulants. Namely, subjects on modafinil have demonstrated the ability to stay awake for periods of up to 64 hours with little decline in their level of performance (Caldwell 1999, Cahill 2005, Estrada 2012). Estrada & al. (2012) have summed up the available data from military studies on healthy adults and report that three daily doses of 200 mg (given at 23:00, 03:00, and 07:00 during a 40-hour period of continuous wakefulness) maintained flight performance at rested levels and attenuated the effects of 40 hours of continuous wakefulness on fatigue, confusion, and physiological arousal. No adverse behavioral effects were noted; however, vertigo, nausea, and dizziness were reported as side effects by the majority of

subjects. Although amphetamine has similar effects on performance during prolonged periods of sleep deprivation, it causes “sleep rebound” – the need to “make up” for lost hours of sleep. Apparently, this occurs at a drastically lower level with modafinil (Lagarde 1995, Cahill 2005, Ballon and Feifel 2006). Moreover, unlike amphetamine, modafinil does not create rapid effects (“rush”), euphoric effects (“high”) or a subsequent decrease in mood and energy (“crash”).

This makes modafinil much less likely to cause addiction (Deroche-Gamonet & al. 2002, Cahill 2005); however addiction cannot be entirely excluded (Volkow & al. 2009, Mohamed 2012) even though no cases of modafinil addiction have been reported to date (Kim 2012), while psychiatric adverse events related to its use have been reported in a few cases (Mariani and Hart 2005, Kanal & al. 2012). Also, unlike methylphenidate and amphetamine, modafinil is much less likely to cause serious cardiovascular adverse events (Minzenberg and Carter 2008).

Apart from vertigo, nausea, and dizziness, insomnia, and lowering of effectiveness of hormonal contraceptives, modafinil can cause epidermic reactions, and negatively influence the immune system (Kim 2012). Indeed, the long term effects of modafinil are unknown, but the wakefulness promoting properties of modafinil may also be related to corticotrophin-releasing hormone (or “stress” hormone), and serum C-reactive protein level (which indicates the inflammation level of an individual) tends to be increased after a single dose of modafinil (Kim 2012). This all points to a conclusion that long-term consequences of modafinil use need to be somehow assessed and compared to the short term benefits.

Furthermore, physiological effects of long-term use and social effects of wide-spread use need to be taken into account before any conclusion on the cost-benefit ratio of enhancement use of modafinil is reached. Even though the exact impact of “performance augmentation” effects of modafinil might be unclear,⁸⁸ the “performance maintenance” effects alone could have drastic social impact, to which I turn now. A tentative conclusion of this Chapter can be that regulatory models which could provide the missing information on long term effects would be most normatively and empirically sound, even if their preliminary assumptions turn out to be incorrect in the long run.

In the literature on cognitive enhancement (CE) there are many authors warning about the problem of indirect coercion to enhance (e.g. Greely & al. 2008, Lieb 2010). There is

⁸⁸ It is an open question how the laboratory observations that modafinil might enable fully rested individuals to hold an average of seven digits (as opposed to the usual six) in short term memory relate to everyday performance or enhance performance in the workplace. See AMA, 2008, p. 159.

some evidence that in certain parts of society this problem may well be on the rise (see Maher 2008, De Santis & al.)⁸⁹. However, some authors are concerned that CE might have effects in many or all parts of society. Recall that George Khushf 2005, 2008), for example, thinks that the so called “second-stage” enhancements will have profound influence through the pressure to enhance in education, the military and the economy. Whether or not modafinil can be seen as a “second stage” enhancement (defined as offering radical increases that could not be studied and quantified) or not is an open question, but there is increasing evidence that modafinil is very likely to be widely used in education (De Santis & al. 2008, Lennard 2009, Mohamed & Sahakian 2012, Ragan & al. 2012), military (Caldwell 1999, Cahill 2005, Estrada 2012, Kim 2012) and business (Smith 2004, Kolker 2013).

There have been some recent attempts to give more substance to claims about social impact by offering examples from branches of the economy that are rarely linked with cognitive enhancement in the literature. Namely, in a seminal paper, Appel (2008) examined the pressure to enhance in complex jobs in order to explore the social aspects of CE drug use. Drawing on Appel, and I have offered the “truckers on modafinil” example that is supposed to illustrate the profound dangers of allowing corporate actors to pursue positional advantage without regulation even if CE might provide only “performance maintenance”.⁹⁰

Recall that the analysis using rational choice modeling and original position with the veil of ignorance confirmed these intuitive examples. Furthermore, anecdotal evidence (Smith 2004, Kolker 2013), as well as appearance of internet sites that offer modafinil without prescription⁹¹ and even video tutorials that teach people how to obtain them⁹² seems to

⁸⁹ According one study (De Santis & al. 2008), 34% of student participants admitted that they were using stimulants illegally. Most illegal users reported using stimulants primarily in periods of high academic stress and found them to reduce fatigue while increasing reading comprehension, interest, cognition, and memory. Furthermore, most had little information about the drugs they used and found procurement to be both easy and stigma-free.

⁹⁰ For reasons of clarity and convenience, the example is repeated here: Consider the example of logistics companies in a laissez-faire market economy. Let’s say that the most profitable trucking route is 1250 km long. The run could be achieved in one day, although with considerable stress and fatigue. Without enhancement drugs, companies offer the service of transportation with the duration of 2 days, with the price including accommodation for the truck-driver. Let’s say that company A decides to assume an employment policy that is preferable to truck-drivers that have no problem in using Modafinil (the medical treatment for narcolepsy) to stay alert and make the run in just one day. The company offers the service for the same price, thus gaining extra profit, but for half the duration. Company B, the chief competitor of Company A, responds by offering the “overnight express” service and accordingly gives current employees the following choice: either they will start using Modafinil in order to cope with the requirements of the job, or they will be laid off. The effects on the market are not hard to foresee. All other logistics companies would either adopt similar policies, or go out of business. The truck-drivers would either use drugs or be out of work. Their choice is dictated by market forces completely beyond their control. Thus, enhancement technologies could have profound influence on the everyday lives of most citizens, as the working day and deadline expectations will change according to the social pressure.

⁹¹ See e.g. <http://medikamenterezeptfrei.biz/modafinil-bestellen/> (Accessed on March 5th 2013).

⁹² See e.g. <http://www.youtube.com/watch?v=m6ECTzO7Ke4> (Accessed on March 5th 2013), and related content on youtube.

provide additional corroboration. Moreover, given the fact that there is some evidence that amphetamine was used extensively by truck-drivers in Australia for the same purpose (Sharwood & al. 2013), the “truckers on modafinil” example has face validity. Whatever the merits of these claims are, they seem to have attracted the attention of relevant policy makers. For example, the Science and Technology Options Assessment study for the European Parliament on human enhancement explicitly warns about “second-stage” enhancements and their potential to produce society-wide harms through indirect coercion (STOA 2009). More recently, the impact of CE technologies for the economy and working conditions in the United Kingdom (UK) has been addressed by the joint report of the Academy of Medical Sciences, the British Academy, the Royal Academy of Engineering and the Royal Society (AMA 2012).

However, the fact that a certain substance like modafinil is used, and indeed that there is social pressure to use it, does not mean *per se* that this is morally problematic. For example, coffee is used as a mild cognitive enhancer (at least in the performance maintenance sense of the term) and it is the second most commonly traded commodity in the world, surpassed only by crude oil (see Trade Commodities, 2011). It is even recommended to long-distance drivers as a “legal stimulant” to combat the effects of fatigue and increase road safety (Sharwood & al. 2013). There are considerable economic and social pressures to use coffee in different kinds of jobs, but this does not generate much controversy. However, caffeine appears suitable for sustaining alertness and combating effects of fatigue only in relatively short (i.e., up to 37-hour) rather than long (i.e., 64-hour) periods of continuous wakefulness, while modafinil is more potent and offers a substantially higher effect of performance maintenance.

Thus, it could be maintained that wakefulness promoting properties of modafinil might be very beneficial for the society at large – by alleviating effects of fatigue during work and even freeing up new time for leisure activities (see Tannenbaum 2012). Sleep deprivation causes difficulties in tasks that require vigilance and monitoring, decision making, awareness, fast reaction time, tracking ability and memory, and modafinil provides rapid relief in exactly these cases, and might even offer enhancement of these cognitive functions to fully rested healthy adults (Repantis & al. 2010). Furthermore, sleepiness is thought to be the cause of a huge number of otherwise avoidable traffic accidents that result in death and injury. For example, up to one in five accidents on major roads in UK is attributed to sleepiness, contributing significantly to the approximate 3000 road deaths recorded annually (HSE 2006). Moreover, fatigue, night work and/or shift-working arrangements have been cited as major contributory factors in numerous well-documented accidents and incidents including Three Mile Island in 1979, Bhopal in 1984, Challenger Space Shuttle in 1986, Chernobyl in 1986,

Clapham Junction in 1988 and Exxon Valdez in 1989 (HSE 2006, p. 10). Bearing all this in mind, modafinil could be seen as a “wonder drug” that will solve many problems that modern societies are facing. Indeed, modafinil may be helpful in many cases and alleviate the effects of fatigue and sleep deprivation for persons whose work is urgently needed and requires sustained periods of productive cognitive activity during the afternoon, night or weekend, outside standard daytime hours, extended work periods of 12 hours or more, rotating hours of work, overtime and/or standby “on call” duties.

However, if modafinil is not regulated appropriately, it might produce an overall increase in above mentioned forms of shift work which would certainly incur significant health related and social costs. Namely, stress, depression, and other types of socio-medical complications of shift work such as increased mortality (Knutson & al. 2004) and even second generation decrease in cognitive performance (Heymann & al. 2007) should be included in the cost-benefit analysis of modafinil and even in the conceptual analysis of its enhancement properties. Furthermore, the fact that modafinil use increases stress and decreases the effectiveness of the immune system by itself should warrant concerns. According to available data from the American Institute of Stress, seventy-five to ninety percent of physician visits are related to stress and the cost to the society has been estimated at \$200 billion to \$300 billion a year (Clark 1995). A drug that increases stress and at the same time causes an additional decrease in immunity implies a considerable rise in social and health related costs.

However, the link between modafinil and shift work in the drug label and social practice promises the most drastic effects. In the past, shift work was traditionally associated with industries where 24-hour operation was either *necessary*, as in the case of essential public services (e.g. hospitals, the police, etc.) or because the industry would otherwise be *unprofitable* (e.g. mining, etc.). However, there is an upward trend in the percentage of people employed in shift work, which reflects an adoption of shift work beyond the traditional sectors, in areas where shift work is highly *profitable* for employers (e.g. supermarkets, petrol stations, call centers, etc.). Although this trend can be seen as a result of overall changes in society, and might even be construed as supported by workers who are prepared to do shift work (HSE 2006), evening, night, weekend, and holiday work are typically not occurring by choice (Heymann & al. 2007). Furthermore, the social costs of shift work take their toll not only on individuals forced to do shift work, but on future generations as well. For example, parental evening and night work can have negative consequences for children and families. Parents who work non-standard shifts are more likely to have children who score poorly on math, vocabulary, and reading tests; who repeat a year; and who are suspended from school.

Families with adults who work the night and evening shifts report lower-quality home environments, and shift-working couples have higher divorce rates (Heymann & al. 2007).

The recent shift towards a 24-hour society and lack of employment options is literally robbing a huge number of people of any other choice, and modafinil can be instrumental in decreasing the employment range of an even greater number of people by “normalizing” an otherwise exceptional condition – work during night. Some statistical data might help put things into perspective: the number of shift workers in the UK has gradually increased in the last quartile of 20th century reaching a peak in 2000, when around 15% of the working population (approximately 3.8 million people), worked shifts “most of the time” (HSE 2006, p. 6). This phenomenon is by no means limited to one country or voluntary. The same percentage of people is working shifts in the US (Barger & al. 2009), and according to one report, over three-fifths of U.S. employees working nonstandard schedules do so because they “could not get another job,” because it is “mandated by the employer,” or because of “the nature of the work” (Heymann & al. 2007, p. 8). Only the third explanation captures the traditional areas of shift work, whereas the first two point toward the effects of economic forces beyond the control of affected individuals, as illustrated by the “truckers on modafinil” example. The potential to create social problems linked with a *laissez-faire* attitude is succinctly formulated in a relatively recent report on the comparative analysis of working times around the world:

In weakly regulated regimes, including those in industrialized countries such as Australia, the United Kingdom and the United States, some forms of flexible working time arrangements – even those that apparently provide a substantial degree of worker influence over their working hours – may not sufficiently protect workers who do not have the collective strength to realize their preferred hours. In the context of countries in which collective institutions are not well developed, and therefore in the vast majority of developing and transition economies, the relaxation of legislated standards on working hours in favor of flexibility, without parallel developments in collective bargaining, cannot help but raise concerns. (Lee & al. 2007, p. 152).

It seems that at least some thought experiments have additional empirical corroboration in the analysis of recent social trends in work, family and health. Rational choice analysis of pitfalls of *laissez-faire* approach to enhancement and available data on long term effects paint a clear picture: instead of helping to alleviate problems, modafinil may exacerbate the problems faced by the population at large. The availability of modafinil may offer a perfect excuse to employers to raise the stakes, increase expectations and basically overwork the unprotected population of the least advantaged. Since available empirical research (e.g. EFILWC 2009) shows that a steady increase in social problems can be expected as working hours increase (e.g. 60% of those working more than 48 hours a week declare that they have difficulties in balancing work and normal life), detrimental effects on the basic structure of society

and the prospects of future generations can be expected. Paradoxically, the short-term cognitive enhancer modafinil might lead to an overall long-term decrease of cognitive ability in disadvantaged populations in society.

Might not these problems be somehow solved? Isn't there some way for modafinil to be used responsibly (Greely & al. 2008) for the benefit of society? A tentative conclusion of this Chapter can be that modafinil could provide both great benefits and great threats of exploitation, depending on the legal framework and regulatory models in place.

The legal framework for the use of older stimulants like amphetamine and methylphenidate is clear and unified across the globe. Namely, the United Nations Convention on Psychotropic Substances (UN 1971) defines Schedules for potentially dangerous psychotropic substances and explicitly lists methylphenidate and amphetamine as Schedule II drugs (dangerous substance with known medical uses). All countries that have signed this Convention have been obligated to regulate them accordingly. Since modafinil didn't exist at the time the international legal framework was established, it is not mentioned in relevant international treaties. This has led to a situation in which every country basically arbitrarily decides whether to make modafinil a controlled substance or not, while the criteria for scheduling are all but transparent (see Nutt & al. 2007).

It could be argued that the gate-keeper model might be adequate in the case of modafinil, even if it was not adequate for other stimulants. Perhaps health professionals should bear all this in mind when making the decision whether or not to prescribe modafinil. After all, the American Neurological Academy has issued an influential set of guidelines which concluded that medical doctors have the right to decide whether to prescribe drugs as enhancement or not based on their expertise and good medical practice (Larriviere & al. 2009). However, recall that there is a fundamental problem with the "gate-keeper" approach. I have argued that medical doctors have the expertise to diagnose illnesses and prescribe therapy, whereas every citizen should have the right to decide for him or herself whether to use enhancements or not. Furthermore, the agency of persons whose personal desire is to enhance is undermined. The medical doctor makes the relevant decision and not the citizen: if he or she thinks that this person's particular case is justified, modafinil will be prescribed, but if not, two socially undesirable consequences can be produced. The first is reaching out to alternative channels of distribution, and the second is "doctor shopping".

Currently, stimulants (old and new) used for enhancement can be obtained illegally from individuals with a valid prescription or via online pharmacies that do not require

prescriptions. This opens up the possibility of uncontrolled and potentially unsafe products being used as enhancers. For example, if an online shop is set up by criminal elements (and if prescription is not required by the pharmacy, this is criminal behavior by itself), which do not have the means of providing modafinil, but have access to say amphetamine or methamphetamine, the enhancement seekers could find themselves addicted on illicit “hard drugs”. Namely, it could be assumed that individuals without prior knowledge of the effects of modafinil would not be able to distinguish it from older stimulants, and might assume that they are safe from the danger of addiction.

The second alternative is also not appealing. If enhancement seekers are faced with a refusal from a health professional, all they have to do is keep changing doctors until they find access to modafinil. Now, recall that the issue of doctor-shopping could be circumvented by introducing a model with sterner regulation by the state or regulatory bodies - enhancement seekers could be limited to only one second opinion. That might resolve the issue of widespread “doctor shopping”, but it should be remembered that the society would then be stuck with the issue of unfair access of already privileged members of society. Furthermore, the issues of paternalism and the accumulation of the power to distribute enhancements in the hands of health professionals make justification of this approach to all citizens very hard.

The discussion so far has identified the Economic Disincentives Model (EDM) as the most effective and legitimate solution for enhancement use of extended release forms of methylphenidate. Since the danger profile of modafinil seems to reflect that of methylphenidate, it is worth considering the implications of a similar approach. If EDM was applied to modafinil, an already existing government agency (e.g. FDA or Ministry of Health) would offer a licensing procedure to pharmaceutical companies to market modafinil for healthy adults. This way all citizens could legally purchase modafinil in pharmacies, but with the imposition of taxes, fees and requirements of additional insurance, it creates financial and regulatory burdens for its use.

Recall that EDM envisions an additional licensing procedure for users - in order to be able to purchase, possess and use small quantities of modafinil, citizens would have to pay fees for a course about known effects and side effects, and pass an exam as proof of knowledge. Furthermore, an additional medical insurance and obligatory annual medical tests would need to be taken in order to obtain (and renew) a license to use modafinil. It should be remembered that the statistical data thus generated would be used for monitoring of unwanted effects and long term consequences of its prolonged use, but that users would have the option to opt out from providing their data if they have concerns about privacy. Recall also that the

prices of modafinil would be regulated – they would contain the standard costs of production and distribution, the profit margin would be limited and an additional tax would be imposed. The model also envisions that the companies earning profits obtained from modafinil would be further taxed and obliged to invest extensively in orphan drugs. The funds gained by such policy would be invested in providing medical necessities for the least well-off and the remaining funds would be allocated to finance education. Bearing in mind the fact that producers of modafinil have benefited from incentives for orphan drugs, this might be a good way to repay the society for the investment society made in something that turned out to be a very profitable product. Also, the issue of long-term physiological effects of modafinil would be settled by data generated with the EDM, and the availability of modafinil to all, along with considerable regulatory burdens for enhancement seekers, should offset any concerns about fairness. Additionally, it will be recalled that organizations may introduce their own norms concerning modafinil use. For example the honor codes of universities should be explicit whether they encourage, discourage or merely tolerate modafinil use.

However, the discussion of social aspects of modafinil use has identified an additional problem that might be harder to solve with any approach, at least in some societies. Namely, by expanding the label of modafinil to include the shift work sleep disorder, the medical support to normalization of night and shift work has received FDA approval and social sanction in the US. An employee that has trouble coping with unreasonable demands from employers merely has to state the “nature of the work” and the prescription of modafinil would not even be off-label. On the one hand (and in the context of the “therapeutic” use of modafinil), physicians could be becoming unwitting tools of ever greater exploitation of employees in an ever widening circle of industries and could even be themselves subjected to increasing expectations of night and shift work (and arguably exploited).

On the other hand, the EDM explicitly dissociates enhancement use from therapeutic use of cognition enhancement drugs. The provisions of EDM were not meant to apply to therapeutic use of drugs. This means that the social pressure on people doing shift-work to use modafinil would make modafinil a drug of choice by employers, not employees, and that complications generated by confounding long term effects of modafinil and shift work would not be captured. Now this could be a minor issue in countries with firm regulation of work time, but in weakly regulated regimes, including Australia, the United Kingdom, the United States and most developing countries, modafinil might cause a considerable social problem. The social impact of modafinil might be greatest in the US due to extreme lack of employee

protection in the issues of paid leave, maximum length of work, night work and minimal provisions for a day of rest each week (see Heyman & al. 2007). Namely, unlike 137 countries that mandate paid annual leave and 121 countries that guarantee 2 weeks or more each year, the U.S. does not require employers to provide paid annual leave. Unlike 134 countries that have laws that fix the maximum length of the work week, the U.S. does not have a maximum length of the work week nor a limit on mandatory overtime per week. Even though only 28 countries have restrictions or prohibitions on night work, and 50 countries have government-mandated evening and night wage premiums, the U.S. neither restricts nor guarantees wage premiums for night work. Last but not least, unlike 126 countries that require employers to provide a mandatory day of rest each week, the U.S. does not guarantee workers this 24-hour break. Due to the specific social harms that could be caused by wide-spread use of modafinil and lack of employee protections, one option would be to consider revisiting and/or revoking the “night-shift worker syndrome” indication for modafinil. This has already been done by the European Medicines Agency (EMA). However, in the US such a move might be blocked by the pharmaceutical lobby and full consideration of the non-ideal conditions there would necessitate a thorough discussion that is well beyond the limits of this dissertation.

At the very least, modafinil should be explicitly taken into account in various “fatigue management” guides and policies and introduced in international treaties. The problem of employers pushing employees into drug use is not new. For example, the self-reported prevalence of amphetamine-like substance use in Australia among truck drivers has been reported to be between 19 and 32% (Sharwood & al. 2013) and this prompted policy makers to introduce measures and to encourage whistle-blowing among employees that feel coerced into taking illegal stimulants (see e.g. RTA 2008). With the imposition of random roadside drug testing (RTA 2008) the prevalence seems to have dropped to 3.9% (Sharwood & al. 2013). However, these costly regulatory measures, where present, only test for cannabis, alcohol, amphetamines, cocaine and opiates (MBRS 2012). Modafinil is neither tested for nor is it clear that targeting users would be the appropriate reaction of society, given that recent reports encourage use of “legal stimulants” in order to decrease safety hazards and costs (Sharwood & al. 2013), and that currently prescription for modafinil is easily obtainable both on and off-label. EDM, on the other hand could be a viable option for regulating modafinil at the level of society, while voluntary associations and organizations might introduce other measures, from banning the use as a requisite of membership, to defining the admissibility of use in honor odes and what if any internal sanctions might be associated with its use.

To sum up: the analysis of currently available data points to a conclusion that more reliable information on the neurophysiological mechanisms of action of modafinil is necessary. Even though the physiological profile of modafinil seems to be beneficial, if inadequately regulated, modafinil can incur additional social and health related costs.

Widespread use of Modafinil may decrease the range of employment options and increase pressure to perform shift work. Apart from inherent properties of increasing stress and decreasing immunity, this can lead to a plethora of indirect adverse health effects in the population, including increased risk of mortality and even a decrease in cognitive ability of future generations. Because modafinil could provide both great benefits and great threats of exploitation, depending on the legal framework, regulatory models which could provide the missing information on long term effects would be most normatively and empirically sound, even if their preliminary assumptions turn out to be incorrect in the long run.

The Economic Disincentives Model is a promising regulatory response which could generate the data needed for a more reliable assessment and funds to offset adverse health and social costs of modafinil use. However, in weakly regulated regimes with extreme lack of employee protection, the “night-shift worker syndrome” indication for modafinil might cause social problems which will be hard to track and solve. Although one solution could be to consider revisiting and/or revoking this indication of modafinil (as has been done by the European Medicines Agency), the arguments presented above cannot resolve this issue.

4. ELECTRO-MAGNETIC ENHANCEMENTS OF COGNITION

Having successfully conducted the case-by-case analysis of medical drugs that are most likely to be used for enhancement of cognitive function by healthy adults, medical devices have to be thoroughly analyzed as well. However, in order to avoid redundant issues in the case-by-case analysis, several questions have to be answered:⁹³

1. What are the relevant cases of CE devices?
2. What are the relevant options for regulating use of CE devices?
3. What are the relevant external considerations for policy on CE devices?
4. What are the expectable future challenges that public policy on CE devices might have to tackle with?

The Scenario 2 from the introduction, although it is obviously fictional, and even unlikely, gives a nice prelude to answering most of these questions.⁹⁴ Recall that the futuristic devices mentioned in the scenario are neuroprosthetics, brain stimulation devices and

⁹³ In what follows, I draw on Dubljevic 2014a

⁹⁴ For the sake of the clarity of the argument, the scenario is repeated here - Scenario 2:

Encrypted transmission from: The department of recruitment and neural resources, Hegemony marine core, Military post VK-72072

Dear sub-lieutenant Pauperson,

regarding your request No. 13-56 for release from active service and issuing a permit to re-enter civilian population, we regret to inform you that your request has been denied.

According to your service and health insurance contract, any and all enhancements that were installed in your body are the property of Hegemony armed forces.

Our records show that after you have been wounded during the peacekeeping intervention in Vaziria, you have had a replacement right arm with retractable blades and built in sub-machine gun, as well as a titanium skull replacement with ventromedial prefrontal cortex inhibitor and targeting computer, video/neural interface night-vision and infra-red vision. All these enhancements are class M devices that cannot be released to the civilian population or foreign powers.

You could only be released from service if and when you have paid for the removal of all the military enhancements, are fitted with civilian replacement enhancements and found gainful employment in a civilian or mercenary corporation.

We are happy to inform you that according to your last monthly medical and neuropsychiatric evaluation, your CNS is in above-average condition, so that you could accumulate sufficient funds for such replacements within 5 years, and gain promotion to the status of lieutenant if you volunteer for a mission behind enemy lines now.

With kind regards,

Richard Bolyar, MD, MBA

Department of recruitment and neural resources, Hegemony marine core, Military post VK-72072

TAG: Be the chosen one! Be superhuman! Join us now! Gain employment, health insurance and enhancement! -----end of transmission

computers directly linked with the brain. So, to answer the first question, these kind of devices need to be included or excluded in the case-by-case analysis. But, according to what criteria?

The first criterion is the ability to increase cognitive performance in the narrow sense (even in principle). The second criterion is realistic possibility of this increase to affect society at large. Additionally, this criterion might make it more clear what exactly needs to be regulated. These two should be sufficient to keep the discussion in the realm of science fact and steer clear of science fiction that serves no clear purpose.

The question of relevant options has been discussed in the conceptual analysis and the previous Chapter dealing with medical drugs. The five general approaches of mandatory use, encourage use, laissez faire, discourage use and prohibition are still relevant, but the danger profiles might differ radically, depending on the physiological effects of the device. Furthermore, the fact that some of the devices mentioned in the literature (e.g., Deep Brain Stimulation) might need to be implanted increases the salience of safety issues and social costs, which points to the third question. Namely, unlike drugs, which are easy to produce, smuggle and use, some of the CE devices require special conditions or training in order to be effectively used, which limits their “social penetration”.

The criteria for external considerations and future expectable challenges are not as obvious as in the case of CE drugs. There are no international treaties and the nature of the topic is so highly prone to utopian and dystopian thinking that it is very easy to err. However, history does provide some guidance, and neuroethics in general and the cognitive enhancement debate in particular could be enriched by revisiting the self-understanding of the social and political role neuroscientists and neuroethicists attributed to findings concerning neuro-modulatory devices.

In 1963 the neuroscientist Jose Delgado conducted and recorded his famous experiment with the charging bull. By eliciting electrical stimulation of the caudate nucleus with a “stimociever” - a radio controlled device implanted in the bull's brain, Delgado was able to stop the bull and turn the beast away from the red flag. Delgado subsequently published a book named *Physical control of the mind: Toward a psychocivilized society* (Delgado 1969). In chapter 20 of that book, Delgado explored ethical considerations pertaining to his work and argued that, on the one hand, this kind of research could benefit society by improving methods of *clinical practice* and *social regulation*, and on the other hand, the research itself should not be regulated whereas the subsequent (mis)use of the

technology might need to be.

This brief review of a development from the pre-history of neuroethics gives a nice overture to put the *political* neuroethics perspective more explicitly into focus. Namely, the interplay between “all things neuro” and the *socio-political system* is lacking recognition in current discussions on the nature, subject and definition of neuroethics. In the absence of regulatory framework and international treaties, the analysis of relevant CE devices hinges on a clear understanding of this interplay in neuroethics. In his influential book, Eric Racine (2010) identified three contemporary perspectives on neuroethics, which track implications of neuroscientific *research*, *neuro-technology* and brain-based *clinical practice* (neurology, neurosurgery and neuropsychiatry). The “Knowledge-Driven Perspective”, associated with the definition provided Adina Roskies (2002) divides neuroethics into two separate branches: the ethics of neuroscience and the neuroscience of ethics.⁹⁵ This perspective emphasizes research, be it neuroscientific or ethical/philosophical, and how different strands of research mutually inform and reinforce each other. The “Technology-Driven Perspective”, associated with the definition provided by Paul Root Wolpe (2004) posits that neuroethics is a “content field” defined by the *technologies* it examines rather than any type of knowledge or research. Of course, this perspective recognizes the relevance of social and policy issues, but limits this relevance to *regulation of technology*. Finally, the “Healthcare-Driven Perspective” associated with the definition provided by Racine and Illes (2008), insists that neuroethics is a sub-field within bioethics that focuses on the ethics of neuroscience research and the ethical issues that emerge in the translation of neuroscience research whose ultimate goal is to “improve patient care”.

However, in order to fully capture the problem at hand, a fourth, political perspective in neuroethics has to be explicitly recognized as well. Unlike these established perspectives which emphasize the impact of neuroscience, neurotechnology and “neuromedicine” (neurology, neurosurgery and neuropsychiatry) respectively⁹⁶, the political perspective in neuroethics focuses on the interplay between the behavioral and brain sciences and the socio-political system – this interplay includes social regulation, but also all other realistic elements of social and political *neurodiscourse*, such as potential social changes stemming from new practices elicited by the “neurorevolution” (Lynch and Larsen 2009). On the one hand, certain

⁹⁵The second branch should not be limited to *neuroscience* of ethics because relevant discussions in neuroethics frequently draw on findings from other fields of empirical moral psychology (e.g. cognitive science of ethics), so the proper name could be *behavioral and brain science of ethics*. Whichever name is ultimately favored, an important task for neuroethics is to identify and analyze the extent to which our concept of morality and moral theory are affected.

⁹⁶ These different views discussed should be considered as identifying certain legitimate areas of emphasis, not as faulty definitions of neuroethics.

forms of brain intervention obviously need to be regulated by the socio-political system, and on the other hand, behavioral and brain sciences can and should inform public policy in terms of realistic scientific, technological and medical developments but also in terms of effectiveness and feasibility of current forms of regulation.

Take the research on the effects of psychoactive drugs on the central nervous system as a case in point: not only does that translate to novel research (e.g. influence of serotonin on moral judgment – see Crockett & al. 2010) and therapeutic tools (see Racine 2010 for an overview), but it also informs the kind of policy that could tackle long standing social problems such as addiction and repeated criminal offenses (see e.g. Carter and Hall 2012, Carter, Hall and Illes 2012). One notable example in the latter context is use of economic incentives as a substitute for punitive measures (e.g., “money for clean urine”) – a policy approach that has met with some success in Australia. But not everything that neuroethics has to analyze in terms of social impact is positive. Recall that Delgado wrote “toward a psychocivilized society” in the sub-title of his book. Visions of drastic social changes abound and have a profound influence in certain positions in neuroethics. So, neuroethics needs to be critical and not ideological, and for this reason, its political dimension must not remain implicit, but rather needs to be stated explicitly.

Thus, a pressing issue is to define what if any roles the political perspective in neuroethics might have, and this will also provide guidance in the context of defining criteria for external considerations and future expectable challenges. Recall that Rawls defined the four roles of political philosophy as criteria for its success and failure. Since in this analysis I extend Rawls' philosophy to the issue of cognitive enhancement, and also emphasize the political aspect of neuroethics, a promising approach could be to define the roles of neuroethics as the more concrete examples of the roles of political philosophy in general. According to Rawls (2001), political philosophy has four important tasks: 1. the practical task of clarifying and resolving conflicts, 2. the task of orienting citizens and 3. reconciling citizens to the social and political world, and finally 4. the task of probing the limits of practicable political possibility.

The task of clarifying and resolving conflicts in political philosophy in general is linked with relevant comprehensive doctrines – religions and secular worldviews (e.g., marxism) which are irreconcilable and at the same time lay a claim on universal truth. In neuroethics, the situation is similar, but somewhat different: the first role could be defined as clarifying and resolving conflicts caused by advances in neuroscientific and neurotechnological interventions in the human brain and society. In this context, an important

issue for external considerations and expectable future challenges is identifying which comprehensive views are likely to be in conflict over CE devices. The analysis so far has identified the pro-enhancement and anti-enhancement group, and these could be linked with the postulated difference in the CE drugs discussion between the substantive cultural value systems of “Psychotropic Hedonism” and “Pharmacological Calvinism” (Klerman 1972). Similar value-orientations could be identified in the case of devices: namely, the substantive value orientation of posthumanists and transhumanists (e.g., Pepperell 2003) is oriented toward radical change of the human condition via experimentation on the human body and even liberation of marginalized groups by merging with machines (Haraway 1991), whereas humanists might be open to new individual experiences but not to experimenting on humans with mind affecting substances and devices (e.g., Glannon 2011) and dignitarians and naturalists (e.g., Kass. 2002) might be opposed to many more practices on the bases of “gut feelings”. It is important to note that this aspect has been recognized (at least implicitly) in discussions of policy. A report for the European Parliament (STOA 2009) envisions conflict as a result of a clash of ideologies that are already present, and notes that the causes of disagreement and conflict stem from irreconcilable worldviews themselves and not only from technological advances (fictional or otherwise). Accordingly, an important task for neuroethics is to differentiate between political aspects of any given “neuro-driven” conflict.

The second role of political philosophy is orienting citizens in the social and political world - defining social and political institutions and explaining how they came to be. Neuroethics again has a similar, but somewhat different task: given that it deals with specific issues relating to behavioral and brain sciences, neuroethics is not limited to political institutions, but defines the scope of impact the “neurorevolution” has had on culture and civilization (in the explication of this opposition I draw on the system-lifeworld distinction in Habermas 2004). It could be assumed that culture, which could be defined in terms of what we as human beings are (and thus would include e.g., religion, art, philosophy etc.), is necessarily opposed to civilization, which could be defined in terms of what we have (thus including technology and instrumental knowledge that can be used to manipulate natural phenomena and social relations). However, even though there certainly is a tension, which does not amount to outright opposition – neuroethics should identify and analyze negative and positive aspects of the ever widening increase in the systematic neuroscience-based influence on social relations and culture. Thus, neuroethics needs to provide an assessment of neuroscientific findings, and analyze whether they could result in changed social practices or novel technologies. This leads us to the other two roles.

The third role of political philosophy is reconciling citizens with their social and political world – explaining the good and right of social institutions. The extrapolated task of neuroethics is twofold. On the one hand, it is reconciling citizens with the reasonable neuroscientific interventions that actually empower, and increase their liberty in both self-expression (culture) and their day-to-day lives (civilization). On the other hand, it is guarding the citizens from unreasonable neuroscientific interventions that could endanger their rights and liberties. This leads to the final role: identifying a *realistic* utopia.

According to Rawls, the final role of political philosophy is probing the limits of practicable political possibility – identifying realistic targets for political change and improvement. Unlike utopian thinking in political philosophy, which posits unrealistic fictional “better” societies, “realistic utopian thinking” identifies concrete changes in laws, regulations and policies that could lead to improved society and social relations. The extrapolated task of neuroethics is again twofold. On the one hand, it needs to identify neuroscientific interventions and technologies that could realistically be expected to change society. On the other hand, it needs to identify realistic public policies that would make these changes for the better and not for the worse. Thus it could be summed up as “probing the limits of reasonable socio-technological possibility” - a realistic extrapolation of future neuroscientific and technological developments and reasoned evaluation and critique of their *social penetration*.

So at long last, the criteria for external considerations and future expected challenges are defined: external considerations encompass reasonableness of allowing public funding for certain neuroscientific interventions (e.g., invasive interventions serving no clear medical purpose could hardly be expected to be financed from public funds), reasonableness of allowing self-funded neuroscientific interventions (e.g., “cosmetic neurosurgery”), and reasonableness of offering products and services as safe and effective. Furthermore, within the case analysis the “political- neuroethical” task is to differentiate between political aspects of any “neuro-driven” conflicts as well as to provide an assessment of social penetration of neurostimulation technologies, and expectable changes in social practices.

4.1. Cognition Enhancement Devices – general issues

Now, having given brief criteria for answering the questions, these should be applied and questions answered at least provisionally.

Ad 1. What are the relevant cases?

In the literature on medical devices used for enhancement, a plethora of devices and techniques has been mentioned (see, e.g. STOA 2009). There has been a lot of speculation on what kinds of medical devices might offer cognitive enhancement (i.e., their effectiveness) and what kinds of ethical (see e.g., Gilbert 2013) and regulatory challenges (see e.g., McGee 2010) that might entail. There have also been some cautious proposals for regulation of various cognition enhancement devices (see Table 4.1.)

Table 4.1. Proposed regulation of cognition enhancement devices

Device	Risk	Efficacy	Policy
tDCS	moderate	possible	Need more research, licensed use
TMS	moderate	unknown	Need more research, prohibit at this time
DBS	high	unknown	Need more research, prohibit at this time
BCI	high	unknown	Need more research, prohibit at this time

Note: tDCS: transcranial direct current stimulation; TMS: transcranial magnetic stimulation; DBS: deep brain stimulation; BCI: brain computer interfaces. Adapted from Blank 2014

Such speculation has been rightly criticized because it starts from a premise that something might perhaps be possible in the future, and then proceeds to assess ethical challenges and solutions for only potential developments (see e.g., Nordmann 2007). Although there are tendencies to “pump-up” the effects in the discussions, in what follows I will carefully distinguish between what is currently not attained (and in the area of speculation) and what is currently available, if not wide-spread.

An example that could be seen as paradigmatic for such speculative “ethical scare” is the discussion on regulation of neuroimplants and other devices that could provide interface with computers (Maguire & McGee 1999, EGE 2005, Warwick 2008). Currently, non-invasive brain-computer interface devices (like the „thought translation device“) are very slow, require extensive training to use, and only offer a window to the world to people suffering from the locked-in syndrome (Birbaumer 2005), but can hardly improve cognition

of fully functioning healthy adults. Since faster devices don't exist (they are still at the level of hypothesis, or in the case of invasive devices at the level of animal models) and the challenges for creating them are considerable (see Heersmink 2013), they are unlikely to pose any urgent ethical problems for the society at large in the near future. They might entail challenges relating to research ethics, but due to reasons of space, that is not an issue that will be taken up here. That is not to say that this issue is not important for other types of investigations in neuroethics. Neuroethics should be able to provide criteria for policy makers and citizens to discriminate between technologies that produce ethical challenges within research itself from those that might entail subsequent (mis)use in the society at large. Thus, the "brain-computer interface" discussion is not dismissed entirely as critics would suggest (Nordmann 2007) – merely identified as being a proper topic of an investigation concerning research ethics issues in neuroethics, and not a topic for a discussion on a society-wide regulatory policy. Experimenting on human beings by implanting a computer chip functioning as an artificial hippocampus (Cohen 2013) might indeed become a pressing issue for ethically guided neuroscientific research. As such, a regulatory response might be warranted at the level of institutional review, but not at the level of state.

Similar holds for existing neuroimplants such as deep brain stimulation (DBS). Even though there have been reports of effects of DBS on enhanced cognition (e.g., Hamany & al. 2008), the excitement about possible enhancement uses ultimately rest on a misunderstanding of exact effects and limitations of the technique. Namely, an investigatory DBS study which was trying to treat obesity in a patient (by trying to dampen the feeling of hunger through stimulation of the fornix) actually reported a memory enhancement effect in the patient - and this incidental finding led to a subsequent phase 1 trial of DBS in Alzheimer's disease for the purposes of "enhancement" of cognition. However, the terms "cognitive enhancement" and "cognitive enhancers" have a long history and specific meaning in Alzheimer's research and in research on schizophrenia. In this literature, the term refers to possible therapeutic interventions to improve memory or cognitive function *in patients suffering considerable cognitive decline*. The fact that the term enhancement (without the added caveats) was used led to unspecific use and amalgamation of two very different uses, as the usual definition of cognitive enhancement in bioethics literature underscores its use in healthy individuals (see Racine and Dubljević In Press).

However, this is not to say that the technique should be ignored by neuroethics – only that it is beyond the scope of this particular investigation. DBS has garnered attention from ethics and to some extent regulatory circles. Several important ethical questions have been

raised with respect to the use and evolution of DBS in both neurological (approved uses) and in neuropsychiatric conditions (investigational uses). Thus again, a regulatory response might be warranted at the level of institutional review, but not at the level of state.

This leaves non-invasive brain stimulation technologies (Pascual-Leone & al. 2011): transcranial direct current stimulation (tDCS) and transcranial magnetic stimulation (TMS) as relevant cases for analysis. Namely, brain stimulation technologies are much more advanced in application than neuroimplants and brain-computer interfaces, and have a much greater potential for enhancement use in healthy adults than DBS. Transcranial magnetic stimulation (TMS) is frequently analyzed in the literature (e.g. STOA 2009) and apparently more than 60 academic articles report use of TMS to produce performance enhancements in perceptual discrimination, motor learning, visual search and task involving attention, memory and language in *healthy human subjects* (see Luber and Lisanby 2013).

Transcranial direct current stimulation (tDCS) has also gained prominence because of cognitive enhancement possibilities (Dockery & al. 2009), and this was also recently recognized by the media, which ensued in plenty of enthusiastic and uncritical coverage (e.g., Adee 2012). A recent special issue of the neuroscience journal *Neuroimage* has provided a multitude of review of studies confirming enhancement properties of tDCS in an extensive range of cognitive tasks on healthy adults (see Clark and Parasuraman 2013).

The fact that tDCS can be widespread - due to low costs and ease of production and use - has caused an upsurge in calls for more regulation concerning the emergent use and marketing practices regarding tDCS (Fitz & Reiner 2013, Anonymous 2013, Bikson & al. 2013, Maslen & al. 2013). Therefore, it needs to be taken seriously as an emerging and possibly problematic social phenomenon.

Ad 2. What are the relevant options?

This question is harder to answer. Namely, relevant options are basically limited by the relevance of the social problem and by the efficacy of proposed solutions. Furthermore, there are issues relating to the *types* of social penetration. The non-invasive brain stimulation technologies (Pascual-Leone & al. 2011), even though they are fairly established as investigatory tools in neuroscience, have very different profiles of social penetration – a fact that needs to constrain both ethical debates and any analysis of relevant regulatory option. As mentioned above, transcranial magnetic stimulation (TMS) is frequently analyzed in conjunction with medical drugs in the literature that deals with ethical and social issues of

enhancements (e.g., STOA 2009). However, the high costs and necessary technical knowledge (Simpson & al. 2009), make the issue of “wide-spread” use of TMS as a *product* for cognitive enhancement only hypothetical. However, the technique could have substantial social penetration as an off label therapeutic and enhancement *service*. Such differences need to be taken into account when discussing relevant options. Furthermore, in cases where different modalities of social penetration are possible, policy options need to seriously take all of them into account. This leads to the discussion of to the next question.

Ad 3. What are the relevant external considerations for policy options?

Media hype and misinformation are very important external considerations that need to be taken into account. Furthermore, lack of existing regulation to build upon is a serious problem for assessing the intended and unintended outcomes of regulation. For example, transcranial direct current stimulation (tDCS) has caused excitement in the lay public and academia as a “portable, painless, inexpensive and safe” (Cohen Kadosh & al. 2012) therapeutic and enhancement device. Not only does tDCS have the potential to become the tool for wide-spread cognitive enhancement, and create social and ethical challenges meriting social regulation, the media hype surrounding it and emergence of commercial applications (Anonymous 2013) make the issue urgent. Therefore, unlike the case with cognitive enhancement drugs where the regulatory environment was deemed inappropriate and inefficient in specific cases, there is almost no regulatory environment for cognitive enhancement devices. As this fact is currently exploited by producers, there might be no time for fine-tuning policy: a regulatory framework that could facilitate responsible use such as EDM or RACE needs to be established as soon as possible. After a policy framework is in place and the legal default (“everything is permissible unless regulated by law”) replaced with some sort of order, it can be superseded afterward with a more efficient and appropriate regulatory response. The key issue is to generate sufficient information about the challenges at hand. This leads to the discussion of the final general question.

Ad. 4. What are the expectable future challenges that public policy might have to tackle with?

Despite their potential benefits, non-invasive brain stimulation techniques do not escape important ethical and social challenges that are associated with all cognitive

enhancement techniques. In addition, their unique characteristics might cause additional ethical challenges. For example, unlike stimulant drugs, which follow a posology with predictable effects non-invasive brain stimulation be used repeatedly on different cortical locations and in various stimulation modalities. This is the common characteristic of both tDCS and TMS. Furthermore, unlike all other forms of cognitive enhancement, tDCS is a device that can be easily built at home from readily available component parts. The media hype surrounding tDCS as a “cool” do-it-yourself gadget, along with marketers targeting adolescents as a population likely use tDCS to enhance performance during gaming, create additional challenges that EDM (or other policies discussed so far) have not been designed to meet.

Namely, if EDM is proposed as a public policy for enhancement use of existing medical devices, it has to be sufficiently specified to account for new categories of “dual-use”. Namely, the categories of military and commercial use need to be specified with particular modalities. Modalities of the commercial use category: commercial product and commercial service need to be explicitly taken into account. Furthermore, additional restrictions on promotional activities might need to be considered. Finally, the category of alternative, non-commercial applications such as home-made devices might create additional challenges to policy.

Although it is impossible to know which form of cognitive enhancement devices will turn out to have the greatest social penetration (commercial or otherwise), the licensing procedure of the EDM (if it is deemed appropriate for the specific cases of non-invasive brain stimulation techniques) will have to be properly specified to tackle future developments.

Bearing all this in mind, the EDM is further improved by the following requirement: even if the licensing procedure is in place and healthy adults could use non-invasive brain stimulation for purposes of enhancement, anyone (licensed or unlicensed) providing TMS as a service or tDCS as a service or a product to minors, would be held liable for criminal negligence and prosecuted.

Having answered (at least provisionally) these important general questions, the case-by-case analysis of cognition enhancement devices can proceed.

4.2. Empirical model IV: Transcranial direct current stimulation (tDCS)

The history of transcranial direct current stimulation is long and complicated (see e.g., Fregni 2005). Technically speaking, early interventions involving electrical stimulation of the brain have always used direct current (DC), as opposed to alternating current (AC) which was introduced toward the end of 19th century. That is why even ancient therapeutic practices as bizarre as placing a live torpedo fish to the scalp to cure a headache could per definition be considered tDCS: they are transcranial (as opposed to intracranial), they used DC and not AC and the desired effect was stimulation of the brain. Thus the writings of Scribonius Largus, Pliny the Elder and Galen of Pergamum describing such cures for headache count as the pre-history of tDCS (see Priori 2003, Stagg and Nitsche 2011). Early therapeutic uses extended to other disorders include those described by Ibn-Sibdah, a 11th century physician, who suggested treating epilepsy with a live electric catfish (see Brunoni & al. 2011a).

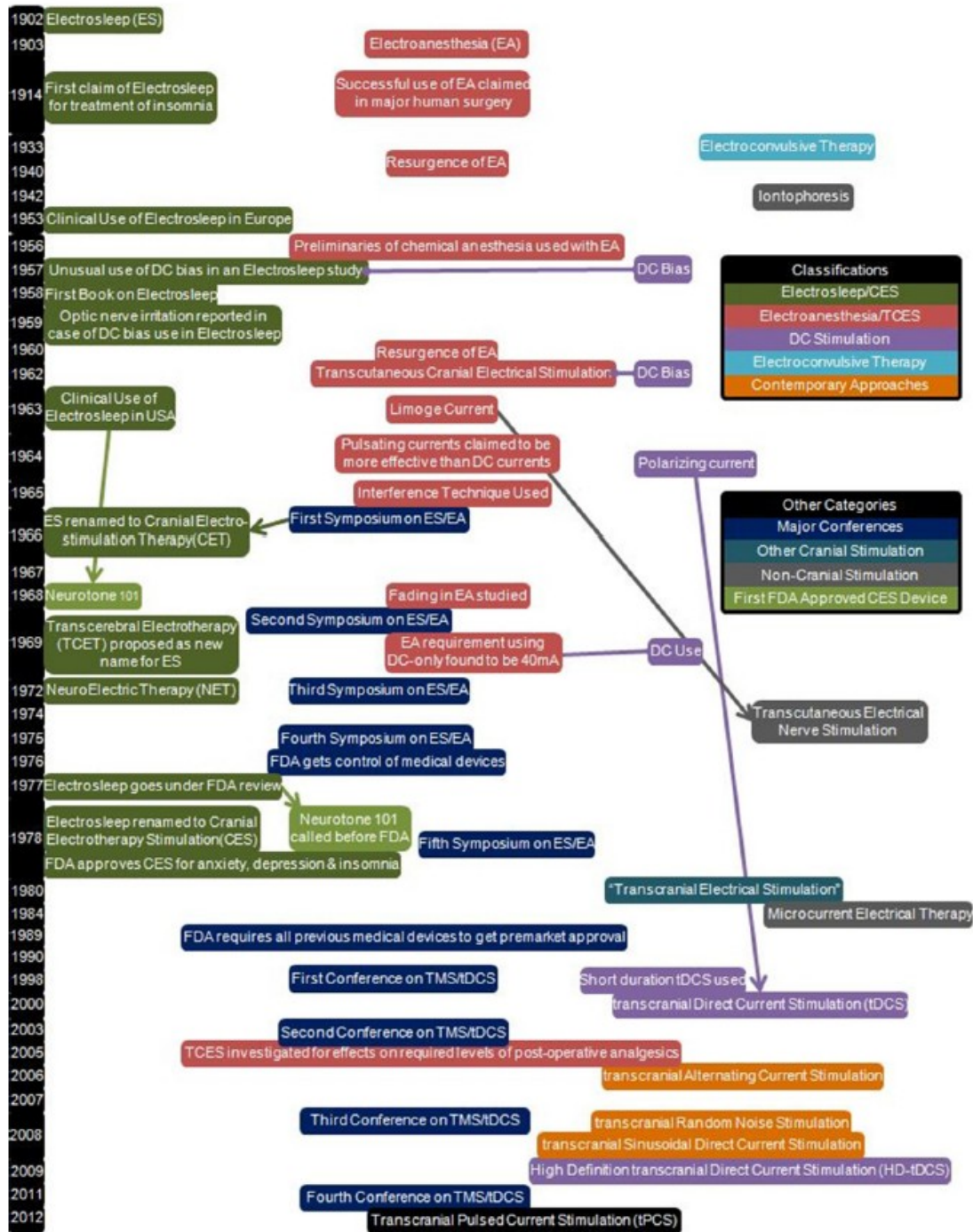
However, all these uses have been largely “shots in the dark”: the physicians in question had no idea what are the effects, but merely used trial and error to treat specific conditions. Furthermore, they used naturally occurring electricity, because they had no knowledge on how to create a *device* for stimulation. With the advent of electrophysiological experiments of individuals such as Walsh, Volta and Galvani in the 18th century, the situation began to change (see Priori 2003). Even though the effects on the brain were unknown (even in the hypothetical sense), the means for stimulation (“galvanic currents”) were recognized and explained. In fact, Galvani's nephew, Giovanni Aldini was the first to systematically report in 1804 (Stagg and Nitsche 2011) the use of galvanic current generated by a device as an experimental treatment for melancholy (See Brunoni & al. 2011a). Indeed, one of the forms of tDCS used today is called “Galvanic Vestibular Stimulation” (Utz & al. 2010).

The development of tDCS is marked by re-curring fits and starts. After a successful application, there would be an initial upsurge of attention in the medical community. However, due to lack of adequate guidance for the specific cortical site for stimulation, the effects would not be replicated. The fact that every investigator used a very different modality (e.g., strength of current), tried to cure a different mental disorder and even called the technique differently was not helpful either. The development of competing electrical brain stimulation therapies, like electro-convulsive therapy (ECT), which unlike tDCS uses AC to

induce seizures, further complicated the picture (see Guleyupogly & al. 2013). All uses of electricity were lumped together as “electrotherapy”, which peaked in popularity in the final decade of 19th century (Clark and Parasurnaman 2013).

With the advent of psychopharmacological interventions, the mainstream interest in tDCS and other “electrotherapies” waned. However, scientific interest continued even though medical practice all but forgot the technique. The history (as opposed to pre-history) of tDCS started with the scientific explanation of the brain polarization effect and subsequent efforts to unify research protocols to facilitate effect replication (see Figure 4.1. below). The first study which reliably demonstrated the brain-polarization effect of DC current on cat brains (Creutzfeldt, Fromm and Kapp 1962) was very much invasive, and transcortical, as opposed to transcranial, but it provided proof of principle. On the one hand, it created impetus for non-invasive research of therapeutic effects on humans, and on the other hand it motivated invasive animal studies on “learning effects” - practically a precursor to the contemporary enhancement effect studies. The study of Redfern & al. (1964) was the first to offer replicable guidelines in an experiment with polarizing DC current for treatment of neuropsychiatric disorders, and as such it heralded modern tDCS studies (see Guleyupoglu & al. 2013). Also, a less known study by Albert (1966) which was technically still tDCS, but invasive (because the electrodes were surgically implanted below the skin and on the skulls of experimental animals) was the first study that showed clear effects of polarizing DC current on learning.

Figure 4.1. Complex history of tDCS: Interplay of names, competing therapies and efforts to establish clarity to the technique



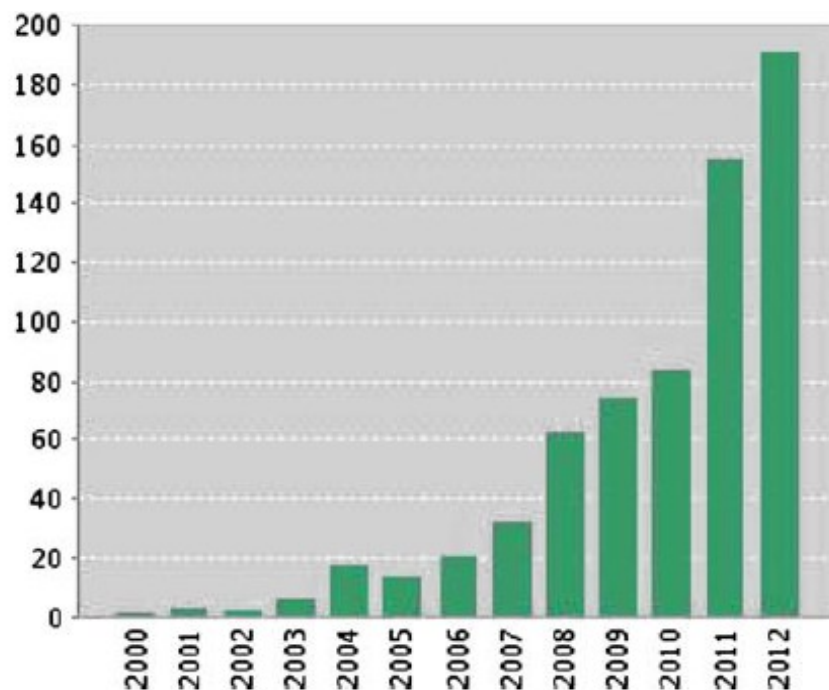
Source: Guleypoglu & al. 2013, p. 299. Note that the name of the figure has been changed.

However, the fact that the early studies were sometimes replicated and sometimes disconfirmed (see Guleypoglu & al. 2013) decreased interest in the technique, which had to compete with (at the time) much more effective pharmacological interventions. The use of tDCS was more or less forgotten in the west, and apart from a steady string of studies in the

Soviet Union (e.g., Rusinov 1965, Mikhailova & Sarkisova 1977, Ilinskiĭ, & al. 1987), only sporadically used for several decades (see Guleypoglu & al. 2013).

The advances in localization and standardization of study parameters at the very end of the 20th century have led to a renewed interest in tDCS (see Brunoni & al. 2011a). In fact, a range of factors contributed to a major resurgence of tDCS as an investigatory, therapeutic and finally enhancement technique (see Figure 4.2.).

Figure 4.2. The number of papers per year including tDCS from 2000 to 2012, from Web of Science



Source: Clark and Parasuraman 2013

To begin with, standardization allowed for replicability, and combined with guidance by neuroimaging techniques as to which cortical locations are stimulated, it made tDCS a very effective tool of neuroscientific investigation (see e.g., Clark & al. 2012). Second, the efficacy of pharmacological interventions for certain disorders (e.g., drug-refractory depression) has reached its limit and this led to a search for alternative or supplementary evidence based therapeutic approaches (see e.g., Priori 2003). Finally, reported enhancement effects, first in implicit classification learning (Kincses & al. 2003) and then in visuo-motor learning (Antal & al. 2004) have led to an explosion of interest, first in the scientific community, followed by the military, the media and the general public (see e.g., Adee 2012).

The replicability of clear cognitive enhancement effects in animals (see e.g., Dockery & al. 2009) and in healthy adults (see e.g., Dockery & al. 2011), virtually guarantees that

tDCS will not fall into oblivion again. Most notably, the findings of therapeutic effects in depression (Fregni & al. 2006) and effects of enhancement in mathematical ability (Cohen Kadosh & al. 2010) deservedly generate interest. Furthermore, the fact that these effects are long lasting and achieved with a non-invasive, cheap, easy to administer, and painless technique guarantees high social penetration. Military agencies such as Defense Advanced Research Projects Agency (DARPA) in the U.S. have fueled the interest by offering extensive funding (see e.g., Clarck & al. 2012), whereas the media have started enthusiastically suggesting related but unproven uses to the general public (e.g., “Schoolchildren who struggle to grasp mathematics could benefit from having their brains roused with electricity” Sample 2010).

It seems that the social penetration of tDCS as a therapeutic, investigative and above all enhancement device is well established. However, the fact that a certain device like tDCS could be used as enhancement, and indeed that there is a possibility of wide-spread use, does not mean *per se* that this is morally problematic. Only if this use generates social and ethical challenges is a regulatory response of the state justified.

In order to understand the complex nature of tDCS, beyond its history, the mechanism of action, uses and adverse effects need to be shortly reviewed. Transcranial direct current stimulation (tDCS) as a non-invasive neuromodulatory technique uses low-intensity direct current to cortical areas in order to facilitate or inhibit spontaneous neuronal activity. Currently, it is primarily used as an investigative and therapeutic tool in the context of pain, depression, and neuro-rehabilitation and learning enhancement after stroke (Fitz & Reiner 2013). As noted above, the ability of tDCS to induce transient improvement in cognitive performance is well established (Hamilton & al. 2011, Dockery & al. 2009, Dockery 2013). Despite its potential benefits, recall that tDCS does not escape important ethical and social challenges that are associated with all cognitive enhancement techniques (see e.g., STOA 2009), and its unique characteristics might cause additional ethical challenges. For example, the regulatory environment surrounding tDCS is less clear than for stimulant drugs, which has been exploited by several companies (see below). Furthermore, it is plausible to assume that it can be widespread, due to low costs and ease of production and use, and because of the apparent cognitive enhancement possibilities. It is also important to note that safety and efficacy of tDCS is demonstrated in controlled laboratory settings, but might cause considerable social problems if used untrained. Namely, unlike stimulant drugs, which follow a posology with predictable effects (and the user thus just consumes a certain dosage), tDCS

is a device that can be easily built at home (via readily available internet do-it-yourself manuals) and be used repeatedly on different cortical locations and in various stimulation modalities (Fitz & Reiner 2013). Recall that stimulation devices such as tDCS have at least five parameters: (1) the intensity of the stimulation; (2) its frequency, (3) the duration of each session; (4) the intervals between sessions and (5) the site being stimulated.

The establishment of safety protocols and the knowledge on how to use tDCS safely has been crucial for the re-invigoration of scientific interest in the technique (see Priori 2003). Articles that note that use of tDCS appears safe and effective (e.g., Poreisz & al. 2007) are referring to a strictly scientific standpoint and investigative use. Opposed to this, enhancement use without supervision might cause serious adverse effects, such as temporary respiratory paralysis (Brunoni & al. 2011a). Some other detrimental effects were caused even with the strict adherence to safety protocols. Cases which were reported in the literature include tDCS induced dermatitis (Riedel, & al. 2011), hypomanic episodes in depressed (Arul-Anandam, Loo and Mitchell 2010) and bi-polar patients (Galvez & al. 2011), and even full-fledged manic psychosis (Brunoni & al. 2011b) when combined with mind-altering substances such as anti-depressant medication.

In addition, due to one-sided, overly enthusiastic portrayal of tDCS in the media, the risks and ethical challenges of enhancement use are likely to be poorly understood by the general public. Therefore, high social penetration might lead to high prevalence of untrained use, which could be dangerous.

Even though most academic articles fuel the public enthusiasm by not delineating the context in which tDCS is safe and effective, there is an additional problematic issue. Namely, publication focus and bias might contribute to misunderstanding of tDCS. Academic articles bolster enthusiasm because potentially detrimental effects are not measured and hence not reported, even though tDCS enhances certain cognitive functions while inhibiting others (Iuculcano & Cohen Kadosh 2013). In a meta-analysis of tDCS studies in motor and cognitive domains (Jacobson, Lavidor and Koslowski 2012) it has been shown that during stimulation one of the electrodes used (anodal electrode) has the effect of enhancing cortical excitability whereas the other (cathodal electrode) actually diminishes it.⁹⁷ Due to the fact that tDCS-induced changes can be prolonged and that the exact mechanisms of tDCS action are currently poorly understood, this raises important ethical concerns, particularly if tDCS is used on populations with developing brains (e.g., children, adolescents).

⁹⁷ The inhibitory effect of cathodal stimulation seems to be consistent in motor studies, but in the cognitive category, memory and executive function are affected, but other functions, whereas the evidence on language ability are not conclusive (see Jacobson, Lavidor and Koslowski 2012).

But what is known about how tDCS induces changes, and what are the safety-protocols for use?

According to Stagg and Nitsche (2011), safe use in most studies entails duration between 10 and 20 minutes and using two surface conductive rubber electrodes (anodal and cathodal) sized between 25 and 35 square centimeters. The size of the electrodes is important because the current is distributed along the electrode surface – it enters through the surface of the anode, passes through brain tissue and exits through the cathode. Accordingly, the smaller the surface, the more current passes through the stimulated region even with the same current intensity (usually between 1 mA and 2 mA).

As for how exactly does tDCS work, Brunoni & al. (2011a) report that the mechanisms of action likely involve different synaptic and non-synaptic effects on neurons and effects on non-neuronal (e.g., glial) cells and tissues within the brain. Long-lasting effects appear to depend on protein synthesis, beyond a mere electronic phenomenon. Anodal stimulation appears to increase intra-neuronal levels of calcium and neurotransmitter-receptor dependent gene expression (see Stagg & Nitsche 2011). However, the primary mechanism of action is the polarization of resting membrane potential (see Brunoni 2011a), with after-effects lasting for up to one hour. The synaptic microenvironment is also modified by tDCS, which affects excitatory and inhibitory neurotransmitters. Given that most of the neurotransmitters and receptors in the brain have electrical properties, and tDCS causes a constant electric field which displaces all electrically charged molecules it might be inducing additional prolonged neurochemical changes (see Brunoni & al. 2011a). The effects of tDCS might be similar to learning – long-term potentiation (LTP), but what exactly are the induced changes is currently unknown.

It has to be noted that enthusiastic public alone does not guarantee that a device with potential detrimental effects will actually create problems. For example, the public was very enthusiastic about hovercrafts in mid-twentieth century, but this enthusiasm didn't amount to much. Some of the reasons for that might be high costs and low availability. However, tDCS promises extreme availability, since it is currently advertised online as an enhancement *product, service*, and as an easy to make *Do-It-Yourself gadget*. Accordingly, the regulatory framework will need to address these three types of social availability of tDCS.

Surprisingly, tDCS devices are easily obtainable via internet even in developed countries in which more conservative attitudes toward novel technologies are dominant. For example, in Germany, a tDCS device can be ordered online and is available for “investigative

purposes”⁹⁸, although no measures are taken to ensure that the device is used by trained professionals. In other countries, tDCS devices are explicitly marketed for other purposes. For example, a Hong Kong based company advertizes tDCS as a treatment and enhancement device and offers shipping worldwide.⁹⁹ In the United States, tDCS as a product is currently marketed and available for enhancement of cognitive function while playing videogames.¹⁰⁰ The producers of the foc.us neurogaming tDCS set (see Display 4.1.) specifically uses lack of clarity in device regulation to promote the enhancement use. The company claims that the device offers no medical benefits, is not a medical device and thus does not fall under the jurisdiction of regulatory agencies such as the FDA. The availability of tDCS with no constraints in knowledge or training seems to be a significant challenge, and as such has already attracted the attention of neuroethicists worldwide (see Fitz & Reiner 2013, Fitz & Reiner In Press, Nature 2013, Bikson & al. 2013, Maslen & al. 2013a,2013b). Some companies do show “self-restraint” in their marketing policy: a device that can be used in the tDCS modality is explicitly marketed by a Canadian company for treatment and enhancement, but with an added note that it will be sold only to qualified physicians.¹⁰¹

Display 4.1.: The online availability of tDCS as an enhancement product, service, and as an easy to make do-it-yourself gadget



⁹⁸ See http://www.neuroconn.de/dc-stimulator_mc_en/ (accessed on September 5th, 2013)

⁹⁹ See <http://www.trans-cranial.com/> (accessed on September 5th, 2013)

¹⁰⁰ See <http://www.foc.us/> (accessed on September 5th, 2013)

¹⁰¹ See http://www.mindalive.com/Products_OASIS_Pro.htm (accessed on September 5th, 2013)

Sources: above <http://www.foc.us/>; lower left: <http://www.trans-cranial.com/> Lower right <http://speakwisdom.wordpress.com/2012/12/09/can-a-simple-safe-tdcs-device-be-built-from-radio-shack-components/>

It has to be noted that even such “self-imposed” constraints do not resolve the issue of “responsible use” of tDCS. Namely, even if tDCS devices as *products* are in fact sold to physicians only, a secondary market for tDCS as a therapeutic and enhancement *service* is on the rise as well, and there appear to be no constraints on the actual training the health professionals should have received in order to be competent to use the device.¹⁰²

However, the most alarming is the virtually omnipresent availability of tDCS as an easy to make *Do-It-Yourself gadget*. A simple internet search instantly yields several web pages that offer detailed instructions on how to build a tDCS device and where to place electrodes to achieve enhancement.¹⁰³ The materials needed to build a tDCS device at home are readily available and relatively cheap. Furthermore, a would-be tDCS user can rely on You-tube tutorials that provide step-by-step instructions how to build a tDCS device, and where to place electrodes.¹⁰⁴

The apparent effectiveness, re-usability and low costs of tDCS suggest a high penetration rate of this technology and tremendous impact in the clinical context and in competitive social milieus (Business, Education, Military, etc.). This leads to the conclusion that a discussion on regulation of tDCS is timely and not premature. There have been some discussions (Fitz & Reiner 2013, Fitz & Reiner, In Press, Anonymous 2013, Bikson & al. 2013, Maslen & al. 2013), however, their focus was on do-it-yourself enhancements and in response to the tDCS neurogaming product, and not on other products that could be used in the tDCS modality or the regulation of tDCS as a service. Since the latter two are on the rise, this presents an important gap.

As illustrated by examples above, the current regulatory regime in both U.S. and E.U. have important blind spots: devices may be designated as safe without any revision of effectiveness claims, and manipulating effectiveness claims (as with the example of the tDCS “neurogaming” set) might lead to admission of devices by regulatory default. Guyuroglu & al. (2013) note one glaring regulatory blindspot that affects both Europe and the U.S. The

¹⁰² See <http://www.transcranialbrainstimulation.com/> (accessed on September 5th, 2013) and <http://www.drmueller-healthpsychology.com/tDCS.html> (accessed on September 5th, 2013)

¹⁰³ See <http://speakwisdom.wordpress.com/2012/12/09/can-a-simple-safe-tdcs-device-be-built-from-radio-shack-components/> (accessed on September 5th, 2013)

¹⁰⁴ See <http://www.youtube.com/watch?v=hgFWEBwT6BE> (accessed on September 5th, 2013) and <http://www.youtube.com/watch?v=h1Y3cpB26IY> (accessed on September 5th, 2013)

European “CE” mark can be obtained by mere compliance with production standards as long as no medical claims are made in the application. Apart from this shortcoming the inadequacy of the system in the U.S. is apparent even in the case that there are claims regarding medical benefits: formerly “cleared” devices that are “substantially equivalent” can provide basis for a similar device to avoid costly and lengthy pre-market approval.¹⁰⁵ Since devices that generate weak electrical currents have been used effectively for rehabilitation of muscle injuries, this leaves the door open for producers claiming medical uses of tDCS. Indeed, the Canadian company that markets tDCS for treatment and enhancement, basically promotes the same device for multitude of uses, from physiotherapy to cognitive enhancement.

Despite recommendations and calls for extending existing legislation for medical devices to tDCS (e.g. Fitz and Reiner 2013, In Press, Maslen & al. 2013), no concrete proposals for regulatory framework for all modalities of tDCS use by healthy adults have been advanced, and this issue merits attention from the academic community and policy makers, particularly given the rapid evolution of neuromodulation techniques. Two approaches that were discussed in the context of cognitive enhancement drugs could potentially be extended to tDCS: the “gate-keeper” model and the Economic Disincentives Model (EDM).

The so-called “gate-keeper” model advises relying on health professionals to act as “gate-keepers” of medical technologies that could be used for cognitive enhancement. Indeed, it could be argued that health professionals should bear in mind all available information about tDCS when making the decision whether or not to allow it to “enhancement seekers”. After all, the American Neurological Academy has issued an influential set of guidelines which concluded that medical doctors have the right to decide whether to prescribe drugs as enhancement or not based on their expertise and good medical practice (Larriviere & al. 2009). Perhaps this advice can be extended to medical devices as well, with or without additional guidance and/or licensing from professional bodies. However, there are several problems with such a “gate-keeper” approach.

If this model was used for “prescribing” tDCS as a product, once the device has been purchased it is beyond the control of the medical professional. The problem of untrained use on any number of individuals remains, as unlike prescription drugs, tDCS is reusable indefinitely. If tDCS in fact can be used responsibly, by taking into account safety settings and

¹⁰⁵See <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/default.htm> (Accessed on November 24th)

procedures, the “gate-keeper” model actually cannot be used for tDCS as a product, only for regulation of commercial uses of tDCS as a medical *service*. In case that this is the only legally available solution to gain access to tDCS, this leads to further problems. It has been argued that medical doctors have the expertise to diagnose illnesses and prescribe therapy, whereas every citizen should have the right to decide for him or herself whether to use enhancements or not (see Chapters 2.2. and 2.3.). Regardless of the laws and regulations that are in place, if citizens view them as overly constraining and unnecessary, they are highly unlikely to obey them. Since tDCS is also available as a *product* or *Do-It-Yourself* gadget it is very likely that a number of people will take advantage of such availability to circumvent the costly “gate keeper”.

This means that the “gate keeper” model for the tDCS service must be amended by additional regulation. The direction and severity of such additional regulation constrains the effectiveness of the model. Now, the gate keeper model might be bolstered by sterner and more prohibitive regulation of tDCS as a product by the state or regulatory bodies. Perhaps possession and use of tDCS can be restricted to health professionals only, and any non-compliance sanctioned with criminal prosecution. Apart from the questionable legitimacy of such a response, two additional socially undesirable consequences would be produced. The first is creating a black market for tDCS, and the second is restricting access to tDCS to only a subset of population that could afford the high fees of medical practitioners. In short, that would make the “gate keeper” model both ineffective and unjust, since the issues of paternalism and the accumulation of the power to distribute enhancements in the hands of health professionals make justification of this approach to all citizens very hard.

A different move would be to offer more permissive additional regulation. The “gate keeper” model could be sufficient to define the individuals that would have the right to apply tDCS to others, but the issue that needs to be tackled is untrained use on oneself, which creates the problem in the first place. The “gate keeper” model might be bolstered with stern regulation of unlicensed application of tDCS to others (especially children) and relatively permissive regulations toward applying tDCS to oneself. Indeed, if the analogy with other technological advancements is taken into consideration, even potentially dangerous technologies have been rendered relatively safe by licensing of users with few restrictions apart from age and health. For instance, a piloting license can be gained by every adult citizen, providing that health problems would not endanger others. On a more permissive range, driver's licenses are available in some countries from the age of 16, and are again limited with certain medical conditions (i.e. sight impairments).

Since tDCS appears to be safe and effective in laboratory settings, it might be plausible to assume that it might be safe and effective in any environment with sufficiently *trained* users. The limits for tDCS use might not need to be as harsh as those for the piloting license, but should not be as permissive as in the case of driving licenses. Since it was noted that tDCS might cause long-term detrimental changes in developing brains, a reasonable precaution could be to set the age requirement at 25.

A more permissive approach to tDCS would mean extending the mandate of regulatory agencies to non-therapeutic uses of stimulation devices as proposed by some authors (Maslen & al. 2013b). However, since the problem identified was untrained use, the mandate would need to be further extended to enforcing the necessary competence of would-be enhancement seekers in order to ensure safe and responsible use. Now, regardless of whether a new agency would be instated (as was the proposal of RACE discussed in Chapter 3.1. above) or the mandate of an old agency extended as EDM envisions, a government agency would first need to offer a licensing procedure to companies to market tDCS devices (like the “neurogaming” head-set) for healthy adults. This way all citizens of age would be able to legally purchase tDCS devices. Unlike RACE, EDM also means that taxes, fees and requirements of additional insurance would be imposed, and it is questionable if the financial and regulatory burdens thus created would be the best solution. However, recall that there is a lack of information on effects and mechanisms of action of tDCS, and apart from limiting the availability of tDCS to minors, the regulatory framework needs to generate the information as soon as possible.

By envisioning the additional licensing procedure for *users* EDM has the potential to provide this information in the shortest amount of time. Since in order to be able to purchase, possess and use a tDCS device, citizens would have to pay fees for a course about safety precautions, proper operation, known effects and side effects of tDCS, and pass an exam as proof of knowledge, most detrimental effects could be avoided. Furthermore, the additional medical insurance would guarantee that any adverse effects generated by tDCS use would not drain public funds. Last but not least, obligatory annual medical tests for obtaining and renewing a license to use a tDCS device would quickly generate the information needed for fine-tuning the policy. Namely, if some other permissive model (such as RACE) was used, the statistical data about unwanted effects and long term consequences of prolonged use of tDCS might be captured by the medical system, but not clearly distinguished from the population of non-users. This means that costly clinical studies would need to be conducted on a sample of users to ascertain the post-market effects of tDCS licenses. The validity of such studies could

be questionable if they are financed by the producers and time lag between reported results (while negative results might be suppressed) and necessary modifications could be extended, and the system could be made even more inert than it already is.

Thus, EDM has the advantage of quickly, cost-effectively and objectively generating data for post-market monitoring. However it should be noted that but users would have the right to opt out from providing their data if they have privacy concerns. The requirement of EDM to regulate the prices of tDCS devices might turn out to be unnecessary. Recall that EDM regulates the prices by including the standard costs of production and distribution, limiting the profit margin and imposing an additional tax. Now, if the data from tDCS users does point to the conclusion that trained use of tDCS is reasonably safe even outside controlled laboratory settings, these requirements, along with further taxing of the companies could be relaxed. However, these requirements would need to be initially enforced. As before, the argument about using the funds gained by EDM to invest in providing medical necessities for the least well-off and/or allocating the remaining funds to finance education still stands. Furthermore, the considerable regulatory burdens for enhancement seekers would limit the social penetration until the issue of long-term physiological effects of tDCS has been settled by data generated. Since tDCS would be in principle be available to all this should offset any concerns about fairness.

This leaves the issue of non-commercial uses of tDCS unresolved. Technically, tDCS as a do-it-yourself gadget defies almost all efforts to regulate the technology. However, having a reasonable legal alternative is enough in most cases to promote registered use. Consider the example of vehicles once again: it is quite possible that someone might try to avoid costs of registering the vehicle, technical check-ups and insurance by stealing the license plates from vehicles of the same type and color, but the fact that it would necessitate too much continuous effort, make this option highly unlikely. Furthermore, apart from using tDCS on others, even unlicensed self-uses could be criminalized and a moratorium on Direct-to-Consumer marketing of tDCS could be enforced. However, such harsh measures should be avoided, unless there are clear indications that unlicensed home uses of tDCS might pose a considerable danger.

To conclude, the analysis of currently available data suggests that more reliable information on the neurophysiological mechanisms of action of tDCS is necessary. Even though the physiological profile of tDCS seems to be safe in strictly controlled laboratory

settings (i.e. with sufficiently trained users), if inadequately regulated, tDCS can incur social and health related costs. The media have enthusiastically reported to the general public that tDCS could be used to enhance cognitive function, tDCS is readily available as a service, product or even a home-made device, and there is currently a regulatory gap, as policy makers are slow in responding to new social challenges created by knowledge transfer from neuroscience and neurology.

With suitable modifications the Economic Disincentives Model (EDM), might provide a starting point for establishing long term physiological and social effects of tDCS and assess its moral acceptability. However, further discussion is needed in order to generate as many proposals for regulatory approaches and specific models as possible. tDCS can be regulated appropriately only as a result of a public discussion on a sufficiently large eligible set of policy options, while EDM might need to be fine-tuned if it is to provide anything apart from a temporary solution.

4.3. Empirical model V: Transcranial magnetic stimulation (TMS)

Does transcranial magnetic stimulation (TMS) need to be urgently regulated as well? This question is not so easy to answer. On the one hand, the social penetration of TMS as a *product* is likely to remain low since the costs are very high (see e.g., Simpson & al. 2009, Sutherland 2013). On the other hand, the use of TMS as a *service* might have a moderate social penetration, especially since enhancement effects have been reported in more than 60 studies (Luber and Lysanbi 2013). But what exactly is TMS?

Transcranial Magnetic Stimulation (TMS) is a technique that uses a device which stores a strong electrical charge in capacitors (Fitzgerald & Daskalakis 2013). Periodic discharge of the stored electrical energy from the capacitors passes a strong electrical current through a magnetic coil. The coil is placed over the specific position on the cranium of the subject (depending on the precise part of the brain that is to be stimulated). The magnetic field thus generated passes through the cranium and induces a weak electric current inside the surface areas of the brain causing hyper- or hypo-polarization of the neurons in the affected brain tissue (Schermer 2013). This simple and very effective principle of non-invasive brain stimulation has the advantage over electrical forms of stimulation in that the magnetic field passes easily and virtually without any resistance through the cranium, and generates the current within the brain structure as opposed to releasing electrical currents from outside the cranium (Richter 2013).

The pre-history of TMS is shorter than in the case of tDCS, whereas the history of modern TMS is much longer when compared to tDCS. As was the case with tDCS, technological limitations constrained the use of the relatively simple principle of TMS, even though the necessary scientific knowledge on alternating electrical current (AC) and electromagnetic induction was available as early as the 19th century. Namely, the serbian-american scientist and inventor Nikola Tesla experimented with physiological effects of high frequency currents, and constructed a variety of flat, cone and helix shaped coils that were used to produce effects on the human body, including the head.¹⁰⁶ Tesla coils produced an ionization of the air by virtue of consisting of a primary and secondary large coils – the experimental subject would sit in the area of magnetic field generated by the coils and experience a “bombardment like” sensation (see Display 4.2).

¹⁰⁶ In this and next three paragraphs I draw extensively on Fitzgerald & Daskalakis 2013. Unless otherwise noted, this is the source of historical information presented.

Display 4.2. Nikola Tesla and an active Tesla Coil



Source: <http://www.teslasociety.com/coil3.jpg>

Tesla coils, even though they were extremely bulky and unpractical for anything apart from experimental use, formed the basis of the latter development by the French scientist d'Arsonval, who used similar equipment as Tesla, but without the second coil (See Display 4.3.). D'Arsonval reported the effects of cranial stimulation with a large magnetic coil including dilation of blood vessels, vertigo, transient loss of consciousness (syncope), and visual flashes of light (phosphenes). As d'Arsonval published in French, his findings were not well known in non-francophone scientific communities, which led to independent researchers basically reporting the same effects in German and English.

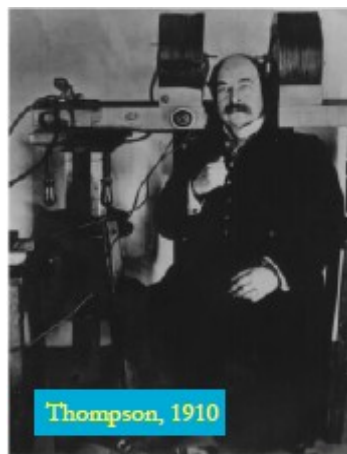
Display 4.3. D'Arsonval (on the right) demonstrates the use of his magnetic coil



Source: <http://ccn.ucla.edu/wiki/images/c/c4/Brainstimulation2012AB.pdf>

Apart from reporting similar effects at the beginning of 20th century in Vienna, Austria, Beer, with the help of Pollancsek, designed and patented a device for use in the treatment of depression and other neuroses. Again, technical issues might have contributed to the lack of use of the device, as the induced fields have been insufficient to have therapeutic effects. However, this has inspired several other investigators: Thompson designed a large coil that induced a magnetic field centered on the head of the experimental subject (see Display 4.4.), and reported phosphene effects (experiencing flashes of light) and even taste sensations; Dunlap tested Thompson's claims controlling for the noise produced by the apparatus and confirmed phosphenes but not other sensations, while Magnusson and Stevens produced definitive visual sensations including flickering and a luminous horizontal bar, by using two elliptical coils.

Display 4.4. Thompson and his coils



Source: <http://ccn.ucla.edu/wiki/images/c/c4/Brainstimulation2012AB.pdf>

The fact that only visual sensations have been reliably reproduced might have contributed to the lack of further scientific interest in the technique. After the initial interest spurred by Thompson, little research has been published in this area for several decades, and the one notable study that was published actually seemed to disprove the scientific field of magnetic stimulation of the brain, even though technical advances facilitated the decrease in size of the necessary coils. Namely, Barlow used a small coil to stimulate the cranium in 1947, and reported visual sensations when the coil was placed next to the temple, but not next to the occiput (the back portion of the skull). The scientific community concluded that brain tissue was not stimulated at all, but that the visual effects were merely the result of retinal stimulation. As a result, the field did not advance significantly until the work of Anthony Barker, who first started investigating the use of short pulse magnetic stimulation on the

peripheral nerves in the human body in 1970s.

Barker was also the first to develop and test the modern-day TMS as a device and technique to noninvasively stimulate the cerebral cortex in 1985 in the Royal Hallamshire Hospital in Sheffield, United Kingdom (Fitzgerald & Daskalakis 2013, Sutherland 2013). Since then, the device and technique have been evaluated by the scientific and medical community in an impressive number of research studies and clinical applications (Rossi & al. 2009). Although TMS has been widely used in a plethora of scientific and clinical studies (see Boniface & Ziemann 2013) and research suggests that it can help people with post-traumatic stress disorder, bipolar disorder and Parkinson's disease, to date, TMS has only been approved to treat major depressive disorder (Sutherland 2013). The fact that the danger profile of TMS could be considered moderate due to the risk of seizures, the most serious TMS-related acute adverse effect (Rossi 2009), might have contributed to the lack of approval for the conditions mentioned above, even though it seems to be effective and might also be beneficial in a variety of other conditions, including schizophrenia, anorexia, Alzheimer's disease, autism and cerebral palsy (Sutherland 2013).

Furthermore, it needs to be taken into account that TMS has different effects and side-effects depending on (1) the intensity of the stimulation; (2) modality of stimulation (3) the duration of stimulation; (4) the intervals between stimulation sessions and (5) the site being stimulated. To elaborate on the variability of intensity: in case of any form of TMS the time-varying magnetic field is generated by a short high-current AC pulse (4–20 kilo Amperes) with high voltages (400–3,000 Volts) sent through the stimulation coil, with the resulting short term magnetic field (a few milliseconds) and peak strengths of 1–10 Tesla (Richter 2013). When the coil is placed above the cranium, the magnetic field will cause DC electrical current to flow in nearby secondary conducting material, such as neurons, and if this current is of sufficient strength, it will produce depolarisation or hyperpolarization of the conducting neural tissue located just under the coil (Fitzgerald & Daskalakis 2013).

The second aspect – modality is even more diverse. The modality of TMS is influenced by the choice of pulse types (single pulse or repetitive stimulation of low or high frequency), coil shape (circular, figure of eight, double cone or H-shaped), the choice of technique (paired pulse, theta burst, etc.). Single pulse TMS has been successfully used even with older monophasic stimulation devices (which had a delay of 3 seconds between charges) to disrupt neural activity and to distinguish between spinal and cortical effects in the nervous system (Rothman 2003). Both single pulse stimulation, which mostly lead to an immediate reaction (e.g. twitching of muscles) and repetitive stimulation (rTMS), which can facilitate

longer lasting changes to neuronal behavior (Richter 2013), can be achieved with the newer, biphasic stimulators, which have a considerably higher rate of recharging capacitors (Fitzgerald & Daskalakis 2013). The different frequencies of rTMS have diverse effects on neural tissue: research indicates that low frequency stimulation (below 5 Hz) is generally less likely to cause seizures and decreases neuronal excitability (Richter 2013), while high frequencies (greater than 5 Hz, but usually 10-20 Hz or more) generally excite the affected neuronal tissue with greater and longer lasting effects, but at the same time increase the danger of adverse effects (Rothman 2003). However, due to the fact that a review of enhancement effects of TMS has established that only 5 Hz (and not 1Hz or 20Hz) stimulation had resulted in cognitive performance enhancement (Luber & Lisanby 2013, p. 962), it might make more sense to always state the exact quantitative parameters of stimulation, or test if different “medium” frequencies (5-9 Hz) might optimize neuronal excitability and offer genuine cognitive enhancement, with less danger of seizures.

Beside the properties of the device that generates the charges, the shape of the stimulating coil also affects the magnetic field properties and conversely effects of brain stimulation (Richter 2013). Initial TMS studies used circular or round coils (Fitzgerald & Daskalakis 2013). These coils generate a ring-like field, which is less focal, but depending on the size can penetrate deeper than other standard coils and stimulate structures of the brain beyond the immediate cortical surface (Rossi & al. 2009). Such larger and deeper fields may be preferred when the desired neuroanatomic stimulation site is not precise, but encompasses a greater cortical area (Fitzgerald & Daskalakis 2013). More focal stimulation requires figure of eight coils, which consist of two circular coils in a single plane, and this shape has the effect of adding the two induced fields at the intersection (Richter 2013), thereby providing better spatial resolution and better control of the precise site being stimulated (Fitzgerald & Daskalakis 2013). The double cone coil is more or less a variation of the figure of eight coils, as it is formed by two large circular wings (see display 4.5.). The wings are placed at an angle of 95°, which enables induction of a stronger field, which penetrates deeper and allows for stimulation of regions located deeper in the brain (Rossi & al. 2009).

Display 4.5. Most commonly used types of coils for TMS: Figure-of-eight, Double Cone and Round Coil



Source: <http://ccn.ucla.edu/wiki/images/c/c4/Brainstimulation2012AB.pdf>

Apart from the more common types of coils, the need to produce more focal effects in the deeper structures of the brain during so-called deep transcranial magnetic stimulation (see Bersani & al. 2013 for a comprehensive overview) has motivated the introduction of more specialized coil designs. Most notably, after rigorous testing at high intensities and frequencies of stimulation, the specialized H-coil (see Display 4.6.) has been approved for use on human subjects in Europe (Rossi & al. 2009). By virtue of having multiple coil windings, the H-coil generates sufficient magnetic field strength at distances of 6 cm (Fitzgerald & Daskalakis 2013) - a major improvement in relation to most conventional coils, which are rapidly losing field strength at greater distances and have the effective distance of 1.5 to 2.5 cm (Bersani & al. 2013).

Display 4.6.: The schematic diagram of the H-coil helmet for deep TMS



Source: http://en.wikipedia.org/wiki/File:H-coil_helmet.jpg

The final issue in the second aspect or modality of TMS used is the choice of technique. The most notable specialized techniques are paired pulse and theta burst stimulation. Paired pulse is an old and reliable technique often used in investigative applications of TMS, and can be used even with older monophasic stimulators. The technique involves the application of two stimuli separated by a varying interstimulus interval in order to establish a functional connection between two different brain sites (Rothman 2003). Theta burst stimulation (TBS) can only be used with rTMS and hence newer, biphasic stimulators. This technique involves several high frequency bursts which are delivered in short intervals (Rioult-Pedotti & Donoghue 2003). The virtue of the TBS paradigm that it is able to produce longer effects with shorter stimulation times: Richter (2013, p. 4) reports that 200 intervals of short, high frequency bursts (50Hz), with average 3 pulses and two second interval pause are commonly used. The pauses between the bursts mitigate the effects of heating and reduce the danger of seizures as long as safety protocol, which limits the total number of pulses to 600 and stimulation intensity to 60% of device output is observed (Rossi & al. 2009).

This leads to the third aspect of variability in TMS – duration of stimulation. Duration of TMS refers to two separate issues: duration of a TMS *session* or a duration of the whole TMS *treatment* (whether the application is therapeutic, investigative or even for purposes of enhancement). A stimulation session consists of several stimulation trains (or a number of

bursts in case of TBS). The increase in knowledge and refinement of technology have changed the length of a typical TMS session: initially 10-20 stimulation trains per session were considered safe, but in recent studies 75 or more trains are the norm (Fitzgerald & Daskalakis 2013), and the most common duration of a TMS session is 15-30 minutes (Richter 2013). Duration of the whole treatment has evolved as well, but the safety profile in this respect is less clear, as cumulative daily or weekly application of TMS still needs to be assessed in terms of safety for both patient populations and healthy adults (Rossi & al. 2009). Initially one or two weeks of stimulation have been considered safe, but recently treatments of six weeks or more have been conducted (Fitzgerald & Daskalakis 2013). Since a greater number of sessions is necessary to prolong the effects of stimulation (Schermer 2013), this trend of increase in TMS duration is likely to continue.

Concerning the fourth aspect of variability in TMS – the interval between repeated sessions, there is no upper limit, but safety guidelines are set for the 15 minute minimal interval between rTMS sessions (Rossi & al. 2009). Finally, the site of the brain being stimulated is of utmost importance to the effects of stimulation. Initially, TMS could stimulate only surface of the brain at various locations, but with the advent of deep TMS the stimulation site variability has increased (Bersani & al. 2013).

The considerable variability of application raises the issues of effectiveness of TMS as an enhancement tool, known side-effects and dangers of TMS and the extent of social penetration that can be expected. As mentioned above, more than 60 studies report cognitive enhancement effects of conventional TMS (Luber & Lisanby 2013) whereas 5 studies report reliable enhancement effects of cognitive capacities of deep TMS (Bersani & al. 2013). What is more, scientific reports are increasingly focused on possibilities of augmenting cognition of human operators of complex technological systems: for example, a review of TMS, leaning on military funding and purposes, explored the ability of TMS to improve „the weakest link in the system“ by „direct augmentation of human performance“ (McKinley & al. 2012, p. 130). Since military funding might be a source of bias in reporting enhancement effects, a more cautious approach makes starting with clinical evaluations of deep TMS more advisable.

The „enhancement effects“ of deep TMS that Bersani & al. (2013) review are actually effects on patient populations, but nevertheless provide the vocabulary for further analysis:

Five studies have evaluated the effect of treatment of deep TMS applied to the prefrontal cortex on cognitive performance of the patients using the Cambridge Neuropsychological Test Automated Battery (CANTAB), the Mindstreams cognitive tests and different ToM [Theory of Mind] tasks to examine specific cognitive abilities including short-term memory, working memory, attention, concentration, affective ToM, cognitive ToM, the ability to temporarily

maintain and use information during execution of tasks, the ability to select and organize external information to provide appropriate responses, cognitive flexibility and the ability to plan strategies for solving tasks. Four studies reported improvements, none of the studies reported worsening. Interestingly, *cognitive improvements were present both in patients who also improved from a psychopathological point of view and in those patients who did not*. In the comparative review ... the modifications induced by deep TMS, standard TMS and ECT [Electro-Convulsive Therapy] in neuropsychological performances of drug-resistant drug-free patients with MDD [Major Depressive Disorder] were compared. Deep TMS was the only technique that *generated clear affective and cognitive improvements in the different CANTAB tasks performed: + 2.29% in sustained attention, + 15.72% in visuospatial memory, + 6.17% in cognitive planning, + 15.89% in spatial memory*. (Bersani & al. 2013, p. 37; explanation of abbreviations and emphasis added).

Again, even though the effects reported are in a patient population, the increases in spatial and visuo-spatial memory are indeed impressive, and provide the impetus for further research on the population of healthy adults. The military is very interested in funding these studies in order to expand technical capabilities and reduce the number of personnel required to process vast amounts of data (McKinley & al. 2012). As scientific studies and TMS applications are publicly available, the sphere of business is certain to pick up the trend, sooner or later. But what about evidence on use in healthy adults? Even though deep TMS is fairly recent, standard TMS has been available much longer and has been tested and evaluated for enhancement effects. On the one hand, like most cognitive enhancement drugs, TMS can provide performance maintenance effects such as reducing the effects of sleep deprivation on working memory (Luber & al. 2013). On the other hand, TMS also offers genuine increases in performance in a range of cognitive capacities, from analogical reasoning (Boroojerdi & al. 2001), to savant-like abilities (Snyder & al. 2006, Snyder 2009).

However, the exact mechanisms by which TMS enhances cognition are unknown, and although TMS of frontal brain regions modulates the activity of a range of neurotransmitters, including Serotonin, Vasopressin, Noradrenalin and Dopamine (Keck & al. 2000), it was generally considered to disrupt neural activity as in „virtual lesion“ studies (Boniface & Ziemann 2003). That is why at first the enhancement effects were seen as a sort of puzzle, leading to several hypotheses. Luber & Lisanby (2013) have reviewed evidence on three different kinds of enhancement effects, along with current hypotheses for explaining the phenomena: (i) enhancement via nonspecific effects of TMS; (ii) enhancement via „addition by subtraction“, and (iii) enhancement effects via direct TMS to specific task-related brain regions.

The first kind of noted enhancement effects were understood as side-effects of auditory and somato-sensory sensations unrelated to the effects of the magnetic field on the brain – the unrelated sensations basically arouse the attention of experimental subjects,

thereby decreasing reaction times (RT). Thus, the “inter-sensory facilitation“ hypothesis (Luber & Lisanby 2013, p. 962) actually tried to explain away any enhancement effects.

The second kind of noted enhancement, and the „addition by subtraction“ hypothesis that explains them, actually account for effects of intercortical inhibition, and what was at the time thought to be general inhibitive nature of real TMS effects. For example, because the left anterior temporal lobe is implicated in the savant syndrome for both autistic savant children and fronto-temporal lobe dementia adult savants, Snyder & al. (2006) stimulated it for 15 minutes with low-frequency (1 Hz) rTMS, and as a result temporarily simulated the savant numerosity skills in normal people for up to one hour. As low frequency rTMS actually inhibited the left anterior temporal lobe, the „virtual lesion“ appears to have unleashed the access to raw sensory details and thus produced the enhancement effects. Apart from the explanation of induced savant numerosity skills, the same hypothesis was used to successfully explain the results of TMS studies in which savant drawing and proofreading skills were induced as well as increased resistance to false memories (Snyder 2009). Luber & Lisanby (2013) in their review of TMS studies reporting cognitive enhancement effects identified 25 separate instances in which „addition by subtraction“ seems be related with the study results.

However, not all TMS induced cognitive enhancement effects could be explained by „addition by subtraction“ or explained away by “inter-sensory facilitation“. A large number of studies on a range of cognitive tasks using both on-line (the cognitive performance is measured during stimulation) and off-line (the cognitive performance is measured after stimulation) testing paradigm (see Table 4.2.) reported enhancement effects, mostly decreases in reaction times (RT), via direct TMS to specific task-related brain regions.

Different hypotheses have been offered to explain this third kind of cognitive enhancement effects of TMS. The “post-tetanic facilitation“ hypothesis, which has been used to explain facilitating effects to cortical processing of short trains of high frequency rTMS, suggests that enhancement effects are caused by excitatory post-synaptic potentials. These potentials are generated by the weak currents induced with the magnetic field (Luber & Lisanby 2013). Another hypothesis is based on scientific evidence emphasizing the oscillatory behavior of neuronal networks which are important for cortical integration, memory, attention and perception. Thus, TMS might be „reseting and driving“ this oscillatory behaviour as the evidence shows that increases are frequency specific (Luber & Lisanby 2013). At any rate, it is clear that TMS does and can produce enhancement effects, but only under supervision by trained professionals, and the serious nature of potential side-effects (See Table 4.3.) further necessitates a controlled environment for any kind of TMS use, and especially for

enhancement uses. The need for professional oversight might change in the future, with the advent of robotized neuro-navigation TMS systems (Richter 2013), but this is likely to increase the costs of an already very expensive technique.

Table 4.2.: Studies reporting cognitive performance enhancements with TMS targeting regions expected to be directly involved in a given task

TMS dosage	On-line/off-line	Reference	Task	Performance effect		
Single pulse	On-line	Butefisch et al. (2004)	Motor learning	Increased accuracy		
		Cattaneo et al. (2010)	Action discrimination	Decreased RT		
		Cattaneo et al. (2008, 2009b)	Letter discrimination	Decreased RT		
		Cattaneo et al. (2009a)	Nonverbal working memory	Decreased RT		
		Grosbras and Paus (2002, 2003)	Backward masking	Increased detection sensitivity		
		Hannula et al. (2010)	Tactile working memory	Decreased RT		
		Renzi et al. (2011)	Numerical magnitude judgment	Decreased RT		
		Stoeckel et al. (2009)	Homophone and synonym judgment	Decreased RT		
		Topper et al. (1998)	Picture naming	Decreased RT		
		Van Ettinger-Veenstra et al. (2009)	Visual discrimination	Increased accuracy		
		Paired pulse	On-line	Gagnon et al. (2011)	Verbal and non-verbal recognition	Decreased RT
				Sakai et al. (2002)	Syntactic decisions about sentences	Decreased RT
				Wipfli et al. (2001)	Memory-guided eye movement	Decreased RT
High frequency	On-line	Borojerdj et al. (2001)	Visual analogic reasoning	Decreased RT		
		Cappa et al. (2002)	Picture naming	Decreased RT		
		Cohen-Kadosh et al. (2010)	Numeral discrimination	Decreased RT		
		Cooper et al. (2004)	Visual attention	Increased accuracy		
		Evers et al. (2001)	Visual go-nogo	Decreased RT		
		Klimesch et al. (2003)	Mental rotation	Increased accuracy		
		Kohler et al. (2006)	Word recognition	Increased accuracy		
		Luber et al. (2007a)	Letter working memory	Decreased RT		
		Mottaghy et al. (1999)	Picture naming	Decreased RT		
		Romei et al. (2011)	Visual discrimination	Decreased RT		
		Schwarzkopf et al. (2011)	Motion discrimination	Increased accuracy		
		Sparing et al. (2001)	Picture naming	Decreased RT		
		Yamanaka et al. (2010)	Spatial working memory	Decreased RT		
Low frequency	Off-line	Waterston and Pack (2010)	Visual discrimination	Increased accuracy		
High frequency	Off-line	(Boyd and Linsdell, 2009)	Motor tracking	Decreased movement error		
		Hwang et al. (2010)	Continuous performance	Increased accuracy		
		Ragert et al. (2003)	Tactile discrimination	Lowered sensory threshold		
		Tegenthoff et al. (2005)	Tactile discrimination	Lowered sensory threshold		
Intermittent theta burst	Off-line	Cardenas-Morales et al. (2011)	Motor choice RT	Decreased RT		

Source: Luber & Lisanby 2013, p. 964.

It is safe to assume that due to high costs and necessary level of expertise required (see Simpson & al. 2009) that enhancement with TMS might be available only as service and not as a product. Even TMS service (based on current prices of therapeutic uses) is expensive: a single TMS session costs 300 USD, and since total duration of a TMS treatment include from 20 to 30 sessions, the total cost of the TMS service is between 6000 and 10000 USD (Sutherland 2013). Obviously, the social penetration of TMS can be expected to be moderate, and at first available only to the more affluent members of the society.

Table 4.3. Potential side-effects of TMS

Side-effect	s-p TMS	p-p TMS	Low rTMS	High rTMS	TBS
Seizure	Rare	Not reported	Rare	Possible	Possible
Hypomania	No	No	Rare	Possible	Not reported
Consciousness loss (Syncope)	Possible as epiphenomen.	Possible as epiphenomen.	Possible as epiphenomen.	Possible as epiphenomen.	Possible
Transient pain (head, neck...)	Possible	Possible but not reported	Frequent	Frequent	Possible
Trans. hearing change	Possible	Possible but not reported	Possible	Possible	Not reported
Tr. psychol. changes	Not reported	Not reported	Overall negligible	Overall negligible	Tran. decrease work. memory
Scalp burns	No	No	Not reported	Occasional	Possible but not reported
Induced electr. currents	Theoretically possible but described as malfunction only if TMS is delivered in the presence of an additional device (pace-maker, cochlear implant, etc.)				
Structural brain changes	Not reported	Not reported	Inconsistent	Inconsistent	Not reported
Histotoxicity	No	No	Inconsistent	Inconsistent	Not reported
Other effects	Not reported	Not reported	Not reported	Tr. hormone changes	Not reported

Note: s-p: single pulse; p-p: paired pulse; rTMS: repetitive transcranial magnetic stimulation; TBS: theta burst stimulation. Adapted from Rossi & al. (2009)

Whatever the extent of social penetration may be (as technological advances may lower the prices) the appropriate regulation of TMS has to be cautious, and sale of TMS as a product to untrained individuals or enthusiastic groups may have to be explicitly prohibited. Caution is advisable not only due to listed side-effects (arguably, with untrained users the side-effects are much more likely), but also due to the possibility of not yet reported adverse cognitive effects and cumulative long term effects. Namely, as was the case with tDCS, the scientific evidence points to the conclusion that TMS is capable of producing cognitive enhancement for the specific tasks measured in the studies, but it is not known if the enhancement effects come at the price of reduction in other cognitive functions and tasks (McKinley & al. 2012). Also, adverse effects of long term (months or years) repeated exposure to TMS cannot be excluded. This includes not only unknown complications due to TMS induced fields, but also other effect such as hearing impairments as TMS coils produce noise levels which may exceed 140 dB (Rossi & al. 2009, p. 12).

Current regulation of TMS assumes its use as a therapeutic and investigatory device,

which leaves the enhancement (or off-label cosmetic neurology) uses unspecified and unregulated. There is an expert consensus on guidelines on the use of TMS in three broad classes, under the mandate of internal review boards (IRB) of research institutions or Ethics Committees of medical facilities, but no consensus on what constitutes normal healthy adults:

“Class 1 (direct benefit, potential high risk): studies in patients with diagnostic or therapeutic primary objective, including the development of new therapeutic indication or protocols, with potential direct individual clinical benefit. Normal subjects should not ordinarily participate in such studies, and the risk level for patients can be theoretically high for stimulation protocols that have been not yet tested for safety.

Class 2 (indirect benefit, moderate risk): studies in patients where the potential clinical benefit is more speculative or where no clinical benefit is expected, but the study is anticipated to yield valuable data for the development of treatments, safety assessment of a cortical stimulation protocol, or improved understanding of pathophysiological mechanisms of neurological or psychiatric diseases. Normal subjects may participate as control subjects. In these studies, regimens that will place subjects at significant risk of seizures or other serious adverse effects should employ only patients and not normal subjects, because exposure to adverse effects is unacceptable for normal subjects when clinical benefit is questionable.

Class 3 (indirect benefit, low risk): studies in normal subjects and patients that are expected to yield important data on brain physiology or on safety, but have no immediate relevance to clinical problems. Normal volunteers should be permitted to participate in rTMS research when it is likely to produce data that are of outstanding scientific or clinical value.

In all classes, every appropriate and feasible safety measure must be instituted, and stimulation parameters and schedules must be chosen with clinical goals and safety considerations in mind. Specifically tailored regimens may pose significant risks in some cases, and, indeed, there could be instances where stimulation parameters outside present safety recommendations could be delivered and adverse effects might be expected and prepared for (i.e., Class 1 studies). Nevertheless, the risks should be outweighed by the potential benefit in serious disorders where alternative therapies also have significant risks (e.g., electroconvulsive therapy or other neuromodulatory techniques which requires neurosurgical procedures). In Class 2 and 3 studies the responsibility rests on the Principal Investigator to prove how the participation of normal subjects will enhance the understanding of brain function or advance the understanding or treatment of a disease, in an important way.

Safety studies of new rTMS devices or alternative procedures of TMS must continue to be performed in normal subjects in a manner analogous to toxicity studies of new drugs. All studies, including safety studies, in normal subjects and patients for whom there is no potential clinical benefit should proceed only with maximally stringent safety measures and limits on stimulation parameters.

The group could not reach consensus about what constitutes a “normal subject”. One view is that such persons should have a normal neurologic examination. Another view is that self-reported information is sufficient to establish normalcy. What is appropriate might depend on the investigation. The definition of normalcy should be considered and approved for each study by the referring IRB.” (Rossi & al. 2009, pp. 34-35, emphasis in the original).

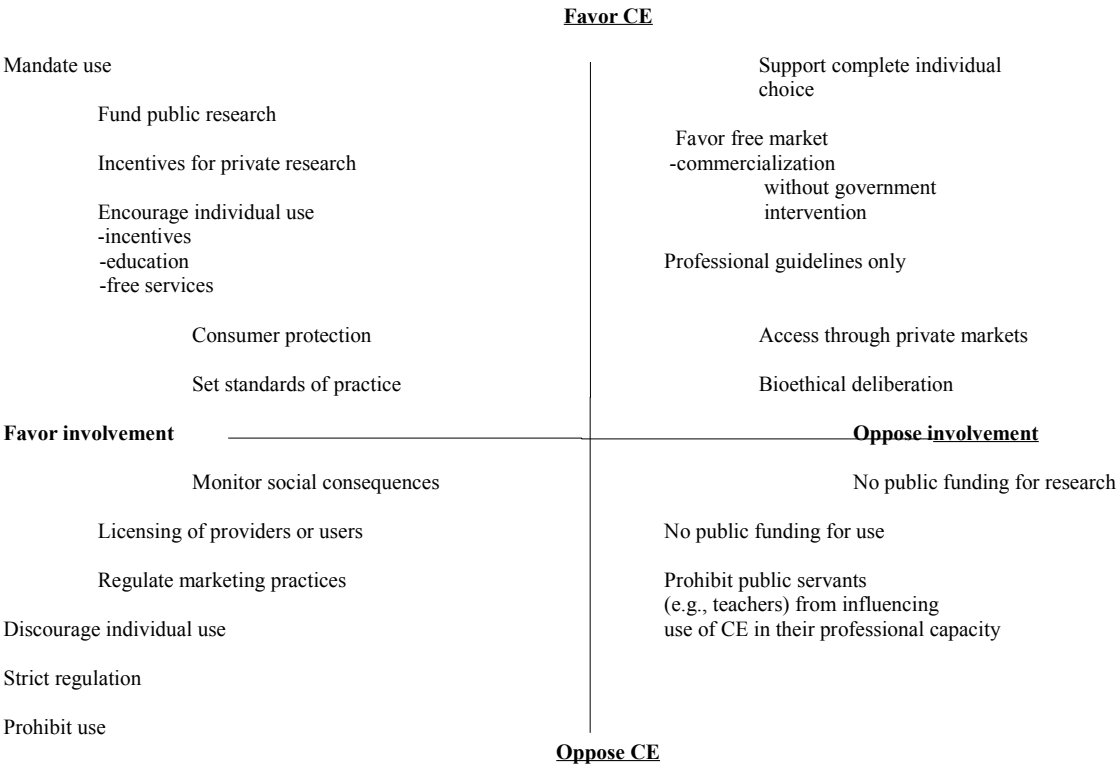
As can be seen from this relatively long excerpt, all three classes exclude enhancement uses of TMS. It could be assumed that such expert consensus on guidelines for use of TMS would be enough to adequately curtail any enhancement uses until more reliable information on risks and benefits of specific TMS stimulation paradigms and frequencies are obtained.

However, such an assumption would be overly optimistic. Consider the example of neuroimaging (a similarly expensive technique requiring expert knowledge to use): even

though there is an expert consensus that the use of functional magnetic resonance imaging outside of controlled laboratory and clinical settings is premature (see Illes & Sahakian 2011), that has not stopped companies and private individuals from using this expensive technology in market research (see <http://www.mtl-carteblanche.com/index-en.html>), for purposes of commercial lie detection (<http://www.nolienri.com/>) and even as evidence in criminal court proceedings (see Patel & al. 2007).

The use of cognitive enhancers in the courtroom is a case in point. Recall that even “addition by subtraction” uses of TMS reliably provide increased resistance to false memories (Snyder 2009). Given that veridical memory is of utmost importance in witness testimony, there have been calls for mandatory use or government incentives for the use of cognitive enhancers in criminal proceedings of capital cases (Sandberg, Sinnott-Armstrong & Savulescu 2011). At any rate, impressive effects of TMS have been reported by the media (see e.g., Sutherland 2013), so it would be naïve to assume that expert guidelines will prevent individuals or groups from using TMS to attempt to “unlock” their inner savant, or enhance certain cognitive capacities (whether they are successful or not). Indeed, relying on professional guidelines only is far from being conducive to curbing enhancement practices – it fits squarely between the Favor cognitive enhancement (CE) and oppose government involvement axes of regulation (See Figure 4.3.).

Figure 4.3. The range of policy options on enhancement



Note: Adapted from Blank 2014

The Figure 4.3. illustrates a range of possible policy responses on the axes of favoring/opposing government involvement and cognitive enhancement (CE) technology. These options are a sample of regulatory responses which have been used by various countries concerning stem cell research, reproductive and genetic technologies or past brain interventions, and they clearly demonstrate the diversity of policy options as well as the often diametrically opposed positions on the role of the government (Blank 2014). However, the government involvement in the case of TMS is already settled as relatively high, at least in some countries.

Namely, the military interest in TMS (see McKinley 2012) will certainly pave the way to more affordable TMS applications, and with the “spill-over” effect these will make their way into the general population either by off-label uses or by enthusiastic pro-enhancement groups practicing “investigatory uses” on their own. Even though TMS might become more affordable in the future, it is highly unlikely that it will be available as a “do it yourself” enhancement gadget like tDCS. That leaves TMS device as a commercial product or TMS sessions as a commercial service.

So what kind of regulation would be appropriate for TMS as a product or as a service? Recall that Blank (2014) concluded that the risks TMS poses are moderate, enhancement potential unknown, and that an appropriate cautious policy would be prohibition until more data is available. Even though in my analysis I disagree with Blank's conclusion regarding the enhancement potential of TMS and, based on available data (see Luber & Lisanby 2013) conclude that TMS does offer enhancement effects, I agree with Blank that the sale of TMS devices would have to be prohibited to anyone apart from recognized research and medical institutions, and that any non-compliance should be sanctioned with criminal prosecution.

However, in case of TMS as a service, the situation is more complicated. Notwithstanding the fact that all governments have a responsibility of ensuring safety and quality control standards as well as consumer protection and fair market practices, the case for prohibition of TMS as a *service* is not as strong. Blank's reliance on the current medical risk assessment system, which compares treatment risk with the expected benefit of reduced morbidity from successful treatment makes him overly risk averse if cognitive enhancement by TMS is offered by a trained professional. As Bostrom and Sandberg (2009) rightly note, cosmetic surgery has offered a precedent for a risk model where client's autonomy overrides at least minor medical risks even when the procedure does not reduce or prevent morbidity. The key issue is that the service is offered by a trained professional. Recall that the analysis of

justice and autonomy has led to the conclusion that in the case of cognitive enhancement technologies which might exacerbate inequalities but are not detrimental to autonomy need to be discouraged, and not prohibited. Even though the adverse effects of TMS can be considerable, to date, there is no data on any addictive effects, or long term debilitating effects on agency.

Furthermore, the existence of tDCS on the market makes the issue of fairness of regulation of TMS untreatable as an isolated case. Consider the case of discourage use type of regulation: if TMS was an isolated case, any discouragement policy would be unfair as it would make the technology inaccessible to the least well off, while more affluent citizens might still afford it. The fact that tDCS, a very affordable enhancement device, is already available offsets the concern for fairness in access in the case of TMS. Thus, TMS should be regulated in such a manner that tDCS and TMS regulation are complementary and within a unified plane of regulatory options (see Figure 4.3.) and not at cross purposes. Also it has to be taken into account that compared to tDCS, TMS can be focused more precisely, but it is less easy to use, more expensive and more risky due to the very real danger of seizures (see Schermer 2013). Thus, appropriate regulation should be designed to protect the interests of citizens, and guard against specific avoidable harms of TMS.

As I have argued that tDCS needs to be regulated urgently, and proposed the suitably modified economic disincentives model (EDM), the most logical step is to assess the appropriateness of similar regulation for TMS. Since TMS, like tDCS, might cause long-term detrimental changes in developing brains, a reasonable precaution would be to again set the age requirement for eligibility for cognitive enhancement with TMS at 25. Thus, even if TMS as a service is available via licensed trained professionals, the service should not be performed on any person below 25 years of age, any non-compliance by service providers should be sanctioned with criminal prosecution and loss of license. On the other hand, due to respect for autonomy, enhancement service seekers should only be fined, and not criminalized.

Thus it seems that a “gate-keeper” should be used for regulation of commercial uses of TMS as a *service*. Now, let us consider if this approach would lead to further problems. As previously mentioned, it is highly unlikely that TMS would be readily available as a *product* or *Do-It-Yourself* gadget, it is highly unlikely people will try to circumvent the “gate keeper”. As for the issue of who could be a “gate keeper”, a licensing procedure could be defined, which should not be limited to health professionals. After all, neuroscientists might be more knowledgeable on the issue than, say a general health practitioner. Thus the licensing

procedure for service providers (and I think that “competent service provider” would be a better designation of the model than the “gate keeper”), should be open to individuals with a specialised education in neurology or neuroscience. But would this “competent service provider” model produce the same socially undesirable consequences as was argued for the “gate keeper” model in the case of tDCS?

More specifically, would a black market for TMS devices be created, and would only the rich be able to afford enhancement with TMS? The issue of affordability of TMS is important, in both counts. Namely, the TMS device is very costly and hard to produce, so the danger of the black market is limited, even though it cannot be entirely excluded. On the latter issue, recall that the military is interested in TMS and that military funded research is likely to lead to a decrease in the costs of TMS as a service. However, the most important issue is the relation between offer and demand – sufficient competition tends to decrease prices. Thus, the “service provider model”, by virtue of being open to neurologists AND neuroscientists, is likely to create sufficient offer, and likely drive TMS service prices down.

But what about other provisions of EDM - taxes, fees and requirements of additional insurance? Furthermore, what about the lack of information on effects and mechanisms of action of TMS? Apart from limiting the availability of TMS as a service to minors, how will this “service provider model” regulatory framework generate the necessary information without increasing already considerable costs?

The answer is relatively simple. Indeed, some of the requirements of EDM could create additional costs and thus should not be enforced separately on TMS. However, the potential of EDM to provide information on long term effects, and safety and efficacy, in a short amount of time is very valuable for society. The most elegant solution is to use the licensing of tDCS users for this purpose. Namely, the required exam for the user license for tDCS should be expanded to include known long-term effects and side-effects of TMS as well, and TMS as a service should only be made available to such “enhancement device” license holders. Thus, there would be no need for a specific additional medical insurance for TMS, as one insurance policy would include both TMS and tDCS, and thus again this would guarantee that any adverse effects generated by TMS use would not drain public funds. Last but not least, obligatory annual medical tests for obtaining and renewing a license would quickly generate the information needed for fine-tuning the policy.

Although there is the danger that the statistical data about unwanted effects and long term consequences of prolonged enhancement use might be confounded by use of multiple techniques (tDCS and TMS), this would only increase the time-span before relevant

information is available, and is not a sufficient reason to abandon the model. Again, due to already high costs of TMS as a service the requirement of EDM to regulate the prices should be postponed, at least until that time at which the prices have decreased considerably due to competition in the market.

To conclude: the EDM for users of tDCS should be extended to TMS as a service. This unified “enhancement device use” license would enable citizens above the age of 25 to purchase and use tDCS devices and to benefit from the “service provider model” as applied to TMS. Only qualified neurologists and neuroscientists could apply for a license to offer TMS as a service. Because of the complexity of the brain, it is questionable whether we will be able to overcome trade-offs between enhancement and concurrent impairment by enhancement devices (see Blank 2014), but citizens certainly have the right to pursue even potentially dangerous activities, as long as safety and quality control standards along with consumer protection and fair market practices are ensured.

5. ANALYSIS OF OBJECTIONS

5.1 Objections to the general approach

Now that the case-by-case analysis has been successfully finished, it is time to revisit the issue of objections to the approach and the solutions offered. Recall that one of the objections to the analysis of cognitive enhancement with the aid of principles of justice was that justice is no better than authenticity or „Playing God” arguments. The objection was temporarily defused with the introduction of the idea of public reason, and the constrained range of political values and intuitions: in this sense, justice arguments are admissible as a basis for public policy, whereas religious and other particularist arguments are not, due to the fact that they hinge on irreconcilable comprehensive doctrines and it is reasonable to disagree with their tenets. However, in order to safeguard the validity of arguments and conclusions in the case-by-case analysis, this objection needs to be fully refuted. After all, if human beings have had conflicting intuitions about what justice requires, how can anyone expect that solutions based on an argument from justice would not lead to a reasonable disagreement as well? History does certainly show many examples of people willing to fight and die for what they believe is just, and other people providing coercion, punishment and even death for exactly the same reasons. Do we have any common ground in viewing justice at all? Why should we take one theory of justice and not some other? A necessarily brief (and up to a point speculative) outline of the development of the philosophical refinement of intuitions about justice might help put things into perspective.¹⁰⁷

The first intuitions about justice have been expressed and defined by Aristotle's definition that justice means giving each his due. Thus, the first basic principle of justice is desert. Rewards (and punishments) should be allocated to those who deserve them. Desert was specified by virtue (arete), and in the context of a political community justice implied that the best (aristoi), or the most virtuous rule the others (hence aristocracy). The wedding of the notion of virtue with judeo-christian religious ethics further implied that the disadvantaged are

¹⁰⁷ In explicating the content of social justice I draw on David Miller (1999) who cites a great deal of research on social justice in the empirical literature. Unsurprisingly, the research shows that citizens usually have only vague, theoretically unrefined representations or intuitions of principles of justice (equality, desert and need) which are elaborated by political theorists and philosophers. The important point is that empirical studies corroborate that people all over the world, in different societies, cultures and stages of technological advancement have the same rough representations and intuitions about justice.

to be helped (paternalistically of course) when they are in need. Thus principles of *desert* and *need* established the claims of justice for two distinct and unequal classes. These are the classical conservative principles of justice, and they could be found in such diverse intuitions on moral obligation as the writings of Burke, the classical elite theory, the Qur'an and mainstream medical ethics (at least up until the '70s).

Two reactions opposed, both theoretically and historically, the classical conservative principles of justice: a liberal and a socialist one. The classical liberal principles of justice of Locke, and more recent libertarian theories such as that of Nozick, correct the injustices stemming from the conservative principles of justice by postulating that *equality* should be the first principle of justice (relating to rights, liberties and acquisition of property), and that ancient privileges are actually undeserved. The concepts of virtue and need are regarded as external to the idea of justice, and free enterprise with equal opportunity constitutes the basis of *desert*. Historically, this conception has also led to injustices, in the first place when equality and equal opportunity was construed as merely formal or when a way of life (such as that of Native Americans) was rejected because it was dependent on a much greater share of the natural resources.

The second reaction gained historical prominence later, although it was present as long as the liberal one, and was elegantly formulated with Marx's definition „from each according to his ability, to each according to his need” (Marx 1875). Thus classical socialist or communist principles of justice are *equality and need*. This view is not without its faults, theoretical and historical alike. The principle of desert is completely lacking, and therefore no rewards or property could be claimed as deserved. Everyone is expected to do as much as possible for the benefit of others and individual reward is not a matter of justice.

The deadlock between conflicting ideas of justice that form the basis of three most important political traditions has been steered to a constructive development by Rawls's account of „Justice as Fairness” first in his *A Theory of Justice* (1971/1999), and later in *Political liberalism* (1993/2005). Rawls was first, but not the last, to actually combine all three theoretical and historical intuitions about principles of justice, and order them according to priority. Recall that he formulates the principles of justice in the following way:

- a. Each person has an equal claim to a fully adequate scheme of basic rights and liberties, which scheme is compatible with the same scheme for all; and in this scheme the equal political liberties, and only those liberties, are to be guaranteed their fair value.
- b. Social and economic inequalities are to satisfy two conditions: first, they are to be attached

to positions and offices open to all under conditions of fair equality of opportunity; and second, they are to be to the greatest benefit of the least advantaged members of society (Rawls 2005, pp. 5-6).

One could be confused about the number of principles, because Rawls states that there are two principles, in which the first principle is obviously a principle of *equality* with an added guard against Marxist/socialist criticism of merely formal equality in liberalism. The second principle has two parts that serve the purpose of setting the standard which inequalities could be justifiable. The first part states in which conditions the outcomes of competitive enterprises are actually *deserved* (the principle of fair equality of opportunity) and the second part that addresses the socialist intuitions that *need* is not a matter of charity, but of social justice (the difference principle). As people should be equal in rights, but are not equal in capabilities, these two parts tack different ways for meeting egalitarian concerns. Equality of opportunity as the basis for desert leaves the normal unequal distribution of capabilities in place, and the difference principle governing overall inequality in prospects in life mitigates the effects of doing so.¹⁰⁸

Rawls has expressed the intuitions about justice that citizens in democratic society hold, and gave them a *liberal* ordering. The difference principle, an addition to suitably formulated classical liberal principles of justice was given third place. In that way, both the intuitions citizens have about need (benefiting the least advantaged) and the necessary qualification of the distribution according to need, due to the free-rider problem, are recognized. Rawls's theory sparked a lot of discussion in the area of practical philosophy, and arguably because it offered a rather neat standard for the problems of social justice, it also received serious attention from economists, legal scholars, political scientists, sociologists, healthcare resource allocators and theologians - in other words anyone concerned with justice.

Some criticisms of his model claimed that the difference principle should not be included in a liberal theory of justice, but others merely attacked the ordering. Theoretically, conceptions have been formed to accommodate what was already happening in political practice as a response to what Rawls called "reasonable pluralism". Namely, although proponents of *classical* conservatism, liberalism and socialism had irreconcilable conceptions of justice, within democratic societies the conflicts have been curbed by the recognition of the validity for intuitions of justice of citizens endorsing opposing views. Such tendencies have lead to political stability in democratic societies although social-democratic, liberal-democratic and moderate conservative parties have been shifting places of power and

¹⁰⁸ For a complete discussion of three philosophical models of relationship between equal opportunity and the goals of health care, see Buchanan & al. 2000, pp.126-141. These models differ from what is offered here, but do take in to account socialist alternative readings.

opposition. Thus, the disagreement they have is not a *strong* reasonable disagreement about the *content* of the principles of justice, but a *weak* reasonable disagreement about the *ordering*, and the idea of public reason sufficiently guards against intrusion from comprehensive doctrines by justifying basic political issues on the basis of shared principles.¹⁰⁹

Indeed, Rawls himself has recognized that some citizens may decide that different orderings of the principles of justice are more reasonable from the liberal one he proposed, at the level of application. That is why he has in his reformulation of the idea of public reason (Rawls 2002) included a specific social-democratic theory of legitimacy and a conservative natural law theory in a family of political conceptions of justice for a well-ordered constitutional democratic society. The problem of reasonable disagreement is solved by explicating the content of justice for public reason that is only differently ordered in reasonable political conceptions of justice which specify the basic rights, liberties and opportunities in a society's basic structure.¹¹⁰

Political conceptions of justice, as opposed to classical versions, in order to be reasonable must accept certain “general facts” of political sociology. The first is the fact of pluralism which means that in any society there is bound to be a diversity of comprehensive religious, philosophical and ethical doctrines, and the second that only oppressive use of state power could maintain the supremacy of one comprehensive doctrine. A stable democracy requires widespread, free support by a clear majority, and the political culture of stable democracies contains fundamental intuitive ideas that can serve as the basis for a political conception of justice.

Reasonable liberal, social or conservative orderings of principles of justice, or ordering at the level of concrete examples (a la Miller) do not create problems leading to a strong reasonable disagreement, as there is convergence on the practical account of what the *content* of justice requires. This means that the arguments from justice are much more robust than say

¹⁰⁹ Bearing in mind the fact that people actually have very vague representations of principles of justice, David Miller has tried to solve the question of application of content of justice by proposing that they be ordered only in context of use. His theory of social justice does not require one to emphasize one of the principles (desert or need or equality) over the others; rather, he postulated that all three are in balance with one another. According to his model, *Desert* is a claim that a person is entitled to a reward based on performance, in other words that superior performance merits recognition (Miller, 1999: 134, 141). *Need* is a claim that a person is entitled to benefits and/or compensation if lacking basic necessities and is being harmed or is in danger of being harmed and/or when this person's capacity to function is being impeded (Miller, 1999: 207, 210). *Equality* refers to the social ideal that society regards and treats its citizens as equals in principle, and that entitlements, such as certain basic rights should be distributed equally (Miller, 1999: 232). The important point here is that the rough content of justice is the same for all citizens in all societies even though technical formulations of political theorists have differences.

¹¹⁰ In the next two paragraphs I draw on Rawls 2005.

arguments from authenticity. Also, the discussion which started from one reasonable political conception of justice to provide rationale for a general case, as well as case-by-case assessments of cognitive enhancement technologies has at least *prima facie* validity. Unless confronted with extremely strong objections on the level of theory or on the level of application, the conclusions are sufficiently grounded to contribute to the political discussion on regulation of cognitive enhancers.

5.2. Could there be a convergence between liberals, socialists and conservatives on policy concerning cognitive enhancement? Objections to the idea of public reason

There are good reasons to analyze a social and political issue such as cognitive enhancement with reference to public reason. The idea of public reason has a central place in the contemporary debates in political philosophy. Following Rawls, it is plausible to start from the assumption that the ideal of public reason should be the rationale for lawgivers, judges, and public officials (even candidates for public offices) while formulating plans, ranking priorities and public decision-making. Since regulation of cognitive enhancement is an issue for public decision-making, it seems plausible to demand that strictures of public reason be observed, lest the decision be made with regard to sectarian reasons and values. However, the very idea of public reason, even though it has been embraced by many, has also been attacked and/or corrected by countless authors, and even Rawls accepted to incorporate some changes in his position. These changes at first glance may seem as slackening of the criteria by including religious reasons and deference to communitarian criticism, so it might seem that my position on exclusion of sectarian arguments (e.g., “Playing God”) has lost its edge.

However, such a view would be wrong, as the revised idea of public reason is not relativist or too inclusive (e.g., by including with the same force “Playing God” or authenticity arguments) but merely more democratic. Namely, as mentioned above it respects the differing intuitions of reasonable citizens on the *ranking* of political values and opens a space for public decisions based on a general and wide reflective equilibrium between *political traditions*. The idea of a family of reasonable conceptions of justice implies that *full justification* occurs only if a decision can be framed in the terms of moderate proponents of all three traditions - liberal, socialist and conservative.

As the idea of public reason has been attacked, defended, explained and reformulated by a host of different authors¹¹¹, it is hard to pinpoint any especially significant issue that

¹¹¹For some explanations of this idea, see: Scanlon 2003; Larmore 2003; Dreben 2003; Nnodim 2004; Button 2005. For some of the criticisms, see: Evans 2003; Friedman 2000; Gaus 1997; Moon 2003; Okin 1994; Sterba 1999; Patterson 2004. Perhaps the most important criticism of Rawls comes from Habermas. His more important critiques can be found in: Habermas 2004; Habermas 2005a, Habermas 2005b; and Habermas 2007. For some of the defenses of the idea of public reasons from different forms of criticism, see: Farrelly 1999; Fernandes De Oliveira 2000; Nussbaum 2003; Roberts Skerrett 2005; Quong 2011.

would have to be resolved in order to defend the extension of public reason to neuroethics of cognitive enhancement. However, a short analysis of the types of objections to this idea, and the changes Rawls has announced might be helpful. That is why I will examine the changes in Rawls' article "The Idea of Public Reason Revisited", while taking in to account the types of objections identified in the literature. Then, I will more closely examine the issue of conceptions and doctrines and different types of reasonable disagreement (strong and weak) they entail. Finally, I will elaborate the implications of this revised idea of public reason for justification of policies, laws and legal decisions in general and for the issue of regulation of cognitive enhancements in particular.

As it is well known, Rawls's reformulation of the idea of public reason offers the possibility of introducing religious reasons (i.e. the whole truth according to a religious doctrine), with the proviso that these reasons are "translated" in due time to the language of political values. A great number of authors critical toward Rawls has made the point of defending religious reasons in public discourse and attacking the secular limitations as unreasonable (see e.g., George 2006; Finnis 1999). That is why it may at first glance seem that including religious reasons means slackening of the criteria of public reason to the point where it serves no purpose. In the more concrete example of cognitive enhancement, it might seem as though "Playing God" arguments can be introduced to formulate a public policy and then a "translation" of the policy itself in the language of political values is all that it takes to make it legitimate.

This view would be mistaken. Inclusion of religious reasons is merely recognition of firm political values espoused by conservative citizens. Citizens more inclined to socialism or liberalism also have a recourse to comprehensive views of say Marx or Kant, which have to be translated to the language of political values. It should be noted that Benhabib's (1986) and Habermas's (2004) markedly secular positions, as well as moderately religiously conservative positions of Finnis (1980, 1983) and Maritain (1951) have been included in the "family of reasonable conceptions of justice", and I will argue that these conceptions are included as representatives and "translators".

However, the objections to public reason are external to Rawls' philosophy and a proper defense of the extension of public reason in the domain of cognitive enhancement needs to refute the criticism at least in principle. In order to be able to do that, different objections to the idea of public reason should be shortly analyzed. In his book *Liberalism Without Perfection* Jonathan Quong has, among other things, offered the taxonomy of

objections to the idea of public reason (Quong 2011, pp. 256-289.). This taxonomy is a starting point for further analysis.

According to the first type of objections, the idea of public reason is either indeterminate or inconclusive, and thus inadequate to solve many of the pressing political issues in liberal-democratic societies.¹¹² This type of objection could be named *the inadequacy thesis*, and matched criticism of abstract nature of Rawls's theory and neglect of real challenges of injustice and pressing political issues. By analogy, the inadequacy thesis could be applied to the extension of public reason in the domain of cognitive enhancement in general and to the proposed public policies of the Economic Disincentives Model (EDM) and Prohibition of production and sale in particular.

The second type of objections is *the antidemocratic paternalism thesis*, which motivated Rawls to revisit many aspects of his position. It is expressed by the claim (which is after Habermas repeated by many others) that the idea of public reason, as formulated by Rawls, is antidemocratic because it "fixes" the content of public reason in favor of a liberal conception of justice in advance of any actual democratic discourse between citizens. According to Habermas, Rawls's veil of ignorance "deprives the citizens of too many insights that they would have to assimilate anew in each generation". The citizens cannot "reignite the radical embers of the original position in the civic life of their society". Principles and norms are paternalistically given by a philosopher-expert and constitutionally institutionalized beyond the reach of citizens. Accordingly, the public use of reason merely promotes the nonviolent preservation of political stability, and deters citizens from realizing their political autonomy (See Habermas 2005a, ch. 2).

It should be noted that Rawls dedicated the largest part of his "Reply to Habermas" to refuting these claims (see Rawls 2005, pp. 372-434). In three distinct chapters he has tried to answer three possible interpretations of the antidemocratic paternalism thesis. Joshua Cohen has analyzed these interpretations (Cohen 2003, especially pp. 111-131) and named the first as the thesis of *institutional subordination*. According to this interpretation, assigning priority to principles of justice may lead to undemocratic solutions as better means of achieving formally defined justice. The second interpretation is the charge of *denigrating* the importance of public argument and political participation. If justice has been rigidly determined before and independent of any democratic practice, democracy is left with the task of preserving the

¹¹²Quong quotes Marneffe, Horton and Reidy as sources of such criticism. Due to the fact that this discussion serves the purpose of defending a certain extension of the idea of public reason and is not a free-standing discussion in political philosophy, I will follow the conceptualisation of the sources of criticism as Quong defined them.

political stability and implementation of principles, instead of discussing their point and merits. The final interpretation is that the theory of justice is founded on *mistrust* of citizens. A philosophical conception of justice, if substantive and not procedural, implicitly assumes mistrust of citizens, as it prescribes prior fetters to their deliberation and public discourse.¹¹³

By extension, the anti-democratic paternalism thesis, with all three interpretations could be used to object to the proposed public policies. The “institutional subordination” interpretation could be used to challenge both EDM and Prohibition responses to cognitive enhancers. Indeed, if these responses are framed as being prior to the actual work of institutions in democratic societies, such an objection would be very damning. It could be applied in the defense of a “gate keeper” response – the prescription of medical drugs by licensed medical professionals, subject to review from professional bodies is an important institution – introduction of EDM (or prohibition) might be seen as a subordination of the medical profession to the power of government, and unjustified infringement on the practice of medicine.

A similar argument could be made with the “denigration of public argument” interpretation. If EDM or Prohibition are established prior to an open public discussion on the appropriate responses to the use of cognitive enhancements by the healthy, based on a philosophical discussion, the public discourse could be impoverished. Finally, the same could be said for the “mistrust of citizens” interpretation – if philosophers and experts decide for the citizens how to respond to the social phenomenon of cognitive enhancement, which might be the hallmark of a technocratic, but hardly democratic society.

The third type of objection stems from positions that make the issue of *religious reasons* paramount in the democratic society. The authors objecting on these grounds come from many different quarters, but share the position that the idea of public reason is problematic because religious reasons are arbitrarily or wrongly excluded.¹¹⁴

Indeed, such an objection can be leveled to the extension of public reason to the issue of cognitive enhancement. If a majority of citizens has firm religious beliefs that oppose any use of enhancements – a view that has been dubbed “psychotropic Calvinism” (Klerman 1972), then public policy if it is to be democratic, needs to take these firm religious convictions and thus the “Playing God” argument into account.

¹¹³ Indeed, Rawls took these objections very seriously. In his “Reply to Habermas” he introduces the rudiments of the idea of a family of liberal conceptions of justice serving as a basis for “overlapping consensus”. Namely, he insisted that other proponents of liberalism (Judith Shklar, Charles Larmore, Joshua Cohen and Bruce Ackerman) have offered reasonable conceptions of justice that could serve as a basis for overlapping consensus along with “justice as fairness” (see Rawls 2005, p. 374, n.1).

¹¹⁴Quong quotes Eberle, Greenawalt, Stout, and Weithman as sources of such criticism.

The fourth type of objection starts from the assumption that the idea of public reason is either too demanding for citizens, or else it is an undesirably high-minded view of democratic discourse, wrongly denigrating the importance of bargaining or interest-group politics.¹¹⁵ This type of objection could be named the *thesis of neglected reality* and extended to the debate on cognitive enhancement. Namely, it could be the case that whatever solution is reached on the issue it will not be the result of philosophical discussions, but rather a result of different alignments of power within society.

The next type of objection could be named *the marginalization thesis*. According to these types of criticism the idea of public reason arbitrarily privileges a mode of discourse which is calm, dispassionate, logical, and analytical, which excludes the emotive, passionate, or rhetorical forms of discourse more common to certain historically marginalized social groups.¹¹⁶

This type of objection could be extended to the debate on cognitive enhancement in two ways. First, it could be directly applied along the lines of feminist influence and could be assumed as an objection from the side of “Cyborg Feminism” (e.g., Haraway 1991). Secondly it could be applied to certain religious or other groups that base their arguments on a “gut reaction” against enhancement (e.g., Kass 2002).

The sixth type of objection could be named *the lack of truth thesis*. According to this type of criticism, the idea of public reason is flawed since it prevents citizens from relying on the whole truth as they see it.¹¹⁷ Indeed, public reason relies on the idea of reasonableness, so any position that claims to know the truth about say enhancement is excluded.

The final type of objection could be named *the thesis of unnecessary exclusion of citizens*. According to this type of view, the constituency of public reason is unnecessarily exclusionary since unreasonable citizens are not included, and are not offered sound justifications for the laws that apply to them. The basis of this objection is the fear that public reason could offer justification for repeating historical injustices toward women and other sensitive groups, since if they are declared unreasonable some of their civic rights could be revoked.¹¹⁸ Again, apart from the natural extension to the Cyborg Feminism that was mentioned earlier, this criticism could be extended to broader communities that have views on the use of technology most other citizens would find unreasonable. On the one hand, there are those who refuse the use of certain forms of technology because they think it is inherently evil (e.g., Amish), and

¹¹⁵Quong quotes Ian Shapiro as the source of such criticism.

¹¹⁶Quong quotes feminist authors Lynn Sanders and Iris Marion Young as the source of such criticism.

¹¹⁷Quong quotes Raz as source of such criticism.

¹¹⁸Quong quotes James Bohman and Marilyn Friedman as sources for such criticism.

on the other hand are transhumanists and posthumanists who endorse radical forms of transformation of the human body (see, e.g. Pepperell 2003).

Summing up the objections is of course not enough. The way Rawls himself changed his position should be shortly examined in order to extrapolate the impact such criticism might have for the extended Rawlsian argument on cognitive enhancement. The three basic changes that Rawls made to his *Political Liberalism* are announced in the introduction to “The Idea of Public Reason Revisited”: 1. the relation of public reason and political liberalism to the major religions; 2. clarification that political liberalism is about a family of reasonable liberal ideas of political justice, while justice as fairness has a minor role as but one such political conception, and deletion of the phrases that imply that Kant’s ideas of practical reason were being used; and 3. addition in the Lecture VII with the seven pages from “The Idea of Public Reason Revisited” on feminism (see Rawls 2005, pp. 437-439).

The objections listed give an overview of a range of criticism that has been leveled against Rawls’ position, but the changes Rawls actually undertook point to the conclusion that not all of them have equal merit. Namely, the *the inadequacy*, *lack of truth* and *unnecessary exclusion of citizens* theses have obviously been ignored, while the *antidemocratic-paternalism*, *religious reasons*, *neglected reality* and *marginalization* theses have been accommodated. Indeed, if the changes in Rawls’ view are scrutinized more closely, it can be concluded that democratic inclusiveness mandates partial inclusion of above mentioned theses (for a longer argument and more details see Dubljević 2010).

Indeed, the criticism of the antidemocratic paternalistic stance of philosopher-experts has had a great impact in Rawls’s work. Introductions to Rawls’s final publications stress the more modest role of the “student of philosophy” and guard against possible interpretations of the project as undemocratic (see Rawls 2001, 2003, 2007). Therefore, it is plausible to assume that inclusion in principle of the point of view of religious or marginalized citizens serves the purpose to make the position more democratic.

To understand how these perspectives are accommodated and how say, “Playing God” or other unsubstantiated arguments are still not allowed into the discourse of public reason, a further analysis of a concept from Rawls’ exchange with Habermas (See Rawls 2005, Lecture IX) is helpful. Namely, while answering to Habermas’s objections to the original position, Rawls introduced the idea of different “devices of representation” for the moral point of view. There he contrasted his own original position with Habermas’s “ideal speech situation”. In the “Idea of Public Reason Revisited” Rawls claims that he has proposed the original position as one way to identify political principles for the content of public reason. As others have every

right to think that different ways to identify these principles are more reasonable, the content of public reason is given by a *family* of political conceptions of justice, and not a single one. These conceptions are characterized by three features: 1. they offer a list of basic rights, liberties and opportunities; 2. they assign special priority to these rights with respect to general good and perfectionist values; and 3. they have measures ensuring for all citizens adequate all-purpose means to make effective use of their freedoms. In comparison to the original formulation, the content of public reason is the same. Yet, in the reformulation, it is provided by different conceptions of justice, and not only by “justice as fairness”. The most plausible explanation of this change is that it is an answer to the charge that the idea of public reason is undemocratic as it “fixes” the content of public reason. Rawls is explicit that

Political liberalism, then, does not try to fix public reason once and for all in the form of one favored political conception of justice. ... For instance, political liberalism also admits Habermas’s discourse conception of legitimacy (sometimes said to be radically democratic rather than liberal), as well as Catholic views of the common good and solidarity when they are expressed in terms of political values (Rawls 2005, pp. 451-452).

Several points should be made here. First, Rawls tried to offer a convincing argument that political liberalism could offer principles of right and justice to deal with the problems raised by marginalized groups and the women’s movement, but respects their considered judgments about the need for a radical democratic approach. Secondly, since religiously inclined citizens have firm moral beliefs, their “devices of representation” should be represented if the project is truly democratic. Therefore, “religious views of *public good and solidarity* expressed in terms of *political values*” could be included (emphasis added) as opposed to doctrinary dismissal or dogmatic demanding that certain coercive laws be passed.

The difference between a *strong* reasonable disagreement about the content of comprehensive doctrines and a *weak* reasonable disagreement about the ordering of political values of a democratic society needs to be noted. Reasonable conceptions of justice stemming from the three great traditions of political thought share the content, but do not share “devices of representation” of the moral point of view, and thus have different orderings that are reasonable. The idea of a “family of reasonable conceptions of justice” makes the idea of public reason more inclusive and more democratic, as citizens are not deprived of choice in fundamental political issues. This has different implications for citizens and public officials in a democratic society as public reason has not lost its strictures. Namely, citizens are respecting the strictures of public reason if they are arguing about legal and political decisions in terms of *one* reasonable conception of justice (liberal, radical-democratic/socialist or

conservative). Public officials, however need to justify public decisions in terms of all three types. Namely, a public decision is truly impartial only if it can be grounded in conceptions with different orderings of political values. A public decision based on one conception only could be seen as partial and would not be fully justified.

This might have important implications for those who seek to extend Rawls's view on justice and justification to other areas. Norman Daniels, to name one example, extended Rawls's view to the issue of health and health care. Daniels has analyzed different conceptions of justice and concluded that there is a convergence on the issue of health (Daniels 2008, pp. 64-78). Now, the choice of included conceptions of justice makes the difference between full justification and *pro tanto* justification. Namely, if all the conceptions analyzed are *secular* and/or liberal, the justification provided is not full. Additional work and analysis (incorporating moderate conservative and moderate socialist conceptions) might be necessary.¹¹⁹ Similarly, the discussion so far has not provided full justification (a fact that has been mentioned several times throughout the text so far). It is important to note that due to reasons of space such an extended discussion cannot be provided here, but that several observations can be made that would facilitate response to the more specific objections to the approach and models of regulation.

Public reason is neither a *strictly* secular nor religious procedure of justification, but rather it exemplifies the universal moral-political basis for reconciliation of legitimate aims of all reasonable citizens. Reasonable citizens have different reasonable rankings of political values, and public reason is not prejudicial toward any reasonable view. Rawls offered three conditions for the acceptance in the family of conceptions of justice, consistent with his claim that political values are neither secular nor religious: 1. Their principles apply to the basic structure of society, 2. They are political conceptions that must be able to be presented independently from comprehensive doctrines of any kind, and 3. They can be worked out from fundamental ideas implicit in the public political culture (e.g. citizens as free and equal, society as fair system of cooperation) (Rawls 2005, pp. 452-454).

In order to fully appreciate the importance of distinction of religious doctrines and moderately conservative conceptions, and secular (e.g., Hegelian-Marxist) doctrines and moderate socialist conceptions, with the inclusion of these *conceptions* in the „family“, the fundamental views they represent should be addressed. The positions included in the family

¹¹⁹ Such analysis could be provided in another book-length project. For example, Shortall (2009) has provided an interesting analysis of the liberal, socialist and conservative takes on human rights. For that purpose he compared the political theories of Dworkin, Habermas and Finnis and analyzed the amount of overlap and tension between these conceptions.

of political conceptions of justice are reconstructions of historically significant traditions in terms of political values. Rawls frequently mentions religiously motivated persecution, which are fortunately at least in constitutional democracies a matter of the past. The Marxist secular comprehensive doctrine with the view on the truth of dialectical materialism also has a history of unreasonable versions leading to persecution. That is why Rawls affirms *reasonable* conceptions stemming from these traditions that reconstructed the original comprehensive doctrine in terms of political values (see e.g., Habermas 1976). This affirmation and inclusion serves the purpose of securing the basis for a broad consensus that would guarantee the implementation of reasonable principles of justice and legitimate policies. These conceptions are important for the stability of constitutional democracy and they answer the question: „how is it possible – or is it – for those of faith, as well as the nonreligious (secular), to endorse a constitutional regime even when their comprehensive doctrines may not prosper under it, and indeed may decline?“ (Rawls 2005, p. 460).

The reformulation of the idea of public reason takes this interplay between nonpublic aspects of doctrines and public aspects of conceptions as the basis, and emphasizes the fact that the purpose of democratic deliberation is public justification. This approach defuses the objection of antidemocratic paternalism as well as the charge that the public use of reason depends on a platform of nonpublic reasons (compare Habermas 2005a, pp. 85-86). It is plausible to assume that the additional forms of discourse Rawls briefly introduced (declaration, conjecture and witnessing) which could be used in a public discussion, but are not part of public reasoning, further clarify this point (see Rawls, pp. 465-466, especially n. 57).

To conclude, Rawls reformulated public reason so that there can be no vestiges of partiality toward liberalism as a political tradition. Socialist and conservative approaches have been admitted to the family of reasonable conceptions of justice, so that citizens which view some political issues as pressing (e.g., gender equality or religious liberties) can find an adequate “translating” conception and publicly reason with fellow citizens.

Thus, the insights and proposals for public policy gained by using Rawls's approach in the case-by-case analysis should be further evaluated by applying different political points of view, external to liberalism. Now, due to reasons of space, such further analysis could not be carried out in this dissertation, so it must suffice to note that additional research applying approaches that are important in the sense of relevant political traditions to the issue of cognitive enhancement is necessary. Furthermore, it has to be noted that the conclusions of the analysis in this dissertation is merely a proposal for the wide public debate on public

policies, which will hopefully motivate moderately conservative and socialist philosophers to approach the issue of cognitive enhancement from the point of view of their preferred „devices or representation“ and political conceptions of justice.

5.3. Specific objections to the argument and the proposed solutions

Now that the general (and anticipated) objections to the extension of Rawlsian conception of justice and idea of public reason have been addressed, it is time to review specific (and published) objections to my conclusions. There has been a considerable amount of constructive criticism regarding my proposal for the taxation approach and the economic disincentives model (EDM), written by some influential neuroethicists.¹²⁰ Some neuroethicists objected to my favoring prohibitive policies to dangerous cognitive enhancement (CE) drugs such as Amphetamine and argued for laissez-faire or even mandatory use of enhancements. Others took issue with the conclusion that EDM could be an option for public policy on extended release forms of Methylphenidate. Furthermore, there are those that think my argument in general and EDM in particular are failing to address the relevant issues in regulation of CE, such as social justice and real autonomy. Finally, there are those who offer suggestions on how the argument and the model of public policy for CE drugs can be improved.

Since it makes sense to respond to similar objections together, I'll first review and respond to the comments coming from the Oxford "pro-enhancement group": Anders Sandberg (2013), Neil Levy (2013) and Julian Savulescu (2013). Then I will explore and answer several objections from neuroethicists that think EDM is too permissive: Hall & al. (2013), Faulmüller & al. (2013), and Van der Eijk (2013). After that, I will engage with the objections from neuroethicists who think my argument in general and EDM in particular are failing to address the relevant issues in regulation of CE: Jamie Nicole LaBuzetta (2013), Brewer and De Grote (2013) and Jessica Flanigan (2013). Finally, I will explore and respond to several suggestions from neuroethicists who focus less on shortcomings, and more on suggestions on how the argument and model of public policy might be improved: Hank Greely (2013) and Forlini & al. (2013).

Even though Sandberg (2013) does not entirely disagree with my analysis concerning the appropriate regulation of Methylphenidate and Amphetamine, he insists that there could exist other enhancers besides psycho-stimulants (such as Modafinil), that might have very different usage and risk profiles and that are likely to lack autonomy-impairing addiction

¹²⁰ An earlier version of the arguments presented here has been published as Dubljevic 2014c.

properties. According to him, they are likely to be even safer than the extended release methylphenidate and are not legislated by international treaties, such as the 1971 UN convention on Psychotropic drugs (UN 1971). As such, they should be regulated even more permissively. He contends that the greatest problem for regulation is insufficient information, and that the method used to regulate enhancers will affect what information will become available for fine-tuning policy.

Although we both agree on the point that bans and laissez-faire approaches do not provide the necessary information, Sandberg argues that adding taxes and fees as suggested in EDM does not give much feedback except usage statistics. Even though he acknowledges that having licensed users undergo regular medical tests (as envisioned by EDM) would provide more relevant information, he considers that EDM would risk creating principal-agent problems between the interests of users, companies, testing bodies and society in general. Society would benefit from extensive and careful testing, while users would not be interested in paying too much money and privacy for it. He concludes that the way to minimize harm would be to accumulate relevant information as early and accurately as possible, which entails a liberal permissible regulation of safer enhancers.

I heartily agree with Sandberg that regulatory models which could provide the missing information would be more effective, even if their preliminary assumptions turn out to be incorrect in the long run. I also agree that there might be more CE drugs to which a moderately liberal regulatory approach could be applied. For example EDM could and should be applied to Modafinil (see Chapter 3.4.) due to the specific social risks it entails. However, even though Sandberg seems to disfavor EDM as a regulatory option, he failed to provide a realistic alternative model, so, apart from extending EDM, there is no feasible alternative option from which to choose. Even though EDM might need lots of fine tuning, that can only be done once it (or a similar model) is implemented and the information on the health costs associated with CE drug use becomes known.

His other concern is with the acceptability of the licensing procedure and other measures in EDM. However, recall that similar requirements are accepted worldwide in the case of vehicles: in order to use them, a person must pay *fees* for a training course and pass an exam as proof of competence. Then, when the vehicle is bought, *taxes* should be paid. In order to use the vehicle, an appropriate *insurance* must be taken and both the vehicle and the driver should be *registered* by a government agency. Finally, while using the vehicle, taxes on fuel, tolls and appropriate fees for regular technical *check-ups* must be paid. Since all these

measures are readily accepted, there is no reason to doubt the acceptability of similar measures in EDM.

But others have different objections: CE can be achieved in more ways than one. Instead of medical drugs, people might be using trace elements, vaccines or medical devices. Neil Levy (2013) agreed that EDM may be appropriate for regulating extended release forms of Methylphenidate and that Amphetamines need to be prohibited. After this endorsement, he took issue with my ruling out of mandatory use for other forms of CE. He argued that in other instances, the costs can be negligible or low enough, and the benefits great enough, to make it appropriate to *require* enhancement. He gives the examples of vaccination and fluoride in the water supply, which, allegedly override any informed choice regarding use. Furthermore, he claims that medical devices that can be used in the transcranial direct current stimulation (tDCS) modality are effective as enhancers and risk free.

As for Levy's comments about the applicability of mandatory cognitive enhancement use and his example of fluoride, there is a huge difference in providing trace elements that might increase the health of the population and providing mind-altering drugs. That being said, the use of fluoride in his example is actually not mandatory. Many people purchase bottled water or use active carbon filtering, and the coercive power of the state is not brought to bear on them to change these practices. Mandatory use is indeed very hard to justify. Even vaccination is mandatory mostly for minors – in this case the state could sometimes override the wishes of the parents because the life and interests of a person not yet capable to make autonomous choices is at stake, and the parent's choice could be dictated by religious or other reasons that the minor might not endorse, or choose to abandon after reaching maturity. However, in the case of adults, barring a major health disaster (e.g., a plague outbreak), coercion backed by the immense power of the state needs to be limited, even if society and individuals might perhaps benefit by state intrusion.

To give one example, governments that have historically made mind-altering drugs mandatory - e.g., Togo militarists in Japan during the 2nd world war (see Iversen 2008 for more details) - have found it easy to make such legal requirements. Making something mandatory is simple: a law that suits the purposes of the elite is just enforced and backed by sanctions. However, such a law would not be legitimate or democratic. Levy is right in that I have dismissed mandatory use without too much space allocated to discussing the issue. However, I have relied on democratic values and the overwhelming demand to respect the autonomy of citizens as being tacitly assumed.

Finally, he mentions tDCS devices as safe and effective cognitive enhancers. However, apart from the problems with *requiring* use of any sort of enhancement, the assertion about safety and efficacy of tDCS needs to be taken with caution. Recall that although investigative use of tDCS does appear safe and effective from a strictly scientific standpoint (e.g., in controlled laboratory settings) enhancement use without supervision might cause serious adverse effects, such as temporary respiratory paralysis (Brunoni & al. 2011a). In addition, even in scientific studies, potentially detrimental effects are not measured and hence not reported, even though tDCS enhances certain cognitive functions while inhibiting others (Iuculcano & Cohen Kadosh 2013). Although for reasons of space I cannot go into more detail, this should suffice to prove that a regulatory approach that enforces being trained in the use of CE and provides information on detrimental effects should take precedence over pro-enhancement regulatory proposals.

However, some might be unconvinced that my conclusions regarding autonomy are sound, and presume that a liberal-consequentialist perspective would render any prohibitive response illegitimate. Julian Savulescu (2013) contends that my proposal is too conservative and too prohibitive when viewed from a liberal consequentialist perspective. He relies on the argument from Mill's *On Liberty* (1859) to show that any intrusion of the state is illiberal and undemocratic.

He takes issue with my claim that the use of amphetamines (like Adderall) would lead to the undermining of autonomy and addiction, and argues that addiction is primarily imprudent pleasure seeking and that addicts are not incompetent and need not be harming anyone else. Consequently, they should be free to harm themselves, and the state should not interfere with their freedom.

First of all, Savulescu's claim that my proposal is too conservative is problematic. Since "conservative" is defined as "averse to change or innovation and holding traditional values" (Oxford Dictionary 2013) and the EDM proposes a drastic change in regulation of Methylphenidate, my proposal is everything but conservative. He might be opposed to prohibition of Amphetamines, but since Amphetamine can cause aggression, impulsivity, manic behavior and psychotic episodes, and so can cause considerable danger to users and others, a form of prohibition might be legitimate even based on a liberal-consequentialist reading. However, one point about the *kind* of prohibition should be noted here. Namely, recall that in Chapter 3 I have emphasized that if an individual, for whatever reason, voluntarily and autonomously chooses to consume illicit drugs with full knowledge of their addictive properties and harmful physiological and social consequences, the society would be

legitimate in punishing the producers and distributors of illicit drugs, while drug addicts might need to be treated and not punished. To conclude, an argument based on autonomy does exclude certain types of prohibition (i.e. prohibition of possession and use) but not others (i.e. prohibition of production and sale).

However, precisely the issue of prohibition elicited other points of view. Namely, not everyone thinks that my proposal is too conservative. Quite to the contrary, some think it is too permissive. Wayne Hall, Brad Partridge, and Jayne Lucke (2013) claim that my proposal sounds plausible but that there is a number of major problems with it. They insist that it should not be assumed that sustained release forms of drugs will be safer than immediate release forms when these drugs are widely used in the community. They also have doubts about the feasibility and effectiveness of EDM. Namely, they think that tight regulations, licensing and high taxes would be major disincentives for both the pharmaceutical industry and would-be stimulant users, so EDM may actually boost the grey or black market for stimulants.

Hall & al. (2013) also contend that EDM would require a modification of the 1971 UN Convention on Psychotropic drugs (UN 1971). Furthermore, they think that the bioethical debate about enhancement use of stimulants might have disastrous consequences. Namely, proposals for liberalization of enhancement use of stimulants might actually lead to severe restrictions if not prohibition even of medical use of these substances, because society might recognize such use as an increasing social problem. This would make the population that really needs these medications as treatment for ADHD and other conditions vulnerable.

I agree with Hall & al. that it should not be taken for granted that sustained release forms of drugs will be safer than immediate release forms. Indeed, in Chapter 3 I have insisted that the danger profile of Methylphenidate would have to be carefully analyzed and empirical studies confirmed by independent researchers before any change in current prohibitive policy is allowed. As for the worry that EDM may actually boost grey- or black-market for stimulants, it is safe to assume that it will not boost it any more than prohibitive policies do. On the contrary, if there are legal means of marketing or obtaining a commodity, the majority will prefer to act within the bounds of the law.

Regarding the conclusion that EDM, or any other liberal policy, would require a modification of the 1971 UN Convention, their argument is not convincing. Article 3 of that convention states that a preparation may be exempted from the current regulatory regime if it is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means. As I noted above, whether this is

the case with extended release forms of Methylphenidate is an empirical question which can be settled with sufficient research.

Finally, adverse reactions by conservative factions are hardly reason enough to censor the bioethical discussion. Indeed, different policies are (and should be) judged by their merits – including the ability to provide reliable information on the prevalence of use. Therefore, even if there was a rash prohibitive response to liberal policies on stimulants that would restrict medical uses, such responses would be short-lived, as they benefit no one and harm the interests of many citizens.

But others might have different objections. They might think that cognitive enhancement can cause more harms than just physiological dangers. Nadira Faulmüller, Hannah Maslen and Filippo Santoni de Sio (2013) argue that new cognitive enhancers are psychologically different from other, well-known drugs such as caffeine, because they are perceived negatively by the public. They point out that psychological valence accounts for much. Namely, some of the “old” substances like alcohol might be objectively more dangerous than methylphenidate. However, they are loosely regulated because they are perceived more favorably, and even as socially desirable. Moreover, new enhancers are not only judged negatively, but their efficacy is strongly exaggerated by lay people. Independently of any direct negative physiological effects, enhancers might generate some indirect psychological costs, such as: attribution of performance (any success users might achieve would be attributed to the enhancer), dehumanization (users might be perceived as being more similar to automatons), and ostracism (enhancement users may be shunned by others).

I agree with Faulmüller and colleagues that views of the lay public need to be taken into account. However, these views can also be changed as a result of sufficient information. Consider yet again the example of tobacco: smokers used to be considered socially more apt and/or desirable, but thanks to the information on objective harms of tobacco, nowadays smoking is more likely to be seen as a sign of weakness or poor taste. Indeed, smokers are increasingly ostracized, and that is precisely the point of any „discourage use“ type of policy, including EDM. As for dehumanization and misattribution of performance, even though some people might have such exaggerated reactions to the use of enhancers, these concerns are generally matters relevant for individual choice, but not relevant for public policy (see Chapter 2). Public policy in democratic societies usually protects autonomous choice of individuals, as long as this does not harm others.

However, some might be convinced that my analogy with tobacco is precisely the reason to support a more prohibitive response. Yvette van der Eijk (2013) claims that arguing

for EDM based on an analogy with tobacco might not be persuasive, since tobacco control policy is taking a turn toward prohibition. She explains the idea of a “tobacco endgame”: the complete phasing out of tobacco consumption by prohibiting sale to newer generations even when they reach the age of adulthood. Apparently, this idea has become popular in the tobacco control literature in recent years, and is already being considered in several countries. She defends such prohibitive responses by pointing out the addictive properties of nicotine, and further distinguishing between recreational and „addiction maintenance“ use. The addictive properties of nicotine guarantee a high proportion of „maintenance smokers“, which in turn means that discouragement policies are unlikely to have much effect. Hence, the only really feasible solution would be to prevent people from becoming addicted in the first place by prohibiting the substance for the newer generation and „phasing out“ the „old“ users.

I agree with Van der Eijk that there is sufficient evidence that smoking is a nasty habit that causes considerable amount of harm and often leads to dependence (see e.g., Nutt & al. 2007). Indeed, most long-term smokers need substantial interference by outside factors in order to get rid of the habit, and even if they are successful there is the danger of relapse. However, we should keep in mind that protecting autonomy and life-plans of some should not be done by severely restricting autonomy and life-plans of all. A harm that is restricted to self should not be made illegal lightly - that would mean that for example a “tattoo free” generation might be the next move of some conservative factions.

Van der Eijk's argument on „addiction maintenance“ has more merit. However, not every dependence is the same. In Chapter 2 I provide a longer argument, but in this context I think it suffices to note that dependence on nicotine does not entirely disrupt all other rational life-plans a person might have, whereas addiction to say heroin does. Recall that while smoking a person can also be meaningfully socially connected in various capacities. Opposed to that, full-blown heroin addicts will often engage in risky, degrading and illegal activities, which is not acceptable as a rational life plan under fair terms of social cooperation. If smokers want to keep their habit in the privacy of their homes, society is hard pressed to find faults in their right to do so.

The question of arbitrary discrimination of younger adults is an additional reason to believe that „end games“ or any other prohibitive policy on tobacco would be a failed and illegitimate social policy. Indeed, even though the idea is being considered in several countries, such a response would be short-lived, at least in liberal-democratic countries.

Having answered the questions and issues raised by the authors who think EDM is too conservative or permissive, it is time to respond to additional points of view. Namely, some

think that the shortcomings of EDM are that it ultimately fails to protect the values of democratic society it purports to defend.

Jamie Nicole LaBuzeta (2013) agrees that the case for regulation of Ritalin and Adderall is compelling. However, she thinks that it can nevertheless be problematic when the same rationale is applied to other drugs with improved risk to benefit ratios. When applied to safer ‘smart drugs’ such as Modafinil, an evidence-based regulatory model might actually seem to compel their use. Such a compulsion would be contrary to the very idea of liberty and autonomy, but perhaps there are other ideas and values that should take precedence.

She argues that it is plausible and reasonable to demand from individuals working in high-responsibility roles, such as military, medical, and aeronautical professions to use a safe and effective cognitive enhancing medication, such as modafinil. She considers different principles that could support her conclusion and opts for Utilitarianism.

First of all, I am well aware that, due to reasons of space, my analysis left out possible new CE drugs such as Ampakines, and military uses of drugs such as Modafinil. However, I believe that EDM can be successfully extended to most new CE drugs that are not too dangerous and/or addictive, and I have argued (see Chapter 3.5.) that this is the case with Modafinil. The reason for this is that newer CE drugs are likely to have many unknown effects. Even if clinical studies prove they are safe and effective for specific pathologies, the data on effects of prolonged use needs to be somehow generated. EDM, with the requirement of annual medical testing and additional insurance is specifically designed to fill that gap.

Regarding mandatory use by certain professions such as pilots, LaBuzetta is right to note that these are issues that EDM did not tackle. Indeed, military pilots are frequently ordered to take even dangerous Amphetamines on prolonged combat missions. This practice might be seen as wrong, or as justified by the inherent danger of combat missions. Whatever our take on this specific practice, issues of autonomy and responsibility need to be taken into account. For example, legal representatives of US Air Force pilots who have killed Canadian soldiers in a “friendly fire” incident while under influence of Dexedrine (Dextroamphetamine) argued that Amphetamine use has diminished autonomy and responsibility of their clients (see Bigelow 2006, p. 238). That is one of the reasons why I think that her choice for Utilitarianism as the right ethical framework for regulating these specific cases is problematic. In addition to that, it demands too much information and cognitive resources for decision making which is not available and thus is not feasible.

Even though I do not have the space to consider all of the faults of Utilitarianism, it has to be said that it runs counter to the most basic requirement of normative claims: Ought

implies Can. Namely, Utilitarianism requires from moral agents to consider all alternative responses, to calculate all consequences of all identified options, to predict and develop contingency plans for all unintended consequences, and to calculate the probability that a certain response sets a precedent for other circumstances where the information may be less reliable. All this creates a nice optimization model, but no mind or machine can solve moral problems in this way. In the real world, even with “safer” smart drugs we just don't know enough to rely on foreseeable consequences alone. That is why in any discussion on regulatory options, in addition to consequences, we need to take rights and virtues seriously.

However, others have different objections: even if we opt for deontological principles, such as justice, EDM may fail to promote it. Cameron Brewer and Heather De Grote (2013) argue that if principles of bio-medical ethics (Beauchamp & Childress, 2009) are considered more thoroughly (specifically, the principles of justice and non-maleficence), EDM must be rejected. They claim that EDM is at odds with the “fair opportunity” rule: it would deny the social benefits of enhancement on the basis of undeserved disadvantageous properties. They grant that some form of “discourage use” model might be applicable, but that it should not be as costly to the consumer as EDM.

According to Brewer and De Grote, EDM would almost certainly create an even greater gap between the haves and have-nots. It would effectively deny the social benefits of extended release formulas of Methylphenidate to the economically disadvantaged. Furthermore, they argue that EDM would harm the interests of the disadvantaged, as it would exacerbate the already increasing academic achievement gap between the rich and the poor. EDM would ensure that only those with higher incomes would be able to buy and use Methylphenidate, while the poor would have to keep their uphill struggle for academic achievement without it.

Since EDM has been developed precisely as a means to protect the rights and interests of the disadvantaged (see Chapter 2), this is a serious objection. However, Brewer's and De Grote's argument would only be convincing if EDM would make CE drugs so expensive as to be unaffordable for the poor. Consider once more the analogy with tobacco: discourage use policies on tobacco introduces taxes, which are sometimes very high. In Norway, they amount to 200%. And yet, even though cigarettes are not cheap, most smokers in Norway live in poorer regions and earn low incomes. Now, it is obvious that extra taxation did not make tobacco unaffordable to the poor. Indeed, recall that EDM envisions that the prices of CE drugs would be regulated: they would contain the standard costs of production and distribution, the profit margin would be limited and an additional tax would be imposed. This

means that regulation could be fine-tuned if it turns out that the poor are disadvantaged in academic achievement due to the price of CE drugs.

An additional problem for Brewer's and De Grote's objection is that they seem to assume that CE drugs would offer only a competitive advantage, and no health disadvantages. This is problematic in several respects. For example, even though nicotine can also be seen as a mild cognitive enhancer, it offers mostly health disadvantages. Given that stimulants are known to cause nervousness, drowsiness, insomnia, adverse effects during pregnancy, and even serious cardiovascular adverse events, ignoring these effects as potential disadvantages seriously undermines the argument. Indeed, EDM's requirements of training and licensing for CE users actually protect the interests and rights of the disadvantaged, who are frequently targeted by promotional practices of the industry which promise social and other advantages by use of their product. That is why I find the argument that EDM would be rejected based on the principle of fair opportunity unconvincing.

But, some might think that autonomy should take precedence over justice, and that my argument for different regulatory responses fails to respect autonomy sufficiently. Jessica Flanigan (2013) argues that even Amphetamine and instant release forms of Methylphenidate should be legally available because 1) prohibitions of recreational drugs are disrespectful to users; 2) even addicts are sufficiently autonomous with respect to their choice to use drugs; and 3) regulators are not in the best epistemic position to judge whether the risks of Amphetamine and instant release forms of Methylphenidate warrant prohibition. She insists that even though some drugs reliably undermine users' life-plans and autonomous capacities, policymakers should nevertheless permit drug use because the appropriate response to the value of autonomy is to respect, and not to promote autonomy.

Flanigan also thinks that my argument rests on a dubious characterization of the psychology of addiction, as some empirical evidence suggests that addicts are autonomous when they choose to use drugs. Finally, she claims that it is illiberal to permit or prohibit drugs based on a judgment about whether the potential benefits to the user justify the risks users face. Her view is that consumers have the authority to decide for themselves whether it is worth it to risk their health for the sake of pharmacological benefits, either for enhancement or recreation.

Even though I agree with Flanigan that autonomy is very important, and that the state needs to respect it, I disagree with her view on what such respect entails. Consider the following analogy: many individuals might find explosives and rocket-launchers helpful or fascinating for their rational life-plans, and these *could* be used responsibly (e.g. as a part of

weapons collection or for leveling the ground). However, the threat of irresponsible use of such objects is such a danger to others that the state is justified in restricting possession of rocket launchers and explosives by members of the general public. As it is reasonable to endorse a system in which people are not allowed to walk around with explosives and rocket-launchers, it is perfectly rational and in accordance to autonomy to limit availability of Amphetamines.

Namely, a substance for which there is overwhelming empirical proof that it can impair cognitive and volitional capacities (the presuppositions of autonomy), and cause aggression, erratic and violent behavior (Miller 2002), is not (and should not be) subject only to the authority of the consumer. However, in my analysis (see Chapter 3.4.) I do note the need to respect even some of the more self-destructive wishes of competent adults. Indeed, I have concluded that when a person does voluntarily and autonomously choose to consume Amphetamines with full knowledge of their addictive properties and harmful physiological and social consequences, the society would only be legitimate in punishing the producers and distributors of these drugs, but not the users.

Having answered the questions and issues raised by the authors who find faults with my argument and EDM, it is time to respond to two additional points of view. Namely, instead of focusing on shortcomings, some neuroethicists have offered constructive suggestions on how the argument and model might be improved.

Hank Greely (2013) starts by praising my scrutinizing of the safety and efficacy of Methylphenidate and Amphetamine. He finds particularly important the analysis of the differences between the extended release and the instant release forms of medications. Greely notes the necessity to go beyond summarizing the existing research to pointing out what further research would be useful. He points out that we know very little about the effects of long-term use, either regular or sporadic, of these drugs on healthy adults. Greely also notes that it is also necessary to have a discussion of mechanisms to assure that unbiased scientists would produce relevant research on various cognitive-enhancing drugs.

After pointing out strengths of my analysis and potential areas of improvement, he briefly criticizes my dismissal of the proposal for a “Regulatory Authority for Cognitive Enhancement” (RACE). Even though Greely agrees with me that creating a new statutory regulatory body like RACE is difficult and expensive, and that it might not conform to the 1971 UN Convention on Psychotropic Substances, he thinks that those flaws might be overcome. His proposal is similar to mine - the use of an existing agency, similar to the Food

and Drug Administration (FDA) in the United States. Greely contends that FDA might be better placed not only to make comparisons between safety aspects of different drugs, but also to forecast problems to which intermediate regulatory models need to respond, and examine, carefully, the match between those problems and available solutions. He points out that the focus of my analysis was on legitimate or appropriate policies, not about feasible politics.

Greely concludes that more needs to be said about foreseeable ways in non-ideal conditions of politics may affect even ideal recommendations. He does note the constraints of space and considers my limited case analysis as a good start for further discussion by experts, governments, and the public.

First of all, I would like to thank Prof. Greely for his constructive suggestions. Indeed, he is right that more needs to be said on a range of topics, from feasible politics via other possible models to discussing further avenues of unbiased research on CE drugs. However, I do feel the need to clarify one issue. Even though he believes that RACE could be amended to outmatch EDM as a regulatory solution, the argument has not been provided yet. Furthermore, the precise reasons why EDM is more preferable to RACE go beyond a limited case analysis of two stimulant drugs and delve deep into the values of a democratic society (see Chapter 2). For example, the questions of justice and accumulation of power cast serious doubts on RACE. The provisions of EDM, on the other hand, are precisely motivated by these “ideal” concerns of respect for individual decision-making and benefiting the least advantaged, as opposed to merely efficiently regulating the market.

The question of more substantive values beyond safety and efficacy is precisely the point which is raised by other neuroethicists with constructive suggestions. Cynthia Forlini, Eric Racine, Jochen Vollmann and Jan Schildmann (2013) agree with my case-by-case approach, but they argue that public policies on CE should not only be based on an assessment of benefits and harms of the substances but also be informed by evidence on the perceptions and views of the groups that are affected by CE (i.e., stakeholders). They point out that assessment of evidence may be influenced by the experts’ personal perceptions, experiences, and values and that the assessment of benefits and harms may well differ depending on whether a person is directly affected by a policy recommendation or not. Forlini & al. emphasize the fact that the involvement of stakeholders affected by policies has been incorporated as a requirement for the assessment of the quality of clinical guidelines. They add that empirical research indicates that stakeholder views on the appropriateness of a policy rest on more fundamental values that could be promoted or jeopardized by a liberal policy.

Forlini and colleagues also point out that their research showed that effort put into an

academic performance, which is linked to the authenticity of persons, is an important value to consider for stakeholders. The further point of criticism Forlini and colleagues raise is that my argument did not distinguish between requirements of moral acceptability (e.g. efficacy, safety and respect for autonomy) from the requirements of moral praiseworthiness (e.g., self-realization, moral growth, justice). They conclude that research on stakeholder perspectives shows that the criterion of moral praiseworthiness captures concerns about the impact of cognitive enhancement might have on values beyond safety and efficacy.

I would like to thank Forlini and colleagues for pointing out aspects that need to be included to increase democratic legitimacy of any proposal regarding regulation of CE. Indeed, the analysis of social harms of stimulants should include the points of view of general practitioners who prescribe stimulants and those who use stimulants, whether to deal with a medical condition or as a study aid. Not only would that provide valuable information, but it would also further promote values of the democratic society. As I have noted above, I also agree with the need to go beyond safety, efficacy and autonomy – the questions of justice and not jeopardizing self-realization (e.g. the right to an open future) are indeed important. However, I strongly disagree with their conclusion regarding authenticity and moral growth as criteria for public policy. Namely, recall that in accordance with the idea of public reason, such non public reasons could be included at the level of personal or even institutional (e.g., University) choice, but not at the level of society.

Having responded to all foreseeable and extant objections, it is time to conclude this relatively long analysis. Although I hope that my responses have captured the issues that might concern the reader, ultimately only an open public discussion on public policy can sufficiently address all the relevant issues.

6. CONCLUSIONS

6.1. General conclusions of the conceptual analysis

After a thorough analysis of general and specific objections to the approach and my proposals for appropriate regulation of cognitive enhancers, it is time to summarize the important points and findings that are resulting from the dissertation.¹²¹ Cognitive enhancement, or to be more precise, biomedical technologies that offer the possibility of improved cognition of healthy human beings, has sparked a considerable amount of discussion, as proponents of enhancement are enthusiastically in favor and opponents fear wide-spread social changes for the worse. Accordingly, the debate on cognitive enhancement is to a large extent a normative one. Although the questions about the actual properties of existing cognitive enhancement drugs (e.g., Ritalin) and devices (e.g., transcranial direct current stimulation - tDCS) are important, along with the questions about prevalence, modalities and reasons for use, and realistic expectations of future developments, the normative issues (e.g., should they be used, for what and by whom) are the most contentious.

The context of ethical evaluation and public regulation of cognitive enhancement consists of several levels of immediacy: a) some cognitive enhancers actually exist and are currently used (which means that ethical and policy discussion is urgent, and this dissertation offers one distinct approach to this discussion,); b) others have been proven to provide enhancement effects only on animal models and it is questionable if they would also work on humans (which limits the ethical discussion to questions of research ethics, and as such the discussion has only briefly reflected on these technologies); and c) some are at the stage of hypothesis (which limits the ethical/policy discussion to the questions of responsibility for public and/or private funding of such research, and as such is beyond the scope of this dissertation).

The normative debate concerning cognitive enhancement has so far revolved around issues such as authenticity (see e.g., Parens 2005), human nature (see e.g., Kass 2003) and utility (see e.g., Levy 2007). However, one of the most contentious issues is the question of fairness, and whether cognitive enhancement (drug or device) use can be defined as “cheating”. Defining a certain practice as cheating is a public endeavor and a social process sometimes driven by group interests. Such processes happen continually which might lead to

¹²¹ In what follows, I draw on Dubljevic 2014a.

alterations of definitions over time, and this work has provided (I hope convincing) arguments, that certain uses of enhancement should be considered as unfair and as cheating. However, providing arguments is not enough to settle the issue. Only informed public debate can hope to reach a consensus, and in many cases, issues continue to be unresolved, and only a mere compromise can be reached. Recall that proponents of enhancement claim that enhancement use of say stimulant drugs by students is not cheating. Since cheating is defined as a) breaking formal or informal social norms and b) attempting to gain an unfair advantage (Harris 2011, pp. 266-267); and since currently, such stimulant drug use is not explicitly banned by all or even the majority of universities, it is not cheating per definition. Furthermore, proponents of cognitive enhancement claim that stimulant use would be an advantage for all if stimulant drugs are permitted as “study aids” (Harris 2011). Harris uses the analogy with education and goes on to say that using cognitive enhancement is comparable to seeking the best, to improving oneself, or one’s children. Furthermore, the costs of stimulant drugs are relatively low, unlike the costs of university education or specialized training. Moreover, the proponents contend that we should use any means of improvement as long as they are effective, and by using examples such as aspirin, literacy, electricity, coffee, and computers, conclude that evolution and progress are synonymous with enhancement (see Harris 2011, Levy 2007).

Even though I respect some of the more laudable goals of proponents of enhancement, I hope that I have provided ample reason to be skeptical towards many of their claims, and that markedly different views of the matter could also be reasonable (see e.g., Selgelid 2007). I have tried to stake out the middle ground in my own position by rejecting the idea of opponents of enhancement that it is wrong *per se*, and rejecting the assertion of proponents that there are no ethical problems with the use of enhancements. I have also started from the premise that rules are put in place when new practices of cheating are discovered, and extended Rawls’ influential theory of justice to make the case that using stimulant drugs and devices in certain contexts is unfair. I have argued (hopefully convincingly) that therapeutic uses of drugs or devices that might improve cognition, in the case of citizens suffering from ADHD or narcolepsy are an issue of providing basic necessities for those who are lacking, benefiting the least advantaged, or restoring citizens to a position of equal opportunity and liberty. On the other hand, using drugs (or devices) for cognitive enhancement without a clear case of medical need is not. Cognitive enhancements are currently being used by individuals as means for obtaining undeserved positional advantage. So, if students use Methylphenidate (Ritalin®) during an exam because they are diagnosed with ADHD they are merely having a

fair opportunity to compete with other students on an equal footing. However, if they use it as enhancement, they are taking a chance with the unknown long-term side-effects in order to gain advantage over others.

Furthermore, I have not been alone in asserting that cognitive enhancers could affect the competition between those who would prefer using them and those who would rather not (see e.g., Sahakian & Morein-Zamir 2007). Several well established authors in the field have commented upon the claim that even for non-users an incentive or even pressure exists to also use stimulants (Forlini and Racine 2009, Sattler & Wiegel 2013). However, I am alone in providing rational choice modeling (see Chapter 3.1.) that explains how this pressure to enhance is generated and expanded. Thus, the “pressure to enhance” is not just a subjective phenomenon, and it really could lead to a situation in which all students need to use cognitive enhancers to be able to compete, or employees in different lines of work might need to use them in order to be able to hold on to their jobs.

The mismatch between the expected utility and health costs between employers and employees called for a firm assertion of employee and citizen rights concerning enhancement. Employers would have a commercial interest to (indirectly) coerce the use of enhancements in order to gain more profit, while employees would have to take the risks of long-term effects because they are not in the position to refuse. The employees are at the same time robbed of the ability to decide for themselves whether to use enhancers or not, and forced to be the ones bearing consequences of the use. In other words, cognitive enhancement, which is encouraged by employers for profit reasons, could create additional disadvantages and needs for those already lacking basic necessities by way of the unknown long-term side-effects and/or through coercion. In the long run, because of competitive pressures and desire to gain at the expense of others, contagion processes might start affecting different dimensions of the basic structure of society leading to an ever increasing number of cognitive enhancement users.

I have argued that this would be unfair, and that the unfairness of a social practice calls for the introduction of rules and explicit norms. However, unlike the opponents of enhancement which argue for prohibition in all cases of enhancement, I have argued that justice requires only rules which discourage the use of stimulant drugs or brain stimulation devices. Thus, cognitive enhancement might be morally problematic, but nevertheless permissible, and the arguments provided hopefully capture intuitive judgments shared by the majority of people (see the short discussion on public attitudes on cognitive enhancement below).

However, I have to stress that I hold no monopoly on arguments from justice. For

instance, in his analysis of cognitive enhancement and justice (including Rawls' principles of justice), Julian Savulescu (2006), reaches a drastically different conclusion: justice requires enhancement. According to Savulescu, nature allots advantages and disadvantages with no regard to fairness. Since enhancement might improve people's lives (and indeed, the effects of stimulant drugs might be more pronounced with those who are at the lower end of the normal distribution of cognitive capacities (see e.g. Lieb 2010), who are in turn the least advantaged), the social distribution of cognitive enhancers should be designed to make sure that everyone, regardless of natural inequality, has a decent chance of a decent life (Savulescu 2006).

The question whether the least advantaged could benefit or be harmed by cognitive enhancers is an empirical issue that could be resolved with new evidence into the physiological and social effects, and the case-by-case analysis provided here (see Chapters 3 and 4) have provided an insight into the available empirical evidence to that effect. On the normative side, however, with the advent of competing theories of justice (e.g., Nozick 1974, Walzer 1983, Miller 1999, Sen 2009) and political tradition of thought (see e.g., Finnis 1980; Habermas 2004), the issue is not likely to be resolved in a single stroke. Most importantly, the issue cannot be resolved by one author or even by philosophical discussion alone – a consensus has to be the result of public deliberation on proposed reasoned solutions (such as my own) that match and make explicit the implicit moral intuitions and social attitudes of citizens in a democratic society. I have argued that different conceptions of justice (liberal, conservative and socialist) might offer guidance in this matter, and I have provided an extensive analysis with the aid of the most important liberal conception of justice, but it remains to be seen if other researchers will be interested in doing such work within the horizon of other traditions of political thought or if the discussion will continue to be dominated by human nature, authenticity and utility arguments. The important point is that citizens care about justice, and it stands to reason that their views on moral appropriateness of cognitive enhancement are influenced by their “sense of justice”.

However, the empirical evidence on social attitudes toward cognitive enhancement is as ambiguous as the theoretical stances. To name one example, in one Australian study, 85% of the sample of the general population believed that the use of medications for cognitive enhancement was morally unacceptable (Partridge, Lucke & Hall 2013). The findings are similar in other countries and populations (compare Dodge & al. 2012, Ragan, Bard & Singh 2013, Dubljević, Sattler & Racine 2014). Also, university students, when interviewed, reveal that the use of cognitive enhancers is typically regarded as unfair (Bell & al. 2013). However, similarly to the academic debate on enhancement, a steady minority of respondents in the

student and general population thinks that use of cognitive enhancers is acceptable and not unfair.

This difference in attitudes might be linked with a) information regarding adverse effects and b) the context of use. On the one hand, some people might think that adverse effects of cognitive enhancers are minor and as such acceptable, whereas the majority is risk averse, and in absence of scientific evidence concerning long-term safety, chooses to avoid and sanction the use of such means. On the other hand, the difference between competitive and cooperative contexts (especially in the examples used to frame the discussion about enhancement) might be the relevant feature that guides normative evaluation.

The fact that some students view cognitive enhancement as cheating and some do not could be related to the different interpretation of the character of university education – whether it is understood as being dominantly competitive (or a zero-sum game) or cooperative (and non-zero-sum). This explanation is in line with the findings from an U.S. based study that enhancement of physical functions in sports is viewed as more problematic than enhancement of cognitive capacity in the university context (Dodge & al. 2012). Indeed, sports are more related to zero-sum expectations than university education. If, as hypothesized above, competitive contexts of cognitive enhancement drug use are actually viewed as being cheating whereas cooperative contexts of CE drug use are actually viewed as being non-cheating, a clarification of context in future empirical studies might provide less ambiguous data on public attitudes on cognitive enhancement.

Thus, future studies might be improved if they check for the context of use of cognitive enhancers as the possible issue framing the normative valence of different responses. Whatever the reasons for normative ambiguity, the solutions for specific cases of cognitive enhancers have taken into account both the empirical information regarding effects and side-effects, and the fact that various cognitive enhancers are used in different contexts. One of the key conclusions was that cognitive enhancement might be acceptable in some contexts, but that it should be discouraged so as not to spill over in all areas of social relation. This implies that *per se* use of cognitive enhancers cannot be deemed wrong on par with exemplary morally reprehensible actions – it is morally problematic only in the reference of competitive contexts and measuring performance. Consider more specifically the issue of measuring performance: it could be argued that cognitive enhancement use might counteract the aim of tests, e.g., in cases where the students' memorization is tested but students have used memory enhancers (Schermer 2008). This problem is similar to the illicit use of calculators (something that is in itself not problematic) when mental arithmetic should be

tested. Thus, we come to the most important problem at hand. If the normative valence of cognitive enhancement depends on context and on proper definition, the conceptual clarification of nuances in the term “cognitive enhancement” is extremely important.

Even though defining cognitive enhancement was not the primary task of this dissertation, the analysis has nevertheless revealed that the concept of justice can be used to dissociate appropriate from inappropriate uses. Cognitive enhancement has been defined as use of medical drugs or devices for non-health related improvement of cognition. This definition has the virtue of dissociating contexts which are socially encouraged, from those which are legitimately discouraged or even prohibited. It also facilitates the issue of distribution of social goods, from the point of view of justice. Namely, preventive, curative, rehabilitative and compensatory use of medical drugs and devices is an important part of meeting health needs. Opposed to that, use of medical means to gain competitive advantage is a costly preference that might cause social problems. In this sense, the technical distinction between therapy and enhancement is a necessary social construct. The definition of enhancement which excludes explicitly stated medical needs is useful to set it apart from therapeutic (i.e. preventive, curative, rehabilitative and compensatory) uses of the same technology. In this sense, it is also useful to clarify the extent of moral unease most people feel about enhancement and the appropriate regulatory response of the state. Namely, if a certain technology or social practice is not yet proven to be detrimental *per se*, but might cause social problems if unregulated, the proper response is some form of discouragement.

However, it has to be noted that in the literature, other notions than cognitive enhancement have also been used to capture the concept of non-medical use of drugs to improve performance. For example, “lifestyle use” of drugs partially captures some instances of medical drug use which do not correspond to a medical situation or a medical need in the traditional sense of the term, but instead to requests for greater performance or lifestyle modulation. Some authors claim that usage of cognitive enhancement in the literature obscures a longer history of non-medical use of drugs to enhance performance – a group of Australian authors (Bell & al. 2012) has argued that the use of drugs for enhancement may fall within a cycle of use for illicit drugs (e.g., cocaine and amphetamines). This conceptualization has the added normative implication of prohibition as the assumed appropriate regulatory response, which might not be fully justifiable on grounds of justice. For this reason, I have argued that the use of medical drugs, such as Adderall (Amphetamine) and Ritalin (Methylphenidate), or devices, such as tDCS, by healthy adults for enhancement of cognitive function has to be dissociated from both therapeutic uses and recreational uses of

illicit substances.

However, the term cognitive enhancement is sometimes used without clarification of nuances in meaning, and it refers to a wide range of practices and assumptions that overlap with other concepts and is often defined differently (and with different normative assumptions) by diverse communities. For example, public health and epidemiological studies (see e.g., De Santis & al. 2008, Franke & al. 2011) usually describe the use of cognitive enhancement drugs as the “non-medical use of prescription drugs,” “drug misuse” or even “drug abuse”. On the other hand, some of the contributions regarding cognitive enhancement in interdisciplinary bioethics literature (see e.g., Harris 2011) as well as in neuroscientific (see e.g., Greely & al. 2008) and clinical journals (Larriviere & al. 2009) have rather optimistic assumptions about effects of cognitive enhancers, which is reflected in their preferred examples (coffee, education, etc.).

An additional hurdle is the understanding of what exactly (i.e., which capacity) is improved by use of cognitive enhancement. The naive and undifferentiated term “cognitive enhancement” (as well as more popular terms for extant enhancers such as “smart drugs”) suggests that the use of, say, stimulants would result in a general improvement in cognition or even IQ. However, it is important to note that current evidence is quite contradictory with respect to the possible “enhancement” effects of currently available cognitive enhancers (see e.g., Ilieva, Boland & Farah 2013). This has led some to conclude that the label “cognitive enhancement” may be a misnomer (see Vrecko 2013, Racine & Dubljević In Press). According to this view, much like a drug undergoing clinical trials cannot properly be called a “treatment” or “therapy” before its effectiveness has been proven, prescription stimulants should not be called “cognitive enhancements” as long as there is no scientific proof that they actually increase cognitive function or IQ. Many of the so-called “smart drugs” have not been tested in the same way or with the same rigor for enhancement purposes as they were for the original therapeutic applications. Some recent reviews have highlighted limited evidence supporting claims of enhancement (see e.g., Repantis & al. 2010).

Furthermore, understanding and defining what constitutes an improvement in cognition is very complex. For an individual interested in enhancement, the effect is contingent on expectations of greater performance in real-life settings, whereas for a regulatory review body, assessing a claim of improved cognition usually involves controlled laboratory settings. Since the use of cognitive enhancers would by definition not be in response to a clear pathology, lesion, or identified behavioral or mental health problem, the baseline measures for evaluation of enhancement effects would likely not be uncontroversial.

Currently available studies have examined the enhancement effects of extant neuropharmaceuticals (see Repantis & al. 2010, Ilieva, Boland & Farah 2013) and brain stimulation technologies like TMS (Luber & Lysanby 2013) and tDCS (Dockery & al. 2009,) on specific tasks conducted in controlled laboratory settings. However, critics point out that these tasks do not fully capture the effect of the technology on the more general capacity underlying the tasks or on other tasks (see Vrecko 2013, Ranisch, Garrofoli & Dubljević 2013, Iuculcano & Cohen Kadosh 2013), and that cognitive enhancers would need to be examined in the context of a real-world performance. The unspecified term “cognitive enhancement” has built in positive normative assumptions in a way that may de-emphasize the possible short-term and long-term risks and side effects associated with the usage of a drug or device to stimulate the brain for non-medical reasons and without any relevant knowledge or supervision.

Obviously, a more nuanced definition of specific aspects of cognitive enhancement is necessary, even if the delineation is another social construct. That is why I have dissociated between “Cognitive performance augmentation” - improvements of cognitive function (such as IQ, working memory, etc.) for which, currently, the evidence is quite contradictory - and “cognitive performance maintenance” effects. “Cognitive performance maintenance” refers to the prolongation of normal levels of functioning and the reduction of effects of fatigue and sleep deprivation, for which there is plenty of evidence (see e.g., Legarde 1995, Estrada & al. 2012). As I have mentioned earlier, new, not yet available drugs, such as Ampakines might provide cognitive performance augmentation in the sense of increase in general IQ, working memory or more accurate recall. But perhaps they will not work on humans. Furthermore, they might have drastic side-effects. Then again, they might be harmless. To be sure, even “cognitive performance maintenance” raises important ethical issues, depending on the side-effect profile of the substances (or devices) used (Chapters 3 and 4).

6.2. Research results – empirical models I-V and proposed public policies

Now, to turn toward the specific conclusions from the case-by-case analysis. So what are the specific ethical issues identified and what are the policy proposals? Even though, for reasons of space, I cannot repeat many of the nuances and the arguments provided, it is nevertheless helpful to identify the major risks, enhancement effects and recommended policy options (see Table 6.1.) for specific, currently available cognitive enhancers.

Table 6.1. Proposed regulation for available cognition enhancement technologies

Enhancer	Major Risks	Enhancement effects	Policy
Ext. Release Methylphen.	Blood pressure increase (BPI)	Maintenance: focus and attention (F&A)	Economic Disincentives Model (EDM)
Inst. Release Methylphen.	BPI, Addiction	Maintenance F & A	Prohibition of unauthorized production and sale to healthy adults
Amphetamine (all forms)	Addiction; BPI, Psychosis	Augment wakefulness (W), Maintain: F&A	Prohibition of unauthorized production and sale to healthy adults
Modafinil (all forms)	BPI; Stress, shift work, immunity	Augment: W, working memory (WM)	Economic Disincentives Model (EDM), Post-market monitoring
tDCS (product and service)	Discomfort, Inhibitory cognitive “costs”	Augment WM, skill learning, reduced reaction times (RT)	EDM, Moratorium on marketing, Post-market monitoring, Service provider model (SPM)
TMS (service)	Syncope, Seizure, Hearing loss	Reduced RT, Savant-like abilities	Service provider model (SPM), Post-market monitoring

Note: tDCS: transcranial direct current stimulation; TMS: transcranial magnetic stimulation

The rational choice analysis of cognitive enhancers (CE) has shown that their use could in fact create considerable social pressure, and that unqualified prohibition and laissez-faire types of policy would neither be effective nor justified. A moderately liberal public policy shows more promise, but not all approaches within this type of policy would be acceptable from the point of view of modern pluralist democracy. The “gate-keeper” approach could not be justified in most instances (and in some specific cases it has to be replaced with the related “service provider model”, see below) whereas an approach based on taxation with suitable models might be legitimate and effective. The Economic Disincentives Model (which would allow legal access to cognitive enhancers with the imposition of taxes, fees and requirements of additional insurance) is the most promising model proposed because it can assure state neutrality on personal preferences, protect the best interest of all citizens, provide reliable data on consumption and demand, and promote effective evaluation of long-term

health costs among CE users.

More specifically, both CE drugs and devices have varying effectiveness and danger profiles. The case by case analysis started with classical stimulants Amphetamine (e.g., Adderall) and Methylphenidate (e.g., Ritalin) and a newer atypical stimulant – Modafinil (Provigil). It has been concluded that the use of stimulants by healthy adults for enhancement of cognitive function has to be dissociated from both therapeutic and recreational uses of these drugs. Also, regulation of their enhancement use has to be made while taking into account relevant differences in the danger profile. On the one hand, extended release formulas of Methylphenidate (e.g. Ritalin-SR) could be regulated permissively, since they cannot be recovered by readily applicable means in a quantity liable to abuse, and apparently do not give rise to a public health and social problem. A taxation approach to regulation of CE drugs is a good starting point for such a moderately liberal public policy that avoids the pitfalls of both laissez-faire and overly harsh prohibitive policies. However, all models of regulation of stimulants are constrained with the requirements of the UN Convention on Psychotropic drugs (UN 1971). Although there are several policies that could be used within the broad taxation approach (Tobacco model, Coffee-shop model, Regulatory Authority for Cognitive Enhancers model and EDM), due to the extant framework of international law, most of them would not be appropriate and legitimate. Namely, only the Economic Disincentives Model explicitly envisions all the measures required by the UN Convention, which makes it the most legitimate public policy on extended release formulas of Methylphenidate for cognitive enhancement use by healthy adults.

On the other hand, the sale of instant release formulas of Methylphenidate (e.g. Ritalin) to healthy adults, along with all compounds containing Amphetamine (e.g. Adderall) or its precursors that would produce Amphetamine via normal metabolism (e.g. Captagon) needs to be prohibited. Although these substances might provide significant benefits if used responsibly, the danger of abuse, and especially the threats of addiction, increased aggression, erratic and violent behavior make their use a potential danger to others. However, the use and possession of small quantities of these substances without a prescription should be treated as a misdemeanor and punishable only by a fine, whereas unauthorized production and sale could be legitimately criminalized and treated as a felony with appropriate sanctions.

As for the newer atypical stimulant, Modafinil, the danger profile is not as clear, because the long term effects are unknown. The analysis of currently available data points to a conclusion that more reliable information on the neurophysiological mechanisms of action of Modafinil is necessary. Even though the physiological profile seems to be beneficial, if

inadequately regulated, modafinil can incur additional social and health related costs.

Widespread use of Modafinil may decrease the range of employment options and increase the pressure to perform shift work. Apart from inherent properties of increasing stress and decreasing immunity, this can lead to a plethora of indirect adverse health effects in the population, including increased risk of mortality and even a decrease in cognitive ability of future generations. Because Modafinil could provide both great benefits and great threats of exploitation, depending on the legal framework, regulatory models which could provide the missing information on long term effects would be most normatively and empirically sound, even if their preliminary assumptions turn out to be incorrect in the long run.

It has been concluded that the Economic Disincentives Model is the regulatory response which could generate the data needed for a more reliable assessment and funds to offset adverse health and social costs of Modafinil use. However, in weakly regulated regimes with extreme lack of employee protection, the “night-shift worker syndrome” indication for modafinil might cause social problems which will be hard to track and solve. One solution could be to consider revisiting and/or revoking this indication of Modafinil, but at any rate post-market monitoring of long term consumption trends and effects is necessary.

The analysis of electro-magnetic enhancers has revealed the need to dissociate between the regulation of the CE devices as products and offering enhancement uses of the devices as a service. Again, non-invasive brain stimulation devices that were analyzed – transcranial direct current stimulation (tDCS) and transcranial magnetic stimulation (TMS) have different effectiveness and danger profiles.

tDCS appears to be safe and effective in laboratory settings, and thus it is plausible to assume that it might be safe and effective in any environment with sufficiently *trained* users. Since it was noted that tDCS might cause long-term detrimental changes in developing brains, a reasonable precaution could be to set the age requirement at 25.

There is a lack of information on effects and mechanisms of action of tDCS, and apart from limiting the availability of tDCS to minors, the regulatory framework needs to generate the information as soon as possible. The Economic disincentives model has been proposed as a first response policy, since tDCS use needs to be regulated urgently. Namely, tDCS devices can be cheaply and easily built at home, and used non-commercially as a do-it-yourself enhancement gadget, and since no data is available on long term effects, adverse effects of untrained use, such as temporary respiratory failure, cannot be excluded. EDM has the advantage of quickly, cost-effectively and objectively generating data for fine-tuning policy.

However, the requirement of EDM to regulate the prices of tDCS devices might turn out to be unnecessary (and with the looming danger of home-made tDCS devices even counterproductive). If the data generated by the EDM from tDCS users does point to the conclusion that trained use of tDCS is reasonably safe even outside controlled laboratory settings, these requirements, along with further taxing of the companies could be relaxed. The considerable regulatory burdens for enhancement seekers would limit the social penetration until the issue of long-term physiological effects of tDCS has been settled by data generated. Since tDCS would be in principle be available to all this should offset any concerns about fairness.

Admittedly, tDCS as a do-it-yourself gadget defies almost all efforts to regulate the technology. However, having a reasonable legal alternative is enough in most cases to promote registered use. That is why unlicensed use of tDCS on others should be criminalized and a moratorium on Direct-to-Consumer marketing of tDCS enforced. However, such measures could be dispensed with if post-market monitoring provides clear indications that home uses of tDCS are not posing a considerable danger.

In addition to regulation of stimulation devices as products, the need to regulate use of enhancement devices as a service is pressing. Namely, tDCS is currently being offered as a service, but even more importantly TMS use is likely to be wide-spread only in the form of service. Namely, due to considerable costs and training required, it is highly unlikely that TMS would be readily available as a *product* or *Do-It-Yourself* gadget. That is why a licensing procedure for service providers needs to be defined, and for reasons of transparency and fairness, this procedure should not be limited to health professionals, but open to all persons with a specialized education in neurology or neuroscience. Due to already high costs (and the need to respect fair access to both richer and less affluent citizens), some of the requirements of EDM which could create additional costs should not be enforced separately on TMS. However, the potential of EDM to provide information on long term effects, and safety and efficacy, in a short amount of time is very valuable for society, and a solution is to offer a unified policy for enhancement devices - using the licensing of tDCS users the purposes of designating availability of TMS. Namely, the user license for enhancement devices would require passing an exam as proof of knowledge about both tDCS and TMS. Furthermore, one additional medical insurance policy would include both TMS and tDCS, and the obligatory annual medical tests for obtaining and renewing the enhancement device license would quickly generate the information needed for fine-tuning the policy on both tDCS and TMS.

The unified “enhancement device use” license would enable citizens above the age of 25 to purchase and use tDCS devices and to benefit from TMS as a service being provided by trained professionals.

6.3. Future technological challenges and pro-active public policy

During the preliminary analysis of both psycho-pharmacological and electro-magnetic enhancers, several other substances and devices or techniques have been mentioned and excluded from the case-by-case analysis. As mentioned above, the ethical and policy discussion on these possible cognitive enhancers is not as urgent. Namely, they have been proven to provide enhancement effects only on animal models and it is questionable if they would also work on humans. Furthermore, some are only at the stage of hypothesis, and again do not pose an urgent ethical and policy challenge. However, scientific and technological progress will undoubtedly create more possible cognitive enhancers, and so it makes sense to return briefly to these excluded enhancers, and to discuss proactive public policy on research concerning future technologies.

As noted before (see Chapter 2), any government funding on enhancement technologies would not be legitimate, but private and corporate actors have every right to follow any research interests, as long as research ethics imperatives are observed. However, as we have seen in the case-by-case analysis, military interest in enhancement technology can be the driving force for newer enhancements. Indeed, many of the studies on specific extant cognitive enhancers have been done for the military, and it stands to reason that amphetamines and other drugs will be tested and used by soldiers.

In this context, it might be important to question the leeway the military has with spending the taxpayer's money, and to ensure that the human and civil rights of the soldiers serving as research subjects are respected. For instance, even though complete transparency and civic oversight of the research funded by the military is perhaps too naïve to expect, control of military research expenditures on enhancement could be controlled by a parliamentary body. Furthermore, the informed consent process of military funded enhancement research should be rigorously examined and the right of the soldiers to refuse to use enhancements (barring state of urgency) based on conscientious objection should be publicly asserted and supported. Moreover, the military should guarantee that any long term medical necessities for which there is a possibility that they resulted from the use of these technologies should be compensated by the military.

On a different note, the use of novel cognitive enhancement drugs and devices in the civilian population should be strictly prohibited until sufficient data has been generated by the research that would indicate that they are safe and effective. Although new

technologies such as ampakines and invasive brain-computer interfaces are still not a feasible technology for human use, it is reasonable to expect that they might be in the future. The fact that the society, and indeed, regulatory agencies have had experience and reliable data (by virtue of the provisions of the economic disincentives model) on current cognitive enhancers should generate the know-how to effectively regulate the use of newer enhancers. Objective measures of the harm profile of specific drugs and devices need to be used and further perfected in order to fine-tune the policies.

This leads to an important issue that needs to be shortly addressed – the methodology used for establishing the danger profiles of existing drugs has been criticized, and this is important to address in the context of the analysis, so as to ascertain the impact the weaknesses in methodology might have for the conclusions and proposed public policies.

6.4. Weaknesses and improvements to the methodology

In the analysis of Methylphenidate and Amphetamines, a key methodological tool for assessing their danger has been the multi-criteria drug harm scale (Nutt & al. 2007, Nutt & al. 2010). However, the methodology of this scale did not take into consideration the difference between prescription Amphetamines with controlled purity and street Amphetamines with varying degrees of additional harmful substances added. Furthermore, newer stimulants like Modafinil were not rated at all. The primary focus of the multi-criteria drug harm scale was on illicit drugs, including recreational drugs such as Ecstasy and herbal stimulants with Amphetamine-like effects, such as Khat. Recall that the analysis explicitly dissociated between recreational uses and users of stimulants and cognitive enhancement users. Recall also that Khat was excluded from the case-by-case analysis as there is no sufficient data on any enhancement effects and uses beyond certain communities with cultural tradition of use of this herbal stimulant. Although the results of the multi-criteria drug harm scale have been used with caution (and I have noted that the methodology could be improved by soliciting ratings from different stakeholders, in order to guard against expert bias), the results have been taken as the only available objective measure of the danger profiles.

However, important criticism has been leveled against the multi-criteria drug harm scale on methodological grounds and the cases of Ecstasy and Khat raise specific concerns. In an illuminating article, Parrot (2007) offers extensive criticism of the specific ratings of the scale in the passage I will quote in full:

Ecstasy users reported an average of eight physical and four psychological problems, which they attributed to Ecstasy use. In many of these Ecstasy/MDMA studies, the non-user control group comprised legal drug users—mostly social drinkers. Hence there is an extensive literature, showing that Ecstasy/MDMA is associated with significantly more functional distress than alcohol used at the same age. ... [furthermore] the lowly position attributed to Khat by Nutt & al. (2007) may reflect its infrequent usage in UK, but in societies where it is widely used, the harm score would be much higher.

In parts of Somalia, Kenya and Yemen, Khat (or Qat) is widely used as a social stimulant. The consequences of its use have been extensively researched, and the findings reveal a range of adverse effects: The psychoactive drug is obtained by chewing khat or qat leaves, but this takes considerable time and effort: In an empirical investigation of 1600 users, the authors noted that: ‘Subjects in the Qat group chewed leaves for at least 4 hours daily for three successive days’. The leaf residues caused significant gastro-intestinal distress, with epigastric bloating, abdominal distension and genito-urinary problems. Tobacco-leaf chewers tend to develop cancers of the mouth, and qat-leaf chewers similarly develop oral cancers. Cardiac, cerebrovascular and other medical problems also occur. The pharmacodynamic effects of cathinone [the active substance in Khat] are broadly similar to other Central Nervous System (CNS) stimulants, with acute mood gains followed by adverse withdrawal symptoms, insomnia followed by delayed waking, reduced daily work performance, anorexia, drug dependency and increased psychiatric distress.

Khat is also associated with cognitive performance deficits. At one Somali University, the 25% of students who were khat chewers had significantly lower academic performance grades, despite coming from higher income families The money spent on khat, the time spent chewing and other aspects of drug dependency can increase psychosocial distress and lead to financial hardship. In northern Kenya many respondents used more than half of their domestic budgets on khat, but few perceived this as a waste of resources.

Since Parrot's (2007) criticism is not isolated but is just one example of valid concerns which include situational factors (see e.g., Caulkins & al. 2011), value judgments (see e.g., Kalant 2010), and lack of input from relevant stakeholders (see e.g., Forlini et al 2013), it makes sense to assess how far this methodological weakness of the multi-criteria drug harm scale affects the conclusions. First of all, as Nutt (2011) rightly notes in his response to critics, the facts that a certain methodology has drawbacks does not mean that this methodology should be abandoned – especially if no alternative method has been proposed. Secondly, the most damning criticism concerns stimulant substances that are less known by experts that have made the assessments, whereas Amphetamine and Methylphenidate are well known and researched. Recall the way the data has been generated in the original multi-criteria drug harm scale: Experts in psychiatry, pharmacology, and addiction rated drugs on three major dimensions of harm (physical health effects, potential for dependence, and social harms) using a four-point scale, with 0 being no risk, 1 some, 2 moderate and 3 extreme risk (Nutt & al. 2007). The numbers used in the analysis represent mean values from multiple assessments. Even though I acknowledge that perhaps dangers of use might need to be dissociated from dangers of abuse, for the purposes of the discussion in Chapter 3, the data is valid – the experts have had plenty of experience with the effects of Amphetamine and Methylphenidate, and the conclusions on the abuse potential were the guiding reason in opting for a more liberal approach with extended release formulas of Methylphenidate, and for the prohibitive response in the case of instant release Methylphenidate and all forms of Amphetamine.

Now, concerns about extending the methodology of the multi-criteria drug harm scale to cognitive enhancers is legitimate and as such should be addressed in the future. This leads to the next important issue that needs to be shortly addressed – what are the open future goals for research.

6.5. Desiderata: Open future goals for research

One of the conclusions of the dissertation was that the ethical and policy analysis of cognition enhancement drugs needs to be supported by the broader framework of the international system of drug control (e.g., UN 1971). Within this system of international treaties, drug scheduling is an important issue, as it determines how drugs are legally regulated and more importantly, how users of drugs are to be treated. Recently, drug scheduling has been criticized as having no footing in scientific evidence (Nutt & al. 2007, 2010). Multi-criteria drug harm scale (MCDHS) has been proposed as a solution to this problem (Nutt & al. 2007, 2010), but several aspects of such analysis remain disputed (see Kalant 2010; Caulkins, Reuter, & Coulson, 2011; Fischer & Kendall 2011; see also Forlini et al 2013 for specific problems with extending MCDHS to stimulants).

I posit that the shortcomings of the drug harm scales can be resolved, notably by adding the perspective of drug users (as opposed to drug abusers) and general medical practitioners along with the expert assessments, dissociating the harms of use from harms of abuse, and focusing on a subset of drugs (legal stimulant drugs with regulated purity) to allow for comparison without mixing different social context of licit and illicit drugs, and dimensions of harm that ultimately result from legal penalties.

As such, a general aim of my future research (stemming from the dissertation) could be to identify and analyze expert and non-expert perspectives on degree of harmfulness in use and abuse of stimulant drugs in the real-world setting to refine the policy implications of MCDHS. More specifically, the MCDHS could be adapted by:

1. Incorporating subjective-effects assessments by users of prescription stimulants as well as general practitioners who prescribe them;
2. Identifying and analyzing the gaps between the perspectives of different types of knowledge users (general health practitioner, patient and or other type of user) and the experts responsible for current drug regulation regime;
3. Identifying and analyzing the difference between harms of prescription stimulant use and abuse; and
4. Identifying and analyzing relevant policy options for regulation of various uses of prescription stimulants.

Such a future research program could lead to the identification of specific harms and social challenges as well as potential ethical solutions in the context of use and abuse of specific stimulant drugs (Modafinil, Methylphenidate and Amphetamine). Furthermore, it would prepare the methodological ground for the analysis cognitive enhancement drugs that could be available in the future (e.g., Ampakines). In order to facilitate understanding among different stakeholders and reduce bias relating to illicit drug use, the brand names of medical prescription drugs (e.g., Provigil, Ritalin and Adderall) should be used within the methodology. Quantitative analysis will have to be applied to the subjective-effects assessments by users of stimulants as well as general practitioners who prescribe them in order to create four distinct sets of drug harm matrices (assessments of use and abuse harms by patients, “study aid” users, general practitioners and experts).

This would improve the methodology of the MCDHS (Nutt & al. 2007, 2010) in line with important criticism (see Kalant 2010; Caulkins, Reuter, & Coulson, 2011; Fischer & Kendall 2011) by reducing status quo bias, and incorporating subjective effects methodology which has been reliably used for decades in measurements of drug abuse liability (see e.g., Fischman, & Folting, 1991). An additional improvement in methodology could be achieved by recruiting the population of ADHD and shift-worker syndrome patients and “study aid” users as opposed to the usual population of abusers/drug addicts (biased toward prison inmates) which would increase the validity of assessment for the real-world setting.

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Wolpe, P. R. (2004): Neuroethics, In Post, S.G. (Ed.): *The Encyclopedia of Bioethics*, New York: MacMillan, pp. 1894–1898.

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Zonneveld, L., Dijstelbloem, H., & Ringoir, D. (Eds.) (2008): *Reshaping the human condition: Exploring human enhancement*. The Hague: Rathenau Institute.

Veljko Dubljević, PhD – Curriculum Vitae:

Banting Postdoctoral Fellow, Neuroethics Research Unit, Institut de recherches cliniques de Montreal (IRCM); 110 avenue des Pins Ouest, Montreal, Quebec, Canada H2W 1R7, and Department of Neurology and Neurosurgery, McGill University, Montreal; Executive director of the Montreal Neuroethics Network. E-mail: veljko.dubljevic@ircm.qc.ca

Academic Career:

2014- Banting Postdoctoral Fellow, IRCM and McGill University, Montreal
2013-2014 Postdoctoral Fellow, IRCM and McGill University, Montreal, Canada
2011-2013 Member of the Research Training Group “Bioethics”, IZEW, University of Tübingen, Germany;
2008-2010 Assistant Lecturer and Manager of the Academic Publishing Centre, Educons University, Sremska Kamenica, Serbia;
2007-2008 Assistant Lecturer, Faculty of Business in Services, Novi Sad, Serbia;
2005-2006 Assistant Lecturer, Faculty of Law and Business, Novi Sad, Serbia;
2002-2005 Teaching Assistant, Faculty of Business in Services, Novi Sad.

Education:

2012-2014 PhD in Philosophy (Neuroethics), University of Stuttgart, Germany
2008-2010 PhD in Political science (Political theory), University of Belgrade, Serbia
2002-2008 Magister in Economics (Business ethics), Educons University, Serbia
1996-2001 Diploma in Philosophy (Ethics), University of Novi Sad, Yugoslavia

Research interests: Neuroethics, Philosophy of neuroscience and technology, Bioethics, Business ethics, Social and political theory, Empirical moral psychology, Moral theory, Philosophy of law

Languages: Serbo-Croatian; English; German; French

Professional activities:

Member of the Canadian Association for Neuroscience (2014-)
Member of the Society for Philosophy and Psychology (2013-)
Co-editor of “Brainstorm” newsletter (Canadian Neuroethics interest group) (2013-)
Member of the International Neuroethics Society - INS (2011-);
Member of the INS Communications Committee (2013-);
Secretary of the Novi Sad Association for Theory, Ethics and Philosophy of Law (2007-);
Secretary of the Centre for Empirical Research of Religion in Yugoslavia (2001-2008);

Peer reviewer for:

Theoretical Medicine and Bioethics (2012-);
Philosophy & Technology, (2013-);
Kennedy Institute of Ethics Journal (2013-);
Ethical Theory and Moral Practice (2013-);
Frontiers in Systems Neuroscience (2014-).

Research funding:

Banting Postdoctoral Fellowship “The ADC of moral judgment” 2014
Brocher Foundation funded project “(Re)defining neuroethics” 2014
Fellowship within the Research-training group Bioethics 2011

Peer-reviewed articles in English:

Dubljević, V. and Racine, E. (Accepted): The ADC of Moral Judgment: Opening the Black Box of Moral Intuitions with Heuristics about Agents, Deeds and Consequences, *AJOB - Neuroscience*.

Dubljević, V. and Racine, E. (In Press): A Single Cognitive Heuristic Process Meets the Complexity of Domain-Specific Moral Heuristics, *Behavioural and Brain Sciences*.

Dubljević, V., Saigle, V. and Racine E. (2014): The Rising Tide of Transcranial Direct Current Stimulation (tDCS) in the Media and Academic Literature, *Neuron*, 82 (4): 731-736.

Dubljević, V. (2014): Response to Open Peer Commentaries on “Prohibition or Coffee-shops: Regulation of Amphetamine and Methylphenidate for Enhancement Use by Healthy Adults”, *American Journal of Bioethics*, 14 (1): W1-W8.

Racine, E., Bell, E., Yan, A., Andrew, G., Bell, L.E., Clarke, M., Dubljevic, V. et al. (2014): Ethics challenges of transition from paediatric to adult health care services for young adults with neurodevelopmental disabilities, *Pediatrics & Child Health*, 19 (2): 65-68.

Dubljević, V., Sattler, S. and Racine, E. (2013): Cognitive Enhancement and Academic Misconduct: A Study Exploring Their Frequency and Relationship, *Ethics & Behaviour*, Published online: 02 Dec 2013, doi: 10.1080/10508422.2013.869747

Dubljević, V. (2013): Autonomy in Neuroethics: Political and not Metaphysical, *American Journal of Bioethics – Neuroscience*, 4 (4): 44-51.

Dubljević, V. (2013): Prohibition or Coffee-shops: Regulation of Amphetamine and Methylphenidate for Enhancement Use by Healthy Adults, Target Article: *American Journal of Bioethics* 13 (7): 23-33.

Bell, E., Dubljević, V. and Racine, E. (2013): Nudging Without Ethical Fudging: Clarifying Physician Obligations to Avoid Ethical Compromise, *American Journal of Bioethics* 13 (6): 18-19.

Dubljević, V. and Racine, E. (2013): Judging Deeds not Psychopaths, *American Journal of Bioethics – Neuroscience*, 4 (2): 33-34.

Dubljević, V. (2013): Cognitive Enhancement, Rational Choice and Justification, *Neuroethics*; 6 (1): 179-187.

Ranisch, R., Garofoli, D. and Dubljević, V. (2013): 'Clock shock', Motivational Enhancement and Performance Maintenance in Adderall Use, *American Journal of Bioethics-Neuroscience*, 4 (1): 13-14.

Dubljević, V. (2012): Toward a Legitimate Public Policy on Cognition-Enhancement Drugs, *American Journal of Bioethics – Neuroscience*, 3 (3): 29-33.

Dubljević, V. (2012): Principles of Justice as the Basis for Public Policy on Psychopharmacological Cognitive Enhancement, *Law, Innovation and Technology*, 4 (1): 67-83.

Dubljević, V. (2012): How to Understand Rawls's Law of Peoples, *Studies in Social and Political Thought*, 20: 85-105.

Books and Book chapters in English:

Jotterand, F. and Dubljević, V. (Eds.): *Cognitive Enhancement: Ethical and Policy Implications in International Perspectives*, under contract at Oxford University Press.

Dubljević, V. (In Press): Enhancement with Modafinil: Benefiting or Harming the Society?, in Jotterand, F. and Dubljević, V. (Eds.): *Cognitive Enhancement: Ethical and Policy Implications in International Perspectives*, under contract at Oxford University Press.

Racine, E. and Dubljević, V. (In Press): Neuroethics: Neuroscience and Society, *Oxford Handbooks Online – Philosophy*

Dubljević, V., Venero, C. and Knafo, S. (In Press): What is Cognitive Enhancement?, in Knafo, S. and Venero, C. (Eds.): *Cognitive Enhancement*, under contract at Elsevier.

Dubljević, V. (In Press): Cognitive Enhancement: A Glance at the Future and Ethical Considerations, in Knafo, S. and Venero, C. (Eds.): *Cognitive Enhancement*, under contract at Elsevier.

Editorial work on published Book Projects in Serbo-Croatian:

Translation of the *Treaty establishing a Constitution for Europe* in Serbo-Croatian (2005)
American Jurisprudence of the 20th Century (2007)

Translation of the *Treaty of Lisbon* (Treaty of EU) in Serbo-Croatian language (2008)
European Union of Nations and Universal Values (2010)

Miscellaneous Publications in English and German:

A Theoretical Investigation of the Post-metaphysical Concept of Autonomy in Neuroethics, Research abstract published in: *American Journal of Bioethics - Neuroscience*; 2012 4/2: 64.

A Theoretical Investigation of Principles of Justice as Criteria for Assessing Psychopharmacological Cognitive Enhancement, Research abstract published in: *American Journal of Bioethics – Neuroscience*, 2013 3/3: 34.

Medikamente zur kognitiven Verbesserung und das Problem der Gerechtigkeit, IZEW Jahresbericht 2012: 12-17.

Meet a member – Interview with Veljko Dubljević, International Neuroethics Society Newsletter, November 2012: 3-4.

Cognitive enhancement and social justice, Kopf Carrier Newsletter, May 2013: 1-4.

Honors and awards:

The Royal Norwegian Embassy Award “For the promising generation” 2001

Matica Srpska Award for excellence during undergraduate studies 2001

University of Novi Sad Award for outstanding quality of Diploma-level work 2001

Educons University, Dean’s Laudatio for excellence in Magister-level work 2008

Mt. Kopaonik School of Natural Law Award 2008

International Neuroethics Society “Michael Patterson” Award 2012

Award from the Scientific Committee of Brain Matters – Vancouver 2014

Recent Conference Presentations:

“The Rising Tide of tDCS in the Media and Academic Literature” – Poster presentation at the Montreal Postdoctoral Research Day, Montreal, Canada, 15.04.2014.

“The impact of a landmark neuroscience study on free will: Reconsidering the legacy of the Libet experiment” – Poster presentation at the World Congress on Brain, Behavior and Emotions, Montreal, Canada, 07-09.04.2014.

“The ADC of Moral Judgment: Tracking Intuitions About Agents, Deeds and Consequences in the Neuroscience of Ethics” – Lightning talk presentation at the Brain Matters Vancouver Conference, Vancouver, Canada, 13-14.03.2014.

“Neuroethics and Justice: Public Reason in the Cognitive Enhancement Debate”, Final Conference of the Research Training Group “Bioethics”, Tübingen, Germany 04-06.12.2013.

“A Review of Social and Normative Aspects of Transcranial Direct Current Stimulation (tDCS) Use for Enhancement Purposes by Healthy Adults“ – Poster presentation at the IRCM Research Day, Montreal, Canada; 17.05.2013.

“A Theoretical Investigation of the Post-metaphysical Concept of Autonomy in Neuroethics“ – Poster and oral presentation at the International Neuroethics Society Annual Meeting, New Orleans, USA; 11-12.10.2012.

“Toward a Legitimate Public Policy on Cognition Enhancement Drugs” - paper presented at the Society for Applied Philosophy Annual Conference, Oxford, UK, 29.06.-01.07.2012.

“Principles of justice as the basis for public policy on psycho-pharmacological cognitive enhancement“ - talk at the European Neuroscience and Society Network final conference “The Mutual Challenges of Neurosciences and Public Health“, London, UK, 25-27.04.2012.

“Principles of justice as criteria for assessing cognitive enhancement“, talk at “Memory Enhancement“ Conference, at Max Planck Institute for Psychiatry in Munich, 21-22.04.2012.

“A Theoretical Investigation of Principles of Justice as Criteria for Assessing Psychopharmacological Cognitive Enhancement“ – Poster presentation at the International Neuroethics Society Annual Meeting, Washington D.C. USA; 10-11.11.2011.

“Why Did Rawls Revisit the Idea of Public Reason“? – Paper presented at the International Symposium “Debating Public Reason“, University of Poitiers, France; 04.-05.11.2011.

Available online at: <http://uptv.univ-poitiers.fr/web/canal/61/theme/28/manif/344/index.html>

“Principles of Justice as Criteria for Assessing Psycho-pharmacological Cognitive Enhancement” – Paper presented at the International Neuroethics Conference “Neuroenhancement”, University of Mainz, Germany; 07-08.07.2011;

Principle organizer of the following (recent or upcoming) events:

- “(Re)defining neuroethics: Exploring the implications and limitations of neuroscience on ethics”, International Expert Workshop selected for implementation by the Scientific Council of the Brocher Foundation on 16/17th December 2014, Geneva, Switzerland;
- “Neuroscience and Ethics in Dialogue”, Lecture series of the Montreal Neuroethics Network, Winter Semester 2013/2014, IRCM, Montreal;
- “Biotechnology – Ethics – Society”, International Symposium of the Research Training Group “Bioethics”, 9-11th February 2012, Castle Hohentübingen, Germany

Recent invited talks:

- “Transcranial direct current stimulation (tDCS): Ethical and policy issues” invited talk at Center for Ethics in the Life Sciences, Michigan State University, United States, 01.05.2014.
- “Policy and regulation of transcranial direct current stimulation (tDCS) use” invited talk at Department of Bioethics, Dalhousie University, Canada, 23.01.2014.
- “Behavioral and Brain Science of Morality and Moral Heuristics“, invited talk at the Mind, Brain and Neuroethics Unit, University of Ottawa, Canada, 15.05.2013.
- “Principles of Justice in Neuroethics of Cognitive Enhancement” invited talk at the German Research Foundation (DFG) sponsored 2nd German-Russian week of young researchers, Yekaterinburg, Russia, 16-21.09.2012.
- “Ethics of Cognitive Neuroenhancement“ - invited talk at the Centre for NanoScience, Ludwig-Maximillan University, Munich, Germany; 29.07.2012.
- “The Economic Disincentives Model as a Legitimate Public Policy on Psychopharmacological Cognitive Enhancement“ - invited talk at the “Health Governance Matters“ Conference, European Parliament, Brussels, Belgium, 16.05.2012.
- “Introducing Neuroethics: (Cognitive) Neuroscience of Morality“ - invited talk at the Ethics Centre, University of Jena, Germany; 18.01.2012.

Blogs: Neuroethics & Law Blog, Invited Guest Blogger for September 2013:

How (not) to argue about cognitive enhancement;

http://kolber.typepad.com/ethics_law_blog/2013/09/how-not-to-argue-about-cognitive-enhancement-by-veljko-dubljevic.html

How to regulate cognition enhancement drugs?;

http://kolber.typepad.com/ethics_law_blog/2013/09/how-to-regulate-cognition-enhancement-drugs-by-veljko-dubljevic.html

How to model indirect coercion to use cognitive enhancement?;

http://kolber.typepad.com/ethics_law_blog/2013/09/how-to-model-indirect-coercion-to-use-cognitive-enhancement-by-veljko-dubljevic.html

How to regulate Ritalin and Adderall; http://kolber.typepad.com/ethics_law_blog/2013/09/how-to-regulate-ritalin-and-adderall-by-veljko-dubljevic.html

Is the Economic Disincentives Model too conservative?;

http://kolber.typepad.com/ethics_law_blog/2013/09/is-the-economic-disincentives-model-too-conservative-by-veljko-dubljevic.html

Is the Economic Disincentives Model too permissive?;

http://kolber.typepad.com/ethics_law_blog/2013/09/is-the-economic-disincentives-model-too-permissive-by-veljko-dubljevic.html

Does the Economic Disincentives Model fail to address the right issues?;

http://kolber.typepad.com/ethics_law_blog/2013/09/does-the-economic-disincentives-model-fail-to-address-the-right-issues-by-veljko-dubljevic.html

How can the public policy on cognitive enhancement be improved?

http://kolber.typepad.com/ethics_law_blog/2013/09/how-can-the-public-policy-on-cognitive-enhancement-be-improved-by-veljko-dubljevic.html

Articles and Book Chapters in Serbo-Croatian:

- Dubljević, V. (In Press): How Neuroethics differs from Bioethics, and does it matter?, in *Primenjena etika*, Novi Sad: Mediterran.
- Dubljević, V. (2012): The Difference Between Justice and Legitimacy as the Basis for an Interpretation of Rawls' Law of Peoples, *Političke perspektive*, 4 (1): 45-71.
- Dubljević, V. (2011): Morality, Religion and the Political Culture of Tolerance, *Religion and Tolerance*, 9 (16): 245-256;
- Dubljević, V. (2011): Habermas's Criticism of "Justice as Fairness" and Rawls's Distinction of Four Roles for Political Philosophy, *Nauka i politika*, 5 (2): 195-204.
- Dubljević, V. (2010): Discourse Ethics of Jürgen Habermas in Relation to Contemporary Science, *Interdisciplinarnost i jedinstvo savremene nauke*, 4 (2): 133-142.
- Dubljević, V. (2010): The Formulation and Reformulation of Rawls's Idea of Public Reason, *Pravni život*, 14: 737-758.
- Dubljević, V. (2010): The Application of Utilitarian Analysis; *Poslovna ekonomija*, 2 (1): 151-167.
- Dubljević, V. (2010): The Application of Categorical Imperative, in *Evropska zajednica naroda i univerzalne vrednosti*, Novi Sad: NATEF, pp. 127-147.
- Dubljević, V. (2009): The Philosophy of Law of Jürgen Habermas, *Pravni život*, 12: 595-609.
- Dubljević, V. (2009): Legitimacy and the Economic Model of Pluralist Democracy; *Poslovna ekonomija*, 1 (2): 200-218.
- Dubljević, V. and Jovanović, A.: *Students' handbook for university entrance exam*, Sremska Kamenica: Educons University Press (three editions: 2007, 2008 and 2009).
- Dubljević, V. (2008): How to Interpret Habermas' Critique of "Justice as Fairness", *Pravni život*, 10: 335-356.
- Dubljević, V. (2007): The Application of "Justice as Fairness" through Notions of the Rational and the Reasonable, *Pravni život*, 8: 399- 414.
- Dubljević, V. (2006): Organizational Justice; *Žurnal za sociologiju*, 4: 76- 85.
- Dubljević, V. (2002): Morality and Religion; in *Religije Balkana: iskustva i perpektive*, Begrade: Belgrade Open School, pp. 180-183.
- Dubljević, V. (2001): Socrates; in *Filozofija – problemski pristup*, Novi Sad: SSFF, pp. 34- 44.
- Dubljević, V. (2001): Philosophy and Modern Science, in *Filozofija – problemski pristup*, Novi Sad: SSFF, pp. 140-143.
- Dubljević, V. (2001): Problems in Methodology of Teaching Philosophy; in *Filozofija – problemski pristup*, Novi Sad: SSFF, pp. 206- 210.

Teaching: Overview of courses and roles

2014: Guest Lecturer

Introduction to neuroethics (topic: Neuroscience of Ethics) - Graduate
Universite de Montreal, Canada

2014: (Adjunct) Assistant Professor, Course Co-coordinator

Neuroethics – Undergraduate,
McGill University, Canada

2013: (Adjunct) Assistant Professor

Research ethics – Undergraduate,
Dresden International University, Germany

2012-2013: (Adjunct) Assistant Professor

Introduction to critical thinking, biomedical ethics and medical philosophy – Undergraduate,
Dresden International University, Germany

2012: Guest Lecturer

Social ethics (topic: Ethics of cognitive enhancement) - Undergraduate
University of Tübingen, Germany

2008-2010: Assistant Lecturer

Philosophy of law and economics - Graduate
Educons University, Serbia

2007-2010: Assistant Lecturer

Business ethics - Undergraduate
Educons University, Serbia

2007-2010: Assistant Lecturer

Introduction to social and political theory – Undergraduate
Faculty for business in services (2007/8) and Educons University (2008/10), Serbia

2007-2010: Assistant Lecturer

Corporate social responsibility - Undergraduate
Faculty for business in services (2007/8) and Educons University (2008/10), Serbia

2005-2006: Assistant Lecturer

Introduction to political philosophy - Undergraduate
Faculty for law and business, Novi Sad, Serbia

2002-2005: Teaching Assistant

Introduction to ethics and business ethics – Undergraduate
Faculty for business in services, Novi Sad

2002-2005: Teaching Assistant

Introduction to social theory – Undergraduate
Faculty for business in services, Novi Sad