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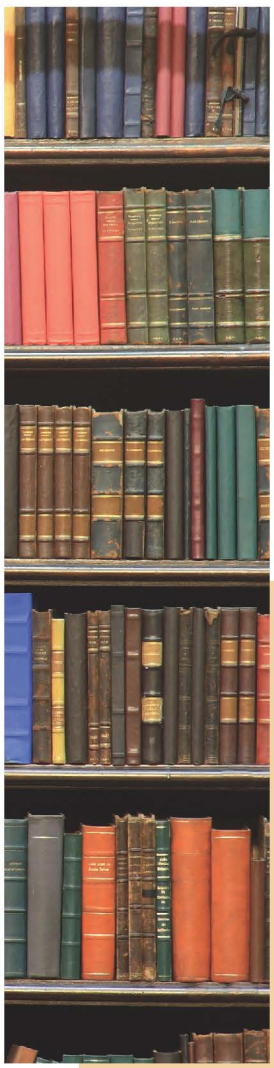

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Workshop on Upcoming issues of EU law [Excerpt - Regulating robotics a challenge for Europe]

WORKSHOP FOR THE JURI COMMITTEE

EN

2014

EUROPEAN PARLIAMENT

DIRECTORATE GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT C: CITIZENS' RIGHTS AND CONSTITUTIONAL AFFAIRS

LEGAL AFFAIRS

UPCOMING ISSUES OF EU LAW

COMPILATION OF IN-DEPTH ANALYSES

WORKSHOP 24 SEPTEMBER 2014

[EXCERPT]

Abstract

Upon request by the JURI Committee, five specific topics have been chosen for the workshop "Upcoming issues of EU law" on the afternoon of 24 September 2014 as being representative of different avenues for the future development of the law and aiming at giving Members of the European Parliament an overview of the work of the Legal Affairs Committee in several of its areas of competence. The workshop focuses both on work that has been accomplished in the past and on challenges that may be expected to arise in the course of the legislature 2014 -2019.

PE 509.987 EN

DOCUMENT REQUESTED BY THE COMMITTEE ON LEGAL AFFAIRS

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LINGUISTIC VERSIONS

Original: EN

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European Parliament, manuscript completed in September 2014.

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DISCLAIMER

REGULATING ROBOTICS: A CHALLENGE FOR EUROPE

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Abstract

Upon request by the JURI Committee, this paper aims at offering an analysis of the interplay between regulation and robotics in the European context. Since robotics represents a technological innovation, which will profoundly modify the societal structure, and a strategic market sector, the need for a legal appraisal and intervention emerge. The European Union is called to design a transparent and carefully tailored regulatory environment so as to influence the development of robotic applications in accordance with its core democratic values.

CONTENTS

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EXECUTIVE SUMMARY

Robotics represents one of the most relevant technological innovations of the current century, a revolution that could impact the economy and society in a twofold sense. On the one hand, those countries that more than others will invest in robotic applications, developing a strong industry in the field, will soon acquire a relevant strategic hedge over latecomers and other players, who nonetheless will be consuming such devices. On the other hand, the advent of these technologies will profoundly modify the societal structure, also – but not only – by reshaping the labour market and subsequent income distribution.

Pursuant to a recent study the application of advanced robotics across health care, manufacturing, and services could generate an economic impact ranging from $1.7 trillion to 4.5 trillion per year by 2025. A large share of this effect could derive from robotics applied to the healthcare domain, by increasing life quality and expectancy. Automation however will also make some tasks currently performed by humans obsolete, requiring new skills and competences to be developed by future generations seeking employment. The emergence of applications that can be installed on the human body attributing radically new capabilities or pushing existing ones beyond limits deemed today to be natural will question our understanding of what being human means. Driverless vehicles may radically transform our transportation system, and force a change in many habits and preferences we today give for granted.

Robotics thus calls for regulation, in order for it not to be 'disruptive' and rather allow its full beneficial potential to be exploited. In particular, despite some scenarios may appear belonging to a distant future, action is already required. Firstly, many applications could be developed in a much shorter time than expected. Secondly, even at the current stage of technological development some policy choices are required that need to be attentively pondered, since they may create some path dependency. Thirdly, other countries are taking action, regulating and in some cases openly favouring the development of robotic technologies and applications.

In deciding if, when, and how to regulate Europe has to adopt a functional perspective. The practical effect of regulation, the incentives it provides need to be very well pondered. Excessively restrictive regulation may in fact only impair the development of a supply side of the economy, impeding research and development of some applications within European countries. However, this would also entail losing the possibility to influence how these technologies shall function and be shaped once they reach the market, eventually even the European market.

Adopting a functional perspective also means to put rights – and fundamental rights as recognized by the European Union – first. On the one hand, this suggests the adoption of a Responsible Research and Innovation approach. On the other hand, it requires that the choice to adopt new regulation shall not mainly depend on the technological aspect of the application considered, such as its ability to operate autonomously or to 'learn'. Rather, the impact the single application may have on society and fundamental rights shall be guiding the choice.

Robotic applications are in fact very different from one another, ranging from an automated vacuum cleaner – which appears to be quite unproblematic – to a prosthetic limb, a personal robot, a driverless vehicle, a surgical robot and a softbot. Addressing them

unitarily does not appear to be the preferable alternative since differences are often more relevant than similarities.

These applications then need to be considered on a case-by-case basis, identifying the issues they raise, and the way they impact fundamental rights, by fostering them or hindering them in some ways. If this analysis is conducted at a sufficiently early stage regulation could contribute to determine how such devices ought to be conceived for rights to be protected (e.g.: privacy by design).

At the same time, if some technologies are thought to positively enhance existing values policy choices could be adopted in order to favour their emergence and diffusion. Robotics for healthcare represents a perfect case in point.

Through the analysis conducted some issues appear to be recurring for different kinds of robotic applications, which deserve to be addressed: (i) liability rules, (ii) standardization, (iii) the regulation of human enhancement. However, despite the issues may be similar the solutions proposed may vary according to the single kind of applications, in light of the considerations just sketched.

Therefore, if liability rules should be perceived as a tool to possibly provide adequate incentives for the development of a desirable technology, the solution proposed for driverless vehicles is fundamentally based on adjustments of already existing insurance law regimes. For robotics prostheses instead it may suggest the adoption of a no-fault scheme, and for personal robots may even suggest the acknowledgment of the machine as a legal person (like for a corporation).

The use of standards, developed by competent supranational technical bodies such as the European Standard Organizations, is perceived as a viable and to some extent preferable alternative for the regulation of some specific aspects of robotics, in particular safety. The adoption of narrow tailored standards, frequently adjusted to accommodate most relevant technological developments, could ensure that the products that reach the European market are safe, leaving to liability rules the compensation function. Moreover, standardization may also be required so as to provide uniform qualification criteria across Europe to license the use of robotic applications by professionals, for instance in the case of surgical robots.

Finally the extent to which emerging technologies could allow to modify the human body, conferring brand new capabilities or pushing limits today deemed natural forward, is unparalleled. This requires us to reconsider what we understand as being human and to what extent modifying one’s body represents the most advanced expression of a right to self-determination of one’s own identity or rather may constitute – in some cases – the violation of a principle of human dignity. Methodological considerations are developed suggesting why and how the European Union should start addressing this complex and challenging issue.

1. ROBOTIC AS A STRATEGIC SECTOR FOR THE EUROPEAN MARKET

Robotics represents one of the most relevant technological innovations of the current century[3], a revolution[4] capable of radically modifying existing economies and societies at least in a twofold sense. On the one hand, those countries that more than others will invest in robotic applications, developing a strong industry in the field, will soon acquire a relevant strategic hedge over latecomers and other players, who nonetheless will be consuming such devices[5]. On the other hand, the advent of these technologies will profoundly modify the societal structure, also – but not only – by reshaping the labour market and subsequent income distribution[6].

Pursuant to a recent study[7] the application of advanced robotics across health care, manufacturing, and services could generate an economic impact ranging from $1.7 trillion to 4.5 trillion per year by 2025. Much of the impact - $800 billion to $2.6 trillion – could come from improving and extending people's lives, in particular through the use of prostheses and exoskeletons. Thanks to such technologies more than 50 million people with impaired mobility in the developed world (including the elderly and people with disabilities) could restore mobility, improve their life quality and increase their lifespan. Robotics for human augmentation may have an economic impact of $600 billion to $2 trillion per year by 2025, preventing deaths, reducing in-patient care time and missed work days. Much of this gain could benefit users directly[8]. Robotic surgery (in particular minimally invasive laparoscopic surgery) is estimated as possibly reducing the number of deaths even as much as by 20% in developed countries (by providing aid to the doctor, autocorrecting movements, and by warning of potential risks), and up to 15% of all surgeries performed in countries with developed health-care systems could make use of these devices.

By 2025, autonomous road vehicles could have a $200 billion to $1.9 trillion impact, saving up to 150.000 lives, and reducing CO_2 emissions by 300 million tons, per year[9].

As per service robots, while it is reasonably foreseeable that personal and household devices meant to perform cleaning and domestic tasks may become sufficiently low cost and therefore widely diffused so that at least 25% (and up to 50%) of the population will be making use of them, commercial service robots may be efficiently used for the care of the elderly and disabled. Overall commercial service robots could take over 4 to 8% of workers tasks by 2025, allowing to free substantial amount of time for more complex and valuable employment of available – human – resources[10].

Finally much work could be automated thanks to industrial robots as well, effectively substituting 15-25% of industrial workers tasks. This data could be of concern for

[3] Gates, W. H. (2007). A robot in every home. Scientific American.
[4] Lin, P. (2012). Introduction to Robot Ethics. Robot Ethics. The Ethical and Social Implications of Robotics. P. Lin, K. Abney and G. A. Bekey. Cambridge (MA), The MIT Press.
[5] Manyika, J., M. Chui, J. Bughin, R. Dobbs, P. Bisson and A. Marrs (2013). Disruptive technologies: Advances that will tranform life, business, and the global economy. McKinsey Global Institute, available at http://www.mckinsey.com/insights/business_technology/disruptive_technologies., 68
[6] Ibid., 15-16 and 68.
[7] The data here provided is all derived from ibid., 68 and 72 ff.
[8] In particular through a QALY approach the impact per person is estimated as ranging from $240.000 to $390.000 (ibid., 74).
[9] Ibid., 81.
[10] Ibid., 75.

legislators, for the effects high levels of automation could have on the labour market. This issue is nonetheless not novel, and actually presents itself cyclically since the industrial revolution. In particular, despite being clear that the development of robotics will positively impact the economy it is not certain how the increase in wealth will be distributed[11]. However, different considerations can be made. On the one hand, there is no doubt that robotic technologies will emerge and become diffused in the next years and decades, and there is no way such a phenomenon could be prevented. Instead, those countries that before others will take the initiative and favour the proliferation of a new industry for the development of these technologies, will certainly profit from an increase in internal revenue and workplaces. On the other hand, the reduction of production costs through robotics could trigger an opposite phenomenon to the one observed over the last years. By lowering the demand for low-skilled-low-cost labour, automation could induce large corporations to relocate their production lines in advanced economies[12]. Finally, governments and policy makers are in the position to take action and prepare individuals to face the challenges these technologies bring about, in particular by investing in higher education for larger shares of the population[13].

Overall robotic technologies appear to be a relevant opportunity that at the same time calls for – early, attentive, and effective – regulation on different levels, for it not to become 'disruptive'[14] and rather allow to exploit its full beneficial potential. At a more general level, a transparent and carefully tailored regulatory environment appears to be a key element for the development of a robotics and autonomous systems market, where products and services can be incubated, tested in real environments and eventually launched[15].

More specifically, the potentially technology-chilling effect of some of the existing and applicable rules needs to be carefully pondered, in order to determine whether the effect attained is actually desirable (and the conclusion may vary according to the specific kind of robotic application considered). Some technologies may indeed raise complex ethical and social issues, that cannot be simplistically overlooked. Yet even in such cases regulation should be attentively designed not to merely impair the development of a supply side of the economy for those specific devices[16], since that would entail reducing the possibility to effectively influence the way that product is conceived, designed, and finally distributed onto the market, including the standards it needs to conform to[17].

Arriving late, not taking timely and adequate action, or lacking a functional approach in this field may represent an extremely costly decision. In the end robots will be out there, in the

[11] Ibid., 16.
[12] Ibid., 68
[13] Ibid. 15
[14] The term is utilized by ibid., *passim*, and suggests that this complex phenomenon needs to be attentively governed.
[15] Recently, within Horizon 2020 a research project was financed by the European Commission – ECHORD ++ – which also aims at developing specialized centers for the testing of robots in safe but real life environments. Similar measures were already adopted in many other industrialized countries including the US and Korea, see fn. 15.
[16] Were too stringent rules adopted, raising initial costs for companies operating within a given legal system, competitors, originally operating in other markets and under other regulations, would find themselves at an advantage; most likely they would develop the application nonetheless, and push the companies operating in the more limited legal system outside the market for that technology. Later though the very product may be sold – unless that is expressly prohibited – in the country affected by more stringent regulations, to the sole advantage of those players, who originally managed to enter the market.
[17] The application produced outside the legal system prohibiting its development and use will abide the different standards set forth by the legal system in which it was researched and conceived. Unless the subsequent use is effectively prohibited in the former country – in case a similar prohibition may prove effective and possible to enforce, and society does not put pressure for the diffusion of the same technology despite the original prohibition – its later diffusion will produce the overall effect of imposing the legal system standards – even of normative relevance – which belong to the second, completely frustrating the original regulation's purposes.

market, in the streets, in our homes, but they will adhere to the standards, values, social fabric of those countries, like China or South Korea, that are proactively confronting the economic opportunities offered by the advancements in robotics[18].

These arguments lead us to identify the regulation of robotics as a pressing issue the European Union is called to address without delay, so as to become an active and possibly a leading player at the international level, and influence its emergence through its core democratic values.

Different and relevant policy choices are in fact already required at the current state of technological development, that will to some extent create a path-dependency. Even more a strategic perspective has to be developed to effectively meet the even more relevant challenges that can already be spotted at the horizon.

2. REGULATING ROBOTICS: WHICH ROLE FOR EUROPE?

For robotics to be seen as a valuable opportunity, its advancement need to grow in accordance with the complementary objective which is enshrined in the European legal system, namely that of being an area of freedom, security and justice. The competing goals of protecting consumers and more generally end-users from harm and fostering innovation have therefore to become embedded in the regulatory endeavour and in the innovation process itself. In this respect, the most proactive regulatory system seems to have to combine multiple tools and constructs: legal rules, technical norms and standards, codes of conducts and good practices. These can guarantee certainty, flexibility, accuracy and context-based interpretation.

Different are the elements to be taken into account that play a role in the regulation of robotic technologies, and can guide the choice among the array of available instruments and approaches.

On the one hand, technological innovation, and innovation in robotics is no exception, has an inherently transnational quality, being the result of the cooperation of articulated research teams spread over different jurisdictions. It is by nature a cross-boundary phenomenon that demands to resort to regulatory instruments able to adhere to the not merely national relevance of the activities – research and industrial production - involved.

On the other hand, scientific and technological advancements occur at a fast pace, leading to changes or even abrupt transformations, that cannot be easily captured by conventional legal instruments. A problem often underlined when confronting the relationship between technology and regulation is indeed the law slow pace, in the sense that technological innovation outrun the ability of the regulator to intervene early enough at the emergence of a new product. The problem of regulatory connection[19] exists not only when a new

[18] Korea has since long taken concrete action in order to favour the development of robotic technologies, see the Korean Act No 9014, 28 March 2008 on Intelligent Robots Development and Distribution Promotion Act (IRDDPA), available in an English translation at http://elaw.klri.re.kr/eng_mobile/viewer.do?hseq=17399&type=sogan&key=13, where art. 1 states 'The purpose of this Act is to contribute to the enhancement of the quality of life of citizens and the national economy by establishing and promoting a policy for the sustainable development of the intelligent robot industry to facilitate the development and distribution of intelligent robots and lay down the foundation therefor'.

[19] The concept of 'regulatory connection' and its three phases – 'getting connected', 'staying connected' and 'dealing with disconnection' – are explained and thoroughly discussed in R. Brownsword and M. Goodwin, *Law and*

technology is emerging and regulators have to face the challenge of "getting connected", but also when the technology is in some way established and widespread, because it simply keeps moving and being transformed. And "staying connected" to technologies that evolve again has a bearing on the normative framework that has to adjust to the intrinsically mutant quality of its object.

Pursuant to these considerations, soft law appears an appropriate option to handle the complexity of technological regulation. Developed by independent agencies, international organizations, non-state actors, it allows taking the transnational character of the phenomenon into account. Consisting of agile and flexible tools, it catches the dynamism inherent in technological innovation, otherwise at odds with long-term legal framing. Said otherwise, in order to escape the constraints of a "hard law" approach, legal systems are thus naturally steered towards 'homeostatic' instruments, capable of adapting themselves to a changing landscape, which cannot always be managed through statutory law.[20]

Technical delegation to independent bodies is also a tool used to handle matters characterized by a strong technological dimension, in order to keep pace with scientific advancements. Technical and safety norms and standards, that are formulated by administrative or non-governmental agencies, technical standard-setting bodies such as the International Organization for Standardization (ISO) and the European Standard Organizations (henceforth ESOs, such as CEN & CENELEC), and professional associations, have increasingly become a tool for regulation in many science-centred sectors, and exert a decisive influence on the application of the law (for instance, contribute to define the concepts of negligence, due care, therefore have a bearing on the allocation of liability by means of the so-called regulatory compliance defence). Technical delegation to independent bodies which are enabled to register variations, assess the need for amendments and implement those amendments allows for the adjustment of the regulatory system without the need for statutory intervention.

Finally, documents like codes of conduct, that can be adopted on a voluntary basis, not necessarily at the central-national level, but by the operators of a certain sector, are also characterized by a closeness to the context to be regulated that allows to neutralize problems of acceptability.

For these very reasons, if flexible regulation by means of soft law is deemed essential to enable, allow, and accommodate advanced robotic technologies, it does, however, present several relevant drawbacks too. Firstly, soft law does not allow the design of a sound regulatory framework, since it has to be consistent with several legal systems, potentially exhibiting relevant differences with one another. In order to meet this pluralism, it either remains at a very general and uncontroversial level, or provides detailed technical solutions to problems regarding primarily the safety of design and use of robotic products, while leaving ethical concerns and the respect of core values untouched. Nevertheless, this is insufficient to effectively govern complexity. Secondly, harmonization pursued by means of soft law depends on the voluntary compliance of multiple classes of agents, and therefore does not provide the actors involved with a sufficient degree of legal certainty.

the Technologies of the Twenty-First Century. Texts and Materials, Cambridge-New York: Cambridge University Press, 2012, 63 ff, 371 ff.

[20] S. Rodotà, Diritto, scienza, tecnologia: modelli e scelte di regolamentazione, in Comandé and Ponzanelli (eds), *Scienza e diritto nel prisma del diritto comparato* (Torino: Giappichelli, 2004), 397-412,409.

The need to resort to technical delegation also implies that regulation will acquire a substantially private nature.[21] Therefore the devolution of technical rule-making to independent agencies or standard-setting bodies ensures the continuous adaptation of norms, but raises doubts about their legitimacy, certainty and accessibility. Combining formal law and technical standards in fact requires the private sector to be included in the legal order; private regulatory bodies will have to comply with the rule of law and promote inclusiveness and participation, but whether they will be able to embrace social and constitutional values (as opposed to self-interest) and give them priority in their regulatory activities can be disputed.

More radically, whether the normative settlement of highly sensitive and potentially risky activities should be delegated to the technical dimension remains questionable. Organisms like ISO usefully develop safety standards for robots, but their activity is mainly directed, and should be, to ensure safety in activities that entail the use of robots. Industries can voluntarily embed in their protocols and products the standards suggested by technical bodies, but issues concerning the impact on fundamental rights deriving from every application to end-users or respect for their other interests not merely related to safety are not included in this form of regulation.

Finally, and more important, less formal and non-mandatory mechanisms do not satisfy a widely perceived need for a general frame of reference – possibly agreed on at an international level – on which technological advance can be grounded, providing sufficient legal certainty to the actors involved. Researchers and manufacturers who work on robotics both at the experimental and at the industrial level claim that they cannot properly appraise the risks and duties entwined in their activities until a clear analysis of the interplay between robotics and regulation has been made and consequent regulatory options are undertaken.

These considerations converge in indicating that a coherent frame agreed at the European level would better serve the purpose of fostering innovation in the robotic domain in Europe, while giving the correspondent market an important competitive push with external markets.

While the reason for the EU assuming a proactive role in the regulation of robotics are clear, different modalities could be deployed in order to provide a sound framework for developments in robotics.

Soft-law tools could be adopted that ensure a coherent, albeit not binding, regulatory environment endowed with supranational relevance. The Nanocode, which has been formulated in the context of nanosciences and nanotechnologies research, [22] represents a model that could be reproduced in other sensitive areas. The advantage of such an instrument is that it would offer qualified policy guidance both to the national and regional authorities and to the researchers and other actors operating in the fields of robotics. The not binding status of its rules would be counterbalanced by the benefits that the compliance to it would ensure: any prototype or product designed and manufactured in accordance to the code should be considered both safe and ethically acceptable, thus fit for the circulation within the European market. Adhering to the code could give a competitive advantage in

[21] F. Cafaggi, New Foundations of Transnational Private Regulation, (2011) 38 *Journal of Law and Society* 20-49, at 28 f, has identified technology as a crucial factor in the growth of private transnational regulation.
[22] See the Commission Recommendation *on a code of conduct for responsible nanosciences and nanotechnologies research*, C(2008) 424 final, 7.2.2008, recommending its adoption by "national and regional authorities,

the market, thanks to the inherent quality of the research and industrial work leading to the final product that the conformity to the EU rules guarantees.

More specific issues, such as liability, privacy, safety standards and personnel qualification, in the processes of manufacturing and using robotic technologies could indeed call for an EU intervention that is endowed with binding force. Depending on the issue at stake, the normative ground for intervention would change, but it is possible to identify several cases (that will be discussed in the following sections) where the adoption of an institutional regulatory instrument seems the most appropriate solution, taking into account the worth of a given technology for the European society, the significance of the interests and values it can serve, and at the same time the strong guarantees it has to be endowed with.

Despite Europe being characterized by a framework of overarching principles, shared among all member states, the extremely general character they present requires further action, at the statutory and judiciary level to achieve concrete implementation. A general frame of principles could be accompanied by more specific regulatory instruments that could focus either on distinct technological applications or on clusters of themes, like liability for damages that concern multiple technologies. These instruments would complement the existent legislation that already applies to robotic technologies both at the European and the national level providing a starting basis that could be further implemented.

3. A COMMON FRAMEWORK OF FUNDAMENTAL RIGHTS AND PRINCIPLES: THE WAY TO RESPONSIBLE RESEARCH AND INNOVATION (RRI)

Indeed, the regulation of robotic technologies does not take place in a void: a theoretical framework and a tissue of rules to which many robotic products and applications can be fine-tuned already exist. Nevertheless, the most general legal and ethical environment to be taken into account is given by a common set of overarching principles that are shared in the contemporary European legal order. A common framework of fundamental rights and values exists, that is accepted and acknowledged by all member states and positively affirmed in the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights.

Human rights are in fact an essential apparatus to deploy in order to promote and guarantee responsible advances in science and technology.

The potential role of a set of overarching principles shared in the European legal order is multi-layered: (i) firstly, it allows to pinpoint the fundamental rights and freedoms that developments in the robotic field may infringe and that, on the contrary, have to be regarded as intangible.

The fundamental rights and principles at stake in the domains affected by robotics can be enumerated: the principles of dignity (Title I of the Charter of Fundamental Rights) equality (Title III), solidarity (Title IV), non-discrimination (art. 21), and justice (Title VI) retain prominent relevance within the value-based structure of the Charter of Fundamental Rights

employers and research funding bodies, researchers, and any individual or civil society organisation involved or interested in N&N research".

of the European Union. The rights to identity and privacy (artt. 7-8), the rights of the elderly (art. 25), the integration of persons with disabilities (art. 26), the right to healthcare (art. 35), and the right to consumer protection (art. 38) stem from those overarching principles.

On the preventative side, this body of principles obliges to design safeguards and limits in the use of technologies, possibly originally embedded in the technical set-up. Robotic applications have to be devised and designed in such a manner that allows to protect values like human dignity, identity, health and privacy. In case a robot might harm those values and the underlying rights, without being possible to prevent similar negative effects through careful design and users' information, a responsible attitude, that could even be supported by a legal ban or a moratorium, would be that of not producing and deploying it.

But the same values can shed light over novel forms of aggression brought about by robotic technologies that it is possible to counteract by means of especially designed legal rules or inventive interpretation.[23] For instance, the purpose of a constitutional understanding of advances in robotics could entail enlarging the scope of existing fundamental rights in the light of risks of infringements never confronted before.

(ii) Secondly, fundamental rights form an essential apparatus to use as a test-bed for the desirability of robotic applications. More precisely, they can contribute to identify the main goals and achievements expected by advancements in robotic research and industrial applications; thus, to pinpoint priorities and therefore justify rules which favour one application, that responds to values and needs deemed fundamental, over others. Robotic products and services that ensure the fulfilment of fundamental rights should in fact be subject to a favourable regime, in order to create incentives for their development. These anchoring principles could therefore operate not only in a shielding fashion, but in a more proactive and orientating guise, by pointing to innovation in robotics that should be fostered through regulation (see *infra*, §§ 5-7).

Technological advances, together with the economic power of companies and research institutions, are often held responsible for producing knowledge and industrial applications without any concern for the exposure at risk of democratic values and human rights. On the contrary, the concern for the protection of fundamental rights potentially undermined by technological developments has recently become a characteristic feature of European science-making. The regulation of technology, both from a methodological and a substantive point of view, has today to be guided by those principles often summarized in the formula Responsible Research and Innovation (RRI).[24] A wide array of disciplines and competences have to be integrated in the analysis, and various stakeholders should participate in the process of identifying and discussing the issues potentially raised by the advent of robotic technologies, in order to let diverse needs, sensibilities, and perspectives emerge.

From the substantive point of view, the two requirements of RRI are ethical acceptability and orientation towards societal needs. Not only do robotic products and applications have to comply with the core values embraced in the European context by the constitutional traditions of Member States and positively affirmed by the Charter on fundamental rights,

[23] See, for instance, M.N. Gasson and B.-J. Koops, Attacking Human Implants: A New Generation of Cybercrime, (2013) 5(2) LIT 248-277.
[24] See, lately, European Commission, *Options for Strengthening Responsible Research and Innovation*, Luxembourg: Publications Office of the European Union, 2013. Also, R. van Schomberg (2001). *Towards*

but also particular attention should be devoted to those technologies that respond to societal needs, and contribute to achieve normative goals such as equality of opportunities, justice, and solidarity. Such technologies that substantially improve the quality of life of the European citizens, especially the more deprived and vulnerable, may well be favoured through the adoption of concrete legislative measures, and may even be recognized a peculiar legal status.

The question whether fundamental rights are threatened by new technical opportunities purported by robotics has to be considered, but research efforts shall also be devoted to investigate whether an efficient and proactive protection of fundamental rights and liberties proclaimed at the European level requires fostering innovation in robotics by means of especially designed legal rules or inventive interpretation. The latter perspective has led for instance to propose special rules in the context of liability for damages deriving from the use of robotic technologies in the field of healthcare, namely surgical robots, prostheses and care robots (see §7).

4. WHAT ROBOTS ARE: THE IMPOSSIBILITY OF AN ALL-ENCOMPASSING DEFINITION AND HOW INSTEAD ROBOTS DIFFER FROM ONE ANOTHER

Before we proceed to identify the most relevant issues raised by the emergence of these technologies we need to clarify what kind of applications we refer to. In particular, it is important to understand if robots may be defined unitarily and thus addressed as such even in a legal perspective, eventually conceiving the "laws of robots".

The Merriam Webster dictionary defines "robot" as

> «1 a: a machine that looks like a human being and performs various complex acts (as walking or talking) of a human being; *also*: a similar but fictional machine whose lack of capacity for human emotions is often emphasized […] 2 : a device that automatically performs complicated often repetitive tasks; 3 : a mechanism guided by automatic controls.»[25]

Such definition is clearly influenced by the literary depiction of robots, and thus incomplete.[26] It is incomplete since many applications do not walk or talk and can either be quite simple, such as a vacuum cleaner, or complex like a surgical or industrial robot. Some are then conceived to mimic human emotions or animal behaviours, for the purpose of keeping company to the elderly or children;[27] others are being developed to perform operations which entail a certain degree of creativity (softbots) or even provide a first assessment of the medical condition of a patient,[28] thus elaborating complicated data in an very different fashion from time to time. Finally, as per the resemblance to human traits, studies show that beyond a given point users find that aspect awkward and unsettling so

Responsible Research and Innovation in the Information and Communication Technologies and Security. Brussels: Directorate General for Research and Innovation, European Commission.

[25] The definition can be found at http://www.merriam-webster.com/dictionary/robot, last access September 2014.

[26] For a taxonomy which takes into account also the different ethical issues raised see Verruggio, G. and F. Operto (2008). Roboethics: Social and Ethical Implications of Robotics. Handbook of Robotics. B. Siciliano and O. Khatib, Springer., 1151 ff.

[27] See PARO http://www.parorobots.com/ last access September 2014.

[28] See WATSON http://www-03.ibm.com/innovation/us/watson/ last access September 2014.

that designers tend to preserve clear cut signs of the mechanical and artificial nature of the machine for it to be more easily accepted in human environments.[29]

Common definitions are indeed little descriptive of real robotic applications and to a great extent misleading, since if one had to discriminate what kind of technology qualifies as a robot the offered criterions would induce wrong conclusions in most cases.

Definitions offered by researchers instead are always more precise and narrow tailored to accommodate the specific field of interest of the speaker,[30] yet the outcome is fragmented and contradictory if considered together.[31]

Finally, robots cannot either be defined through their ability to autonomously perform a task[32]. On the one hand, not all robots are autonomous in such sense, on the other hand that only represents one of the possible control mechanisms[33] used when conceiving and designing such machine. Moreover it fails to provide sufficient guidance when attempting to distinguish a robot from other applications, which still operate unattended and eventually interact with human beings (an automatic cash dispenser for instance).

The reason why the term "robot" cannot be defined in a way to include all possible applications which are still considered to belong to the vast family of robotics, is its a-technical nature, both from an engineering and even more from a legal point of view. Being derived from science fiction[34] the word solely means labour and more precisely enslaved labour.

The technologies developed and the applications existing are so diverse from one another that maintaining the use of said term may only serve the purpose of synthesis, allowing to indicate an extensive set of objects.

Therefore, rather than a definition, a classification ought to be created, where various criteria are considered such as: (i) embodiment or nature; (ii) level of autonomy; (iii) function; (iv) environment; (v) and human-robot interaction,[35] and single applications should then be analysed accordingly.

If then a notion of robot was to be elaborated for merely descriptive–thus neither qualifying nor discriminating–purposes it may be said it is:

> *a machine, which (i)may be either provided of a physical body, allowing it to interact with the external world, or rather have an intangible nature–such as a software or program–,(ii) which in its functioning is alternatively directly controlled or simply supervised by a human being, or may even act autonomously in order to (iii) perform tasks, which present different degrees of complexity (repetitive or not) and*

[29] For a minimal and essential reference see Mori, M. (2012). "The Uncanny Valley." IEEE Robotics & Automation Magazine(June): 98., translation by Karl F. MacDorman and Norri Kageki of the original 1970 seminal article.
[30] For a complete survey see Salvini, P. (2013). Taxonomy of Robotic Technologies. Robolaw Grant Agreement Number: 289092, D4.1., 17.
[31] See Bekey, G. A. (2012). Current Trends in Robotics: Technology and Ethics. Robot Ethics. The Ethical and Social Implications of Robotics. P. Lin, K. Abney and G. A. Bekey. Cambridge (MA), The MIT Press., 17.
[32] The one offered in the text is the translation from the Italian «*una macchina che svolge autonomamente un lavoro*», found in Santosuosso, A., C. Boscarato and F. Caroleo (2012). "Robot e Diritto: una Prima Ricognizione." La Nuova Giurisprudenza Commentata: 494., 498.
[33] See Salvini, P. (2013). Taxonomy of Robotic Technologies. Robolaw Grant Agreement Number: 289092, D4.1., 8.
[34] Čapek, K. (1922). R.U.R. (Rossumovi univerzální roboti).
[35] See Salvini, P. (2013). Taxonomy of Robotic Technologies. Robolaw Grant Agreement Number: 289092, D4.1., 22 and ff.

may entail the adoption of not predetermined choices among possible alternatives, yet aimed at attaining a result or provide information for further judgment, as so determined by its user, creator or programmer, (iv)including but not limited to the modification of the external environment, and which in so doing may (v)interact and cooperate with humans in various forms and degrees.

The consequence for the purpose of the present analysis is such that we may not unitarily address issues posed by robots[36]. A driverless vehicle, a robotic prostheses, a surgical robot, a robot companion, a drone, a softbot are all very different from one another. The inherent technical differences of such applications cannot be overlooked without losing insight.

5. FROM "THE LAWS OF ROBOTS" TO A FUNCTIONAL REGULATION OF ROBOTICS

The conclusion that robotic technologies are quite diverse from one another – and so are the issues they raise in an ethical and legal perspective –, together with the fact that no technical aspect alone justifies the adoption of ad-hoc regulation, leads us to conclude that there is no need to develop 'the laws of robots'. The aim of the European Union shall not be the adoption of a unique body of laws – or a code – to address robots as a unitary phenomenon, since there is no one-fits-all solution for these applications and differences are more relevant – at times – than similarities. Indulging in that kind of speculation is a mere science fiction exercise, which does not help the advancement either of the European society as a whole or of its economy.

The most appropriate approach is thus that of a case-by-case analysis, where single classes of applications (e.g. prostheses, driverless vehicles, softbots, and robot companions to name some specific examples) are considered. The specific legal and ethical issues they raise need to be identified, firstly through an analysis in light of the ECHR and other applicable documents and principles.

Only then, a solution may be elaborated in order to favour – or eventually disfavour in case the specific application is deemed highly undesirable – its emergence and specific policy arguments need to be formulated to support that conclusion. To this purpose many other criteria, besides technical aspects, need to be taken into consideration: market failures, the effect on competition, the novelty of the technology, its potential immediate and long term application, dual use, to name a few. For many such aspects the relevance of attentive applied ethics analysis is essential.

To better clarify this concept the case of robotics for healthcare may be considered, where applications, which profoundly differ from one another, still share some relevant common aspects in a functional perspective. In particular, they all contribute to foster the same fundamental values and principles, protecting the person and human life in all its forms and stages.

[36] Leroux, C., R. Labruto, C. Boscarato, F. Caroleo, J.-P. Günther, S. Löffler, F. Münch, S. Beck, E. May, H.-S. Corinne, M. De Cock Buning, L. Belder, R. De Bruin, A. Bonarini, M. Matteucci, P. Salvini, B. Schafer, A. Santosuosso and E. Hilgendorf (2012). Suggestion for a Green Paper on Legal Issues in Robotics. Contribution to Deliverable D.3.2.1 on ELS Issues in Robotics., available at http://www.eurobotics-project.eu/cms/upload/PDF/euRobotics_Deliverable_D.3.2.1_ELS_IssuesInRobotics.pdf, last access August 12th 2013, p. 7.

5.1. Robotics for healthcare

Indeed, the various robotic technologies currently researched in the domain of healthcare represent a perfect case in point to exemplify the double-edged role that an approach based on fundamental rights and RRI (see §3) plays with respect to the regulatory endeavour here discussed.

This field should be considered strategic for European intervention in response to the challenges of increasing the quality of healthcare, and offering better treatment to the patients in terms of early diagnostic and effective treatment of diseases; reducing the costs associated with modern medicine; supporting disabled people with technologies that overcome their motor or sensor impairment; confronting the problems brought about by demographic change, with population ageing, increasing demand for healthcare, decreasing availability of care providers, excessive burdens for family carers.

In particular, care and companion robots are being developed for the assistance of the elderly and disabled. Said applications are designed to perform several different functions: from telepresence and monitoring, to assisting in daily activities (ex. in fetching objects, reminding of taking drugs, connecting to family or healthcare professionals), and ultimately facilitating or correcting movements. This type of technology is meant to help them live an independent life and be socially active.

Robotically assisted surgery has been introduced in order to perform operations with more precision, to reach sites into the patient's body without requiring open surgery, while still ensuring the same or greater accuracy in vision and action, overall allowing to reduce post-intervention recovery time.

Advanced prostheses and exoskeletons are meant to improve the quality of life of people with disabilities, by restoring or supporting lost or compromised functions, such as the ability to mover or grasp objects, more generally all the tasks that a person without physical impairments is able to perform, ultimately promoting their social inclusion.

The very development of these applications is triggered by policy tendencies and social phenomena widely observed in the socio-economic structure of European countries, that robotic research directly attempts to address. Therefore, precisely because such robotic devices meet qualified social needs – inclusion of vulnerable persons, supply of personal care, in the light of population ageing and demographic change, with expected shortage of (informal and professional) caregivers, better quality in healthcare – and allow to accomplish values we hold dear, they deserve special attention in a legal perspective.

On the other hand, the very same technologies exhibit features that can put some of the fundamental rights they are intended to promote at risk. For instance, the prospect of using assistant robots for the elderly raises several issue related to the ethics of care and generates concern for the emotional implications, and therefore the impact on the identity and privacy of the person, that such devices entail. Bionic prostheses, interfaced with the neural system, promise enormous benefits for people with disabilities, but again can be questioned for their bearing on the right to bodily integrity and to identity, and for creating new forms of vulnerability. More precisely, they open up a far-ranging set of problems, as the new type of human-machine interaction they realize leads to the dilemmas entrenched in human enhancement debate (§9). Data protection and data security in the healthcare scenario also figure as relevant concerns to be taken into account from a human rights

viewpoint, having in mind the great potential for the collection and storage of sensitive data that robotic technologies display.

After sketching such a complex picture, suggesting the expediency of some political and legislative action, it shall be further stressed that European Union is also in the best position possible to directly intervene. These challenges do, in fact, fall quite well within the bundle of competences and sectors of intervention of the EU. The protection of health and the right of access to healthcare represent fundamental rights established in the EU Charter of fundamental rights (art. 35), and art. 168 of the Treaty on the Functioning of the European Union (TFEU) identifies the promotion of public health as a core area for the action of the EU. Therefore the improvement of medical products and procedures, and of safety and efficiency in healthcare delivery are suitable objectives of EU policies to be accomplished also by means of technological progress, in particular robotics. The free flow of goods in the EU market might also be compromised by different regulations in different countries; in the sector of medicines, the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (Directive on clinical trials) has addressed the same problem, providing a common framework that ensures the free marketability of the final products in all member states.

Legal issues in this field are nevertheless considered as one of the most relevant points, that if not carefully and timely considered may hinder innovation. Numerous are the problems that in this perspective need to be addressed, starting with the unsuitability of the actual trial procedures – mainly conceived for testing medicines – for the purpose of experimenting new medical robotic devices. In the healthcare setting, the added vulnerability of patients and the close interaction that is necessary to address their needs, suggests to require that devices abide stricter standards than those set forth for other applications of more general use. Moreover, the (at least partial) autonomy of robots deployed in care tasks increases the risks of unforeseen behaviour, that cannot be properly controlled by an impaired user or in emergency situation. Data protection and data security in the healthcare scenario also figure as relevant concerns to be taken into account while designing a safe environment for robots actions, considering the enormous potential for collecting and storing data – and sensitive data in this case – that robotic technologies display.

To sum up, the healthcare domain, broadly intended, more than others requires regulatory intervention in order to protect fundamental rights. But considering that these types of robotic technologies can be deployed in order to foster fundamental values, regulators should provide the right incentives for their development, which we deem desirable from a constitutional viewpoint. A regulatory approach which is meant to support the development of a truly European market for this kind of products, which respond to societal needs, should aim at overcoming economic constraints that make this sector not sufficiently attractive for private investments and provide greater certainty for innovators.

6. IDENTIFYING RELEVANT ISSUES AND SKETCHING SOME PROPOSALS

By applying the considerations briefly sketched, all kinds of robotic applications can be analysed, in order to determine whether specific issues may be identified that call for some action on the side of the legislator.

However, the questions posed by applications that technologically show some degree of similarity may well be quite different. <The analysis is in fact guided by policy arguments rather than technological considerations.

Indeed, in a functional perspective the same trait or characteristic of the device may be problematic or not: the ability of a vacuum cleaner to operate unattended does not raise the same issues as that of a driverless vehicle. It does neither promise to impact society in a comparable fashion. A driverless vehicle may indeed be perceived as a possible way to reduce – in a medium to long run and if sufficient and effective investments are made – the number of accidents on our streets, favour the mobility of children, elderly and people with disabilities, revolutionize transportation and potentially reshape traffic and the way cities are designed.

At the same time, very different applications, such as driverless vehicles and robotic prosthetic limbs, may give rise to one identical legal issue, namely that of liability – who should be held liable in case the device malfunctions, leading to an accident – and yet require different solutions (see §8).

By analysing a selection of robotic applications, which we researched and discussed within the RoboLaw project, we have identified some major and to some extent recurring legal issues, that deserve particular consideration by the European Union already at this stage of technological development. Such issues, which we will now address more in details providing some examples of analysis and offering some possible solutions, are that of liability (§7); standardization (§8) and human enhancement (§9).

7. LIABILITY RULES AS A TOOL TO INCENTIVIZE SAFETY BUT ALSO SPREAD DESIRABLE TECHNOLOGIES: GENERAL CONSIDERATIONS

Regulation should be tailored in order to balance opposing interests, but also – once desired policies are identified – taking into account the concrete effects and impacts of the rules on the market, not relying entirely on general assumptions and unverified considerations about their presumed – or expected – consequences.

In this perspective some rules are of considerable relevance, namely liability rules.

Liability rules by shifting the cost connected with an undesired and harmful event force the wrongdoer to internalize the consequences on others of his actions and choices. Theoretically the adoption of the correct liability rule should ex ante induce the socially desirable behaviour, in terms of reduction of number of accidents and increase in safety

investments, and ex post ensure recovery of the suffered harm by the single individual involved in the action.

In modern market economies next to traditional tort rules, generally applicable to any individual, product liability – and enterprise liability – rules were progressively adopted in order to provide better protection to consumers. These alternative systems, opting for strict liability (objective or semi-objective) standards, are intended at once (i) to ensure higher investment in products' safety and (ii) ease the consumer's position in grounding his claim against producers.

The European solution, represented by the Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (henceforth DPD) , is in this respect not so different from the North American one, as emerging from the Restatement (in particular Rest. 3rd on Torts: Product Liability) .

Although, both the European and North American systems have been criticized for their overall effect. While the increase in safety standards cannot be substantially appreciated such regulations in some cases produce a technology chilling effect. Moreover, by requiring complex litigation – in particular with respect to the design defect of the device – they often raise the costs of compensation (reducing the percentage per euro invested that is used to make the victim of the accident whole) while still leaving a relevant degree of uncertainty on the victim, who subsequently may decide not to sue .

The ineffectiveness of existing liability rules in increasing product safety on one hand, the potential technology-chilling effect they produce on the other hand, lead us to conclude that in this field some reform may be beneficial. The conceivable solutions vary according to the kind of applications considered, and may amount to disentangling the two issues – that of safety and that of compensation –, which are normally addressed unitarily, from one another.

In order to promote clear safety requirements for different kinds of applications the role of ESOs could be emphasized. Independent bodies with the highest technical expertise could be required to provide and frequently update clear ex ante requirements, narrowly tailored for the specific application – or class of applications – (e.g. upper limb prosthesis or exoskeleton). Producers would be bound pursuant to a binding normative act to conform to such standards in order to release their products onto the market (see §8 for a more detailed discussion).

As per the issue of full compensation alternative mechanisms to the one of the DPD can be thought of, ranging from liability exemptions, liability caps, and no-fault compensation schemes (no-fault plans).

The possibility to introduce liability exemptions is already contemplated by art. 16 of the DPD, despite it requiring the introduction of a high liability cap that may substantially reduce the effectiveness of the measure.

Excluding the possibility for users to sue the producer under the DPD or other regulation does not automatically lead to more dangerous products and subsequently an increase in the number of accidents. On the one hand, market forces may provide adequate incentives in competitive markets, in particular because of the effect on reputation, since quality is the most relevant way to secure the loyalty of clients. On the other hand, the provision of high

technical standards for the certification and commercialization of the device provides sufficient guidance to the design of safe products. Such a solution clearly minimizes the technology-chilling effect by allowing the producer to identify and quantify the costs he has to face during the design phase, but leaves the issue of compensation of the victim – be it the user of third party involved in the accident – unresolved. A liability exemption was introduced in the US for commercial aircrafts and recent studies show that there was no increase in the number of accidents, while the regulation allowed an industry, which was about to collapse, to prosper again.

A liability cap instead is a form of ex ante quantification of the maximum amount the harming party – producer – may be called to pay to the victim in case liability is established. It still requires traditional tort rules to be applied in order to first determine whether the defendant is liable and thus required to compensate, and therefore does not represent a radical solution to the above sketched issue of easing the position of the victim in the trial. The predetermination of the amount the producer is required to pay does theoretically provide a higher degree of ex ante certainty, but if fixed too high it is ineffective, if fixed too low it may give rise to problems of undercompensation of the victim.

No-fault plans instead represent an alternative form of compensation, similar to a first party insurance, typically administered through public agencies. Victims can file a claim to a fund and obtain immediate compensation once the circumstances of the accident are ascertained to be those covered by the fund. No fault has to be established, and in the cases here considered even the defectiveness of the product would not have to be proved. Litigation costs would be avoided, compensation would be prompt and certain, despite normally lower in value. The most comprehensive no fault plan is that of New Zealand, but there are some European examples as well in Sweden and France . Those contributing to the fund are those who are bearing the cost of compensation, and could be both private and public players. Normally no-fault plans are deemed creating moral hazard problems. Some of those issues could however be tackled through the combination of other mechanisms (administrative sanctions, criminal liability rules as well as ex ante regulation of safety standards).

Since the possible solutions for the – classes of – applications considered may be different, some brief considerations with respect to each will be now discussed.

7.1. Driverless vehicles

That of liability is possibly the most relevant issue raised by driverless vehicles that could have a clear technology-chilling effect, delaying its emergence[37].

Driverless vehicles need to take into account a number of factors: street rules, other vehicles on the road, passers-by both abiding and violating the street code, all in a complex environment. Therefore, while it is conceivable that once technology has sufficiently advanced, and vehicles do not require human intervention and supervision, a strict standard of liability may appear uncontroversial, before such level of sophistication is

[37] Broggi, A., A. Zelinsky, M. Parent and C. E. Torpe (2008). Intelligent Vehicles. Handbook of Robotics. B. Siciliano and O. Khatib, Springer.; Manyika, J., M. Chui, J. Bughin, R. Dobbs, P. Bisson and A. Marrs (2013). Disruptive technologies: Advances that will tranform life, business, and the global economy. McKinsey Global Institute, available at http://www.mckinsey.com/insights/business_technology/disruptive_technologies.;Schellekens, M. (2014). Self-Driving Cars. Guidelines on Regulating Robotics. E. Palmerini., 59 ff.

acquired the same standard may discourage the very development of that technology, placing too relevant – and too uncertain – a risk on producers[38]. Even more, during that time, the apportionment of liability between the driver – still to some extent in control or anyhow supervising – and the producer ought to be clarified, as well as the standard of safety the vehicle ought to match in order to be deemed safe[39].

These issues are definitely not novel for the law and to some extent closely resemble those that automobiles raised since their first emergence in society. Hence, one may conclude that there is no need to take immediate action. Courts using existing law could case by case determine the required level of care on the side of the driver supervising the vehicle, as well as the level of safety a vehicle is required to ensure in order not to be deemed defectively designed.

However, automated driving could easily represent a break through innovation that may be reasonable to incentivize by creating the most favourable – legal – conditions for its emergence. The number of deaths due to traffic accidents could be dramatically reduced (considering that 97% of current accidents are imputed to human error) by taking man out of the loop. Transportation could be revolutionized even for people, who today encounter greater difficulties in their movements – elderly, children and people with disabilities – having to rely on others for it. Moreover providing incentives to the advancement of such technologies would allow the European car industry to advance and keep the pace if not anticipate its most relevant competitors.

Liability rules could thus be used towards this end. If technical standards were sufficiently narrow tailored, and frequently updated, by competent and independent bodies (such as ESOs and ISO) to ensure adequate levels of safety, the issue of compensation could be addressed through alternative mechanisms.

An EU wide solution[40] could build onto already existing insurance – and eventually compulsory insurance – mechanisms.

(a) Third Party Insurance

If the owner were legally bound to purchase a third party insurance for the driverless vehicle, the insurance company would bear the economic consequences of the malfunctioning. If we assume that through detailed ex ante technical standards the level of safety reached was equal or higher to the current, then it is even foreseeable that insurance premiums will diminish together with the number of accidents.

Eventually the insurance company may be entitled to act in recourse towards the producer, was the accident a consequence of the malfunctioning of the vehicle[41]. That possibility however, would not substantially diminish the technology-chilling effect of current liability

[38] Schellekens, M. (2014). Self-Driving Cars. Guidelines on Regulating Robotics. E. Palmerini.
[39] Alternatively the same level of safety as that of the average driver may be required, or the highest standard (safer than the best human driver), for a discussion see ibid., 58.
[40] An EU wide solution is preferable since it is relevant that the users of automated cars can use their cars throughout the EU and are not limited to their own country or a limited number of countries within the EU. Moreover only such a solution would provide the required incentives for the advancement of technology and the development of a market. Ibid., 63.
[41] Ibid., 64 ff.

rules. The insurance company, rather than the single user, would bring the action against the producer[42].

The policy choice could thus be made to introduce a liability exemption for producers in all cases where the vehicle met the mentioned technical standards (as determined and updated by a supranational independent technical body referred to above) and was accordingly certified.

(b) A first-party insurance or no fault scheme.

Alternatively, the victim of the accident could claim compensation directly to his own insurance or to an ad-hoc established fund. In such cases proving that a given driverless car was involved in the accident would suffice to ground the right to receive compensation for the harm suffered, without the need to establish fault or defect.

Normally the administrative costs associated to such procedures are deemed to be lower since they do not require complex litigation, the award of damages is faster and therefore a higher percentage per euro invested in the system reaches the victim.
Since the party purchasing the insurance or paying a fee to the fund is the one actually bearing the economic consequences of the accident, alternative systems could be conceived where such costs are split between users and producers.

A similar system should be coupled with a liability exemption to deny the single user action against the producer. Safety would be ensured through the mechanisms sketched above.

The two alternatives briefly described could lead to similar outcomes, both in terms of shaping of incentives and ease of compensation of the victim. The choice among them would therefore substantially rest on various policy considerations, also involving which option would be easier to implement.

7.2. Robotic Prostheses

A similar kind of reasoning can be extended to prostheses, where the interaction of brain and machine represents the most complex and relevant aspect, together with the unlimited number of ways in which the artificial limb may be used[43].

A robotic prosthesis is in fact controlled through a brain-machine interface that interprets the biological signal generated by the wearer, and translates it into commands to the single motors and actuators that – operating simultaneously – enable the artificial limb to perform the intended movement[44].

Since a limb follows the wearer in all his day-to-day activities, which cannot be fully anticipated *ex ante*, the consequences of a possible malfunctioning of the device appear extremely hard to foresee. The same technical failure in a robotic hand for instance could generate extremely diverse outcomes. Was the wearer holding an object it may fall and

[42] We may discuss whether the insurance company, rather than the single user, is better suited to determine when an action against the producer is actually grounded, and thus the design may be deemed defective, and unreasonably dangerous.
[43] See Bertolini, A. (2013). "Robots as products. The case for a realistic analysis of robotic technologies and the law." Law Innovation and Technology **5**(2).; Salvini, P., M. Controzzi and M. Cempini (2014). Robotic Prostheses. Guidelines on Regulating Robotics. E. Palmerini., 109 ff. and citations there included for further reference.

break, thus resulting in property damage; if the wearer was performing a normal but potentially dangerous action (driving[45]) he may injure himself, and in some cases third parties.

By applying an objective standard of liability – such as that emerging from the DPD – the economic consequences of all the negative events described would be borne by the producer. The cost of such liability actions would be hard to foresee given the infinite number of ways the device could be used in, potentially extremely high, and for these very reasons hard to insure as well. That, together with the high research and development costs could discourage the development of an otherwise desirable technology, which could instead dramatically improve the living conditions of people with disabilities.

The adoption of ad-hoc regulation in this field is therefore advisable in a public policy perspective. Even more, the European Union may be required to take action, since a very straightforward claim in this direction is set forth by art. 4 of the UN Convention on the Rights of People with Disabilities (henceforth CRPD), ratified by the EU, together with many single member states, on December 23rd 2010[46].

Art. 4 CRPD states that:

> 'States Parties undertake to ensure and promote the full realization of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability. To this end, States Parties undertake: [...] g) To undertake or promote research and development of, and to promote the availability and use of new technologies, including information and communications technologies, mobility aids, devices and assistive technologies, suitable for persons with disabilities, giving priority to technologies at an affordable cost; [...]'

Indeed such provision may be understood as requiring the adoption of a regulatory framework favourable to the development of robotic prostheses and thus including even alternative liability criteria. Their discrimination – with a more favourable liability regime – would therefore be neither unreasonable nor unjustified.

(a) A No-fault scheme

If safety was better ensured through the adoption of narrow tailored technical standards (see §8), compensation could be more effectively provided through a no-fault scheme, covering all accidents which involved the use of a prosthesis, and were not intentionally caused or due to a completely unrelated causal chain.

The main advantages of such a system would be to: (i) eliminate any risk for the producer to be sued for damages, once the device was certified as being safe (no action would be

[44] Carpaneto, J. Ibid., 118 ff.
[45] Christian Kandelbauer an Austrian bilateral amputee, whose arms were replaced by two prostheses by Otto Bock (www.ottobock.com), one of which made use of the biological signal derived from the nervous system, was allowed to drive a car specifically adapted and certified for his needs. Unfortunately he was involved in an accident were he lost his life. Here we are not claiming in any way that the cause of the accident is to be identified with a malfunctioning of the prostheses. Rather, we are using the case as a possible exemplification of what kind of problems may arise, if a similar accident occurred and it was necessary to determine whether it was due to a malfunctioning of the prostheses. For more information, see http://www.theguardian.com/world/2010/oct/22/christian-kandlbauer-arm-dies-crash.
[46] Schulze, M. (2010). Understanding The UN Convention On The Rights Of Persons With Disabilities. New York, Handicap International.

granted to the user against the producer); (ii) eliminate the risk for the victim not to be able to provide sufficient evidence of a malfunctioning that indeed occurred.

Producers would be required to contribute to the fund through a tax (or percentage of the resale price of the device), thus internalizing at least part of the cost they may potentially generate. States in some cases may contribute to the fund as an action to subsidize the diffusion of those technologies, which could as well be understood as the implementation of a welfare state policy in favour of people with disabilities.

The positive effects on administrative costs and percentage of compensation awarded to the user, which it may be assumed a similar solution could generate, were already described above when addressing driverless vehicles. A major difference could however be appreciated. Unlike with driverless vehicles the number of potential users of prostheses is limited. For this reason, it is foreseeable that insurance would be hard to obtain in the market. That coupled with the intention to favour the wearer lead us to conclude that a no-fault plan (publicly administered or at least subsidized) is a preferable alternative to a first party insurance.

7.3. Surgical Robots

The liability issue raised by surgical robots is instead partially different from those sketched above. These kind of robotic applications could in some cases be understood as very specialized and advanced surgical instruments, bringing some techniques – such as laparoscopic surgery – a step forward, being less invasive and in some cases allowing to perform otherwise unthinkable procedures.

The liability of surgeons operating with such devices should be kept clearly distinct from that of the producer for its malfunctioning.

(a) Liability of the surgeon

Since these technologies could be effectively used to perform surgeries to patients on a distance (also known as telemedicine)[47] issues of conflicts of law can be foreseen. It is therefore advisable, at least within the European Union, that a uniform standard of liability is adopted. In this respect a negligence standard is certainly preferable, so as to allow the judge, in the single case, to assess all relevant variables influencing the surgeon's performance.

(b) Liability of the producer

A major risk for the development of surgical robots is represented by a potential tendency to transform all current liability actions brought against surgeons in product liability claims against the producers of the devices. Indeed, the strict liability standard the producer is bound to may be more favourable to the patient than the normal negligence standard than applies to medical doctors. The shift in litigation could however not really correspond to the existence of a design or production defect in the machine, and produce an overall

[47] The patient and the surgeon may in a foreseeable future be placed in different countries, since the machine which is materially operating could be remotely controlled by a console somewhere else in the world. For a discussion see Azzarri, F. and A. Bertolini (2014). Computer integrated surgical systems. Guidelines on Regulating Robotics. E. Palmerini., 98.

technology chilling effect that could be particularly detrimental, impairing the development of a competitive market. Currently, in fact, the market for surgical robots has only but a few players worldwide, and the adoption of more attentively tailored measures could help increase competition (allowing new devices to emerge, lowering prices, improving the quality of the product and service offered to the consumer-patient).

To this end, a possible solution might be to limit the ability of the single patient to sue the producer[48]. The patient could still sue the surgeon for medical malpractice, as well as the hospital for the machine's failure, since the latter decided to employ it for the operation. The hospital may then sue the producer in recourse, were the accident due to a malfunctioning of the robot.

At the same time, it shall be noted that currently existing surgical robots, such as the DaVinci, are capable of recording all commands the machine received during the operation and all the data it acquired. However, this information is normally not directly accessible neither to the hospital nor to the patient, substantially limiting the possibility to obtain necessary evidence to be used in case of litigation against the hospital, surgeon, or producer. It is therefore advisable that regulation is passed imposing this information to be made available to the patient after the intervention took place, upon simple request[49].

7.4. Personal Care Robots

One relevant use of personal care robots is as assistive aids for the elderly and people with disabilities. The demographic shift, which will be even more serious over the next few decades[50], will probably focus on these categories, the main target of this field of robotics at least at the beginning. The purpose being to supply continuous assistance and improve the quality of everyday life.

The devices that could be labelled as such may indeed be extremely diverse for the purposes they serve and the abilities they have. A recent project financed within FP7 – Robot-ERA[51] – developed three different kind of platforms: a domestic, a condominium, and an outdoor robots interacting with one another. The first assists the person at home (with the possibility to be remotely controlled by a help or medical centre in case of emergency); the second capable of interacting with the first and third robot in order to receive and deliver goods from the one to the other; the third intended to navigate in the streets, reach for a shop, make a purchase and deliver it to the second. Many more systems can be conceived, and functions attributed to the robots, therefore a detailed analysis of the risks associated with their use cannot, at this stage, be conducted.

It is however possible to foresee two potential issues, respectively concerning the liability of the producer and of the user.

(a) Liability of the producer and the legal personhood of the robot

The multiple scenarios and interactions such robots may be programmed to have may cause some effects to be unforeseeable. This may cause the development risk defence set

[48] Ibid., 101.
[49] Ibid., 99 ff.
[50] Morris et al. (2013). Smart-Home Technologies to Assist Older People to Live Well at Home, Aging Sci.
[51] Seventh Framework Programme (FP7/2007-2013) under grant agreement num. 288899, FP7 - ICT - Challenge 5: ICT for Health, Ageing Well, Inclusion and Governance

forth by art. 7 DPD to be effectively applied, shielding the producer from liability. For this same reason, it may be also anticipated that users will find providing sufficient evidence of the malfunctioning of the machine problematic. To this purpose, it may be advisable to require such robots to be equipped with recording mechanisms (black boxes) so as to identify the inputs it received, the interactions it had, the data it registered and eventually the choices it made in order to perform its task.

Moreover, in some cases a viable solution may be to attribute the robot legal personhood[52]. For merely functional purposes, the robot could be considered a separate entity provided with a given capital with which it could perform its tasks, assume obligations and respond of eventual liabilities. A similar option would not imply recognizing the robot as an autonomous being, because of some intrinsic characteristics. Rather, it would constitute a policy choice similar to that made with corporations, for the purpose of shielding the humans behind the robot by creating a separate entity provided with sufficient economic resources for its operation. The person providing the resources to the robot would be the one ultimately bearing the costs of the damages the robot caused. However, if a fee was paid to the robot for the services it performed, while part of the retribution could be paid to the owner as a dividend, the rest could be used repay eventual damages caused.

Such a solution, if coupled with a share mechanisms, may also favour the circulation of the ownership of robots, and be used to attribute the cash flows generated by the machine. Finally, such solution may be also used to permit to the robot to enter in some transactions for which it was expressly authorized (for instance performing a sale).

It shall however be noticed that some of these results could actually be effectively achieved through insurance mechanisms.

(b) Liability of the user

The more the liability of the producer will be hard to assess the more likely users will purchase first and third party insurance to be shielded from damages deriving from the use of such devices.

This outcome, however, may be deemed undesirable, for it would leave most of the burden on users who, in some cases at least, may be individuals requiring particular protection (such as elderly or disabled). In those cases alternative systems, including no-fault plans may be envisioned as possible solutions. Nonetheless, being the spectrum of possible applications so wide, at the current state of technological development, it is not possible to determine which alternative solution may be preferable and more effective[53].

(c) Long term care insurances

While today approximately 10% of the world's population is over the age of sixty, by 2050 this proportion will have more than doubled[54]. The current system of institutionalised care,

[52] The concept of legal personhood, also known as legal personality, juridical personality, entails the recognition of an entity by the legal system, attributing rights and obligations directly to it. While human beings are provided of legal personality from the moment of their birth, non-human entities may be attributed legal personality, causing them to become legal – or artificial – persons. Typical examples are corporations and non-profit organizations. See Walker, D.M. (1980) The Oxford Companion to Law, Oxford: Clarendon Press, under the entry 'Person', 949.
[53] See also Nocco, L. (2014). Care Robots. Guidelines on Regulating Robotics. E. Palmerini., 187 ff.
[54] Pollack, M. (2005). Intelligent Technology for an Aging Population. The Use of AI to Assist Elders with Cognitive Impairment, 26(2) AI Magazine, 9-24.

largely funded through social security systems, as well as personal and family resources, is not financially stable[55].

Long-term care, entailing assistance with daily tasks such as dressing, bathing, and using the bathroom, may be provided through personal care robots, an alternative to nursing homes, which are often expensive.

Long-term care insurance contracts may provide required financial funding, by paying for the purchase or lease of the robot and related expenses. The costs associated may be spread by providing sufficient incentives – even in the form of tax reliefs – for individuals to enter such contracts at a sufficiently early age[56]. Applying similar solutions may even reduce healthcare costs by preventing unnecessary and lengthy hospitalizations, and would be in line with what the CRPD art. 19, and 31 through 40 requires[57].

8. STANDARDIZATION

The use of technical standards may prove a useful and to some extent necessary tool for the effective regulation of emerging technologies, in particular robotics. How already anticipated above (§2) the use of delegated legislation, in particular at a supranational level, may be a viable solution for the adoption of standards and criteria, profoundly influenced by technological advancement, which therefore need to be constantly updated by a competent body of experts in order to be sufficiently narrow tailored to be actually meaningful[58].

The development of this approach was deemed of growing importance also by the European Commission in its Communication to the European Parliament, the Council and the European Economic and Social Committee of 1 June 2011 – A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020[59], where it is stated:

> «[...] in the future, European standardization will play a crucial role in a wide variety of areas, wider than today, ranging from supporting European competitiveness, protecting the consumer, improving the accessibility of disabled and elderly people to tackling climate change and the resource efficiency challenge».

Standardization may indeed prove to be the most effective tool in order to ensure the development of safe devices; at the same time, it could also be used to address some relevant professional requirements, thus easing the circulation of professionals across Europe.

[55] Kapp, M.B. (2001). The Nursing Home Crisis: Views From A Trustee In The Nonprofit Sector. J. Health Care L. & Pol'y, 308.
[56] Nocco, L. (2014). Care Robots. Guidelines on Regulating Robotics. E. Palmerini., 189 ff.
[57] Friedman, J.L., & Norman, G.C. (2012). The Norman/Friedman Principle: Equal Rights to Information and Technology Access, 18 Tex. J. on C. L. & C. R. 47.
[58] See also Zei, A. (2013). Shifting the boundaries or breaking the branches? On some problems arising with the regulation of technology. Law and Technology. The Challenge of Regulating Technological Development. E. Palmerini and E. Stradella. Pisa, Pisa University Press.
[59] 'COM (2011) 311 final.

8.1 Product Safety

As mentioned above (§7) existing liability rules do not appear to provide adequate incentives for the design of safe devices. Said otherwise, market mechanisms and other regulations do better serve the purpose of ensuring that only sufficiently safe products reach the European market. Among the latter certainly many European directives, such as the Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) (henceforth AIMDD)[60], the Council Directive of 14 June 1993 concerning medical devices (henceforth MDD)[61], and Directive 2006/42/EC of the European Parliament and the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (henceforth MD)[62], do play a central role.

However, those regulations do still appear quite general in their formulation, and certainly were not narrowly designed to accommodate a single class of applications. The AIMDD for instance covers any medical device ranging from a pace maker to a robotic limb. The MDD instead has an even wider range of application, that extends to include an exoskeleton or orthoses[63], as well as surgical gloves. Finally, the MD is as wide as to include in its definition of machinery « an assembly of linked parts or components, at least one of which moves […]» (art. 2 MD), that alone would encompass most kinds of robots and much more.

These regulations set forth requirements that producers need to abide in order to obtain an EC marking allowing the commercialization of their product. However, the meeting of such requirements does not suffice in excluding liability should an accident later occur involving the use of the device[64].

Should the EU decide to adopt the perspective here suggested, namely that of disentangling – in some cases – the issue of safety from that of compensation, it would be advisable to further develop technological standards. Currently neither the ISO nor the ESOs have developed specific standards for robotic prostheses. The former instead has recently adopted a standard for personal care robots.

The adoption by supranational and technically competent bodies of narrowly tailored standards, constantly updated according to the best scientific knowledge available, could prove a more efficient solution to address the issue of safety. Unlike a complex legislative procedure, the adoption of technical rules could be simplified, once the impartiality and competence of the body called to intervene is assured. Those standards ought to have a much narrower object than that of existing directives and should allow to differentiate single kinds of applications.

Once the requirements are set sufficiently high, and take into account all the relevant scientific knowledge, it is reasonable to assume that the certification obtained may justify even some forms of liability exemptions or capping as those described above for specific kinds of robotic applications.

[60] OJ L 189, 20.7.1990, p. 17
[61] OJ L 169, 12.07.1993, p. 1–43
[62] OJ L 157, 9.6.2006, p. 24
[63] For a better understanding of what an orthoses is and how it functions, see Salvini, P. and M. Cempini (2014). Robotic Prostheses. Guidelines on Regulating Robotics. E. Palmerini., 113 ff.
[64] See Bertolini, A. Ibid., 135 ff.

To this end, at a European level, the role of ESOs should be further incentivized, and measures adapted in order to ensure the highest degree of competence, independence, and effectiveness is achieved, while respecting all core European democratic values (see §2).

8.2 Professional requirements: the case of robotic surgery

Through multiple interviews conducted, within the RoboLaw project, with medical doctors and other professionals involved in the use of robotic surgery the issue emerged of the absence of adequate training and certification procedures for surgeons intending to make use of such technologies. Currently any doctor may decide to perform a given operation with a robotic application if that was available in the structures he has access to, irrespective of whether he has acquired any previous experience or training.

In this field however the specificity of the instrument utilized certainly requires ad-hoc training and preparation, which may be deemed necessary in order to grant the highest degree of professional competence, as well as protect the patient's health. Accidents and negative consequences of potential failures of the apparatuses may in fact be limited through training and specialization.

Indeed, it is worth noting that given the high number of lawsuits filed in the US against Intuitive Surgical, Inc. (the producer of the daVinci robot), accusing the company of not properly training the surgeons, the manufacturer, together with the U. S. Department of Defense, identified ten research institutions and hospitals, which are renowned for their experience in operating with the daVinci system (among which EndoCAS[65]), to develop a training protocol called 'Fondamenti di chirurgia robotica' (Foundations of robotic surgery)[66]. This initiative aims at producing an internationally recognized standard of qualification for surgeons intending to make use of robotic devices, as already required since 2009 to surgical trainees specializing in laparoscopy in the United States.

It seems therefore necessary that the European Union defines the minimal professional requirements that the surgeon must show in order to be allowed to use a greatly complex device like a surgical robot. To this purpose, specific training which allows the surgeon to obtain a European certificate of his abilities to perform robotic-assisted operations, after passing a final exam, could be introduced. This procedure, that in the member states could be arranged by the Faculties of Medicine or by University Hospitals, should provide for a certain amount of hours including theoretical lessons, training with the simulator, and participation in computer-assisted interventions. Moreover, the qualified surgeons should periodically attend continuing education courses to renew the validity of their certificate and eventually update it for the use of more advanced devices, over the time developed and acquired by hospitals[67].

A European regulation on the qualifying certificate for using surgical robots would also promote the free movement of professionals among member states, as well as ensure a more efficient and transparent recognition of professional qualifications, as stated in Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market

[65] www.endocas.org
[66] http://www.unipi.it/index.php/tutte-le-news/item/4449-arriva-la-patente-per-operare-con-il-robot-da-vinci
[67] See Azzarri, F. and A. Bertolini (2014). Computer integrated surgical systems. Guidelines on Regulating Robotics. E. Palmerini., 95.

Information System Otherwise, should some member state fix specific subjective requirements to perform robotic-assisted operations, the surgeons coming from other member states may not have full access to the profession[68].

9. REGULATING HUMAN ENHANCEMENT TECHNOLOGIES

Piercing into the debate on human enhancement is a natural outcome of the research on robotic prostheses and, more generally, on body implants, since said technologies not only can restore lost or impaired functions, but can also improve and strengthen them to a degree otherwise not attainable by human beings. A wide range of robotic technologies, such as advanced prosthetics, brain implants, cochlear and retinal implants are being developed in order to help individuals suffering from motor disabilities, blind or deaf people to recover the function and capability they have lost (or were born without). At the same time these technologies have the potential of being used well beyond the restoration of existing human functions, in order to add new capabilities or augment the existing ones and therefore overcome the levels of ordinary human functionality. The convergence of robotics and neuroscience will lead to the development of advanced neuro-prosthetics, and eventually, it is estimated, to the emergence of a culture of techno sapiens, individuals who utilise information technology and neuro-technologies to enhance their capabilities, giving way to a condition of "prosthetic knowledge". [69] The contested theme of human enhancement therefore comes up. Robotics qualifies in fact as one the most powerful means to achieve the enhancement of the human being (although it can be considered less controversial than others since it does not introduce changes in the human nature that can be passed on to the offspring).

The subject of human enhancement, being extremely broad and rich, can hardly be captured in an adequate way. The reasons that make the theme at the same time complex and evanescent depend on several elements: the discussion is widespread throughout diverse disciplines that confront it from their peculiar angle; it is very fragmented since multiple perspectives open up, depending on the technical mean used to achieve enhancement or the kind of function it impacts on; there are no clear-cut stances that stem from the fundamental principles shared at the European level. "Genetic" and "pharmacological", "cognitive" and "physical", "moral" or "mood" enhancement pose different problems, and a provisional conclusion has been offered exactly in the following terms: 'each kind of enhancement will need to be treated on its own, weighing the benefits of the technology against the costs it may impose, as well as the costs of regulation'. [70]

Another reason that explains the difficulties in offering a comprehensive account of the debate is that it grounds on concepts and assumptions that are not fully defined and continue to be discussed among scholars, engendering further complexities to be dealt with. For one thing, it is coined by a discussion of the ambiguous notion of the "natural" and reposes over a distinction, deep-rooted in the current landscape between therapy and enhancement, often intended as a boundary-marking line. According to this characterization, enhancement is everything that goes beyond the mere restoration of good health or of a given normal functioning. This implies some assumptions: (a) an objective,

[68] Ibid., 95-96.
[69] W. Wallach, From Robots to Techno Sapiens: Ethics, Law and Public Policy in the Developments of Robotics and Neurotechnologies, 2011 *Law, Innovation and Technology*, 3(2), 185-207.
[70] H.T. Greely, Regulating Human Biological Enhancements: Questionable Justifications and International Complications, *University of Technology Sidney Law Review* 4, 2005.

medically founded concept of health; (b) a scientific notion of normal functioning. But such a narrow explanation does not even cover all those cases in which therapy produces effects that go beyond the mere restoration of good health or normal functioning. Therefore this binomial cannot function properly because it is blurred in itself, reposing, as it does, on concepts of normalcy and disability, health and illness, human functioning and human capacities that are culture-based notions, change over time, and can hardly be defined and distinguished in an uncontroversial fashion. At the same time, this alternative, which permeates the debate, cannot be dismissed if only because for pragmatic reasons: it serves to decide, for instance, whether an intervention should be paid for by a health system or insurance company or not. [71]

Secondly, the debate has stalled on unilateral and polarized positions, "transhumanists" v. "bioconservatives" being the most renowned opposition, that is unable to reconcile and mediate among the conflicting groups and then achieve a more reasonable and complex stance onto the ethical and social issues raised by human enhancement technologies.

In order to confront the problem in a regulatory perspective, two methodological points have to be stressed. First of all, we should move past the contemporary discussion on human enhancement and go beyond sterile disputes between its supporters and detractors. This renewed approach should be informed by a broad interpretation of the notion of "human enhancement" in order to include not just the technical interventions themselves, but the social and cultural dimension as well that are entrenched into them. Technologies in fact are not just tools that humans use in order to interact with and experience the surrounding world. They also are means of mediation that shape their world and themselves. [72]

Secondly, human enhancement affects society at large. Human enhancement technologies feed new hopes and create social expectations, make new tools available both for individuals and society, foster threats and concerns, and present risks, that need to be dealt with in a public discussion and not only in academic or expert circles. Thus it requires public debate and stands in need of regulation. Experts alone are partial actors for a successful decision-making process. Only a public, democratic debate can develop policies, which allow for an ethical use of enhancing technologies that improve the human condition. Law and ethics are mutually involved in shaping the normative stance towards this phenomenon, which cannot be appraised from a purely technological standpoint.

Indeed, the discussion is already developing not only on a theoretical level, but it has invested political institutions that have commissioned reports and studies on the topic, which proves to be a prominent aspect of the current bioethical scenario. [73] Several EU funded project investigate the theme in an interdisciplinary manner and engage in the attempt to involve the general public in the reflection about this emerging field. [74]

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[71] S. Coenen, M. Schuijff, & M. Smits, The Politics of Human Enhancement and the European Union. In J. Savulescu, R. ter Meulen, G. Kahane (eds.), *Enhancing Human Capacities*. Oxford: Wiley Blackwell, 2011, 521-535, at 523.

[72] F. Battaglia & A. Carnevale (eds.), *Reframing the Debate on Human Enhancement*, Special issue of Humana.Mente, vol. 26, May 2014.

[73] See British Medical Association, *Boosting your brainpower: ethical aspects of cognitive enhancement*. London: British Medical Association, 2007; Danish Council of Ethics, *Medical Enhancement. English Summary*, Copenhagen, 2011, available at http://etiskraad.dk/Udgivelser/~/media/publications-en/Medical%20enhancement.ashx; President's Council on Bioethics, *Beyond Therapy. Biotechnology and the Pursuit of Happiness,* 2003; A. Nordmann, *Converging Technologies. Shaping the Future of European Society*, Report of the High Level Expert Group on "Foresighting the New Technology Wave". Luxembourg: Office for the Official Publications of the European Communities, 2004.

[74] See, for instance, ENHANCE; EPOCH – Ethics in Public Policy Making: The Case of Human Enhancement; TECHNOLIFE – A transdisciplinary approach to the emerging challenges of novel technologies: Lifeworld and

This extended body of research and literature[75] and the public discussion that is engendering can uncover all the philosophical and ethical aspects involved and reveal common threads and shared beliefs even between positions commonly considered in radical contrast. Regulators should learn from each rationale and ethical standpoint and eventually intervene in order to clarify the constraints that apply to the phenomenon from a legal point of view and take into account the values and concepts that have a bearing on the issue of human enhancement.

9.1. Human enhancement and the virtues of a common European approach

A common European approach to the topic should be looked for. Firstly, a policy identified at the European level would ensure consistency with the constitutional common framework and with the precautionary principle as broadly embraced in European science society. The values at stake, that represent also relevant objectives of the European institutions' activities, are safety and protection of health of European citizens; individual autonomy and human dignity possibly compromised by the risk of indirect coercion, inherent in the more radical versions of the discourse about human enhancement; justice in the access to human enhancement technologies, and of discrimination towards the enhanced-not. Autonomy and self-determination play an important role, but tend to be presented as the ultimate answer to the problem, in an oversimplified proposition of the complex issues at stake. Since modifying or enhancing our bodies with technology is already possible, and relatively common, changing one's body through technology starts to be conceptualized as a right, [76] an open possibility that becomes part of the right to freely construct one's identity using all the socially available opportunities, even with recourse to artificial devices, and then have this self-constructed identity recognized externally. This new dimension can thus dilate the scope of the fundamental human rights, [77] in order to include access to technologies that allow human enhancement.

However, the answer to the problem cannot be confined entirely to the private individual sphere. In a community of rights, any regulatory assessment cannot be tackled from an individualistic point of view; it is not just a question of personal choice, because these issues affect the structure of society and values enshrined in the legal order, such as distributive justice, solidarity and dignity. First, there is the question of how the exercise of the enhanced capacity impacts on the rights of members of the community; secondly, there is the question of whether human enhancement poses any threat to the basic conditions that are deemed essential for an entire community. In fact, as people experiment with more enhancements, this has a bearing on human identity as a whole, since the notion of enhancement relies on our understanding of what it means to be

imaginaries in foresight and ethics; NERRI – Neuro-Enhancement: Responsible Research and Innovation (on the specific theme of neuro-enhancement).

[75] In addition to the articles and documents cited in the footnotes of this section, see for a general overview S. Coenen, M. Schuijff, M. Smits, P Klaassen, L. Hennen, M Rader, & G. Wolbring (2009). Human Enhancement *Science and Technology Options Assessment on Human Enhancement,* available at https://www.itas.kit.edu/downloads/etag_coua09a.pdf.

[76] The California think-tank Institute for the Future has drawn up a legal framework, called Magna Cortica, in order "to create an overarching set of ethical guidelines to shape the developments of brain enhancement technologies" (the text is retrievable at www.openthefuture.com.). In this context, a right to self-modification (and cognitive augmentation) has been forged, together with the right to refuse modification (since refusing cognitive augmentation might come to be regarded as irresponsible or controversial).

[77] S. Rodotà, Of machines and men: the road to identity. Scenes for a discussion, in M. Hildebrandt and A. Rouvroy (eds), *Law, Human Agency and Autonomic Computing. The Philosophy of Law Meets the Philosophy of Technology* (Oxford-New York: Routledge, 2011), 179-198, at 180.

physically or mentally "normal", while technological advances in prosthetics and exoskeletons could lead us to perceive normalcy and disability in a different way. [78] When the purpose of being equipped with a technological appliance is not that of restoring lost functions, the procedure does not impinge on a recognized and uncontroversial basis like the fundamental right to health. But even if that were the case, the freedom to opt out from enhancing technologies has to be granted, and therefore alternatives have to be provided. The choice not to be enhanced has a significance that has already been shown by the experience with cochlear implants, that is refused by a certain number of its potential users, because they consider deafness not be a disability, but a difference that is a constitutive part of their identity.

Other overarching principles orienting the discussion are those of equality and non-discrimination towards the enhanced-not, preventing a societal division among natural individuals and augmented ones. Issues of justice in the access to human enhancement technologies also arise, although they are not distinctive of this phenomenon. A utilitarian perspective, that support any innovation veering toward the maximum collective wellbeing, and therefore approves of enhancement almost by definition, appears no more useful or decisive to guide the discourse: first of all because frailty, vulnerability[79] and dependence[80], that transhumanists want to transcend[81], is valued in our societies and, according to a certain perspective, is something that makes us better people; secondly because the ultimate goal of invulnerability is not realistically attainable. If enhancing technologies can diminish suffering and disabilities, they will always create new forms of vulnerability[82], like dependence itself on the biological and technological systems that augment the brain capacities. [83]

Finally the value of human dignity: this category expresses multifarious meanings, but one of them impinges upon the uniqueness of each person. The individual distinctive identity of each person, where the idea of an intrinsic dignity manifests itself, opposes those interventions that will lead to a reduction of human biological variability, to supersede eccentric features that are deemed to be less than performing, to standardize the human species, be it in the direction of augmenting its biological structure.

A legal understanding and approach agreed at the European level, to sum up, cannot be absent from the discourse on human enhancement technologies, that has to set limits and boundaries if we are to protect fundamental rights and to align technological developments with societal needs and fundamental values.

However, other more pragmatic reasons encourage to adopt a common stance on the topic, and not leave it to a merely national dimension. Apparently the regulation of this field falls outside the direct competence of the European Union as resulting from the Lisbon Treaty; at the same time since the Member States' legislations substantially differ from one another on issues of bioethics, it is reasonably foreseeable that this will also be the case with human enhancement, thus raising multiple questions. European institutions are interested by the impact that diverse regulations may have on the free flow of goods and services between Member States. Human enhancement could be seen as a competitive advantage.

[78] R. Brownsword, Regulating Human Enhancement: Things Can Only Get Better?, (2009) 1 Law, Innovation and Technology 125–152.
[79] Coeckelbergh, M. (2013). Human Being @ Risk, Springer.
[80] MacIntyre, A. (2009). Dependent Rational Animals. Why Human Beings Need the Virtues. London, Duckworth.
[81] Bostrom, N. (2005). "The Fable of the Dragon-Tyrant." Journal of Medical Ethics **31**(5): 273.
[82] Coeckelbergh, M. (2013). Human Being @ Risk, Springer.
[83] M. Coeckelbergh, *Vulnerable Cyborgs: Learning to Live with our Dragons*, Journal of Evolution and Technology, 22 (2011), 1-9.

Would it be possible to consider it as a service, for the purposes of art. 56 TFEU, and thus permit the advertisement within one member state of those practices which are prohibited there but allowed in another one? [84] Would it instead be possible to deny access in one European country to a European citizen, who underwent an enhancement practice prohibited there, that is instead allowed in the member he comes from? May freedom of movement within the European Union (pursuant to art. 45 TFEU and *Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member* States) [85] be used as an argument for the adoption of some fundamental and common principles in this subject matter?[86] Transnational regulation appears therefore necessary in order to avoid that restrictive regulation or a ban in one country is weakened by a more permissive legislation in competing countries. [87]

Given the experimental nature of most enhancing technologies, the duty to comply with actual regulation for medical research is also a problem to be afforded within the, equivocal but to some extent inevitable, alternative between therapy and enhancement. The issue here is that while medical devices fall under an established and very rigorous European framework, currently there is no regulation for devices developed for other purposes, like enhancement. Pragmatic reasons, as mentioned above, also underpin this distinction, and policy guidance could support national decisions both at the regulatory and at the more practical level, for instance about appropriate registration of interventions in health institutions, or in case hospital ethical committees will be called to decide on a case-by-case basis.

For these grounds, despite the most relevant issues posed by human enhancement appearing to be remote and lying in the background of more pressing considerations, it is advisable that on the one hand an informed public debate is initiated – as well as further research publicly financed –, and on the other hand that the European Union takes timely measures to develop and adopt clear guidelines in this field, which appear to follow from its policy and regulatory interest and both desirable and appropriate with respect to its competencies and goals. [88]

[84] See for instance the decision in Society for the Protection of Unborn Children (Ireland) Ltd v. Stephen Grogan and Others, Case C-159/90 [1991] ECR I 4733.
[85] OJEU, L 158, 30.4.2004, p. 77.
[86] See also Bertolini, A. (2014). Robotic Prostheses. Guidelines on Regulating Robotics. E. Palmerini., 156.
[87] Greely, 2005, cit.; Coenen, Schuijff & Smits, 2011, cit.
[88] R. ter Meulen, Human Enhancement: A Policy Perspective for the European Union, in T. Boer & R. Fischer (eds.), *Human Enhancement. Scientific, Ethical and Theological Aspects from a European Perspective*. Strasbourg: Church and Society Commission of the Conference of European Churches (CEC), 2013; Coenen, Schuijff & Smits, 2011, cit.

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PHOTO CREDIT: iStock International Inc.

ISBN: 978-92-823-5995-2
DOI: 10.2861/6936

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