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Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues

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ABSTRACT

Robots are slowly, but certainly, entering people's professional and private lives. They require the attention of regulators due to the challenges they present to existing legal frameworks and the new legal and ethical questions they raise. This paper discusses four major regulatory dilemmas in the field of robotics: how to keep up with technological advances; how to strike a balance between stimulating innovation and the protection of fundamental rights and values; whether to affirm prevalent social norms or nudge social norms in a different direction; and, how to each treated in the context of a particular 'modality' of regulation: law, market, social norms, and technology as a regulatory tool; and for each, we focus on particular topics – such as liability, privacy, and autonomy – that often feature as the major issues requiring regulatory attention. The paper then highlights the role and potential of the European framework of rights and values, responsible research and innovation, smart regulation and soft law as means of dealing with the dilemmas.

KEYWORDS: Robotics regulation regulatory dilemmas technology regulation smart regulation responsible innovation soft law

1. Introduction

Robots are nowadays a matter of fact for professional users, as witnessed by robots exploring the surface of Mars, repairing oil pipes deep in the ocean, performing surgical operations in hospitals, defusing or firing bombs in the battlefields, performing manufacturing tasks in factories – just to name a few applications. However, robots are also becoming popular in people's daily lives, for so-called non-professional users. We can see robots at work in homes doing household tasks, such as cleaning sitting rooms, preparing and cooking food, mowing the lawn or playing games with students and children. In addition, in many cities, public transportation means are becoming increasingly robotic, e.g. with driverless undergrounds and metro systems. Automobiles too are endowed with new capabilities such as adaptive cruise control, lane-keeping systems, emergency braking systems, electronic stability control, intelligent parking assist systems; and developments in fully autonomous vehicles, such as the Google car, are speeding up. Thus, robots are becoming increasingly prevalent in daily, social, and professional life.

After ICT, biotechnology, nanotechnologies, and neuroscience-related technologies, robotics is increasingly being put on the agenda as a next major broad field of previous broad technological fields are, in various ways, enablers of robotics, as evidenced by terms used to designate a robot, or some aspects of its design, such as softbots, biorobotics, nanobots, and neurobotics; putting these together with long-existing mechatronic, industrial robots as well as futuristic humanoids, androids, and cyborgs, robotics appears a wide-ranging field indeed. What binds all these forms together is a sense that the technological products display some level of autonomy in their functioning, which gives a new edge to the interaction between humans and technology; and it is this characteristic that makes robotics as a whole a relevant field for regulators and regulation scholars to engage with. Are our existing normative frameworks adequate to deal with developments in robotics? Can new robotic technologies, particularly if they feature increasing levels of autonomic behaviour, be regulated within existing legal and ethical frameworks, and if not, should existing laws be made more generic so that provisions also encompass robotic technologies, or should we rather aim for *sui generis* laws for robots? And are fundamental assumptions underlying regulatory frameworks, such as a very generic distinction between 'things' and 'humans', sustainable in the longer term, if (bio)robotic applications are increasingly built into human bodies? These are some of the more general and fundamental question that the development of robotics raise.

To map the main regulatory challenges of robotics, the authors have collaborated in the RoboLaw project, which was the first research project entirely dedicated to the study of law and robotic technologies to receive funding from the European Commission research framework programmes.[2] It was carried out by an interdisciplinary group of experts in the fields of law, philosophy, ethics and robotics, from the Scuola Superiore Sant'Anna (Italy), Tilburg University (the Netherlands), University of Reading (United Kingdom) and Ludwig Maximilian University (Germany). The main objective of the project was to understand the legal and ethical implications of emerging robotic technologies and to uncover (1) whether existing legal frameworks are adequate and workable in light of the advent and rapid proliferation of robotics technologies, and (2) in which ways developments in the field of robotics affect norms, values, and social processes we the Guidelines on Regulating Robotics we developed with regulatory proposals for the European Commission, aiming at establishing a solid framework for the development of a European 'robolaw'.[3]

In order to delineate the scope of the paper, we start with a conceptual discussion of what robots are and what makes them distinct from other technologies. Subsequently, the core of the paper presents four major regulatory dilemmas, which are discussed in relation to illustrative examples of robotics. To put the regulatory dilemmas into perspective, we associate each one with a particular modality of regulation: law, market, social norms, and technology as a regulatory tool; and for each, we focus on particular topics – such as liability, privacy, and autonomy – that often feature as the major issues requiring regulatory attention. This is not to suggest that particular regulatory dilemmas are uniquely confined to particular regulatory modalities or to specific regulatory issues, nor that they are particularly associated with specific types of robots; rather, the heuristic of this structure allows us to demonstrate a wide range of regulatory questions that are raised by the broad range of robotics, without trying to be exhaustive, but nevertheless putting emphasis on the main issues that require the attention of regulators. After the discussion of the major regulatory challenges, we provide some guidelines for regulators to deal with these challenges.

2. On robots

The many ways in which robotics technologies are combined with other technologies and are applied in the creation and allocation of services and products, as well as the many ways in which the term robot is used by experts and laypeople, makes it difficult to provide a generally acceptable definition of what a robot is. In the framework of the RoboLaw project, we decided to avoid restrictive definitions in favour of a more inclusive approach, which is able to make sense of the variety of existing applications, technological combinations and language uses. We identify robots by positioning them within five dimensions,[4] which have been definitions of robots. These are:

1. *nature*, which refers to the material in which the robot manifests itself;
2. *autonomy*, which refers to the level of independence from external human control;
3. *task*, which refers to the application or the service provided by the robot;
4. *operative environment*, which refers to the contexts of use; and
5. *human-robot interaction*, which refers to the relationship established with human beings.

Within each dimension, a wide range of possibilities exists. In some cases, these possibilities may be spread across the entire spectrum, such as in the category of autonomy, which covers both robots that have full autonomy and robots that are fully controlled by humans, albeit at a distance (through tele-operation), or in the category related to nature, which may include physical as well as virtual robots.[5] These categories have mainly hermeneutic and analytical value, and may be helpful to assess to what extent a particular application can be designated as a robot, and particularly what kind of robot. However, this does not provide a heuristic in itself to delineate the scope of the term 'robot'.

To provide a tentative answer to the demarcation question, we can ask what makes robots unique with respect to other devices. Common assumptions of what constitute robots refer to *autonomy*, namely the ability to work without human intervention; *physical nature*, that is, the ability to move and act in physical environments; and *human-likeness* as the main distinguishing features of a robot. However, none of these characteristics are necessary or sufficient criteria, as robots can be non-autonomous (such as surgery robots), non-physical (such as softbots), or non-human-like (such as industrial robots). A concrete definition can be found with Richards and Smart who define a robot as 'a constructed system that displays both physical and mental agency, but is not alive in the biological sense'.[6] This definition moves away from the anthropomorphism described above but keeps the (autonomy). Agency in their view is subjective, the system must only appear to have agency to an external observer to meet the criteria.[7]

In this article, it is argued that the key aspect of a robot has to do with the ability to execute a programme (software) in order to carry out specific tasks.[8] In other words, it is the possibility to inscribe certain behaviour[9] in an object, as well as the possibility to implement such behaviour (thanks to the object properties), that distinguishes a robot from an ordinary object or a natural phenomenon. The task can be a very simple action, such as switching colours with periodic frequency (e.g. a traffic light),[10] or a very complex one, like driving a car in a public area (e.g. an autonomous [or driverless] vehicle). As a matter of fact, although the latter robot evidently possesses more capabilities since it can perceive the environment, process data, make decisions, and move in the environment, while the former is just a pre-programmed device (i.e. an automa), both the traffic light and the autonomous vehicles have been programmed, that is, they are controlled by a computer that executes instructions to make them act. The difference lies in the complexity rather than in the type. It is worth noting that programmability is independent from the physical nature of the 'thing', which can be made of biological material (e.g. nanorobots) as well as of mechatronic components (e.g. the Honda robot called Asimov). Furthermore, the ability to execute instructions is independent from the level of autonomy. As a matter of fact, even a tele-operation device such as the Da Vinci robot in use for some surgical operations, in contrast to a knife, needs to be programmed in order to faithfully and seamlessly respond to the surgeon's movements. Finally, programmability has nothing to do with human-likeness. As a matter of fact, the shape of the robot should be determined by its function, and an anthropomorphic form may not always be the best design solution, as witnessed by the Roomba vacuum cleaner that does not at all resemble a cleaning lady.[11]

3. Regulatory dilemmas

Regulation can be described as the intentional attempt to influence the behaviour of people (or other entities with a [legal] capacity to act). This formulation shows that, although we might be tempted to speak of 'regulating robots', it is not the robots themselves that are the target[12] – in the sense of the regulatee – of regulatory intervention (at least not until robots acquire a legal capacity to act, which may occur somewhere in the longer term),[13] but the people designing, building, or working with robots. Hence, 'robotics regulation' is a more appropriate term to indicate the field we are discussing in this article, meaning that the regulation is aimed at influencing the behaviour of people in the context of developments in the field of robotics.[14]

Law is the most obvious example of regulation, but behaviour is also influenced by other intentionally used mechanisms. Lessig identifies four tools in the regulatory tool-box: law; social norms; market; and architecture (i.e. technology as a regulatory tool).[15] The law often plays a role in the other regulatory instruments as well, as a contextual or facilitating factor (for example, through creating a basis or framework for competition or backing up social norms). From the perspective of the regulator facing challenges posed by robotics, each modality of regulation is relevant to consider – including the contextual role of the law if policy measures use other regulatory modalities than primarily legal interventions – but no regulatory modality is ideally fit to deal with the regulatory challenges of robotics. In this section, we discuss various regulatory dilemmas that have to be addressed when considering different types of regulatory intervention, illustrated by several issues that often arise in the context of robotics regulation, and by various robotics applications.

3.2. Law

A first major regulatory challenge in technology regulation is how to keep up with technological advances. A common complaint is that law always lags behind technological development.[16] This is framed in terms such as a 'pacing problem'[17] or 'regulatory disconnect'.[18] New technologies may exhibit gaps in the existing regulation or give rise to undesirable conflicts and call for changes. We are then legal certainty. Not the technology, but rather the adverse effects of technology should be regulated. To achieve this, regulation should abstract away from concrete technologies to be sufficiently sustainable and thus be technology-neutral. The challenge is to do so in a way that it simultaneously provides sufficient legal certainty.

Another, related, dilemma presents itself in the regulation of emerging technologies. On the one hand, we have the concern that premature and obtrusive legislation might hamper scientific advancement and prevent potential advantages from materialising, and burden competitiveness or cause economic or other inefficiencies. At the same time, somehow paradoxically, the lack of a reliable and secure legal environment may equally hinder technological innovation.

With every new technology the call that the law lags behind can be heard, often as a knee-jerk reaction and without exploring the actual state of the art with respect to the technology and the law. Often it turns out that the existing legal frameworks are relatively robust; civil liability regimes have coped with many technological advances quite satisfactorily.[20] Law certainly affects what and how technology develops; product liability, for instance, may have a chilling effect on the development of fully autonomous vehicles if it would be the prevailing mechanism to regulate damages caused by these vehicles.[21] However, determining whether the legal frameworks are indeed adequate to cope with the technological advances and not inadvertently hampering innovation is not trivial. And if the law is inadequate, then how do we determine how to change it?

An area where we can see some of the problems regarding the regulation of technology is that of surgical robots. Surgical robots are relatively new, but are clearly gaining ground. Their introduction in the operating theatre is the result of an effort to improve the quality and precision of surgical procedures and follows the birth and evolution of Minimally Invasive Surgery, which originated in the 1980s.[22] One of the prominent examples of a surgical robot is the Da Vinci Si HD Surgical System. This system consists of a console unit, incorporating a display and electronic controllers operated by a surgeon, and a patient side, which contains four with an endoscopic camera. The Da Vinci system certainly does not resemble a classic (anthropomorphic) robot, but when the control unit is distant from the manipulators, the latter certainly seem to exhibit agency. It is a robotic system because the movements of the surgeon are processed by the system's computer, filtering out surgeon tremor and applying variable motion scaling to increase the accuracy of the surgeon's actions. Although promising results are being achieved with it,[23] the system is not perfect. For instance, it lacks proper haptic feedback, making it difficult to identify tissue consistency which hampers distinguishing between tumour and normal tissue, and making it difficult to accomplish intracorporeal suturing and knot tying.[24] The system also suffers instrument malfunctions, including broken tension wires or wire dislodgements from the working pulleys and locked instruments and fractures in the protective layers around the instruments. The incidence of critical failures, however, appears to be very low compared with the conversions reported during manual laparoscopic operations.[25]

How are these kinds of (surgical) robots regulated? In the EU, there is no specific regulation for this class of robots. From a legal point of view, in Europe, Da Vinci like surgical robots are qualified as a Class IIb medical device based on Annex IX of Council Directive 93/42/EEC of 14 June 1993 (Medical Devices Directive, MDD).[26] This Directive aims at regulating safety of medical devices and basically determines that products that have a CE marking are allowed on the EU market. Class IIb products need to undergo the procedure for declaration of conformity (Annex II, full quality assurance), or type-examination (Annex III). Surgical robots, by being labelled medical devices, are treated no different than other medical devices used in surgical operations, such as scissors and scalpels. The MDD solely regulates the function, design and construction requirements of medical devices and not the risks involved in robot surgery, which are determined by a complex human-machine interplay. There are no specific qualifications for the surgeons operating by means of surgical robots, yet the operation of such machines differs significantly from traditional surgery. For instance, properly coping with the 3D images produced by the system and controlling manipulators with seven degrees of freedom require training. Not

Da Vinci's manufacturer, claiming the company has provided insufficient training to surgeons before using the robot.[27] But is this out of the ordinary? The US is host to many medical suits and whether or not the surgical robots represent something special in this case is hard to say without going through the medical claims.

Yet, the qualitative difference between surgical robots and many other medical devices may warrant the question of whether specific legal requirements may be required for medical staff operating these robots. One could argue that professional liability might provide appropriate incentives to properly train robo-surgeons, but since improper surgery may result in death of patients, imposing ex-ante requirements on robo-surgeons may be more appropriate.[28] Alternatively, if the surgical robots themselves indeed are significantly different, then specific regulation addressing the specific issues would be more appropriate.

Another area raising legal questions is bionics, more specifically robotic prostheses. A prosthesis is ‘a device that physically replaces a missing body part, which may be lost due physical injury, disease, or congenital conditions’.[29] Traditionally, these devices were very simple (think wooden leg), but nowadays, with miniaturisation both in electronics and in mechatronics, sophisticated prostheses become available that offer their users multiple degrees of freedom and in some cases even provide functionality close to, or even better than the body parts they replace. Next to prostheses we find orthoses, which modify the structural and functional characteristics of neuromuscular and skeletal systems, and exoskeletons, robotic exoskeletal structures that typically operate alongside human limbs. Together they belong to the category of hybrid bionic systems, which consist of a biological part linked to an artificial part through a control interface.[30] We may be tempted to see these prostheses as replacement for missing limbs restoring functionality to the bearer. But why would we stop at restoring? The motors in the prosthesis can be made stronger than human muscles; indeed, a major goal of exoskeleton research is to develop exoskeletons that greatly enhance human capabilities.[31]

Robotic prostheses raise ethical and legal issues because they further problematise the distinction between therapy and enhancement that not only features in debates a distinction is traditionally made between *restitutio ad integrum* (reconstituting human intactness) and *transformatio ad optimum* (reshaping the human being in a better way).[33] This is not only a conceptual difference, but carries with it a distinction between actions that are morally unproblematic (therapy) and actions that are morally problematic (enhancement). The distinction is, however, not unproblematic itself, because it builds on a presupposed vague notion of 'normal' health conditions. But also, many of the ethical concerns explicitly put forward in the general debate on human enhancement, especially those in which notions such as unnaturalness, fairness, injustice, and dignity are called upon, appear to be multi-layered and often overlapping with other arguments, which troubles the debate considerably.[34] Both within the EU and in the US, the distinction between therapy and enhancement is used to make recommendations about policies and governance of technologies for human enhancement.[35] Consequently, restorative use of certain practices is permissible, such as prescribing Ritalin (methylphenidate) for children diagnosed with ADHD, whereas use of Ritalin by students wanting to increase their short-term memory and concentration is prohibited, or at least seen as problematic by some. The latter is inspired by considering Ritalin a neuro-enhancer, which allows their users to 'cheat' when competing at exams with non-Ritalin users.[36] But is it really cheating, or is it merely comparable with drinking coffee (or even 'Pocket Coffee') and energy drinks to stimulate concentration? How should we cope with prosthetics and similar technologies that have dual-purpose applications of both therapy and enhancement?

Instead of looking at the merits of technologies that can change the human condition, a distinction is being created between uses that appear morally good *prima facie* (therapy) versus those that are morally problematic (enhancement) in policy and regulation. As Koops[37] shows, the distinction is used in different manners by different participants in the debate. Often it is used to frame different territories, using spatial metaphors that indicate that therapy and enhancement are different fields, separated by a (thin, fuzzy, or shifting) line. Another prominent frame is the slippery slope, in which the move from therapy to enhancement is concerns of medicalisation of 'normal' conditions. A third frame is to describe the move from therapy to enhancement in terms of psychopharmaceuticals moving beyond original purposes to serving other purposes; this can be considered as a form of 'function creep'. A fourth frame is to portray the difference between therapy and enhancement by using metaphors that label the latter as a matter of (subjective) individual choice (e.g. 'lifestyle drug', 'elective'), in contrast to therapy that is, by assumption, a matter of need or necessity.[38] Within these frames, different metaphors are applied, which trigger specific issues and directions of solutions to perceived problems. If the frame is that of different territories, problems are framed as classificatory in nature: we need to define proper boundaries and put an application in its proper place. If a slippery slope frame is adopted, this usually involves pejorative language and is normatively laden: enhancement is down the slope, which should be avoided. Similar connotations apply to the 'function creep' frame, although the implicit solution here is not to avoid enhancement but to find a legitimate basis for it, possibly by transplanting medical regulation. Finally, the 'individual choice' frame suggests it is not a matter of public policy, so that there is no need for regulating enhancement (unless clear and present dangers to health and safety, for instance, are involved). Thus, in regulating bionic prosthetics, it is important to be aware of the framing of the regulatory challenge, as the metaphors used influence the direction in which regulatory solutions will be sought.[39]

Another approach to the distinction between therapy versus enhancement is to take a liberal approach and focus on individual capabilities as a guiding light for making policy decisions about technological development. Martha Nussbaum, building on Amartya Sen's work, has developed a Capability Approach for assessing people's well-being. Essentially, the human capability approach champions

> people to have the freedoms (capabilities) to lead the kind of lives they want to lead, to do what they want to do and be the person they want to be. Once they effectively have these freedoms, they can choose to act on

The Capability Approach addresses the question of human functioning beyond the question of disease, disability and physical performance.

The (10) central human functional capabilities Nussbaum has in mind range from life, bodily health, bodily integrity, through emotion, practical reason, imagination and affiliation, to play and control over one's own environment.[41] The notion of capability is closely connected to the idea of personal choice and deliberation. In this account, individuals therefore have the opportunity of choosing whether they want to put a certain capability into functioning or not. This approach therefore entangles the concept of capability within a political rather than physical sphere. By looking at capabilities from this perspective, the political and cultural context takes a central position. States should protect capabilities and make sure that people not only have nominal rights, but they have the capability of exercising them in a specific cultural and social environment. This also holds for assessing the relation between technology and humans, as Oosterlaken and Van den Hoven have argued.[42] The Capability Approach offers a conceptual framework to address the question of what are the human capabilities that are affected by robots and other technologies and that are relevant for the EU regulatory framework. It does this by offering a different angle to the question of robots and capabilities in which human rights and opportunities play a central role. For example, within this approach it makes sense to ask how robotic technologies promote or demote elements of the list of internal and combined capabilities described above. Or how robots could (or whether they should) be employed as a means to protect some capabilities if they are considered, based on some normative analysis, as having priority over other capabilities in certain contexts. Or how robots, by taking up routine and automatic tasks, are enablers for human beings to devote themselves to the performance of 'properly human' capabilities such as practical reasoning and imagination.[43]

The distinction between therapy and enhancement is not the only one that increasingly becomes problematic due to technological advancement. Also the distinction between 'persons' and 'things' is at stake in the age of (robo- and of the human body. They are operated by Brain-Computer Interfaces (BCI), which may be non-invasive, pervasive or partially invasive. Due to the fact that non-invasive interfaces, consisting for instance of recording brain activity through sensors outside the body (electroencephalograms, or EEC), cannot achieve the same level of performance (due to attenuation by the skull) as invasive BCI techniques, there is a drive towards invasive techniques. As a result, the prosthetics (or at least relevant parts) cannot be taken off. Neil Harbisson, one of the few officially recognised cyborgs,[44] has an ‘antenna’ osseo-integrated[45] in his skull that transforms colour frequencies into sound frequencies. The device is intended to remedy his achromatopsia, but actually allows him to also perceive colours outside the human spectrum. Another example of a cyborg is Christian Kandlbauer, a bilateral amputee whose arms were replaced by two different prostheses, one of which uses signals derived from the nervous system. Obviously, these prostheses should be regarded as objects or things before they are implanted, but what happens when they are an inseparable part of their host? The technologies we have used in the past to enhance our bodies (including our brains) – clothes, glasses, books – could always be relatively easily distinguished from the body, making ‘body’ a useful boundary marker. That becomes much more difficult with BCIs and other robotic technologies. And this challenges the assumptions underlying different legal regimes for living persons and non-living matter.

It can be argued that once a device is part of the human body, the full constitutional protection of the human body comes into play. This would mean that public spaces or offices cannot restrict access to these ‘cyborgs’ or require the removal or deactivation of the device, perhaps except for reasons of safety of the wearer and third parties.[46] Equally, search and seizure restrictions should apply to those devices as to the human body, since once installed they cease to be mere objects and become body parts. This shall also apply to the possibility to access possible recording mechanisms installed onto the prosthetic device in order to keep track of received and processed biological signals and the signals then transmitted to the motors and actuators allowing the movement of the prosthesis, irrespective of techniques.

In conclusion, the current legal frameworks are based on a certain understanding of the human person, both in terms of a normative therapy/enhancement distinction and in terms of a fundamental body/environment distinction, both of which are challenged by robotics developments. As a result, the legal frameworks will have to be adapted, but they cannot simply be made more 'technology neutral' to embrace robotics. In many occasions it is not a matter of (re)classifying the technology to fit particular existing legal distinctions. The problem is that fundamental concepts are becoming problematic as boundary-markers (e.g. bodily integrity in a world of human-machine interfaces).[48] Frameworks have to be revised at a more fundamental level, requiring regulators to reflect on the question: what precisely do we want to achieve with regulating integrity of the person? What precisely do we want to achieve with medical law?

3.3. Market

A second major regulatory challenge in technology regulation is how to strike a balance between stimulating, or at least not stifling, technological innovation and ensuring that new technologies do not pose unreasonable risks to health and safety or to the protection of fundamental rights and values. A key legal instrument that helps in striking this balance is liability law, which can deal with eventual adverse effects of technological innovations. However, liability risks can have a stifling effect on innovation if technology developers and producers fear they may have to carry highly burdensome costs for products of which they cannot calculate the risks. Thus, a major issue in the context of the regulatory challenge of balancing innovation and legal protection is whether the regulatory tilt of the incentive scheme embedded in existing liability law leans more towards fostering innovation of a particular technology or towards protecting society from possible risks of new and complex technologies.

Whether liability law provides more positive or negative incentives for technology developers to innovate is a question that requires a close look at the particular technology will operate. Moreover, the policy question has to be addressed, whether the existing combination of incentives is desirable, in that (i) it attains the results it is was conceived to attain – for instance ensure the safety of products distributed onto the market – and (ii) no policy argument can be formulated suggesting a different balance would be preferable.

Within this general framework, which holds true for any kind of product and service, some additional concerns should be taken into account when discussing robotics that, to a great extent, influence the assessment sub (ii) above. Indeed, robotics represents one of the major twenty-first-century technological innovations, one that will modify economies[49] and societies. In particular, those countries that more than others invest in robotic applications, developing a strong industry in the field, will soon acquire a relevant strategic edge over latecomers and other players, who nonetheless will be consuming such devices.[50] At the same time, this will also profoundly modify the labour market and income distribution,[51] in a way that it is not clearly foreseeable, and yet requires early intervention for it not to become 'disruptive'[52] and rather allow the full beneficial potential of robotics to be exploited.

At a 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.[53] From this perspective, the foreseeability of the outcome arising from the application of liability rules assumes particular relevance.

More specifically, the effect of applicable rules needs to be carefully pondered. Some technologies may indeed raise complex ethical and social issues that cannot be 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,[54] since that would entail reducing the possibility to effectively influence the way the product is conceived, designed, and distributed onto the market, including the standards it needs to conform to.[55]

regulating technologies and surrender to market forces; rather it should attentively pick the desired gifts of the 'evil deity'[56] in a way that is aware and fully coherent with its policies and its desired social objectives. In this field more than others, regulation should be tailored in order to balance opposing interests but also take 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 effect.

In this regard, liability law is of considerable relevance. Liability rules, through shifting the costs connected with an undesired and harmful event, force the wrongdoer to internalise the consequences that his actions and choices may have on others. Theoretically, the adoption of the correct liability rule should *ex ante* induce socially desirable forms of behaviour, in terms of reducing accidents and increasing safety investments; it should also *ex post* ensure compensation of harm suffered by individuals.

In modern market economies, next to traditional tort rules that are generally applicable to any individual, product liability – and enterprise liability – rules have been progressively adopted in order to better protect consumers. These alternative systems, opting for strict liability (objective or semi-objective) standards, are intended at the same time to ensure higher investment in product safety and to ease the consumer's position in grounding his claim against producers. The European solution, represented by Directive 85/374/EEC on Defective Products (henceforth DPD), is in this respect not so different from the US approach, as emerging from the Restatement (in particular the Second Restatement on Torts).

Both the European and American systems have, however, been criticised for their overall effect: while an increase in safety standards cannot be substantially assessed,[57] such regulations are deemed to produce a technology-chilling effect[58] and in some cases raise the costs of compensation (reducing the percentage per euro invested that is used to compensate victims).

robotic technologies, such as driverless vehicles and bionic prostheses. In particular, with driverless vehicles, the high number of factors an automated system needs to take into account (street rules, other vehicles on the road, passers-by both abiding and violating the street code, complex environment) is quite relevant. While it is conceivable that once technology has sufficiently advanced to produce a truly autonomous machine – capable of assessing all these variables – producers could feel safe enough in ensuring their product does not require human intervention and supervision, and therefore assuming liability for negative consequences[61] should the system fail or cause an accident. However, imposing a strict standard of liability on producers before such a level of sophistication is reached – which may take quite a number of years yet – may discourage the very development of that technology, liability being judged to represent too considerable, and too uncertain, a risk.

This reasoning can be extended to bionic prostheses, where the complex interaction of brain and machine represents one major obstacle, together with the unlimited number of ways in which an artificial limb may be used.[62] The producer is therefore exposed to all harmful consequences the malfunctioning of the limb may lead to, which are potentially unlimited and extremely hard to assess *ex ante*, with similar discouraging effects on the development of such applications.

The conclusion to be derived from these considerations, though, is not that all robotic applications should be treated alike and that developments be left to the market. Distinctions need to be made, which do not rest – at least not entirely or mainly – on technical considerations. It is thus not the autonomous nature of robotic applications that calls for a modification of existing rules, rather their social desirability, which requires an actively assumed policy decision.[63] Theoretically this entails admitting the possibility for governments to identify and choose the kind of technology they want to favour and to adopt corresponding and coherent incentives. Within the market perspective depicted above, this means affirming the relevance of constitutional values and the protection of individuals as a priority.

be different. In some cases, driverless vehicles for instance, it may be ascertained – possibly after some theoretical and empirical analysis – that an insurance system may counterbalance the possible shortcomings of applicable rules. In contrast, other cases, such as prostheses, may call for the adoption of a liability exemption – possibly coupled with an alternative compensation scheme for victims – given the high social benefits of such applications.

It should also be stressed that such considerations do not entail accepting higher levels of risk or lower safety investments in product development; quite the contrary. Since it may be argued, at least in some cases, that the current system does not provide adequate incentives, alternative solutions may be considered that eventually disentangle the issue of safety from that of compensation. In other words, under certain conditions the fixation *ex ante* of high technical standards producers have to conform to before the product can be released onto the market, may provide sufficient indication on how to design sufficiently safe devices, and also provide adequate certainty with respect to which investments producers are required to make. At the same time, compensation of victims that will inevitably emerge at some point, may be addressed somewhat differently by choosing rules whose primary objective is precisely that of distributing – socialising – a cost, rather than punish the violation of a desired standard.

In any case, the decision whether or not, and how, to adapt existing liability schemes ought to be grounded in the weighing of all the mentioned factors – an innovation-stimulation perspective on the one hand and safety on the other hand – in light of and pursuant to the prevailing social values and constitutional interests that reflect the social desirability of the given technology, in which the European regulatory system is rooted.

3.4. Social norms

In Lessig's framework, one modality of regulating technology is through social norms. According to Lessig, social norms constrain human behaviour in several ways: 'Norms control where I can smoke; they affect how I behave with members of taxes. Differently from law, the enforcement of social norms is not operated by the government, but by the community. The price for infringement however is not necessarily milder. In some cultures, smoking in presence of children or pregnant women or at the dinner table can trigger strong disapproval from the community, resulting in stigmatisation and ostracism. Law indirectly regulates human behaviour through social norms, for example, by implementing educational campaigns to stimulate use of seat belts or disincentivise smoking or drug abuse. Educational campaigns are expected to influence people's knowledge, understanding, opinions and values about something (e.g. smoking) and in this way change their behaviour (e.g. reducing the community's acceptance of smoking in public spaces). There are also subtler ways of regulating through social norms, for example, by creating a culture wherein certain actions are indirectly regulated through social structures. For example, although abortion is a constitutional right in the United States, social structures are shaped to make access to abortion more difficult, as the government has the right 'to bias family-planning advice by forbidding doctors in (government-funded) family-planning clinics from mentioning abortion as a method of family planning'.[65] In this case, the objectives of the regulators are also achieved, not through specific laws but by creating a culture and a shared morality in a certain community that approves of some forms of behaviour and disapproves of other forms.

A major regulatory dilemma associated with social norms is whether regulators should follow, and possibly back up by public policy, prevalent social norms, or whether it should attempt to introduce policy measures that go against the grain of social norms, possibly with the aim of changing how society, or majority groups within society, view certain technologies. This is particularly relevant when the public tend to oppose certain new technologies, while regulators have reasons to stimulate these technologies on grounds of social or economic benefits. In the case of robotics, one issue to consider in this respect is the value of human autonomy, which informs many public debates about robotics, as many people feel threatened by the prospect of robotics replacing humans in various activities (such as nursing or driving cars), whereas regulators – while not losing sight of the importance of reasons of efficiency or safety. Therefore, it is relevant to analyse which social norms related to robotics prevail and how regulators should take these into account.

Social norms related to robotics are strongly influenced by media portrayals of robots, as robots – more than other types of technological artefacts – spark people's imagination. Images of humanoid automated machines threatening humanity populate Western science fiction literature[66] and cinema.[67] Robots are not simply a piece of machinery. The humanoid appearance and their capacity to sense, process (think) and act seem to make robots direct competitors of human beings. Robots, as the ultimate embodiment of the industrial revolution,[68] overrule human beings with their capabilities of acting in autonomous and efficient ways.[69] However, robots' incapacity to have emotions and feelings has often raised questions concerning robots' capabilities to act morally and respectfully towards human beings,[70] and has been used by some critical voices as a reason to dismiss robots.[71] Literature and cinema are only one externalisation of the social norms in a community. They are echoed by philosophical debates about the desirability of robots. While some authors have welcomed the entry of robots in several use contexts as a step towards automation that would free human beings from repetitive tasks,[72] others have pointed out the risks of automation for human flourishing.[73]

Social norms vary in time and place. With respect to robots we see clear differences between Japanese versus Western cultures. The Japanese seem to embrace 'all things robotic, from hundred foot tall warfighting mecha to infantile therapy robots',[74] while western cultures fear automatons. The difference in attitude is attributed to the Japanese adoption of animism, the notion that all objects have a spirit – even man-made objects – originating from the Shinto faith.[75] As a result, Japanese culture predisposes Japanese to see robots as helpmates. Western culture is more premised on the image portrayed by Mary Shelley's *Frankenstein*, life created by humans that will ultimately turn against their makers. These cultural biases underlie global differences in people's attitudes towards robots, but also within single cultures there is polarisation. Robots are capable of taking over an and robots will take over a significant number of jobs. Frey and Osborne,[76] for instance, predict such a loss for 50% of American jobs over the next 20 years. Traditionally, routine cognitive and manual tasks have been taken over by computers and robots. Currently, also non-routine tasks are within the realm of automation. As argued by Frey and Osborne, tasks such as legal writing and truck driving are considered as tasks performable by robots.[77] To be sure, robots do not only cause job losses but also create jobs; the primary social concern is not so much that jobs for humans will disappear, but that the nature of jobs will change, with low-skilled jobs being replaced by higher-skilled jobs – a development that may exacerbate social inequality in the labour market.

The rise of the robots will thus affect many and not only on the level of employment. Robots affect humans on a different level as well. They will touch on human values, such as autonomy and privacy, and as such raise normative questions about the desirability of robots. These questions underlie the regulatory debate around robots: are robots promoting human autonomy? In which cases should robots be used and in which contexts should they not? How to solve conflicts in values that affect social norms?

One of the prominent domains in which robots will likely be employed is healthcare. To maintain the high standard of care in times of declining resources,[78] robot care will be a necessity. In this context, liberty and autonomy are at stake. Patient autonomy as the right of patients to make decisions about their medical care without their healthcare provider trying to influence their decision, is an established foundation of care.[79] Care robots, in interacting with humans, should not harm people or threaten their autonomy.[80] Following Isaiah Berlin, autonomy can be divided into two forms: positive autonomy and negative autonomy.[81] Autonomy as self-determination can be called negative freedom, or 'being free from'. Autonomy as the ability to make a meaningful choice can be called positive freedom or 'being free to'. Pontier and Widdershoven further divide negative autonomy into the sub-principles of physical integrity, mental integrity and privacy. Positive autonomy deliberate decision, and reflection.

The interference of care robots with patient autonomy in the ways outlined above is inevitable. Even relatively simple care robots introduced in homes of elderly people to monitor their behaviour affect people's choices as soon as they take action to prevent harm, such as turning off a cooker they might have accidentally left on.[82] There could be a slippery slope towards 'authoritarian robotics', which might include the equivalent of imprisoning elders to prevent them from running into dangerous situations outdoors.[83] The question here is whether the safety and health gains are great enough to justify the resulting restriction of the individuals' liberty.

Robots will not only negatively affect the autonomy of their patrons, they may also increase their autonomy by offering them affordances they would otherwise not have. The fact that patients (or elderly) can be monitored 24/7 and be assisted if anything goes wrong may offer them greater freedom to move around in and out of the house and to make errors, knowing that they have a personal guard that will (prevent or) correct these. Increased social mobility, inclusiveness, and empowerment are potentially within reach.

Human autonomy is also at stake in the case of driverless cars. Car manufacturers and research institutes invest heavily in getting driverless cars to the market. Google, one of the well-known pioneers in this field, is testing cars in real-world settings in California,[84] and Uber has started the roll-out of some 100 self-driving specially modified Volvo XC90 sport-utility vehicles in Pittsburgh to serve as taxis.[85] Uber's cars are still fitted with a human supervisor in the driving seat, but the writing is on the wall: the driverless car is coming.

Both public and private investment in these robo-cars is significant. Public investment, in Europe for instance by the European Commission,[86] is warranted on the premise that automated vehicles hold the promise of increasing traffic safety by reducing accidents due to human error, such as those resulting from driver distraction or reduced vigilance. They are also expected to reduce fuel consumption

consumption, road safety and accessibility of transport are indeed high on the European Commission's list of priorities.[87] For car manufacturers, driverless vehicles mean new and different markets, but potentially also a totally different cost structures because safety measures in cars based on human driver characteristics (limited view, slow responses) no longer need to steer the design.

An interesting question is how well driverless vehicles fit into cultural and social norms. Looking at one expression of popular car culture, television commercials, we see an image of cars as the symbol of ultimate freedom. Most car advertisements either feature an endless road with no or hardly any traffic, or bustling city life, again with hardly any traffic.[88] This image is not in line with the reality of most of us; traffic congestion is a daily chore. But the culture of mobility nurtures the pleasures of driving (BMW's slogan for a while was 'the ultimate driving machine'), and the outburst of 'road rage'.[89] As Paul Gilroy notes, 'cars are integral to the privatization, individualization and emotionalization of consumer society as a whole', in part due to the 'popular pleasures of auto-freedom – mobility, power, speed'; cars in many ways 'have redefined movement and extended sensory experience'.[90] Most drivers will agree that we do not have this experience in a taxi, or even as a passenger in someone else's car. The driverless car takes away (part of) this pleasure and freedom of driving a car. And hence it may affect our sense of autonomy. We will all become passengers in our own cars.

Also the opposite holds. Driverless vehicles offer a great sense of autonomy to people who did not (or no longer) have the privilege of driving a car before, such as the blind, elderly, etc. The driverless car may give them a feeling of liberation, empowerment and social inclusion. It is precisely this aspect that Google invokes with their promotional video showing a blind person 'driving' one of their driverless vehicles. Loss of autonomy for the traditional 'petrol head' may mean gaining autonomy for the traditionally disenfranchised in a culture of automobility. Driverless cars create affordances for the latter.

We would like to echo Mimi Sheller's account of automotive emotions:

> health and life, environmentally destructive, based on unsustainable energy consumption, and damaging to public life and civic space. Too many people find them too comfortable, enjoyable, exciting, even enthralling. They are deeply embedded in ways of life, networks of friendship and sociality, and moral commitments to family and care for others.[91]

The same holds for the driverless car. We need to understand 'the "deep" social, material and above all affective embodied context'[92] of cars, including the sense of autonomy 'drivers' experience if we want to reap the benefits that driverless cars potentially have for society.

These two examples show that robots potentially affect human autonomy, but how this happens and is appreciated depends on numerous considerations. Regulation of robotics in specific areas such as care or mobility builds on moral positions concerning robots, on the context and on positions and perceptions of stakeholders. In order for regulation to be balanced, it is important to acknowledge the role of existing social norms in the debates about robots, understand where they come from, explore the values at stake, deliberate on which values to bring forward in some situations and how, and where relevant modify social visions that are based on confused debates about social norms and value conflicts.

Sharkey and Sharkey point at the experiences with taking autonomy seriously in the context of smart homes (which, although immovable, share many characteristics with care robots), and Orpwood and others[93] point out that consultation and customisation led to finding a balance between protecting an elderly person's physical health, whilst still preserving his freedom and control over his life. The way this was achieved was relatively straightforward:

> [c]onsiderable effort was made to develop systems that increased his safety, but that did not remove control from him entirely. For instance, the cooker or taps would be turned off automatically if left on for some time, but he could override this.[94]

robot implementation. This type of value elicitation, to identify the issues at stake and the values that are debated, is important to avoid impasses in regulation and polarised debates. Tackling this debate is important for regulation because social norms are truly powerful in determining the acceptance of regulation. It is important to acknowledge furthermore that social norms affect the technology that is the object of the regulatory action but are also at the same time influenced by the technology: meanings and values changes because of changing affordances. Social norms thus also influence technologies and law, and vice versa.

3.5. Code

The newest kid on the regulatory block is code, or architecture. Behavioural norms can be embedded into technology in such a way that deviation from the norm is impossible, or at least hard. Code is a prominent mode of regulation in the internet age, which fully depends on mediating technologies. The software that makes up the internet defines what people can and cannot do.[95] What makes architecture unique in comparison with the other regulatory modalities is its self-enforcing nature. Whereas social and legal norms require individuals to assess whether or not to follow the norm, technology can simply inhibit non-compliance. This raises a classic regulatory dilemma: effectiveness versus legitimacy.[96] While the effectiveness of techno-norms will generally be very high, their legitimacy may be questionable depending on how they were established and whether they are transparent. In this context, different regulators can be distinguished. Many techno-norms will be defined and implemented by robot designers without those affected by the norms being consulted. To take an example from outside the robotics domain, it is the creative content industry that decided to segregate the market for DVDs and hardcoded this in the guise of region codes into DVD players and DVD discs.[97] This kind of techno-regulation lacks legitimacy as we know it from public regulation. In the context of robots, also a second source of techno-norms needs to be distinguished: the democratic legislator. Norms enacted by the legislator may also need to be implemented in robots. For instance, autonomous vehicles, such as the Google car, will need to observe traffic regulations and this likely requires degree of legitimacy due to their pedigree. Legitimacy of norms not only depends on pedigree, however, but also on whether the content of the norms can be known. This might be problematic in case of techno-regulation in robots. Robots will likely not come with an extensive list of what they allow their users to do. We will have to discover and guess through trial and error.[99]

Brownsword points us at yet a deeper level of legitimacy issues.[100] Legitimacy ultimately comes down to respect for human rights and human dignity. This requires humans to be able to make choices to behave in the morally right way. They should do the right things (act morality) for the right reasons (agent morality). Techno-regulation, due to its 'perfect' enforcement, potentially takes away this moral freedom. In some cases of techno-regulation, such as man-high metro turnstiles, there simply is no choice but to enter the platform with a valid ticket. In cases of norms embedded into robots, it is up to the designers to decide whether the human can go against the robot's actions. Embedding kill-switches or even implementing Asimov's law of robotics[101] is not going to satisfactorily solve this issue, because of the radical consequences of the former (a non-functioning robot) or the inconclusiveness of the latter.

The effectiveness versus legitimacy dilemma can be illustrated by a topic that prominently features in many robot applications: privacy (and data protection). Most robots will be equipped with a large array of sensors, many of which will collect and process personal data (information about identified or identifiable individuals). Care robots, for instance, may monitor the health status of 'their' patients and base decisions on these data or transfer the data to other systems and individuals. While at present we may think of Personal Care Robots as entities that autonomously operate in the individual's environment, it is more appropriate to think of them as networked devices, with collection, processing and storage of data taking place anywhere ranging from the device to somewhere in the cloud.[102] This makes it very difficult to pinpoint what happens with respect to the personal data processed by 'the robot'. But also the actions of the robot may well extend beyond its own 'embodiment'. It could enable or disable smart devices used by its patron to control other devices in the smart environment (control lights, temperature, etc.). It is more appropriate to talk of network robot systems[103] instead of seeing personal care robots as embodied by a piece of plastic or metal. Whether and how robots collect and process personal data will be determined by their software,[104] and whether and to what extent this software complies with data protection and privacy regulation is decided by the robot's developers.

The data protection legal framework in Europe[105] provides detailed requirements and constraints on the processing of personal data and contains new provisions regarding automated decision-making and profiling that produce interesting challenges for robot developers. Article 22, for instance, gives data subjects[106] the right not to be subjected to decisions based solely on automated processing where the decision produces legal effects or similarly affects her. Arguably, care robots significantly affect their users, by providing medication and helping out in their daily life. The data subject's explicit consent legitimises automated decisions. Consent has to be freely given, specific, informed and unambiguous by means of statement or clear affirmative action by the data subject. This raises all sorts of questions, for example, does consent need to be provided for every (significant) decision of the robot or only once during configuration; who needs to provide consent (e.g. 'patient', visitors); and how does the consent and topic of consent need to be recorded? Clearly, there is a tension here between legal compliance and the robot's effectiveness and efficiency. The issues regarding consent are even more poignant in the case of personal care robots, given that these are likely deployed in the context of weaker parties: elderly, dependent patients, children. Who consents to the use of carebots for children or the elderly, and is consent fully informed?

Enforcement of the data protection and other legal requirements can partly be embedded in the design of the robots through techno-regulation. For instance, when equipped with cameras, faces could automatically be blurred in order to prevent the processing of sensitive personal data (such as relating to ethnicity or medical conditions). Also, the deletion of data after analysis or actions and certain forms of purpose limitation and access to data can be hardcoded. However, principles, impossible, due to the intentional open texture of many provisions. Thus, techno-regulation in this case can, in theory, improve effectiveness of enforcing data protection rules, and therewith also the legitimacy of care robots' functioning, but whether this is feasible in practice remains to be proven. Moreover, the normative aspect should not be overlooked: if rules are hard-coded and self-enforcing, they become invisible and people will start forgetting it was a rule in the first place,[108] which may lead to an erosion of the morality of data protection law and pose a legitimacy challenge in the longer term.

On the other hand, embedding (legal) norms in robots is a necessity if we want to have robots in our midst. For example, social robots in hospitals might be expected to observe social rules, and robotic street cleaners and automated cars will have to observe traffic regulations. This not only implies that designers will have to build technologies capable of operating within these constraints, but also that certain kinds of robots will have to be able to 'reason' explicitly with legal norms or at least to execute particular norms in particular circumstances. The European Parliament report on robots states that until robots 'become or are made self-aware, Asimov's laws must be regarded as being directed at the designers, producers and operators of robots, since those law cannot be converted into machine code'.[109] It is unclear whether the report specifically addresses Asimov's laws, which are fairly abstract, or legal norms more generally. The latter is unsustainable. Given that different jurisdictions have different norms, and these change over time, the robots will have to be able to deal with varying and changing rules themselves. Think of a self-driving car. If driving on the right-hand side would be hardcoded, then entering the UK is not an option. The car should be able to adopt the English traffic rules.[110] The artificial agency of robots requires designers and regulators to address the issue of regulating robot behaviour in a way that renders it compliant with legal norms. Regulation by design offers a means for this.

Surveillance robots (particularly civil drones) pose similar questions in terms of data protection law, with the additional issue arising of the legitimating ground, as data processing by surveillance drones cannot be based on consent. In the context of the workplace[111] and depending on the jurisdiction, restrictions on workplace monitoring may inhibit the use of robots with capabilities for monitoring the performance of employees. But surveillance robots also raise some broader privacy questions in terms of spatial privacy (the home and other protected spaces), bodily privacy (a chilling effect on nude sun-bathing?), relational privacy (a possible chilling effect on meeting people in public – but traditionally effectively anonymous – places). Here, again, safeguards can, in theory, be hardcoded (e.g. limiting the duration or resolution of footage; automatic scrambling of faces; having a warning light or sound when taking pictures), but hardcoded rules will often be too rigid (not allowing for context-sensitivity or multi-purpose use). This undermines the legitimacy of rule enforcement, and raises similar issues as mentioned above that disappearing rules may affect people's sensitivity for moral thinking and decision-making.

Another issue arising out of the collection and processing of personal data of Personal Care Robots (PCR) users is the purposes for which data are being collected. The robot may gather significant amounts of data and build extensive profiles of its users and their environment that may be used beyond the purposes of treatment and care. It could easily turn into 'Big Brother' kinds of control, not only steering the user's activities, but also nurturing 'the feeling of being observed and evaluated'.[112] Conflicts of interest between the PCR user and others can easily be imagined here as well. Given that PCRs might well be financed through insurance schemes and may actually be owned by insurance companies, the robot may be programmed to nudge their users into specific (company-approved) lifestyles. Similar conflicts of interest may also exist between the person dependent on the PCR and their relatives, who may have an interest in controlling them. The robots may be programmed to empower the individual, but also to limit their autonomy.[113] To what extent does the robot provide transparency about its (programmed) intentions and effects on the autonomy and other rights of the users and people in their environment?

enforcement of legal requirements, but it should be carefully studied to what extent effective techno-regulation (which is neither too over-effective nor too under-effective) is feasible. Moreover, the fact that techno-regulation may come at a cost of undermining legitimacy-related values needs to be taken into account.

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4. Dealing with regulatory dilemmas

4.1. A strong framework of rights and values

Regulatory dilemmas can only be resolved if there is some anchor point. In Europe, such an anchor point can be found in the common heritage of human rights and fundamental values. The regulatory challenges of the kind highlighted above can thus be situated in a framework of common overarching principles that constitute the European sphere of rights and freedoms.

The attitude of the European institutions towards research and industrial development in key areas such as ICT biotechnology, neuroscience, and nanotechnology is characterised by an overall concern for the protection of fundamental rights and values, such as dignity, safety, equality and non-discrimination. These are embedded in, inter alia, the European Convention on Human Rights and the EU Charter of Fundamental Rights. In turn, this general concern for protecting fundamental rights and values impresses common features to innovation processes and scientific advancements, which have to conform to certain normative standards. These norms not only guide innovators, but can also be used to hold them accountable with respect to the fundamental rights and values.

Both at the EU level and within national states, scientific knowledge, technological force and economic power tend to be tamed in their otherwise open development through multiple strategies and constraints. This tendency to protect democratic values and human rights that are potentially undermined by technological developments explains phenomena such as the proliferation of advisory bodies, the order to receive funding and have their results recognised, and the codes of conduct that inform, on a voluntary basis, the activities of researchers who operate in sensitive fields.[114]

These strategies try to ensure that a responsible and anticipatory attitude will reduce risks of harms to rights and values, and therewith provide guidance to the actors involved. But even in the absence of specific normative or deontological tools that regulate the conduct of researchers and others involved in scientific and technological activities, a more general frame exists that offers a robust basis on which scientific knowledge can be produced and applications can be developed and eventually be launched into the market.

The potential role of a set of overarching principles shared in the European legal order is multi-layered. First of all, it forms an essential apparatus to use as a test-bed for the desirability of robotics applications. The principles help to identify priorities and therefore justify rules that favour one application, responding to values and needs deemed fundamental, over others.[115] Second, it can contribute to design safeguards and limits in the use of technologies, and possibly require that they are embedded in the design right from the start.[116] These anchoring principles can also act in a more general orientating function, by pointing to innovations in robotics that should be fostered though regulation or, on the contrary, alert for novel forms of harmful uses brought about by robotic technologies that the regulators can counteract by means of especially designed legal rules or inventive interpretation.[117] More precisely, on the one hand, the constitutional framework could point towards developments in robotics that would better fulfil fundamental values and ensure the implementation of rights, so as to impress socially beneficial connotations onto the scientific endeavour.

Within the value-based framework of the EU Charter of Fundamental Rights, the principles of equality, solidarity, and justice retain prominent relevance, while the principle of non-discrimination (art 21), the rights of the elderly (art 25) and the integration of persons with disabilities (art 26), the right to healthcare (art 35) and to consumer protection (art 38) are corollaries, whose scope is often remitted to purpose of a constitutional understanding of advances in robotics could also entail enlarging the scope of existing fundamental rights in the light of risks of infringements never confronted before.[118]

Robotic products and services for healthcare are, in both respects, an exemplary case. Care and companion robots are being developed for the assistance of the elderly and the disabled, to help them live an independent life and be socially active; advanced prostheses and exoskeletons can improve the quality of life of persons with various types of disabilities and promote their social inclusion; surgical robots can dramatically improve the quality of medical treatment through high-precision surgery. These applications deserve special attention, since they meet relevant 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 us to accomplish values we hold dear. 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 that we deem desirable from a constitutional viewpoint.[119]

But the very same technologies exhibit features that challenge concepts, categories and the kinds of legal safeguards that are deemed to protect the fundamental rights at stake. The prospect of using assistant robots for the elderly raises several issues related to the ethics of care and generates concern for the emotional implications, and therefore the impact on the identity and privacy of persons, 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. Measures taken to limit vulnerabilities do not lead to a linear diminishing of technology-related risks; rather, they transform human vulnerabilities, in various, unpredictable, and sometimes invisible ways.[120] Thus, the role of a strong framework of fundamental rights and values in the common European tradition is highly important in the regulation of robotics, but it cannot be safeguarding certain rights or values have on other rights and values. Second to stay alert to the need for updating, expanding or changing the framework in light of changes in society and value systems that are brought about through the mutual shaping process of technologies, social processes, and normative outlooks.

Although the rights-based framework as outlined may provide a fruitful backdrop for assessing and regulating robotic technologies, we should also be wary of the fact that there is a technology push. Technological innovation is seen as an important factor in solving societal problems and promoting the economy, well-being and 'happiness'.[121] This creates a strong technology push and in assessing (or weighing) values affected by technology 'pushing principles' such as security tend to override other considerations. This means that, although there is a clear set of values and rights embedded in the European rights framework, trade-offs are constantly being made, making the protection of the rights mentioned above not self-evident.

4.2. Soft law

A bundle of technical, social, and political factors play a role in the regulation of robotic technologies and inform the choice of the array of instruments suited to incorporate these factors. The key elements to be taken into account are the transnational nature of technological innovation and its shifting and sometimes abruptly transforming nature; the technicalities inherent in the regulation process of such phenomena and the need to resort, to some extent, to technical delegation; and the extremely general character of constitutional norms and fundamental principles shared at the European level.

Technological innovation, often the result of a cooperation of research teams from different jurisdictions, is a cross-boundary phenomenon, which can be more easily captured by soft law tools than by single-state regulation. Independent agencies, international organisations such as ISO, and other non-state actors, have developed a wide range of soft law instruments. These allow taking into account both the development. At the same time, soft-law measures are consistent with the process of technical delegation to lower-order, more detailed, or more voluntary forms of regulation, which is often used for regulating matters with a strong technological dimension. Technical and safety norms and standards, formulated by administrative or non-governmental agencies, standard-setting bodies and professional associations, ensure the continuous adaptation of rules and implement the amendments needed without the need for statutory intervention.[122] Documents, such as codes of conduct, can be adopted on a voluntary basis, which may enhance the level of acceptability for stakeholders[123] and thus increase the chances of (self-)enforcement. Such adoption of (voluntary) standards may occur at the level of the nation state, but also by actors within a certain, possibly transnational, sector.

Lighter and more flexible measures of the kind depicted above would permit to start building a legal environment for robotic technologies, but also present drawbacks. Soft-law mechanisms that need to fit in with the international quality of research and industrial production of high-tech services and products have to be consistent with several and diverse legal systems. Therefore, they would either remain at a very general and uncontroversial level in order to meet this pluralism and provide legal certainty, or they would provide detailed technical guidance that would only concern the safe design and use of robotic products. In other words, the wide scope, in geographical and political terms, that these transnational instruments should reach allows convergence over some elementary content of regulation, but this kind of general consensus that remains limited to certain elementary aspects is insufficient for governing such complex matters. Moreover, the harmonisation pursued by means of soft regimes depends on the voluntary compliance of multiple classes of actors, which carries a considerable risk of selective and self-interest-based compliance instead of comprehensive and collective-interest-based enforcement. It is doubtful whether this can sufficiently protect the needs and rights of less powerful stakeholders, including the end users of robotics appliances.

setting bodies results in the rules that are implemented typically having a private character, both in a procedural (coming from private parties) and in a substantive (possibly prioritising private over collective interests) sense. This phenomenon raises problems of democratic control and legitimacy, as it potentially undermines procedural values such as due process, accountability, and transparency.[124] In the same way, regulating by code gives rise to a tension between effectiveness and legitimacy. Soft law, by being more proximate to the issues and the actors it aims to regulate, can result in aims less difficult to achieve and agree on, but also less neutral, independent and inclusive.

The normative settlement of highly sensitive and potentially risky activities should therefore not take place exclusively in a largely technocratic context involving only non-state actors through forms of self-regulation. Thus, although soft law has considerable potential to address the need for transnational and flexible solutions to regulatory problems, it can only be used to complement, and where possible to fill in, regulatory approaches based on a strong framework of rights and values.

4.3. Responsible research and innovation

Many regulatory issues raise the question of when regulators can or should intervene if they want or ought to regulate. David Collingridge pointed out an intrinsic dilemma in technology regulation: controlling a technology is difficult in its early stages because not enough is known of its possible or probable effects, and it is also difficult once the technology is well-developed because by then intervention is expensive, drastic, or impossible because the technology cannot be reversed.[125] We therefore need ways to regulate in early stages when it is still possible, albeit in the dark, to regulate, which calls for innovative approaches. One such approach that features increasingly on the policy and academic agendas is responsible research and innovation (RRI).[126]

This approach can be described as

> a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the

> innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).[127]

The responsibility in innovation thus refers to incorporating social and ethical values or aspects in the innovation process. In this respect, responsible innovation is a close relative of corporate social responsibility, with which it shares a strong family resemblance. It also builds on various areas of scholarship: its roots lie in various strands of Science, Technology, and Society Studies, such as Technology Assessment, particularly the later generations of Constructive Technology Assessment and Participatory or Public Technology Assessment,[128] Value-Sensitive Design,[129] and applied ethics. Responsible innovation research is not conducted in ivory towers, but in labs and work spaces where innovation happens in practice; it brings together scientists, social scientists, and humanities scholars to jointly explore how research and innovation can be 'responsibly' shaped. Overall, responsible innovation can best be characterised as a combination of two things: an ideal – something we strive for even though we realise it can never be fully attained – and a project: a joint enterprise of an increasingly large community of people who want to bring us closer to this ideal.

There are many ways to approach responsible innovation in practice, but all approaches share a common factor: the engagement with stakeholders in innovation processes, which can be seen as the major characteristic of RRI. There is some risk, however, of seeing stakeholder engagement as a silver bullet in responsible innovation. As Blok and Lemmens point out, power asymmetries between stakeholder groups affect the framing of societal problems[130] and the responsiveness and the 'response-*ability*' of actors in the innovation process; thus, the practical applicability of the concept of responsible innovation may be questionable.[131]

Apart from stakeholder engagement as a common factor, two broad types of approach can be distinguished: a product approach and a process approach. The enterprise of responsible innovation can be seen as a product (something that is

The *product approach* can be characterised by a focus on developing a method, a framework, or guidelines that can be used to make innovation in a certain context more responsible. Often, it involves the development of a normative framework (consisting of ethical and legal values and norms) that is subsequently applied to a technology (concrete applications or a more abstract class of technology), and this often is accompanied by an argument that the normative framework should be applied from the start of the technology development process. Responsibility in innovation processes has to move 'upstream', and many projects aim at developing tools that actors at the source of the stream can use to take account of ethical and social values. Risk assessment methods and the precautionary principle are examples of such tools.[132] At the other end of the spectrum, the *process approach* can be characterised as a focus on developing self-learning procedures that can be used to make innovation in a certain context more responsible. In contrast to the product approach, the aim is less to develop substantively responsible frameworks or methods, but rather procedures or practices that are procedurally responsible. It is often associated with general procedural values such as legitimacy, inclusiveness, and accountability, while the substantive values are context-specific and need to be elicited through stakeholder involvement during the process itself.

It is important to realise that 'as an innovation itself, responsible innovation must abide by its own framework in this regard, and be anticipatory, reflective, deliberative, and responsive in its constitution and implementation'.[133] Thus, responsible innovation research and implementation projects in the robotics field could benefit from internalising the very process approach that many researchers advocate as the best approach to responsible innovation. This implies that responsible robotics innovation projects should also build in reflection and deliberation – with peers from the responsible innovation research community – in the design of their projects.

4.4. Smart regulation

The development of the concept of responsible research and innovation has close parallels in legal theory and regulation studies. The past decades have witnessed a soft law' approaches and other forms of regulatory innovation. The development of 'smart regulation' or 'responsive regulation'[135] and 'participatory governance'[136] shares many characteristics with developments in Science, Technology, and Society Studies and applied ethics, such as a focus on an ongoing and reflexive process of learning, and a 'participatory turn' of stakeholder involvement. Thus, regulatory innovation[137] is a close relative of responsible (research and) innovation, and one that regulators need to take seriously if they want to address the regulatory challenges of complex technological developments that have broad and systemic implications for many social processes. Similarly, the rise of the study of 'code' or 'techno-regulation'[138] parallels the development of value-sensitive design, in an enterprise of embedding, in a responsible way, values and norms in the design of technology.

The need for a proactive and mixed approach that can keep pace with innovation in the robotics field is better illustrated in the context of specific applications.

Healthcare robotics does not progress in a legal vacuum; detailed regulation exists at the European and national level, that can cover most new and sophisticated products such as different types of bodily implants and robotic limbs interfaced with the neural system.[139] This regulation, however, is hardly adequate to facilitate the advancements in this field as rapidly, effectively and safely as an up-to-date and purpose-built legal framework could. The most important issues concern devices aimed at enhancement, which could fall outside the scope of this regulatory scheme because this is based on the notion of restoration,[140] the under-regulation of the clinical investigation phase, and the risks in terms of cybersecurity that connected devices present.[141]

Although not especially directed at robotic products, substantial improvements may come from the final approval of the Regulation on medical devices,[142] which will replace the current directives after a revision process that originated in 2008. The actual proposal has been adopted after the launch of a public consultation to gather stakeholders' views, and an impact assessment on the revision of the current framework has been carried out. The compromise text resulting from the into account the weaknesses of the previous documents with regard to the abovementioned points. For instance, the proposal introduces specific rules aimed at including non-therapeutic devices within the notion of medical devices. It also tries to align the experimentation phase – which so far has been very poorly regulated – with the existing complex body of law for pharmaceutical clinical trials. However, other issues are hardly or not addressed. For instance, notwithstanding the fact that security against cyber-attacks is considered to be critical for implanted medical devices, and that vulnerabilities to external interferences of ICT devices are regarded as one of the most pressing legal issues within this field,[144] the revision process has paid considerably less attention to the problem of cybersecurity. The additional risks inherent in the use of medical appliances, sometimes implanted in the body, with data processing capabilities, real-time communication with external sources and direct connection to the web have not been addressed in a timely and satisfactory manner, compared to the approach followed in, for instance, the USA.[145] Also, the proposal focuses too much on command and control measures, without taking into account other regulatory modalities. Addressing risks requires looking at the various modalities and finding the right mix of instruments. Cybersecurity management is an area where a combination of regulatory modalities (law, soft law, and code) seems to be the most effective approach; it particularly needs to include general principles that in turn enforce high-level security standards, developed by independent technical bodies, and also require manufacturers to devise security measures and security checks during the design and the development of the medical device.

The length of the revision process of the Regulation outlined and the insufficient attention to cybersecurity and privacy needs, also supports the claim that a more flexible approach may be more appropriate. Instead of aiming at lasting regulation that sets the standards for many years or even decades to come (and that thus provides legal certainty), regulation needs to become more cyclic and interactive and involve more stakeholders than the state and business, also involving quasi-regulators such as interest groups, professional bodies and industry associations. This means a shift from classic or responsive regulation to ‘smart regulation’.[146] This control to warnings, notices, guidance, incentives, advice, and dismissal. Regulatory Impact Assessments, periodic evaluation, and sunset clauses are means to integrate reflexivity in the process and re-evaluate effectiveness and reach of the various instruments.

Smart regulation and the instruments mentioned above are by no means guarantees that effective and efficient outcomes will be reached, however. Especially when involving the entire spectrum of stakeholders, risks of regulatory capture[147] exist, leading to private interests being served by the regulation. Flexibility and reflexivity on the one hand mean that regulation can respond to new issues and needs, but on the other hand weakens legal certainty. And also regulation without appropriate enforcement may be nothing but a paper tiger. This underlines the need for a carefully selected mix of regulatory instruments, grounded in a strong framework of rights and values that can normatively guide the resolutions of unavoidable tensions arising between flexibility and legal certainty.

5. Conclusion

Although robots are hard to define and comprise a vast variety, ranging from softbots through humanoid personal care robots to biomedical implants, they share a key aspect: the ability to execute a program (software) in order to carry out specific tasks. It is the possibility to inscribe certain behaviour in an object, as well as the possibility to implement such behaviour, that distinguishes a robot from an ordinary object or a natural phenomenon. Robotics regulation similarly knows no single definition. Here, we have understood it as meaning that the regulation is aimed at influencing the behaviour of people in the context of developments in the field of robotics. We have discussed examples of a wide variety of types of robots to highlight that with respect to robotics regulation, no one-size-fits-all solution is feasible or desirable. There is no room for a ‘Law of the Horse’, to refer back to one of the memes in the domain of technology regulation.[148] Instead, a mosaic of development of robot applications and protect the values that are dear to us.

We have highlighted a number of the regulatory challenges in the robotics domain. It is not always clear whether issues are the result of a serious regulatory disconnect, or whether they result from the more general ‘pacing problem’ of legislators trying to keep up with technological developments. If there is a regulatory challenge, which of course raises issues of its own – who defines or decides whether there is a challenge, whose challenge is it, who are affected by it, etc. – then the question is when to intervene, i.e. the well-known Collingridge dilemma: regulators cannot intervene too early, nor too late, an extremely challenging tight-rope walk. As in other domains, there will be a strong pull from innovators and developers to facilitate their particular enterprise through regulation (e.g. self-driving cars). Regulatory capture is around the corner.

Context-specificity is also a regulatory challenge. Robots differ substantially in many characteristics and need to be addressed at concrete levels in their own contexts. A pertinent question is at which level regulation should be attempted. Does it make sense to regulate ‘service robots’ in general, or is ‘personal care robot’ a more appropriate level? Or what about ‘non-social personal assistant robots’, to traverse just one dimension of robot types? And should care robots for medical applications be regulated differently than care robots in youth or elderly care, or should they rather be combined with companion robots and robo-toys across sectors?

Yet another challenge is addressing the appropriate regulatee and regulatory modality. In this respect, we have pointed at the potential of enhancing the enforcement of norms through techno-regulation; however, dealing with global diversity of norms becomes a serious issue to handle if norms are to be embedded in robots’ design. Another challenge lies in the trade-off that frequently has to be made between and with regard to regulation through social norms: here, a major regulatory dilemma is whether regulators should follow, and possibly back up by public policy, prevalent social norms, or whether they should attempt to introduce policy measures that go against the grain of dominant social norms, aiming instead to change how society, or majority groups within society, view certain technologies.

substantive challenges to address, beyond the obvious challenges of health and safety that always feature in new technologies. We have discussed challenges for liability regimes (risk regulation versus innovation stimulation), privacy (data protection but also non-informational forms of privacy) and autonomy (covering both negative [being free from unreasonable limitations on autonomy] and positive aspects [stimulating capacity to exercise autonomy]). While legal regimes can be adapted to accommodate such substantive challenges, regulators must also be aware of fundamental but rather invisible challenges at a deeper level of the law. Robotics also challenge assumptions underlying regulatory frameworks as a whole, such as the distinction between things and humans, and the distinction between therapy and enhancement. This requires careful reflection on what regulation aims to achieve, when society slowly but inexorably changes shape through fundamental socio-technical changes.

To address these regulatory challenges, we have offered various guidelines in this paper that regulators might adopt. Generally and most importantly: regulation should be grounded in a set of overarching principles shared in the European legal order. The role of a strong framework of fundamental rights and values in the common European tradition is highly important in the regulation of robotics. It cannot be treated as a given, however: the framework itself also requires continuous attention.

The first challenge for the regulator is clearly defining the problem and challenges to be addressed. Problems and challenges need to be carefully defined. This requires not only looking at the effects of a particular robotic technology on society and its potential regulatory disconnect, but also careful value elicitation, considering not only the social and material values at stake, but also the affective embodied context in which robots operate. The question to ask here is what values do we actually cherish that are affected by the technology? A challenge here is to go beyond superficially analysing speech of relevant stakeholders. Speech is not neutral and issues or merits of technology are (sometimes unintentionally) framed in particular ways to nudge recipients to take a certain stance. The frames used in approach facilitating determining whether and into what direction regulatory action is required is the capability approach. It offers a conceptual framework to address the question of what are the human capabilities that are affected by robots and other technologies and that are relevant for the EU regulatory framework. Within this approach, a question could, for instance, be how robots, by taking up routine and automatic tasks, are enablers for human beings to devote themselves to the performance of 'properly human' capabilities such as practical reasoning and imagination.

Once challenges are defined, regulatory action will have to be devised. In this stage it is desirable to carefully distinguish objectives of the intervention(s) and adopt instruments focused on the main objective. Many (legal) instruments contribute to achieving multiple aims, which may in fact hamper achieving the main aim in a particular context. Liability law is an example here. Liability rules, through shifting the costs connected with undesired and harmful events, force manufacturers to internalise the consequences of their design may have on others. Hence, they purport to promote investment in safety and risk reduction *ex ante*. Liability rules also, ensure, *ex post*, compensation of harm suffered by individuals in case the product fails. Using this instrument to improve/guarantee safety of, for instance, autonomous vehicles, may be undesirable because of the potentially significant burden related to compensation. The aim of increasing investment in safety may need to be disentangled from that of compensation for damages. Technical safety standards may contribute to investing in safety, whereas the compensation for damages, may be addressed somewhat differently by choosing rules whose primary objective is precisely that of distributing etc.

The way the regulator addresses challenges in a highly dynamic and evolving area such as robotics needs to be adapted to the dynamics of the field. The timeframe and size of effects of technological developments are such that we cannot wait for the technology to settle and then take corrective actions by the regulator. Making sure technology benefits human and societal goals should be a shared responsibility of industry and regulator. This requires adopting the framework of order. This not only means that products should promote the relevant values, but also that the entire design process should embrace the values promoted by the European legal order. Self-reflexivity, value based design and shared responsibly may allow us to steer away from the Collingridge dilemma because it promotes a constant reflection on where we are heading, rather than being faced with discrete moments to decide whether to intervene or not. This is not a call for self-regulation – there are distinct roles for the regulator and the regulatees – but the latter also need to take responsibility to guide technology developments in the right direction.

The regulator may need to adapt to the dynamics of the field as well. Regulation needs to become more dynamic, cyclic and interactive and involve more stakeholders than the state and business, also involving quasi-regulators such as interest groups, professional bodies and industry associations. This makes the process more complex because there are more entities involved at more times, raising more interests and concerns, but it allows getting a more complete and diverse perspective on the challenges and potential solutions, and may contribute to acceptance of regulatory interventions by the relevant stakeholders. We thus promote a shift from classic or responsive regulation to ‘smart regulation’.

In regulating technology dominated fields, a lesson seems to be that regulation should be technology-neutral to prevent the regulation being outpaced by technological paradigm shift or innovation. Legal provisions that protect ‘secrecy of communication’, rather that ‘secrecy of the post’ are more sustainable in an era of rapid technological changes (we have moved from letter, telegram, fax, email, to Tweets to communicate in exceedingly rapid succession). The drawback of technology-neutral norms is that they tend to be more abstract (e.g. ‘communication’) than technology specific norms (e.g. ‘postal mail’) and hence potentially offer less legal certainty. Technology-neutrality should therefore not be a goal in itself, but is rather a means to cope with change that in itself requires self-reflection and may require additional measures or guidance.

Regarding instruments at the regulator’s disposal it is increasingly clear that legislation is just one of the regulatory instruments. A carefully balanced mix of law, employing black letter law.

We end with one potential area of further research. The ‘Law of the Horse’ was already mentioned as a dead end to approach technology regulation. A specific technology, usually, is not the target of regulation, but then what could be fruitful targets? Criminal law defines punishable offences, typically without going into detail about the means (homicide, instead of homicide by strangulation). Health and safety concerns (in relatively specific domains) are another regulatory target. The processing of personal data is yet another example of a regulatory target. In other words, to move forward, we need to articulate a cross-domain target or concern that unifies our regulatory approach to robotics.

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Additional information

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Notes

1 In fact, the European Parliament, Committee on Legal Affairs, has drafted its first report with recommendations to the Commission on Civil Law Rules on Robotics on 27 January 2017 (2015/2103(INL)).

2 See <www.robolaw.eu>.

3 RoboLaw Deliverable D6.2 <www.robolaw.eu/RoboLaw_files/documents/robolaw_d6.2_guidelinesregulatingrobotics_20140922.pdf> (accessed 18 March 2017). The project website contains many of the deliverables the final guidelines build on, see <www.robolaw.eu/deliverables.htm> (accessed 18 March 2017).

5 Within the physical sub-group, a further distinction could be made between biological and non-biological material.

6 Neil Richards and William Smart, ‘How Should the Law Think About Robots?’ in Ryan Calo, A Michael Froomkin and Ian Kerr (eds) *Robot Law* (Edgar Elgar, 2016) 3–22, 6.

7 Ibid, 5.

8 Remarkably, among the meanings of the word robot is also ‘a person who behaves in a mechanical or unemotional manner’ (*Oxford English Dictionary*, 2014). Indirectly, such meaning confirms the explication of a robot as based on the notion of programmability. The reference to mechanics and lack of emotions can be associated with what is highly deterministic and predictable (i.e. a programme).

9 However, behaviour is not the correct word, since it refers to the final outcome of programmability, as perceived by a human being. A better way would be to say that it is the possibility to instruct or task a ‘thing’ to do something, which turns that thing into a robot. Such an understanding would be in line with the etymology of the world robot, which comes from the Slavonic language ‘robota’ and means: ‘forced labour’ (*Oxford English Dictionary*, 2014).

10 Curiously, in South African English a traffic-light is also called a robot (*Oxford English Dictionary*, 2014).

11 Making robots resemble humans too much, without associated behavioural refinement can provoke a response of disgust and repulsion that may be counter-productive (M Mori, The Uncanny Valley (trans by Karl F MacDorman and Takashi Minato) (1970) 7 (4) *Energy* 33; Bibi van den Berg ‘The Uncanny Valley Everywhere? On Privacy Perception and Expectation Management’ in Simone Fischer-Hübner, Penny Duquenoy, Marit Hansen, Ronald Leenes and Ge Zhang, *Privacy and Identity Management For Life: 6th IFIP WG 9.2, 9.6/11.7, 11.4, 11.6/PrimeLife International Summer School* (Springer, 2011) 178–91.

Robots, Laws in Robots: Regulating Robot Behaviour by Design' (2014) 6(2) *Law, Innovation and Technology* 194, on how robots indirectly are regulatees by means of their design.

13 Cf Andreas Matthias, 'The Responsibility Gap: Ascribing Responsibility for the Actions of Learning Automata', (2004) 6 *Ethics and Information Technology* 175; Peter M Asaro, 'Robots and Responsibility from a Legal Perspective' unpublished manuscript (2007) <www.peterasaro.org/writing/ASARO%20Legal%20Perspective.pdf> (accessed 18 March 2017); Ugo Pagallo, *The Laws of Robots Crimes, Contracts, and Torts* (Springer, 2013); Samir Chopra and Laurence F White, *A Legal Theory for Autonomous Artificial Agents* (University of Michigan Press, 2011); Steffen Wettig and Eberhard Zehendner, 'A Legal Analysis of Human and Electronic Agents' (2004) 12 *Artificial Intelligence and Law* 111, 112.

14 Cf Lyria Bennett Moses, 'How to Think about Law, Regulation and Technology: Problems with "Technology" as a Regulatory Target' (2013) 5(1) *Law, Innovation and Technology* 1–20. See also Leenes and Lucivero (n 12).

15 Lawrence Lessig, 'The Law of the Horse: What Cyberlaw Might Teach' (1999) 6 *Harvard Law Review* 501.

16 Lyria Bennett Moses, 'Agents of Change: How the Law "Copes" with Technological Change' (2011) 20(4) *Griffith Law Review* 764 <http://ssrn.com/abstract=2000428> (accessed 18 March 2017).

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18 Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford University Press, 2008).

19 Bert-Jaap Koops, 'Should ICT Regulation be Technology Neutral' in Bert-Jaap Koops, Miriam Lips, Corien Prins and Maurice Schellekens (eds), *Starting Points for*

Asser Press, 2006) 77–108.

20 See Chris Holdere, Vikram Khurana, Faye Harrison and Louisa Jacobs, ‘Robotics and Law: Key Legal and Regulatory Implications of the Robotics Age (Part I of II)’ (2016) 32 *Computer Law & Security Review* 383, who cite the UK Department for Transport as confirming that the situation with highly automated vehicles is not significantly different to any situation with technologies such as ABS and Adaptive Cruise Control in which strict manufacturer liability applies.

21 See RoboLaw Deliverable D6.2 (n 3) s 4.3.

22 Ibid, 76.

23 See e.g. AL de Souza and others, ‘Total Mesorectal Excision for Rectal Cancer: The Potential Advantage of Robotic Assistance’ (2010) 53 *Diseases of the Colon & Rectum* 1611; P Stádler and others, ‘Robotic Vascular Surgery: 150 Cases’ (2010) 6 *The International Journal of Medical Robotics and Computer Assisted Surgery* 394.

24 See RoboLaw Deliverable D6.2 (n 4) 82, with references.

25 NT Nguyen, B Nguyen-Shih and others, ‘Use of Laparoscopy in General Surgical Operations at Academic Centers’ (2013) 9(1) *Surgery for Obesity and Related Diseases* 15; C Freschi, V Ferrari, F Melfi, M Ferrari, F Mosca and A Cuschieri, ‘Technical Review of the da Vinci Surgical Telemanipulator’ (2012) *The International Journal of Medical Robotics and Computer Assisted Surgery* 396.

26 The MDD is foreseen to be replaced by the Regulation of the European Parliament and of the Council on medical devices 2012/0266 (COD). Council and Parliament agreed on a final text on 15 June 2016; final formal adoption is expected during the first semester of 2017: see <https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision_en> (accessed 18 March 2017).

27 In a decision of the Kitspa County Superior Court in the State of Washington (no 09-2-03136-5, 25 March 2013), the jury found the company did not fail to

in surgery.

28 This position was underscored by the surgeons interviewed in the RoboLaw project, see RoboLaw Deliverable 6.2 (n 3) 94.

29 *Oxford English Dictionary*, 2014.

30 Silvestro Micera and others, 'Hybrid Bionic Systems for the Replacement of Hand Function' (2006) 94(9) *Proceedings of the IEEE*, 1752.

31 The Berkeley Lower Extremity Exoskeleton (BLEEX) and SARCOS: see <http://spectrum.ieee.org/automaton/robotics/robotics-software/sarcos_robotic_exoskeleton> (accessed 18 March 2017), being examples of such human enhancement technologies.

32 See Federica Lucivero and Anton Vedder, 'Human Enhancement: Multidisciplinary Analyses of a Heated Debate' in Federica Lucivero and Anton Vedder (eds), *Beyond Therapy v Enhancement? Multidisciplinary Analyses of a Heated Debate* (Pisa University Press, 2014) for an overview. See also Urban Wiesing, 'The History of Medical Enhancement: From Restitution Ad Integrum to Transformatio Ad Optimum?' in Bert Gordijn and Ruth Chadwick (eds), *Medical Enhancement and Posthumanity* (Springer, 2010) 9–24.

33 See Lucivero and Vedder (n 32).

34 Ibid, 9.

35 For instance Mihail C Roco and William S Bainbridge (eds), *Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science* (Kluwer Academic, 2003); Fritz Allhoff and others, *Ethics of Human Enhancement: 25 Questions & Answers* (US National Science Foundation, 2009); Huub Zonneveld Dijstelbloem and Danielle Ringoir, *Reshaping the Human Condition: Exploring Human Enhancement* (The Rathenau Institute, 2008); James Wilsdon, *Better Humans? The Politics of Human Enhancement and Life Extension* (Demos, 2006); Rinie van Est and others, *Future Man – No Future*

(The Rathenau Institute, 2008); Christopher Coenen and others, *Human Enhancement Study* (Science and Technology Options Assessment [STOA], European Parliament, 2009).

36 Also in the case of ADHD use, questions arise. Ritalin alters young adults' personal identity: isn't this drug equalising these young people to a standard average, reducing their creativity in view of a socially constructed standard of 'normality'?

37 Bert-Jaap Koops, 'The Role of Framing and Metaphor in the Therapy Versus Enhancement Argument' in Lucivero and Vedder, *Beyond Therapy v Enhancement?* (n 32) 35–68.

38 Ibid, 41.

39 Ibid, 62–63.

40 Thomas Gries and Wim Naude, 'Entrepreneurship and Human Development: A Capability Approach' (2011) 95 *Journal of Public Economics* 216 as quoted in RoboLaw Deliverable D4.3 Taxonomy of human capabilities in a world of robotics <http://www.robolaw.eu> (accessed 18 March 2017).

41 Martha Nussbaum. *Women and Human Development: The Capabilities Approach* (Cambridge University Press, 2000) 78–80.

42 Ilse Oosterlaken and Jeroen van den Hoven, *The Capability Approach, Technology and Design* (Springer, 2012).

43 RoboLaw Deliverable D4.3 (n 40) 20.

44 See Neil Harbisson (Wikipedia) <https://en.wikipedia.org/wiki/Neil_Harbisson> (accessed 18 March 2017).

45 This is 'the formation of a direct interface between an implant and bone, without intervening soft tissue': see Benjamin F Miller and Claire B Keane, *Miller-Keane Encyclopedia & Dictionary of Medicine, Nursing, & Allied Health* (Saunders, 1992).

47 Ibid.

48 See more extensively on this Bert-Jaap Koops, ‘On Legal Boundaries, Technologies, and Collapsing Dimensions of Privacy’ (2014) 3 *Politica e Società* 247.

49 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, to name one specific example: James Manyika and others, Disruptive Technologies: Advances That Will Transform Life, Business, and the Global Economy (McKinsey Global Institute, 2013) 68, 72ff <http://www.mckinsey.com/insights/business_technology/> (accessed 18 March 2017).

50 Ibid, 68.

51 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. However, different considerations can be made. On the one hand, there is no doubt that robotic technologies will emerge and become widespread 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. See Manyika (n 49) 68.

52 The term is utilised by Manyika (n 49) and suggests that this complex phenomenon needs to be attentively governed.

53 Recently, within Horizon 2020 a research project was financed by the European Commission – ECHORD ++ – which also aims at developing specialized centres for

already adopted in many other industrialized countries including the US and Korea: see Manyika (n 49).

54 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, however, 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.

55 The application produced outside the legal system prohibiting its development and use will conform to 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 (if such prohibition would be effective and possible to enforce, and society would 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 – that belong to the second, completely frustrating the original regulation’s purposes.

56 Guido Calabresi, *Il dono dello spirito maligno* (Giuffrè, 1996).

57 Theoretically the adoption of a strict liability standard does not provide additional incentives in investing in safety than a normal negligence standard, but simply forces the producer to buy additional insurance for those events falling outside his control – which therefore could not have been avoided despite acting diligently – and which are thus still imputed to him as a cost: see Richard Posner, *Economic Analysis of Law* (Wolters Kluwer, 2007). Empirically no effect of product liability rules was measured on product safety in the US legal system: see for a discussion Mitchell A Polinsky and Steven Shavell , ‘The Uneasy Case For Product Liability’ (2009–10) 123 *Harvard Law Review* 1437. Market forces – in particular the

deciding to invest in quality, and thus in safety. In many European member states the level of litigation based on product liability has been particularly low since its adoption. Since it cannot be assumed that all products commercialized in Europe are intrinsically safer than American ones, other justifications need to be found. It could be argued that other norms and standards provide consumers with better protection than product liability rules, and thus the underlying rationale of such rules is frustrated.

58 In particular, it is claimed that *ex ante* uncertainty about the cases where the producer may be held liable and excessive litigation may drive otherwise healthy companies outside the market. A similar effect was measured in the US with respect to the commercial aviation industry, which was almost erased by the high levels of litigation it attracted. With the adoption of the General Aviation Revitalization Act of 1994 (Act Aug 17, 1994, PL 103–298, § 1–4, 108 Stat 1552; Nov 20, 1997, PL 105–102, § 3(e), 111 Stat 2215) the investment in safety by producer did not appear to decline, since the number of registered accidents actually diminished because of the higher investment in safety by the users: see Eric A Helland and Alexander Tabarrok (2012), 'Product Liability and Moral Hazard: Evidence from General Aviation' (2012) 55 *The Journal of Law and Economics* 593.

59 Maurice Schellekens, 'Self-Driving Cars' in Erica Palmerini (ed), *Guidelines on Regulating Robotics* (2014), 57ff.

60 Andrea Bertolini, 'Robotic Prostheses' in Erica Palmerini (ed), *Guidelines on Regulating Robotics* (2014), 136ff.

61 In fact, producers seem to take up this glove already. In October 2015, Volvo Car Group President and CEO Håkan Samuelsson announced that 'the company will accept full liability whenever one of its cars is in autonomous mode': Fortune (October 7, 2015), Kirsten Korosec <http://fortune.com/2015/10/07/volvo-liability-self-driving-cars/> (accessed 18 March 2017). He was followed by other car manufacturing CEOs.

malfunctioning occurring in each of these circumstances could produce radically different consequences: see for a discussion Bertolini (n 60) 139ff.

63 See Andrea Bertolini, 'Robots As Products: The Case For a Realistic Analysis of Robotic Technologies and the Law' (2013) 5 *Law Innovation and Technology* 214.

64 Lessig, 'The Law of the Horse' (n 15) 507.

65 Lawrence Lessig, 'The New Chicago School' (1998) 27 *Journal of Legal Studies* 670.

66 From Karel Čapek's *RUR* (1921) to Charles Stross's *Saturn Children* (2008) and Ian Tregellis's *The Mechanical* (2015).

67 E.g. 2001 *A Space Odyssey* (dir Stanley Kubrick, UK/USA 1968), *Westworld* (dir Michael Crichton 1973), *Bladerunner* (dir Ridley Scott, USA/Hong Kong/UK 1982), *I Robot* (dir Alex Proyas, USA/Germany 2004), *Her* (dir Spike Jonze, USA 2013), the TV series *HUM∀NS* (dir various, UK/Sweden 2015), its Swedish original *Äkta människor* (creator Lars Lundström, Sweden 2012), and HBO's *Westworld* (dir various, USA 2016).

68 This aspect is particularly visible in the movie *Metropolis* (dir Fritz Lang, Germany 1927).

69 Contrast this however with a report about the Darpa Robot Challenge by *Time* journalist Lev Grossman, 'Iron Man', *Time* (8 June 2013) 73–74, quoted in Thomas Burri, 'The Politics of Robot Autonomy' (2016) 2 *European Journal of Risk Regulation* 350. It begins as follows: 'Let me correct an impression you may have: Robots are pretty much idiots. They can't do very much, and they do it with a slowness that would try the patience of a saint who was also an elephant. Samuel Beckett would have made a good roboticist. It is a science of boredom, disappointment, and despair.' Burri notes that the Darpa promotional videos show one of the contestants, RoboSimian egressing from a car in three seconds and Chimp, another contestant climbing the stairs in four seconds. These were time-lapse videos; the robots actually took several minutes to complete these tasks.

wikipedia.org/wiki/Three_Laws_of_Robotics> (accessed 18 March 2017).

71 See for instance Thomas Metzinger, *Being No One: The Self-Model Theory of Subjectivity* (MIT Press, 2004), quoted in Wendell Wallach and Colin Allen, *Moral Machines: Teaching Robots Right From Wrong* (Oxford University Press, 2009) 205. See also Mark Coeckelbergh's analysis of the strong 'emotion' view: Mark Coeckelbergh, 'Moral Appearances: Emotions, Robots, and Human Morality' (2010) 12(3) *Ethics and Information Technology* 235.

72 See RoboLaw Deliverable D4.3 (n 40).

73 Compare, however, Nick Bostrom, who in recent work takes a more nuanced approach. There is little reason to assume that a robot or a superintelligence will necessarily share human values, and no reason to believe it would place intrinsic value on its own survival either: Nick Bostrom, *Superintelligence: Paths, Dangers, Strategies* (Oxford University Press, 2014).

74 Christopher Mims, 'Why Japanese Love Robots (and Americans Fear Them)' (*MIT Technology Review*, 12 October 2010) <www.technologyreview.com/s/421187/why-japanese-love-robots-and-americans-fear-them/> (accessed 18 March 2017).

75 Naho Kitano 'Animism, Rinri, Modernization: The Base of Japanese Robotics' (Workshop on Roboethics: ICRA'07, Rome, 10–14 April 2007).

76 See Carl Benedikt Frey and Michael A Osborne, *The Future of Unemployment: How Susceptible Are Jobs to Computerization?* (Oxford Martin, 2013) for an overview.

77 Ibid, 4, 14–22. See also Frederico Pistano, 'Robots Will Steal your Job, But That's Ok: How to Survive the Economic Collapse and Be Happy' <http://robotswillstealyourjob.com/read> (accessed 18 March 2017).

78 See Drew Terry, Nicolas Simshaw, ML Cumming and Kris Hauser, 'Regulating Healthcare Robots in the Hospital and the Home' (WeRobot conference 2015) <www.werobot2015.org/wp-content/uploads/2015/04/Simshaw-Hauser-Terry-Cumming

Ageing, http://www.who.int/topics/ageing/en/ (accessed 18 March 2017).

79 It is one of the four principles of biomedical ethics, as postulated by Tom Beauchamp and James Childress in their classical textbook *Principles of Biomedical Ethics* (Oxford University Press, 1985). The other three are beneficence, non-maleficence, and justice. The European Parliament Draft report on Civil Law Rules on Robotics (2015/2103(INL)) also points out that autonomy, beneficence, and non-maleficence are part of the guiding ethical framework (7) <www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML%2BCOMPARL%2BPE-582.443%2B01%2BDOC%2BPDF%2BV0//EN> (accessed 18 March 2017). Interestingly, autonomy is defined as ‘the capacity to make an informed, un-coerced decision about the terms of interaction with robots’ (15).

80 Matthijs A Pontier and Guy AM Widdershoven, ‘Robots that Stimulate Autonomy’ in Harris Papadopoulos, Andreas S Andreou, Lazaros Iliadis and Ilias Maglogiannis (eds), *Artificial Intelligence Applications and Innovations: 9th IFIP WG 12.5 International Conference, AIAI 2013* (Springer, 2013) 195–204.

81 Ibid.

82 Amanda Sharkey and Noel Sharkey, ‘Granny and the Robots: Ethical Issues in Robot Care for the Elderly’ (2012) 14 *Ethics and Information Technology* 27.

83 Ibid, 33.

84 On 7 August 2012, Google reported that their self-driving cars (‘about a dozen’ of them) had completed more than 300,000 miles of testing: ‘The Self-Driving Car Logs more Miles on New Wheels' (*Official Google Blog*, 7 August 2012) <http://googleblog.blogspot.nl/2012/08/the-self-driving-car-logs-more-miles-on.html> (accessed 18 March 2017). On 28 April 2014, Google reported their cars to have covered ‘thousands’ of miles on the streets in Mountain View, California: 'The Latest Chapter for the Self-Driving Car: Mastering City Street Driving' (*Official Google Blog*, 28 April 2014) <http://googleblog.blogspot.nl/2014/04/the-latest-chapter-for-self-driving-car.html> (accessed 18 March 2017).

-s-first-self-driving-fleet-arrives-in-pittsburgh-this-month-is06r7on> (accessed 19 March 2017).

86 The Commission communication of 15 February 2006 on the Intelligent Car Initiative – ‘Raising Awareness of ICT for Smarter, Safer and Cleaner Vehicles’ [COM(2006) 59 final – Not published in the Official Journal] highlights the potential of intelligent cars for the European Union and calls for the establishment of an Intelligent Car Initiative to support policies and innovation in this area. In May 2010 the EC launched the Digital Agenda for Europe tackling the issue of how digital technologies can help societies and policy makers address various challenges. One of the areas of application of the digital agenda concerns mobility and intelligent cars have a prominent role in it: see <http://ec.europa.eu/digital-agenda/en/node/76926> and <http://ec.europa.eu/digital-agenda/en/node/76926> (accessed 19 March 2017) for a database featuring a variety of EC-funded projects developing ICT-based system and services for road.

87 See <http://ec.europa.eu/transport/index_en.htm> (accessed 19 March 2017).

88 Elizabeth C Hirschmann, ‘Men, Dogs, Guns, and Cars: The Semiotics of Rugged Individualism’ (2013) 32 *Journal of Advertising* 9.

89 Mimi Sheller, ‘Automotive Emotions: Feeling the Car’ (2004) 21(4/5) *Theory, Culture & Society* 221.

90 Paul Gilroy, ‘Driving while Black’ in D Miller (ed), *Car Cultures* (Berg, 2001) 89, quoted in Sheller (n 89) 228.

91 Sheller (n 89) 236.

92 Ibid.

93 Roger Orpwood, Tim Adlam, Nina Evans, James Chadd and David Self, ‘Evaluation of an Assisted-Living Smart Home for Someone with Dementia’ (2008) 2(2) *Journal of Assistive Technologies* 13.

95 Lessig, ‘The Law of the Horse’ (n 15).

96 Roger Brownsword, ‘Code, Control, and Choice: Why East is East and West is West’ (2005) 25 *Legal Studies* 1.

97 See extensively on this topic, Ronald Leenes, ‘Framing Techno-Regulation: An Exploration of State and Non-State Regulation by Technology’ (2011) 5 *Legisprudence* 143.

98 See Leenes and Lucivero (n 12).

99 Which may be slightly harder than in the cases described in Orpwood and others (n 93). The European Parliament is aware of this issue and has incorporated transparency requirements in its proposal for a licence for designers (EP 2015/2103(INL) 18.

100 Roger Brownsword (n 96) 17; Roger Brownsword, ‘In the Year 2061: From Law to Technological Management’ (2015) 7 *Law, Innovation and Technology* 1.

101 Asimov (n 70).

102 See Bibi van den Berg, ‘Mind the Air Gap: Preventing Privacy Issues in Robotics’ in Serge Gutwirth, Paul De Hert and Ronald Leenes, *Data Protection on the Move* (Springer, 2016), who argues that to limit privacy problems, robots should not be connected to the internet.

103 Alberto Sanfeliu, Norihiro Hagita and Alessandro Saffiotti, ‘Network Robot Systems’ (2008) 56 *Robotics and Autonomous Systems* 793, doi:10.1016/j.robot.2008.06.007.

104 It should be noted that ‘software’ increasingly becomes a blurry notion. Future robots will likely not come with their software installed by the manufacturer in a complete version, but rather consist of a software platform that also allows third party applications, similar to that on smartphones.

106 In the context of a household robot this might be anyone the robot encounters in its daily operation.

107 See Bert-Jaap Koops and Ronald Leenes, ‘Privacy Regulation Cannot Be Hardcoded. A Critical Comment on the ‘Privacy by Design’ Provision in Data-Protection Law’ (2014) *International Review of Law, Computers & Technology* 159.

108 See Brownsword (n 96).

109 European Parliament, Committee on Legal Affairs, Report with recommendations to the Commission on Civil Law Rules on Robotics, 2015/2103(INL) 27 January 2017, 4.

110 See extensively on this Leenes and Lucivero (n 12).

111 See for instance *Niemietz v Federal Republic of Germany*, 251 Eur Ct HR (ser A) (1992).

112 Ryan Calo, ‘People Can Be So Fake: A New Dimension to Privacy and Technology Scholarship’ (2009) 114 *Penn State Law Review* 809.

113 See above, section 3.4, and more extensively, Jason Borenstein and Yvette Pearson, ‘Robot Caregivers: Harbingers of Expended Freedom for All?’ (2010) 12 *Ethics and Information Technology* 277.

114 A straightforward example is offered by the Code of conduct for responsible nanosciences and nanotechnologies research, recommended for adoption by ‘national and regional authorities, employers and research funding bodies, researchers, and any individual or civil society organisation involved or interested in N&N research’, through the Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research: C(2008) 424 final, 7.2.2008.

115 See section 3.3 above; cf also Andrea Bertolini, ‘Robotic Prostheses as Products Enhancing the Rights of People with Disabilities: Reconsidering the Structure of

116 Cf section 3.5 above.

117 Mark Gasson and Bert-Jaap Koops, ‘Attacking Human Implants: A New Generation of Cybercrime’ (2013) 5 *Law, Innovation and Technology* 248. See also Bert-Jaap Koops, ‘Concerning “Humans” and “Human” Rights: Human Enhancement from the Perspective of Fundamental Rights’ in Bert-Jaap Koops and others (eds), *Engineering the Human: Human Enhancement Between Fiction and Fascination* (Berlin-Heidelberg, 2013) 174ff, stating, with regard to the prospect of human enhancement, that new fundamental rights may be necessary to ensure legal protection both to enhanced and non-enhanced humans.

118 Bert-Jaap Koops and others, ‘Robotic Technologies and Fundamental Rights: Robotics Challenging the European Constitutional Framework’ (2013) 4(2) *International Journal of Technoethics* 15.

119 This specific perspective has led to proposals for special rules in the context of liability for damages deriving from the use of prostheses, in order both to shield the producer from excessive liability (thus providing correct incentives for expanding research and the market for such technologies), and to compensate the victims: see section 3.3 above.

120 See Mark Coeckelbergh, *Human Being @ Risk: Enhancement, Technology, and the Evaluation of Vulnerability Transformations* (Springer, 2013).

121 Even lending a strong hand to *solutionism*. See Evgeny Morozov, *To Save Everything Click Here* (Allen Lane, 2013) for a critical account of this movement.

122 David Weimer, ‘The Puzzle of Private Rule-Making: Expertise, Flexibility, and Blame Avoidance in US Regulation’ (2006) 66 *Public Administration Review* 569.

123 An important factor in whether the outcomes of self-regulatory processes are indeed accepted by the stakeholders is who are at the table. See Ciara Bracken-Roche, ‘Domestic Drones: The Politics of Verticality and the Surveillance Industrial

124 For a condensed analysis of both the strengths and the weaknesses of soft law see Roger Brownsword and Morag Goodwin, *Law and the Technologies of the Twenty-First Century. Texts and Materials* (Cambridge University Press, 2012) 377–78.

125 David Collingridge, *The Social Control of Technology* (St Martin's Press, 1980).

126 For an overview of the landscape of responsible innovation, see Bert-Jaap Koops, 'The Concepts, Approaches, and Applications of Responsible Innovation' in Koops and others (eds), *Responsible Innovation, Volume 2* (Springer, 2015), on which this section is based.

127 René von Schomberg, *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields* (European Commission, 2011) 9.

128 For an overview, see José van Eindhoven, 'Technology Assessment: Product or Process?' (1997) 54 *Technological Forecasting and Social Change* 269.

129 Batya Friedman (ed), *Human Values and the Design of Computer Technology* (University of Chicago Press, 1998).

130 See Bracken-Roche (n 123) for an account of the framing of problems surrounding drones in Canada.

131 Vincent Blok and Pieter Lemmens, 'The Emerging Concept of Responsible Innovation: Three Reasons why it is Questionable and Calls for a Radical Transformation of the Concept of Innovation' in Koops and others, *Responsible Innovation, Volume 2*.

132 One approach to embed the relevant values into the entire design process is by adopting the impact assessment methodologies. These were developed for many specific domains, such as the environment, privacy (PIA), data protection (DPIA) and robots. For the latter, see Eduard Fosch-Villaronga, 'Creation of a Care Robot Impact

Business and Industrial Engineering [illegible].

133 Richard Owen, Jack Stilgoe, Phil Machaghten, Michael Gorman, Erik Fisher and David Guston, ‘A Framework for Responsible Innovation’ in Richard Owen, John Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (John Wiley & Sons, 2013) 46.

134 Cf section 4.2 above.

135 Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press, 1995).

136 Archon Fung and Erik Olin Wright, *Deepening Democracy: Institutional Innovations in Empowered Participatory Governance* (Verso, 2003).

137 Julia Black, Martin Lodge and Mark Thatcher (eds), *Regulatory Innovation: A Comparative Analysis* (Edward Elgar, 2005).

138 See section 3.5 above.

139 See section 3.2 above.

140 See section 3.2 above.

141 For an overview, see Erica Palmerini, ‘A Legal Perspective on Bodily Implants for Therapy and Enhancement’ (2015) 29 *International Review of Law, Computers & Technology* 226.

142 Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, 2012/0266 (COD). The text has gone for high level linguistic corrections and will be brought to a vote in the EP in March 2017.

143 Council of the European Union, Interinstitutional file 2012/0267 (COD), Brussels, 15 June 2016.

Future: Law and Policy Implications' (The Brookings Institution, September 2014) <www.brookings.edu/research/reports2/2014/09/cyborg-future-law-policy-implications> (accessed 19 March 2017); Stephen S Wu and Marc Goodman, 'Neural Devices Will Change Humankind: What Legal Issues Will Follow?' (2012) 8 *The SciTech Lawyer* 3.

145 FDA, 'Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software' (14 January 2005) <www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf> (accessed 19 March 2017); FDA, 'Content of Premarket Submissions for Management of Cybersecurity in Medical Devices' (2 October 2014), <www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf> (accessed 19 March 2017).

146 See Robert Baldwin, Martin Cave and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press, 2012) 266, referring to Neil Gunningham, Peter Grabosky and Darren Sinclair, *Smart Regulation: Designing Environmental Policy* (Oxford University Press, 1999).

147 George Stigler, 'The Theory of Economic Regulation' (1971) 2 *The Bell Journal of Economics and Management Science* 21; Jean-Jacques Laffont and Jean Tirole, 'The Politics of Government Decision Making: A Theory of Regulatory Capture' (1991) 106 *Quarterly Journal of Economics* 1089.

148 Frank H Easterbrook, 'Cyberspace and the Law of the Horse' (1996) *University of Chicago Legal Forum* 207.