Law, Innovation, & Society
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The Everyday Cyborg: Mapping Legal, Ethical, & Conceptual Challenges

Workshop 2

The addition of non-biological parts and devices to the human body raises novel legal, ethical, and conceptual challenges which have neither been adequately explored nor addressed. Drawing from and extending the work of Haddow and colleagues, we use the term 'everyday cyborg' to describe such integration between persons and things, subject and object, and the organic and inorganic. Thus, for us, everyday cyborgs are persons with simple prostheses and implants, as well as those with more complex replacements and augmentations. Some examples of these include artificial joint replacements and aesthetic limbs, internal cardioverter defibrillators and implantable pacemakers, externally worn insulin pumps, and retinal prostheses and myoelectric prosthetic limbs.

As technology develops and these parts and devices become more sophisticated and deeply integrated into the human body, new questions emerge which the law is ill equipped to deal with. The increasing ubiquity of these prostheses and implants and the diverse functions that they perform further compound these difficulties. For some of the issues in this context, please refer to the first workshop report (available on request from the organisers).

This second workshop brought together experts from law and legal practice, philosophy, science and technology studies, the social sciences, and the biomedical sciences to continue with the identification and mapping process that began at the first workshop, and to provide a forum for interdisciplinary discussion. Short summaries of the papers and discussions are presented here.

Everyday Cyborgs represent the literal integration of persons & technology

Session 1 – Medical Devices, Everyday Cyborgs, & Regulatory Challenges I

Speakers: Prof. Daithí Mac Síthigh, Ms Judith Rauhofer

Daithí Mac Síthigh

The Everyday Cyborg: A Question of Cyberlaw?

Many IT laws are now being revisited and revised to accommodate the changes that have taken place and issues that have arisen since they were first enacted

The law relating to information technology has been the subject of development since the 1990s. Notable reforms include the introduction of the UK Computer Misuse Act 1990 (the first specific computer crime legislation in the UK), the European Union (EU) Data Protection Directive in 1995, the EU Electronic Commerce Directive in 2000, the Information Society (copyright) Directive in 2001, and the Budapest Convention on Cybercrime in 2001. This presentation explored how Information Technology (IT) Law has been shaped by these developments, where we are now, and what are the challenges in relation to the interaction between law and technology. In particular, it considered what this body of law mean for the issues raised in the 'Everyday Cyborg' project. Given that a number of these laws were first attempts to address the issues raised by emerging technologies, they are in some ways ill-equipped to deal with the challenges arising from current technologies and the changing nature of these technologies. Consequently, they are now being revisited and revised to accommodate the changes that have taken place and issues that have arisen since they were first enacted. Additionally, new legislation regarding current concerns such as autonomous vehicles and algorithmic transparency, are about to be implemented. With regard to the implications of these developments in IT law for everyday cyborgs, a number of observations can be made.

The first concerns the issue of definitions, specifically, the need for legislation to provide these or choose not to do so, and to identify its scope and limits. For example, the Computer Misuse Act does not provide a definition for what constitutes a computer. This has been problematic in identifying whether a device or action in respect of a device falls within the remit of the Act, particularly, when considering prosecutions under the Act. Prosecutors have attempted to resolve the problem by referring to the definitions of computer in other areas of law such as the law of evidence. The second observation relates to the issue of defences, in particular, how should the law work these out and how can it strike the right balance and facilitate 'normal' use. As an example, the Data Protection Directive contains an exemption from the rules on protecting personal data where that data is processed for journalistic activities. Questions have arisen in cases as to what constitutes 'journalistic' in this context. The broader issue here is that the law cannot define everything because concepts evolve and exceptions can become problematic or even redundant. The third observation is about drafting choices, specifically, the extent to which the law should be specific and broad. For instance, should law and regulation in this context be 'technologically neutral'? Mac Síthigh suggested that the idea that laws can make no reference to specific technologies is unrealistic because legislators usually have specific use and technologies in mind when drafting these and often use existing provisions in one area as a template/starting point, and then modify and add other definitions as appropriate. Another question that the law has to confront in this context is how it identifies the balance of rights that exist, how this balance is reflected in a technological context, and managed in light of changing conditions.

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Judith Rauhofer

The Internet of Bodies – What Could Possibly Go Wrong?

The 'Internet of Bodies' is a term that is often used to refer to the next generation of the 'Internet of Things'. It has been coined to describe the shift that has occurred in this context from a collection of objects connected to the internet and each other, to a scenario where those devices are attached to, or incorporated within the human body, and constantly generate, collect, and transmit a continuous stream of information about a person's health status or bodily functions. Examples of these devices include pacemakers, cochlear implants, and digital pills. While there may be a number of reasons why these devices are attached to the body, ranging from medical treatment, medical research, or elective physical enhancement, much of the privacy issues associated with the Internet of Things are raised and amplified in this context because most of the data collected by these devices can be classified as sensitive personal data which is accorded special protection under the EU data protection law.

This paper examined the data protection and privacy issues arising from the Internet of Bodies and 'everyday cyborgs'. For instance, 'what measures do we need to put in place to ensure that the established principles of data minimization, purpose limitation, and limited retention are met?' Rauhofer argued that the best way to minimise data abuse is to minimise data generation in the first place. The less data we have, the less people can use it in an unauthorised way. However, this might be problematic because of resistance from device manufacturers and industry who are becoming increasingly data heavy and whose focus appears to be to collect as much data as possible even if the purpose and use of the data is not known, in the hope that something will come of it.

Another question addressed was how consent can be considered voluntary in the medical device context, especially where individuals might have to make a choice between a life-saving treatment and a refusal to use such devices? Rauhofer argued that individual consent cannot be the focus of the legal framework, but rather that data sharing should be premised upon the public interest and whether disclosure of data is in the public interest. In addition, she suggested that the law might need to exclude certain data uses. This approach would be similar to that adopted in consumer protection law, where companies are prevented from putting certain provisions in a contract because it would be to the detriment of a consumer (even if a consumer would have ordinarily consented to those provisions). Furthermore, there is a need to focus on the bigger questions which will necessarily involve a better understanding of the short, medium, and long term risks of data collection/usage, the potential harms that could result from these (tangible/intangible, individual/collective/societal), and the power imbalances between data subjects, the medical establishment, the industry, and the state.

Session 2 – Medical Devices, Everyday Cyborgs, & Regulatory Challenges II

Speakers: Prof. Marie Fox, Prof. Jean McHale, Dr Mark Flear

Marie Fox

Troubling Legal Embodiment: Haraway's Everyday Cyborgs and Embodied Integrity

This paper re-examined the conception of the 'cyborg' in Donna Haraway's work by analysing the implications of her first Cyborg Manifesto (and second manifesto on companion species) for a materialist feminist legal theory. Fox discussed Haraway's potential influence in relation to the

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rethinking of the legal concept of bodily integrity. Drawing from her recent work with Michael Thomson, which sought to 'articulate a more relational and less static or boundaried conception' of embodied integrity, she explored the effects of discourses of bodily integrity and the role of these in reinforcing 'conceptions of the human and of legal personhood'.

Everyday cyborgs challenge traditional perceptions of bodily Integrity and 'personhood', but 'this challenge is simultaneously contained' because the notion of the cyborg is 'tied to humanist conceptions of the person'. Fox argued that Haraway does not tie the cyborg to personhood in the same way as recent work in this area, but rather that the cyborg is informed and transformed in Haraway's work by reference to companion species. She suggested that the law needs to move away from an invasion narrative which sees bodies as fixed/static to a notion of embodied integrity because 'embodiment shifts attention from the singular body or even multiple bodies as objects of analysis by mandating a broader focus on lived experience and the question of how we inhabit and experience the world through our bodies' (Fox & Murphy, 2013).

Jean McHale

Brexit, Medical Devices- and the Government's Elusive Impact Case Study

In this presentation McHale discussed some initial observations from an ongoing ESRC Brexit Priority project: 'Health Law Outside the EU: Immediate, Intermediate, and Long Term Impacts'. She examined the implications of Brexit for the regulation of medical devices in the immediate, intermediate, and long term future in the UK. As a member state of the EU, the regulation of medical devices in the UK has been guided by the EU Medical Devices Directives - the UK's Medical Devices Regulations 2002 implements three European Union Directives. However, the introduction of new EU Medical Devices Regulations in May 2017 which replace the Directives, coupled with the implications of Brexit, poses particular problems for medical device regulation in the UK.

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The new Regulations (Regulation (EU) 2017/745 on medical devices – MDR - and Regulation (EU) 2017/746 in vitro diagnostic medical devices – IVDR) are scheduled to be fully implemented by Spring 2020 and 2022, respectively. We are currently in the transition period where stakeholders are still subject to the old Regulations but can choose to adopt the new regulations. With the UK set to leave the EU on 29th March 2019, this implementation timetable creates uncertainties regarding medical device regulation in this jurisdiction. However, if the UK wants to trade with the EU, then regulatory alignment will be necessary. In particular, its framework will need to be compliant with various aspects of the EU system such as CE marking.

Mark Flear

EU Regulation of Medical Devices: Sociotechnical Order and Implications for Brexit

In Flear's previous work, he examined the impact of the EU's regulatory approach on the development of health technologies including medical devices. He suggested that EU law and regulation largely seeks to facilitate and safeguard the commercial availability of products that comply with safety and quality standards. Additionally, he argued that this is 'underpinned by a specific sociotechnical imaginary,' that of the 'EU as a human rights and bioethics friendly market' organisation. At the workshop, he explored the concept of imaginaries, specifically, the sociotechnical imaginaries of the EU and the UK and the implications arising from these.

Sociotechnical imaginaries in this context can be defined as 'collectively held, institutionally stabilised, and publicly performed visions of desirable futures, animated by shared understandings of forms of social life and social order attainable through, and supportive of,

advances in science and technology' (Jasanoff, 2015). Flear contended that the particular market orientation of the EU has implications for the UK and its impending exit from the Union. In particular, following its departure from the EU, the UK will need to ensure that its regulatory framework for health technologies comply with EU law and regulation. This, he argued, is 'underpinned by the EU's need and desire to perpetuate its sociotechnical imaginary and through it to maintain its legitimacy'. By ensuring its law and regulation aligns with that of the EU, the UK will also be aligning its sociotechnical imaginary with the EU's. Furthermore, he suggested that 'the Institutional reality of EU and global standard setting' means that in relation to medical devices regulation, the UK will be at a disadvantage once it departs from the Union. Rather than its present position as part of the EU where it is involved in helping to set the standards, the UK will need to comply with standards set by others.

Session 3 - How to Think About Everyday Cyborgs?

Speakers: Dr Aisling McMahon, Ms Catriona McMillan

Aisling McMahon

Patents, the Human Body, and the Biotechnology Directive 98/44EC

Advances in biotechnology pose a number of ethical questions for the patent system. Some of these include: 'whether and to what extent biotechnological inventions should be patentable?' and 'whether isolated elements of the human body, e.g. genes, should be patentable?' In this paper McMahon analysed the conception of the human body and associated inventions within the European Biotechnology Directive 98/44EC for the patentability of biotechnological inventions. It explored how these are conceptualised within the Directive. She suggested that the conception of the human body within the Directive is based upon arbitrary technical distinctions which are no longer sustainable in view of developments in biotechnology and the changing nature of these technologies.

The conception of the 'human body' within the European Directive is based upon arbitrary technical distinctions which are no longer sustainable in view of developments in biotechnology and the changing nature of these technologies

One of these technical distinctions is that drawn between the body and isolated elements of the body. Under this distinction, the body as a mere discovery is not patentable, but isolated elements of the body or those that are produced by technical means are patentable. This distinction, McMahon argued, is 'wholly artificial' and does not reflect the potential impact that patents on isolated elements of the body could have upon downstream interactions relating to bodies. For instance, a patent granted in respect of an isolated gene could potentially restrict who can isolate that gene, and thus restrict diagnostic testing.

Additionally, questions arise as to whether the conception of the 'human body' under Art 5 of the Directive includes an 'element' attached onto or incorporated into the human body. For example, where a prosthetic device is patented, does the device upon attachment or implantation *become* part of the body and thus unpatentable? She suggested that in view of the narrow conception of the human body within the Directive, it does not because the nature of the prostheses (the invention) is unaltered. Furthermore, questions also remain regarding what impact (if any), such patents could have on the actions of individual patients once a prosthetic device has been attached onto (or implanted within) the body.

Examining the law & everyday cyborgs through a liminal lens might more effectively accommodate the 'transformative, processual nature' of these entities

Catriona McMillan

The Liminality of Everyday Cyborgs

McMillan discussed everyday cyborgs and the conceptual and legal issues associated with these through the lens of liminality. A concept associated with the work of Arnold Van Gennep, liminality is used in anthropology in relation to processes of change and transformation. It is a way of thinking about issues of uncertainty and instability arising from these. She drew on some of the findings from the on-going Liminal Spaces Project to offer an analysis of everyday cyborgs as liminal beings/entities. The Liminal Spaces Project explores the 'spaces in between' (or liminal spaces) law and practice in the field of health research.

McMillan argued that everyday cyborgs transgress normative legal and biological boundaries and exemplify the type of challenges that the law has to address when faced with those who occupy liminal spaces. In addition, the devices that are attached to or incorporated within the cyborg are also between legal boundaries. She contended that the law is ill equipped to address the challenges and has yet to answer many of the questions raised in this context. She suggested that if law were to analyse some of these challenges and questions through a liminal lens ('for example, are everyday cyborgs permanently liminal'), it might more effectively accommodate the 'transformative, processual nature of everyday cyborgs'.

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