The Six Million Dollar Man: Regulatory Challenges and Strategies in the Age of the Cyborg

I Introduction

"Better. Stronger. Faster". That was the phrase used to describe astronaut Steven Austin after he was rebuilt as a cyborg in the 1970's television series, *The Six Million Dollar Man*. At the time, the existence of a man-machine hybrid with such astounding abilities was confined to the realm of science fiction. However, rapid technological advances have brought such a prospect within the ambit of reality. Today's biomedical engineers have developed prostheses which confer the ability to *hear* colour,[1] move following signals from the spinal cord,[2] and restore feelings to amputees through neural pathways.[3] Regulators of such technologies face unique challenges which call into question the partite nature of the underlying legal framework. This paper will outline such challenges and the strategies which may be employed to address them.

II The Current Regulatory Framework

Before proceeding, it is necessary to define 'cyborg'. Grant Gillett provides an apt description- cyborgs are "part human, part machine complexes which function as a whole." [4] This paper is less concerned with static devices such as hip replacements, instead focusing on invasive technology which can be programmed to perform a task within the body; substituting or augmenting ordinary physiology through a feedback loop. A cyborg can range from a person implanted with a pacemaker to someone using a Brain Computer Interface (BCI) to control the movement of a prosthetic.

In New Zealand, regulation of medical devices is delegated to the Medicines and Medical Devices Safety Authority (MedSafe) under statute. The Medicines Act 1981 defines a medical device as "any device, instrument, apparatus, appliance, or other article that is intended to be used in, on, or for human beings for a therapeutic purpose." Therapeutic purpose is not limited to remedial measures but covers a broad range of objectives, including modification of the human anatomy or physiology.[5]

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[1] Benjamin Wittes and Jane Chong *Our Cyborg Future: Law and Policy Implications* (Brookings, Washington D.C., 2014) at 10.
[2] Christopher McFadden "13 Prosthetic Arms and Legs and More That Appear to have Come from the Future" (4 August 2018) Interesting Engineering <www.interestingengineering.com> at [11].
[3] Arizona State University. "New prosthetic hand system allows user to 'feel' again: The Neural-Enabled Prosthetic Hand (NEPH) system marks first time bidirectional prosthesis can be used in home setting." (7 November 2018) Science Daily <www.sciencedaily.com >.
[4] Grant Gillett "Cyborgs and Moral Identity" (2006) 32 J Med Ethics 79 at [1].
[5] Medicines Act 1981, s 4.

Similarly to Australia and the European Union, medical devices in New Zealand are categorized according to risk. Devices of the nature discussed are deemed high risk and accordingly fall into either Class III or Class AIMD. A manufacturer must upload product information to the Web Assisted Notification of Devices (WAND) Database but MedSafe approval is not required before the device can be marketed.[6]

The current regulations are minimal and product focused. Delegation to a regulatory body and the generality of the statutory language aid in preventing descriptive disconnection as technology advances. However, the framework does not do enough to protect the safety of end-users, nor does it address the pluralistic nature of cyborgs. New draft legislation requires pre-market approval of medical devices by MedSafe. The authority must be satisfied that the device is safe and efficacious, and the likely risks of use are outweighed by the likely benefits.[7] Although this legislation is an improvement, it remains limited in scope and focused on pre-implantation safety rather than the treatment of devices once integrated with the person.

The risk/benefit analysis regulators are required to perform under the proposed legislation is ambiguous regarding the level of risk a device may pose and still be approved. It contains no provision requiring a strong precautionary approach or the minimization of potential harm, hence the regulatory tilt is arguably permissive. This is likely because the drafters were envisaging technology designed to restore lost bodily function, which has huge public policy benefits and raises minor ethical qualms. Medical devices which challenge society's fundamental conception of humanism and confer abnormal abilities require explicit contemplation by regulators.

II Regulatory Challenges and Strategies

A Upstream Regulation and Ethical Debate

The ethical pluralism which exists in the cyborg debate makes regulating difficult. For decades, art and literature have fostered the 'man against machine' rhetoric; the idea that cyborgs are the competitors of the 'natural human' and technology will inevitably turn against its makers.[8] Those who fear this narrative advocate for a restrictive approach to regulation or outright prohibition.

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[6] Ministry of Health *Therapeutic Products Regulatory Scheme: Consultation document* (December 2018) at 6.
[7] Ministry of Health *Draft for Consultation: Therapeutic Products Bill* (2018) s 95.
[8] Ronald Leenes and others "Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues" (2017) 9(1) Law, Innovation and Technology 1 at 21.

Biomedical engineering is nevertheless recognized by many as an invaluable tool capable of restoring function to impaired individuals. Few have moral concerns with the implantation of pacemakers to treat arrythmia. However, the more advanced technology becomes, the greater the caveats placed on its use. These caveats present themselves as a simple fear of the unknown, but stem from a deep-rooted aversion to the idea that the 'self' is malleable rather than defined by strict parameters.

The knee-jerk solution to ethical pluralism is self (rather than state) regulation. Under this framework, consumers have the choice whether or not to have medical devices implanted. The current New Zealand regulatory scheme is largely libertarian by virtue of omission. There are no outright prohibitions on specific devices or procedures (bar xenotransplantation), although this is likely because advanced technologies such as BCI's are not yet marketable. Self-regulation is problematic for two main reasons. First, it does not solve the problem of how to treat cyborgs once 'created', nor what rights to afford them. Second, the decisions made by individuals are not self-regarding. A person who elects to enhance their body through machine integration automatically renders the 'non-enhanced' at a cognitive or physical disadvantage.[9]

Given the embryonic nature of biomedical engineering, regulators face a paradox. Early regulation is problematic because many of the risks associated with novel medical devices are unknown and cannot be evaluated in a cost/benefit analysis. Additionally, regulations risk being outpaced by innovation. Conversely, late regulation creates interim uncertainty, leaving manufacturers and consumers unsure where they stand. Under-regulation may stifle technological process to the same extent as over-regulation, as developers attempt to operate in a regulatory void with indeterminate costs and liabilities.

A primitive solution to this 'pacing problem' is framing regulations in technologically neutral language which is capable of covering a broad range of medical devices as they morph and evolve. The trade-off to this flexibility is legal certainty. However, the delegation of regulatory power from Parliament to MedSafe is likely to increase the responsiveness of regulation to technological change through reducing red tape.

B Person vs Property

[9] Erica Palmerini "A legal perspective on bodily implants for therapy and enhancement" (2015) 29(2-3) International Review of Law, Computers and Technology 226 at 239.

Law functions as a boundary-maker. It draws a line in the sand between what is right and wrong. However, it also firmly distinguishes between 'people' and 'things'; the latter commodified and the former inalienable. Cyborgs merge the biological human with the inorganic device, raising questions which challenge the implicit dichotomy between subject and object.[10] Muireann Quigley writes:[11]

> By constructing medical devices as risk objects … we fix them in time and substance. They are what they are at the time of implantation: objects discrete from persons. They are conceptually removed from the embodied (or at least conjoined) future for which they are destined.

The distinction drawn between property and personhood is illustrated in the case of *R v Bentham*, where the appellant stuck his fingers inside his jacket to give the appearance he had a gun in order to facilitate a robbery.[12] The Court of Appeal found him guilty of possessing an imitation firearm, but this decision was overturned by the House of Lords. Lord Bingham stated "No-one cannot possess something which is not separate and distinct from oneself. An unsevered hand or finger is part of oneself. Therefore, one cannot possess it."[13] A prerequisite of property is therefore that it is distinct from the person. This does not pose problems for medical devices before they are attached or implanted, but should the boundary be maintained after integration?

Crimes against the person are treated significantly more seriously than crimes against property. The maximum penalty for wounding with intent is twice the maximum penalty for intentional damage to property.[14] This reflects the heightened moral value placed on the right to bodily integrity as compared to proprietary rights. But surely the law ought to distinguish between damage to household commodities and damage to a prosthetic limb which is of the same importance to an amputee as its biological equivalent is to an ordinary human? The segregation of law into regulatory 'silos'; premised on the body as disparate from its environment, needs reworking.

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[10] Muireann Quigley and Semande Ayihongbe "Everyday Cyborgs: On Integrated Persons and Integrated Goods" (2018) 26(2) Med.L Rev 276 at 288.
[11] At 286.
[12] *R v Bentham* [2005] UKHL 18.
[13] At [8].
[14] Crimes Act 1961 s 188 and s 269.

Linda MacDonald Glenn describes the case of a quadriplegic veteran who requires a mobility assistance device to function.[15] The device, although not permanently integrated with the body, acts as an extension of the lower limbs and is essentially a prosthetic. It was damaged beyond repair by an airline in transit, rendering the veteran bedridden for 11 months (causing ulcers to develop). The airline argued that the damage was merely to the device and not the person. Although the matter was settled out of Court, it is unlikely that a Judge would have conceded that the device was an extension of the body rather than a separate object. However, there would be serious legal repercussions if the airline had harmed the veteran's biological person, even if the resulting damage was less dire. Glenn uses the case to highlight the incongruities which follow from the strict person-property dichotomy. She poses the metaphysical (but quasi-legal) question of how much of a human being can be replaced until they cease to become human, a puzzle which parallels the "Ship of Theseus" thought experiment.[16]

A further challenge for regulators in the criminal sphere is addressing the liability of 'bio-hackers' who cause damage indirectly through interference with a device's ability to supplement or replace bodily function.[17] The margin between crimes against the person and cybercrime becomes blurred in such scenarios. It is questionable whether hacking causing bodily injury, or in severe cases, death, can be prosecuted as an offence against the person under the Crimes Act given that the actus reus is usually a direct physical act.[18] Instead, Section 250 and 252, which concern damage to and unauthorized access to a computer system respectively, are likely to apply in such a case. The statutory definition of 'computer system' is broad enough to include implanted medical devices which store data provided a communicative link exists with another device.[19] Techno-exceptionalism is arguably unnecessary given the ability of the existing law to cover novel situations. Hacking into a neuroprosthetic with intent to injure somewhat parallels the hijacking of a hospital's life support system, which is contemplated in the current legal framework.

Much has been made of the strict categorization system the law imposes on that which it regulates. Nevertheless, the categories are not fixed indefinitely but are moulded over time by

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[15] Linda MacDonald Glenn "Case Study: Ethical and Legal Issues in Human Machine Mergers (Or the Cyborgs Cometh)" (2012) 21(1) Annals Health L 175.
[16] This experiment essentially asks 'As the components of the ship are gradually replaced, at what point is it no longer the original ship?'. See also *Sorites Paradox*.
[17] Mark N Gasson and Bert-Jaap Koops "Attacking Human Implants: A New Generation of Cybercrime" (2013) 5(2) LIT 248.
[18] See Crimes Act 1961 s 189 (Injuring with Intent).
[19] s 248.

social norms and technological development. One only has to flick through a legal history book for evidence of this: women were originally 'commodified' as property, later prohibited from commodifying their bodies, and later still granted the right to self-determination through prostitution reform. A similar narrative exists regarding slavery and people of colour. It is easy to renounce these historical episodes, but what they ultimately demonstrate is the law's fluid approach to personhood. Given that bodies were once treated as things, it is not inconceivable that things be treated as part of the body- especially when they function as one.

Although devices such as neuro-prostheses are revolutionary, the merging of humans with technology is not unprecedented. For example, the advent of the internet has enabled the storing of memories and information externally rather than in the brain.[20] What makes drawing the boundary between body and object difficult in the present case is their vital interplay and the inability to separate one from the other.

A regulatory shift in paradigm is already occurring. The Supreme Court of the United States in *Riley v California* held that a cellphone could not be searched without a warrant, stating:[21]

> Modern cell phones … are now such a pervasive and insistent part of daily life that the proverbial visitor from Mars might conclude they were an important feature of human anatomy.

Although Roberts CJ was speaking metaphorically, the decision highlights judicial recognition of the indeterminacy of the bodily boundary. The German Civil Senate has also recognized that the concept of the 'body' extends beyond the amalgamation of its physical parts, holding that the destruction of frozen sperm constituted bodily injury despite precedent which treated removed organic matter as objects possessed by the subject rather than part of the subject themselves.[22] While medical devices are synthetic rather than biological, they form a "functional utility" with the natural body and hence should be treated as such.

The preceding discussion highlights the need for regulators to recognize that the body is becoming a problematic boundary marker. Current regulations, which treat medical devices as objects, do not adequately address their classification once integrated with the person.

C Therapy vs Enhancement

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[20] Bert-Jaap Koops "On Legal Boundaries, Technologies, and Collapsing Dimensions of Privacy" (2014) 3(2) Politica e Società 247 at 4.
[21] *Riley v California* 573 US. 373 (2014) at [7] per Roberts CJ.
[22] [1993] 124 BGHZ 52.

The installation of a pacemaker to monitor and normalize heart rhythm is fundamentally different from the fitting of a cochlear implant in a healthy ear to enable hearing at frequencies outside of biologically defined parameters. Society makes a normative distinction between therapy (correcting a health problem) and enhancement (improving 'normal' function). Technological advances blur the line between these treatments and raise key questions for regulators, the preliminary one being how to define normality.

Media portrayal of cyborgs as lacking the human capacity for mercy, empathy, and self-reflection has fostered an 'Us and Them' dichotomy. Although technological integration will extend capabilities, it is feared we will lose our humanity and "taint nature" in the process.[23] Enhancement is also associated with cheating and unfair advantage- as evidenced by Oscar Pistorius's plight to compete in the 2008 Olympic Games on his carbon-fibre prosthetics.[24]

These concerns are not specific to cyborgs. The use of cognitive enhancers has already become ubiquitous; just look down at the cup of coffee on your desk for proof. Examples of legal 'enhancements' abound- from vaccinations to hormone replacers. Smart phones and laptops enable humans to store information and communicate in ways which were inconceivable just decades ago, and the advent of Google Glass suggests that the integration of the biological with the synthetic to improve capabilities is coming sooner than anticipated.[25] The bright line between acceptable 'therapy' and unacceptable 'enhancement' is better represented as a continuum. Proponents of the 'slippery slope theory' fail to realize that society is already sliding down it.

Augmentation advocates see the ability to enhance oneself as intrinsically linked to the right of self-determination. In his draft *Magna Cortica* (a quasi-statute concerning cognitive enhancement), Jamais Cascio includes the right to self-modification.[26] From an efficiency standpoint, the integration of humans with technology to expand neurological and physical capabilities is entirely positive. A libertarian approach yields the same conclusion. Applying John Stuart Mill's harm principle, there is no justification for limiting an individual's right to act freely when such action poses no harm to others.

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[23] John Hewitt "The Magna Cortica: A bill of rights for our future, implant-enhanced brains" (14 May 2014) ExtremeTech <www.extremetech.com>.
[24] Terence Davidson "Should Oscar Pistorius be Allowed to Compete at the Olympic Games?" (MA Thesis, Victoria University of Wellington, 2013).
[25] Wittes and Chong, above n 1 at 11.
[26] Jamais Cascio "Magna Cortica" (13 May 2014) Open the Future <openthefutore.com>.

The problem is that self-enhancement does not operate in a vacuum, hence relative subordination may be seen as a 'harm'. As stated in the Nuffield Report on Novel Neurotechnologies:[27]

> The public (as opposed to individual) benefit that would be served by widespread enhancement is questionable when individual positional advantages enjoyed by those with improved capacities are, inevitably, enjoyed at the expense of others.

What initially appears a matter of choice may become an ultimatum: evolve or die. It is not inconceivable that legally permitting citizens to enhance their bodies through becoming 'cyborgs' will cause a technological arms race as people scramble to secure a cognitive or physical advantage over their peers. But could this argument not be advanced against existing 'commodities', such as education?

A regulatory challenge specific to cyborgs is how to address human enhancement when it is a corollary to therapy. Legal prohibition of the former may inadvertently condemn the latter. A bionic arm is much stronger than its biological counterpart and not as sensitive to damage. The antenna attached to Neil Harbisson's skull not only corrects his achromatopsia by enabling him to 'hear' colour but allows him to perceive ultraviolet and infrared light inaccessible to regular humans.[28] The idea that therapy is the antithesis of enhancement is thus fallacious.

Amartya Sen's 'Capabilities Approach'- built upon by Martha Nussbaum, provides a useful framework for developing regulation. Instead of partitioning technology into two separate boxes, regulators should question what the technology enables people to *do*. Does it extend or enable capabilities such as bodily health, practical reason and affiliation? [29] This approach echoes the argument of transhumanist Nick Bostrom, who proposes that "dignity … consists in what we are and what we have the potential to become, not in our pedigree or our causal origin."[30]

Restrictive regulation risks stifling innovation given that radical enhancement technology is on the horizon rather than the doorstep. Bostrom proposes that the development of legal

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[27] *Novel Neurotechnologies: Intervening in the Brain* (Nuffield Council on Bioethics, June 2013) at 173.
[28] Neil Harbisson, Transpecies Activist "The Human Eyeborg" (Speech at TEDx Gateway, Mumbai, 12 February 2013).
[29] Mark Coeckelbergh "Human development or human enhancement? A methodological reflection on capabilities and the evaluation of information technologies" (2011) 13 Ethics Inf Technol 81.
[30] Nick Bostrom "In Defense of Posthuman Dignity" (2005) 19(3) Bioethics 202 at 213.

mechanisms which protect equality, rather than prohibit enhancement, is a better method of mitigating the risk of a chasm opening up between the non-enhanced and enhanced. He states:[31]

> We can work to create more inclusive social structures that accord appropriate moral recognition and legal rights to all who need them, be they male or female, black or white, *flesh or silicon*.

Such mechanisms should be developed through public consultation given the society-wide implications. Special consideration ought to be given to the views of the disabled who may be especially prejudiced by regulation which limits access to restorative technology.

IV Conclusion

There are significant challenges faced by regulators in the field of 'cyborg law', such as defining the boundary between property and personhood and between therapy and enhancement. However, this is only the tip of the iceberg. The plethora of issues regarding privacy; such as the ownership and use of data generated by medical devices, are not examined here for the sake of brevity but warrant a paper in themselves.

Although the context is novel, similar problems have arisen before in the criminal, property and privacy spheres. A separate 'law of the horse' is neither needed nor practical given the robust nature of the existing law. Instead, regulators must be prepared to expand definitions once viewed as concrete and consider not just the safety of medical devices pre-market but the social, ethical and proprietary implications once integrated with the person.

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[31] At 210.

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