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Medical Devices Regulation

New Concepts and Perspectives Needed

Shawn H. E. Harmon

39.1 INTRODUCTION

This section of the Handbook explores how technological innovations and/or social changes create disturbances within regulatory approaches. This chapter considers how innovations *represent* disturbances with which regulatory frameworks must cope, focusing on innovations that can be characterised as 'enhancing'. Human enhancement can no longer be dismissed as something with which serious regulatory frameworks need not engage. Enhancing pursuits increasingly occupy the very centre of human experience and 'being'; one can observe widespread student use of cognitively enhancing stimulants, the increasing prevalence of implanted technologies, and great swathes of people absently navigating the physical while engrossed in the digital.

Given the diversity of activities and technologies implicated, the rise and mores of the 'maker movement',[1] and the capacity of traditional – commercial – health research entities to locate innovation activities to jurisdictions with desirable regulation, it is impossible to point to a single regulatory framework implicated by enhancement research and innovation. Candidates include those governing human tissue use and pharmaceuticals, but could also include those governing intellectual property, data use, or consumer product liability. The medical devices framework, one might think, should offer a good example of a regime that engages directly and usefully with the concepts implicated by enhancement and the socio-technical changes wrought by enhancing technologies. As such, this chapter focuses on the recently reformed European medical devices regime.

After identifying some enhancements that are available and highlighting what they mean for the person, the chapter introduces two concepts that are deeply implicated by enhancing technologies: 'identity' and 'integrity'. If regulation fails to engage with them, it will remain blind to matters that are profoundly important to those people who are using or relying on these technologies. Their observance in EU Regulation 2017/745 on Medical Devices (MDR),[2] and EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices (IVDR),[3] is examined. It is

[1] C. Howard et al., 'The Maker Movement: A New Avenue for Competition in the EU', (2014) *European View*, 13(2), 333–340; M. Tan et al., 'The Influence of the Maker Movement on Engineering and Technology Education', (2016) *World Transactions on Engineering and Technology Education*, 14(1), 89–94.

[2] Regulation (EU) 2017/745, 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017.

[3] Regulation (EU) 2017/746, 5 April 2017, on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017.

concluded that they are, unfortunately, too narrowly framed and too innovator driven, and are therefore largely indifferent to these concepts.

39.2 ENHANCING INNOVATIONS

Since the first use of walking canes, false teeth and spectacles, we have been 'enhancing' ourselves for both medical and social purposes, but the so-called technological 'revolutions' of late modernity – which have relied on and facilitated innovations in computing, biosciences, materials sciences and more – have prompted changes in the nature and prevalence of the enhancements that we adopt. We now redesign and extend our physical scaffolding, we alter its physiological functioning, we extend the will, and we push the potential capacities of the mind and body by linking the biological with the technological or by embedding the latter into the former.

In the 1960s, Foucault anticipated the erasure of the human being.[4] We might now understand this erasure to be the rise of the enhanced human, which includes the techno-human hybrid (cyborg).[5] This 'posthuman' thinks of the body as the original prosthesis, so extending or replacing it with other prostheses becomes a continuation of a process that began pre-natally.[6] Even if one does not subscribe to the posthuman perspective, 'enhancing' technologies are commonly applied,[7] and are becoming more complex and more intrusive, nestling *within* the body, and performing not only for us, but also on and within us.[8] Examples include a wide range of smart physiological sensors, cochlear implants, implanted cardiac defibrillators, deep brain stimulators, complex prostheses like retinal and myoelectric prosthetics, mind stimulating/expanding interventions like nootropic drugs, neuro-prosthetics, and consciousness-insinuating constructs like digital avatars, which allow us to build and explore wholly new cyber-environments.

These technologies have many labels, but they all become a part of the person through processes of bodily 'incorporation', 'extension' or 'integration'.[9] Depending on the technology, they allow the individual to generate, store, access and transmit data about the physiological self, or the physical or digital realms they occupy/access, making the individual an integral element of the 'internet of things'.[10] The resultant 'enhanced human' not only has new material characteristics, but also new sentient and sapient capacities (i.e. to experience sensation or to reason and cultivate insight). In all cases, the results are new forms of co-dependent

[4] M. Foucault, *The Order of Things: An Archaeology of the Human Sciences* (London: Routledge, 1966).

[5] See D. Haraway, *A Cyborg Manifesto: Science, Technology and Social Feminism in the Late Twentieth Century* (London: Routledge, 1991).

[6] N. Hayles, *How We Become Posthuman: Virtual Bodies in Cybernetics, Literature and Informatics* (University of Chicago Press, 1999); S. Wilson, 'The Composition of Posthuman Bodies', (2017) *International Journal of Performance Arts & Digital Media*, 13(2), 137–152.

[7] D. Serlin, *Replaceable You: Engineering the Body in Postwar America* (University of Chicago Press, 2004).

[8] S. Harmon et al., 'New Risks Inadequately Managed: The Case of Smart Implants and Medical Device Regulation', (2015) *Law, Innovation & Technology*, 7(2) 231–252; G. Haddow et al., 'Implantable Smart Technologies: Defining the 'Sting' in Data and Device,' (2016) *Health Care Analysis*, 24(3), 210–227.

[9] M. Donnarumma, 'Beyond the Cyborg: Performance, Attunement and Autonomous Computation', (2017) *International Journal of Performance Arts & Digital Media*, 13(2), 105–119; A. Brown et al., 'Body Extension and the Law: Medical Devices, Intellectual Property, Prosthetics and Marginalisation (Again)', (2018) *Law, Innovation & Technology*, 10(2), 161–184; M. Quigley and S. Ayihongbe, 'Everyday Cyborgs: On Integrated Persons and Integrated Goods', (2018) *Medical Law Review*, 26(2), 276–308.

[10] The billions of objects linked in networks and exchanging information now includes us, all melting into the fabric of our personal, social, and commercial environments: S. Gutwirth, 'Beyond Identity?', (2008) *Identity in the Information Society*, 1(1), 123–133.

human-technology embodiment. Even more radical high-conscious beings can be envisioned. Examples include genetically designed humans, synthetically constructed biological beings, and artificially intelligent constructs with consciousness and self-awareness.[11] The possibility of more radical high-conscious beings raises questions about status that are beyond the scope of this chapter.[12]

39.3 CORE CONCEPTS IMPLICATED BY THE NEW HUMAN ASSEMBLAGE

This increasingly complex and commonplace integration of bodies and technologies has given rise to theories of posthumanism and new materialism to which the law remains largely ignorant.[13] For example, there is a growing understanding of the person as an 'assemblage', a variably integrated collection of physiological, technological and virtual elements that are in fluid relation to one another, with some elements becoming prominent in some contexts and others in other contexts, with no one element being definitive of the 'person'.[14] The person has become protean, with personhood-defining/shaping characteristics that are always shifting, often at the instigation of enhancing technologies. This conditional state – or variable assemblage – with its integration and embodiment of the technological, makes concepts such as autonomy, privacy, integrity, and identity more socially and legally significant than ever before. For reasons of space, I consider just integrity and identity.

Integrity often refers to wholeness or completeness, which has both physical and emotional elements, both of them health-influencing. Having physical integrity is often equated with conformity to the 'normal' body. The normativity of this concept has resulted in prosthetic users being viewed as lacking physical integrity.[15] However, there is a growing body of literature suggesting that physical integrity need not impose compliance with the 'normal' body.[16] Tied to the state of physical integrity – however we might define it – is the imperative to preserve physical integrity (i.e. to respect the individual and avoid impinging on bodily boundaries), and this implicates emotional/mental integrity. One study uncovered twelve conceptions of integrity, concluding that integrity is supported or undermined by one's view of oneself, by others with whom one interacts, and by relationships.[17] Ultimately, integrity is a state of physical and emotional/existential wellness, both of which are influenced by internalities and externalities, including one's relationship with oneself and others. Critical elements of integrity – feelings of

[11] The first practical technology for genetically designed humans – CRISPR Cas-9 – is being refined and applied: S. Harmon, 'Gene-Edited Babies: A Cause for Concern', (2019, *Impact Ethics*), www.impactethics.ca/2019/03/08/genome-edited-babies-a-cause-for-concern. Synthetic beings would be the result of designed biological systems relying on existing and new DNA sequences and assembled to support natural evolution: J. Boeke et al., 'The Genome Project—Write', (2016) *Science*, 353(6295), 126–127. Multiple fields are working on artificial human-type cognitive function, which involves perception, processing, planning, retention, reasoning, and subjectivity: V. Müller (ed.), *Fundamental Issues of Artificial Intelligence* (Cham, Switzerland: Springer, 2016).

[12] D. Lawrence and M. Brazier, 'Legally Human? "Novel Beings" and English Law', (2018) *Medical Law Review*, 26(2), 309–327.

[13] R. Braidotti, *The Posthuman* (Polity Press, 2013); R. Dolphijn and I. van der Tuin, *New Materialism: Interviews and Cartographies* (Open Humanities Press, 2012).

[14] G. Deleuze and F. Guattari, *A Thousand Plateaus* (London: Continuum, 1987); M. DeLanda, *Assemblage Theory* (Edinburgh University Press, 2016).

[15] T. Tamari, 'Body Image and Prosthetic Aesthetics: Disability, Technology and Paralympic Culture', (2017) *Body & Society*, 23(2), 25–56.

[16] S. Harmon et al., 'Moving Toward a New Aesthetic' in S. Whately et al. (eds), *Dance, Disability and Law: Invisible Difference* (Bristol: Intellect, 2018) pp. 177–194.

[17] I. Widäng and B. Fridlund, 'Self-Respect, Dignity and Confidence: Conceptions of Integrity among Male Patients', (2003) *Journal of Advanced Nursing*, 42(1), 47–56.

wholeness, of being 'onself', or of physical security,[18] notions of optimal functioning, interactions with others,[19] and so on – are agitated when technologies are introduced into the body, and there is scope for the law to modulate this agitation, and encourage wellness.

Identity has been described as a mix of *ipse* and *idem*[20] (see also Postan, Chapter 23 of this volume). *Ipse* refers to 'self-identity', the sense of self of the human person, which is reflexive and influenced by internalities such as values and self-perceptions. It is the point from which the individual sees the world and herself; there is nothing behind or above it, it is just there at the source of one's will and energy, and it is persistent, continuous through time and space but by no means stable.[21] *Idem* refers to 'sameness identity', or the objectification of the individual that stems from categorisation. One might hold several *idem* identities depending on the social, cultural, religious or administrative groups to which one belongs (i.e. the range of public statuses that may be assigned at birth or throughout life, or imposed by others). It expresses the belonging of one to a category, facilitating social integration. Ultimately, identity is both internal and fluid, and external and equally fluid, but also potentially static.[22] It can be constructed, chosen or imposed. It can be fragmented and aggregated, and it can be commodified. Both *ipse* and *idem* elements will be shaped by enhancing technologies, both mechanical and biological, which have been described as 'undoing the conventional limits of selfhood and identity'.[23] Empirical research has found that both elements of identity in prosthetic users, for example, are deeply entangled with their devices.[24]

Of course, neither integrity nor identity are unknown to the law. Criminal law seeks to protect our physical integrity, and it punishes incursions against it. Human rights law erects rights to private and family life, which encompass moral and physical integrity and the preservation of liberty.[25] Health law erects rights to physical and mental integrity through mechanisms such as consent, best interests and least restrictive means.[26] Law is also a key external shaper of identity, creating groups based on factors such as developmental status (i.e. rights of fetuses to legal

[18] G. Haddow et al., 'Cyborgs in the Everyday: Masculinity and Biosensing Prostate Cancer', (2015) *Science as Culture*, 24(4), 484–506.

[19] How others perceive us is linked to how they look at us. Staring is the complex phenomenon of observation and internalisation with many facets: R. Garland-Thomson, *Staring: How We Look* (Oxford University Press, 1996). It is often defined as an oppressive act of disciplinary looking that subordinates the subject: L. Mulvey, 'Visual Pleasure and Narrative Cinema', (1975) *Screen*, 16(3), 6–18; F. Michel, *Foucault Live: Interviews, 1961–1984* (Semiotext(e), 1996); A. Clark, 'Exploring Women's Embodied Experiences of 'The Gaze' in a Mix-Gendered UK Gym', (2017) *Societies*, 8(1), 2.

[20] M. Hildebrandt, 'Profiling and the Identity of the European Citizen' in. M Hildebrandt and S. Gutwirth (eds), *Profiling the European Citizen: Cross-Disciplinary Perspectives* (Berlin: Springer, 2008), pp. 303–326.

[21] Gutwirth, 'Beyond Identity?'

[22] S. Lasch and J. Friedman (eds), *Modernity and Identity* (Oxford: Blackwell, 1992); D. Polkinghorne, 'Explorations of Narrative Identity', (1996) *Psychological Inquiry*, 7(4), 363–367; A. Blasi and K. Glodis, 'The Development of Identity: A Critical Analysis from the Perspective of the Self as Subject', (1995) *Developmental Review*, 15(4), 404–433; L. Huddy, 'From Social to Political Identity: A Critical Examination of Social Identity Theory', (2001) *Political Psychology*, 22(1), 127–156.

[23] M. Shildrick, 'Individuality, Identity and Supplementarity in Transcorporeal Embodiment' in K. Cahill et al. (eds), *Finite but Unbounded: New Approaches in Philosophical Anthropology* (Berlin: de Gruyter, 2017), pp. 153–172, p. 154.

[24] S. Popat et al., 'Bodily Extensions and Performance', (2017) *International Journal of Performance Arts & Digital Media*, 13(2), 101–104.

[25] *Husayn* v *Poland* (2015) 60 EHRR 16 (ECHR). See also *Dickson* v *UK* (2008) 46 EHRR 41 (Grand Chamber).

[26] The 'Mental Capacity Act 2005' stipulates that third-party decision-makers must make decisions that are only in the subject person's best interest as understood from the perspective of that person. Where a decision interferes with the person's physical integrity, the option that represents the least restrictive means must be adopted.

standing and protection),[27] sexual orientation (i.e. right to marriage or work benefits)[28] and gender (i.e. right to gender identity recognition).[29] It also defines 'civil identity', a common condition for access to basic services.[30] And notions of identity have been judicially noticed in relation to new technologies: in *Rose* v *Secretary of State for Health*,[31] which concerned disclosure of information about artificial insemination, the court found that information about biological identity went to the heart of identity and the make-up of the person, and that identity included details of origins and opportunity to understand them, physical and social identity, and also psychological integrity.

Unfortunately, these two increasingly important concepts have not been well-handled by the law. They are subject to very different interpretations depending on one's view of human rights as negative or positive.[32] Severe limits have been placed on the law being used to enable or impose those conditions that *facilitate* individuals living lives of meaning and becoming who they are (or wish to be). Narrow views as to what counts as a life of worth have resulted in limitations being placed on what individuals can do to become who they wish to be, with decision-makers often blind to the choices actually available (e.g. consider discourses around a 'good death' and medical assistance in dying). Thus, at present, neither integrity nor identity are consistently articulated or enabled by law. This could be the result of their multifaceted nature, or of the negative approach adopted in protecting them,[33] or of the indirectness of the law's interest in them.[34] The question of their treatment in health research regulation remains, and it is to this that we now turn.

39.4 CORE CONCEPTS AND MEDICAL DEVICE REGULATION

The market authorisation framework for medical devices is an example of health research regulation that shapes the nature, application and integrative characteristics of many enhancing technologies. Thus, it is profoundly linked to practices aimed at expanding and diversifying the human assemblage, and so it might be expected to appreciate, define and/or facilitate the concepts identified above as being critical to the person. In Europe, the development and market authorisation of medical devices is governed by the previously noted MDR and IVDR, both of which came into force in May 2017, but which will not be fully implemented until May 2020 and May 2022 respectively.[35]

[27] *Vo* v *France* (2005) 40 EHRR 12 (ECHR).

[28] International Covenant on Civil and Political Rights (1966), Art. 23(2); International Covenant on Economic, Social and Cultural Rights (1966), Arts. 6(1) and 7.

[29] European Convention on Human Rights and Fundamental Rights (1951), Art. 8 (right to private life); *Goodwin* v *United Kingdom* (28957/95) [2002] IRLR 664.

[30] E. Mordini and C. Ottolini, 'Body Identification, Biometrics and Medicine: Ethical and Social Considerations', (2007) *Annali dell'Istituto Superiore di Sanità*, 43(1), 51–60.

[31] [2002] EWHC 1593 (Admin).

[32] J. Marshall, *Personal Freedom through Human Rights Law?* (Leiden: Martinus Nijhoff, 2009).

[33] The existing right to privacy is extremely limited, and predominantly 'negative', not allowing the construction of positive claims related to identity: P. De Hert, *A Right to Identity to Face the Internet of Things* (Strasbourg: Council of Europe Publishing, 2007), www.cris.vub.be/files/43628821/pdh07_Unesco_identity_internet_of_things.pdf.

[34] S. Harmon et al., 'Struggling to be Fit: Identity, Integrity, and the Law', (2017) *Script-ed*, 14(2), 326–344.

[35] European Commission, 'Medical Devices: Regulatory Framework', (European Commission), www.ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en; CAMD Implementation Taskforce, 'Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap', (2018). During the transition, devices can be placed on the market under the new or old regime. It is unclear what impact these Regulations will have post-Brexit, but the UK, which implemented the old regime through the Medical Devices Regulations 2002, will have to comply with EU standards if it wishes to continue to trade within the EU. The Medicines and Healthcare products Regulatory

As will be clear from other chapters, the framing of regulatory frameworks is critical. Framing signals the regime's subject and objective; it shapes how its instruments articulate problems, craft solutions and measure success. It has been observed that the identification, definition and control of 'objects' is a common aim of regulatory instruments; specific objects are chosen because they represent an opportunity for commerce, a hazard to human health, or a boon – or danger – to social architecture.[36] Certain fields focus on certain objects, with the result that silos of regulation emerge, each defined by its existence-justifying object, which might be data, devices, drugs, tissue and embryos, etc., and the activity in relation to that object around which we wish to create boundaries (i.e., production, storage, use).

The MDR and IVDR are shaped by EU imperatives to strengthen the common market and promote innovation and economic growth, and are thus framed as commercial instruments.[37] Their subject is *objects* (e.g. medical devices), not people, not health outcomes and not well-being. MDR Article 1 articulates this frame and subject, stating that it lays down rules concerning placing or making available on the market, or putting into service, medical devices for human use in the EU.[38] MDR Article 2(1) defines medical device as any instrument, apparatus, appliance, software, implant, reagent, material or other article intended to be used, alone or in combination, for human beings for a range of specified medical purposes (e.g. diagnosis, prevention, monitoring, prediction, prognosis, treatment, alleviation of disease, injury or disability, investigation, replacement or modification of the anatomy, providing information derived from the human body) that does not achieve its principal intended action by pharmacological, immunological, or metabolic means.

The MDR and IVDR construct their objects simultaneously as 'risk objects', 'innovation objects' and 'market objects', highlighting one status or another depending on the context and the authorisation stage reached. All three constructions can be seen in MDR Recital 2 (which is mirrored by IVDR Recitals 1 and 2):

> This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the … enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked …

They then classify devices on a risk basis, and robust evidence and post-market surveillance is imposed to protect users from malfunction. For example, MDR Recital 59 acknowledges the insufficiency of the old regime, stating that it is necessary to introduce specific classification rules sensitive to the level of invasiveness and potential toxicity of devices that are composed of substances that are absorbed by, or locally dispersed in, the human body; where the device

Agency has highlighted its desire to retain a close working partnership with the EU: MHRA, 'Medical Devices: EU Regulations for MDR and IVDR', www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr; Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, not yet approved.

[36] G. Laurie, 'Liminality and the Limits of Law in Health Research Regulation', (2017) *Medical Law Review*, 25(1), 47–72; C. McMillan et al., 'Beyond Categorisation: Refining the Relationship Between Subjects and Objects in Health Research Regulation', (2021) Law, Innovation and Technology, doi: 10.1080/17579961.2021.1898314.

[37] MDR Recital 2 cites the Treaty of Union as a foundation for its remit to harmonise the rules for market-access and free-movement of goods, and for setting high standards of device quality and safety.

[38] IVDR Article 1 parallels this language for *in vitro* diagnostic medical devices, which are defined as any medical device that is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, for a number of purposes.

performs its action, where it is introduced or applied, and whether a systemic absorption is involved are all factors going to risk that must be assessed. MDR Recital 63 states that safety and performance requirements must be complied with, and that, for class III and implantable devices, clinical investigations are expected.[39] These directions are operationalised in MDR Chapters V (Classification and Conformity Assessments),[40] and VI (Clinical Evaluation and Clinical Investigations).[41] IVDR Recitals 55 and 61, and Chapters V and VI are substantively similar.

The above framing imposes a substantial fetter on what these instruments are intended to do, or are capable of doing. It serves to largely erase the person and personal experience from their perspective and remit. The recipient of a device is constructed as little more than a consumer who must be protected from the harm of a malfunctioning device. An example of the impoverished position of the person is the Regulations' treatment of risk. They rely on a narrow understanding of risk, framing it as commercial object safety at various stages of development and roll-out. Other types of risks and harms are marginalised or ignored.[42] Thus, there is no acknowledgement that their objects – medical devices – will not always be – and will really only briefly be – 'market objects'. Many devices will become 'physiological objects' that are profoundly personal to, and intimate with, the recipient. Indeed, many will cease to be 'objects' altogether, becoming instead components of the human assemblage, undermining or facilitating integrity, and exerting pressures on identity. As such, the nature of the risks they pose changes relatively quickly, and more so over time.

Had broader human well-being or flourishing been foregrounded, then greater attention to public interest beyond device safety might have been expected. Had legislators given any consideration to the consequences of these technologies once integrated with the person and becoming a part of that human assemblage, then further conditions for approval might have been expected. Developers might have been asked to present social evidence about the actual need for the device, or the potential social acceptance of the device, or how the device is expected to interact with other major – or common – health or social technologies, systems, or practices. In short, the patient, or the non-patient user, may have featured in the market access assessment.

The one exception to the Regulations' ignorance of social experience is that relating to post-market surveillance. MDR Recital 74 requires manufacturers to play an active role in the post-market phase by systematically gathering information on experiences with their devices via a comprehensive post-market surveillance system. It is operationalised in Chapter VII.[43] However, while these provisions are useful, they fail to acknowledge the now embodied condition of the regulatory object, and the new personal, social, ethical and cultural significance that it holds. In

[39] The insufficient nature of the Regulations' transparency of clinical evidence to front-line actors has been noted: A. Fraser et al., 'The Need for Transparency of Clinical Evidence for Medical Devices in Europe', (2018) *Lancet*, 392 (10146), 521–530.

[40] MDR Arts. 51–60. Art. 51 creates the classes I, IIa, IIb and III, which are informed by the device's intended purposes and inherent risks.

[41] MDR Arts. 61–82. Art. 61 states that clinical data shall inform safety and performance requirements under normal conditions of intended use, the evaluation of undesirable side-effects and the risk/benefit ratio.

[42] This narrowing has been recognized in the broader health technologies context: M. Flear, 'Regulating New Technologies: EU Internal Market Law, Risk and Socio-Technical Order' in M. Cremona (ed.), *New Technologies and EU Law* (Oxford University Press, 2016), pp. 74–122.

[43] MDR Arts. 83–100. Art. 83 states that manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system for each device proportionate to the risk class and appropriate for the device type. IVDR Recital 75 and Chapter VII are substantively similar.

other words, they evince an extremely 'bounded' perspective of their objects. Such has been criticised:

> The attention of law and regulation on 'bounded objects' . . . should be questioned on at least two counts: first, for the fallacy of attempting to 'fix' such regulatory objects, and to divorce them from their source and the potential impact on identity for the subjects themselves; and, second, for the failure to see such objects as also experiencing liminality.[44]

This is pertinent to situations where technologies are integrated into the body, situations which exemplify van Gennep's pattern of experience: separation from existing order; liminality; re-integration into a new world.[45] The features of this new world are that the regulatory object (device) becomes embodied and incorporated in multiple ways – physical, functional, psychological and phenomenological.[46] Both the object (device) and subject (host) are transformed as a result of this incorporation such that the typical subject–object dichotomy entrenched in the law is not appropriate;[47] the Regulations' object-characterisations are no longer apropos and their indifference to the subject is potentially unjust given the 'new world' that now exists.

This cursory assessment suggests that the Regulations are insufficient and misdirected from the perspective of ensuring that the full public interest is met through the regulated activity. As previously observed, new and emerging technologies can be conceptually, normatively and practically disruptive.[48] Technologies applied to humans for purposes of integration – treatment or enhancement – are disruptive on all three fronts, particularly once they enter society. Conceptually, they disrupt existing definitions and understandings of the regulatory objects, which are transformed once they form part of the human assemblage. Normatively, they disrupt existing regulatory concepts like risk, which are exposed as being too narrow in light of how these objects might interact with and harm individuals. Practically, they disrupt existing medical practice – blurring the lines between treatment and enhancement – and regulatory practices – troubling the oft-relied-on human/non-human and subject/object dichotomies.

This assessment also suggests that the historical boundaries between, or categories of, 'devices' and 'medicines', are increasingly untenable because of the types of devices being designed (e.g. implanted mechanical devices and mixed material devices that interact with the physiological, sometimes through the release of medicines). This area of human health research therefore highlights both fault-lines within instruments and empty spaces between them. It might be that the devices and medicines regimes need to be brought together, with a realignment of the regulatory objects and a better understanding of where these objects are destined to operate.

39.5 CONCLUSIONS

As the enhanced human becomes more ubiquitous, and the radical posthuman comes into being, narrow or negative views of integrity and identity become ever more attenuated from the technologically shaped lived experience. Moreover, the greater the human/technology integration, the greater the engagement of integrity and identity. Insufficient attention to these concepts in regulatory frames, norms and decisions raises the likelihood that such will undermine rather

[44] Laurie, 'Liminality and the Limits of Law', 68. Also, McMillan et al., 'Beyond Categorisation'.
[45] A. van Gennep, *The Rites of Passage* (University of Chicago Press, 1960).
[46] Quigley and Ayihongbe, 'Everyday Cyborgs', 305.
[47] D. Dickenson, *Property in the Body: Feminist Perspectives*, 2nd Edition (Cambridge University Press, 2017).
[48] R. Brownsword et al. (eds), 'Introduction', *Oxford Handbook of the Law and Regulation of Technology* (Oxford University Press, 2017), pp. 3–38.

than support or protect human well-being. Only with clear recognition will the self-creation – the being and becoming – that they underwrite be facilitated through the positive shaping of social conditions.[49]

The MDR and IVDR are directly implicated in encouraging, assessing and rolling out integrative technologies destined for social and clinical uses, but they do not match the technical innovation they manage with sufficient regulatory recognition of the integrity and identity that is engaged. Despite their recent reform, they do not evince a greater regulatory understanding of the *common* natures and consequences of tissue, organ and technological artifacts, and they therefore do not represent a significantly improved – more holistic and less silo-reliant – regulatory framework.

Had they adopted a broader perspective and value base, they would have taken notice of people as subjects, and crafted a framework that contributed to the development of innovations that are not only safe, but also supportive of – or at least not corrosive to – what people value, including integrity and identity. At base, they would have benefited from:

- a clearer and broader value base;
- an emphasis on decisional principles rather than narrow (technical) objects on which rules are imposed; and
- greater notice of what the devices become once they are through the market-access pipeline.

Ultimately, medical device regulation is an example of health research regulation that operates in an area where innovation has created disturbances, and those disturbances have not been resolved. Though some have been acknowledged – leading to the new regime – the real disturbances have hardly been appreciated.

[49] De Hert, note 33, argues that there ought to be a clear right to identity because people cannot function without it; it is like living, breathing, or being free to feel and think, all of which are minimal requirements for social justice in a rights-conscious society. Such recognition of identity paves the way for identity to be recognised as a right protected by law. He says that 'states should undertake to respect the right of each person to preserve and develop his or her ipse and idem identity without unlawful interference' (1). For more on identity as an emerging legal concept: L. Downey, *Emerging Legal Concepts at the Nexus of Law, Technology and Society: A Case Study in Identity*, unpublished PhD thesis, University of Edinburgh (2017).