LAW, INNOVATION AND TECHNOLOGY
2020, VOL. 12, NO. 2, 284–296
https://doi.org/10.1080/17579961.2020.1815403

Routledge
Taylor & Francis Group

Regulating innovative health technologies: dialectics, dialogics, and the case of faecal microbiota transplants

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ABSTRACT

This paper interrogates the common characterisation of innovative health technologies 'leading', while law and regulation 'lag' behind. We analysed the case of faecal microbiota transplants (FMT), an innovative procedure whose regulatory status remains in flux worldwide. We searched the literature for papers that described the regulation of FMT, and coded these according to a simple analytic framework. We identified 21 relevant papers. To date, no jurisdiction has implemented FMT-specific regulation. Instead, FMT is dealt with under a range of approaches, which include fitting it within existing regulation, and the use of 'soft' law. We found that metaphor, or argument by analogy, played a central role in delineating the potential regulatory options. We also found the relationship between innovation and regulation to be more 'dialogic' than oppositional, dialectical, or akin to a race. These findings underscore the importance of case-by-case investigation to determine the applicability of general narratives about law and regulation to specific instances of innovative technologies.

ARTICLE HISTORY Received 12 July 2019; Accepted 14 September 2019

KEYWORDS Regulation; innovation; health technology; faecal microbiota transplant

1. Introduction

The relationship between innovative health technologies and the law is often characterised as one in which technology leads, while the law is 'outpaced', 'lagging' or 'limping' behind.[1] Innovation in health, as in other domains, is seen as a fluid, fast-paced process, dependent on flexible, open-ended thinking, and a tolerance for risk and uncertainty. Laws and other forms of

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[1]Lyria Bennett Moses, 'Understanding Legal Responses to Technological Change: The Example of in Vitro Fertilization' (2005) 6 *Minnesota Journal of Law, Science & Technology* 505, 516; Lyria Bennett Moses, 'Agents of Change: How the Law "Copes" with Technological Change' (2011) 20 *Griffith Law Review* 763, 764; Dianne Nicol and others, 'Precision Medicine: Drowning in a Regulatory Soup?' (2016) 3 *Journal of Law and the Biosciences* 281.

regulation, by contrast, are often regarded as static systems, slow to adapt and rigid once in place. In this characterisation, the goals of regulation – protecting patient safety, ensuring access to effective therapies, controlling public spending on healthcare, and promoting the ethical conduct of researchers and clinicians – can appear to frustrate the translational goals of innovative health research and development. This kind of relationship can be described as *dialectical*: regulation is seen to oppose or block innovation; then, in the struggle of competing forces, new forms of regulation emerge, only to be later challenged by further innovations.

This dialectical dynamic – opposition, followed by synthesis and then further opposition – has previously played out in the context of innovations such as IVF, human gene therapy, autologous stem cell therapies and embryonic stem cell research. It is currently manifest in debates around precision medicine technologies such as genome editing using the CRISPR-Cas9 system, drug/diagnostic pairs, and 3D bioprinting. This dynamic is important because it shapes and constrains the range of regulatory responses which are deemed possible, in response to innovation. In the 2014–16 debates surrounding the UK's *Medical Innovation Bill*, for example, the bill's proponent Lord Saatchi argued that the common law was stifling medical innovation by imposing too stringent a test of negligent liability on doctors.[2] He proposed that a legal exemption be created for doctors so they would face no liability in negligence for performing innovative therapies, under certain conditions.[3] While the bill ultimately failed, discourse surrounding it exemplified the belief that regulation and innovation are diametrically opposed to one another; it was argued that the laws had a negative effect on medicine as they could not accommodate innovation.[4]

The premise of this paper is that the relationship between innovative health technologies and the law should not be presumed to be dialectical but, rather, as a matter for empirical investigation in each new case. We use the case study of faecal microbiota transplantation to put this the relationship between innovation and regulation under the microscope. *Is there* a lag between the two? What is the reason for the lag? Through what kinds of strategies do laws and other regulation seek to 'catch up' with technology? And how could these be improved? To what degree do the forms of regulation contribute to or guide the emergence of innovation?

We begin by defining the key concepts, 'innovative health technology' and 'laws and other forms of regulation'. We then explain how faecal microbiota

[2]*Medical Innovation Bill 2014* (UK).
[3]Ibid s 1.
[4]Bernadette Richards and others, 'The Medical Innovation Bill: Still More Harm than Good' (2015) 10 *Clinical Ethics* 1. Instead of the Bill, the UK Parliament passed the *Access to Medical Treatments (Innovation) Act 2016* (UK), which allowed for the creation of a register of innovative treatments. See, too, the contributions to (2019) 11 *Law, Innovation and Technology* (special issue on regulating innovative treatments).

transplantation fits our criteria for an innovative health technology, and how it is currently regulated. Finally, we outline our approach to the case study, which uses qualitative content analysis of scholarly papers, and set out our findings. This study leads us to suggest that, in this case at least, the encounter between innovative health technologies and the law is more *dialogic* than *dialectic*: more a dialogue than a race. We found that regulatory pathways were determined at key decision-points, one of the most important of which was the choice of analogy to describe regulatory interactions. That is: based on key characteristics, which existing technology, or technologies, does the new technology resemble? We conclude by noting some implications of our findings for the regulation of innovative health technologies more broadly.

2. Framing the case study: key context and concepts

2.1. What are innovative health technologies?

All health technologies involve 'the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives'.[5] We define *innovative* health technologies as having two additional characteristics. First, they are radically new. They represent a paradigm shift, and 'open up new possibilities and allow us to do things that haven't been done before,' as opposed to being merely 'a variation or extension or improvement on something we can already do'.[6] Secondly, they are health technologies at an early or investigational stage of their life cycle, with their full range of applications not yet fully understood. They are 'still emergent … and have not yielded many applications and societal consequences'.[7]

2.2. What is law and other regulation?

Over the past three decades, the field of regulatory scholarship has significantly reshaped our understanding of regulation, both in its meaning and in its scope. In particular, regulation is no longer considered the exclusive purview of the State and its laws: though these remain important, regulation today is widely described as 'decentred'.[8] What this means is that regulation is no longer top-down and linear, but rather encompasses a wide array of actors

[5]World Health Assembly, Resolution on health technologies, WHA60.29, 60th World Health Assembly, 2007; available online at https://www.who.int/healthsystems/WHA60_29.pdf?ua=1 (accessed March 2019).

[6]David Hunter, 'How to Object to Radically New Technologies on the Basis of Justice: The Case of Synthetic Biology' (2013) 27 *Bioethics* 426.

[7]Philip AE Brey, 'Anticipatory Ethics for Emerging Technologies' (2012) 6 *NanoEthics* 1, 1.

[8]Julia Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World' (2001) 54 *Current Legal Problems* 103. See also Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press 2007) 4.

and activities, interacting within 'regulatory space'.[9] Regulation can take the form of formal, direct mechanisms – e.g. statutes, regulations, policies – as well as less formal, and less direct mechanisms – e.g. industry self-regulation, stakeholder forums, funding decisions. In this paper, we adopt Black's definition of regulation, which is that 'regulation, or regulatory governance, is the organised attempt to manage risks or behaviour in order to achieve a publicly stated objective or set of objectives'.[10] Following Morgan and Yeung, we use the expression 'laws and other forms of regulation', or 'law and regulation', to emphasise that, as legal scholars, we bring a legal perspective to this expanded view of regulation.[11] In the context of innovations in health care, we are particularly interested in the impact of therapeutic goods regulation, professional ethics and discipline, tort laws, healthcare complaints, and intellectual property laws, but we recognise that these well-mapped areas of legal inquiry have roots that grow out into less well known areas of normative control.

3. Qualitative content analysis

3.1. FMT as a case study

We selected the case study of faecal microbiota transplantation (***FMT***) in order to investigate the ways in which innovative health technologies encounter law and regulation. Described by one of its pioneers as a therapeutic strategy 'at the fringes of medicine',[12] FMT 'consists of the infusion of faeces from a healthy donor to the gastrointestinal (***GI***) tract of a recipient patient, in order to treat a specific disease associated with alteration of gut microbiota'.[13] Although its mode of action is not yet completely understood, broadly speaking, FMT treats disease by 'restoring the phylogenetic diversity and microbiota more typical of a healthy person'.[14] There is now a robust body of evidence to support the efficacy of FMT as a treatment for recurrent *Clostridium difficile* infection (***rCDI***),[15] an 'aggressive intestinal

[9]Leigh Hancher and Michael Moran, 'Organizing Regulatory Space' in Robert Baldwin, Colin Scott and Christopher Hood (eds), *A Reader on Regulation* (Oxford University Press 1998); Susan MC Gibbons, 'Mapping the Regulatory Space' in Andrew Smart (ed), Jane Kaye and others, *Governing Biobanks: Understanding the Interplay between Law and Practice* (Hart Pub 2012).

[10]Julia Black, 'Learning from Regulatory Disasters' (2014) 10 *Policy Quarterly* 3.

[11]Morgan and Yeung (n 8) 14.

[12]Thomas J Borody and Alexander Khoruts, 'Fecal Microbiota Transplantation and Emerging Applications' (2012) 9 *Nature Reviews Gastroenterology & Hepatology* 88, 91.

[13]Giovanni Cammarota and others, 'European Consensus Conference on Faecal Microbiota Transplantation in Clinical Practice' (2017) 66 *Gut* 569, 569.

[14]Colleen R Kelly and others, 'Update on Fecal Microbiota Transplantation 2015: Indications, Methodologies, Mechanisms, and Outlook' (2015) 149 *Gastroenterology* 223, 223.

[15]National Institute for Health and Care Excellence (2014) 'Faecal microbiota transplant for recurrent Clostridium difficile infection' (IPG485). Available online at https://www.nice.org.uk/guidance/ipg485 (accessed March 2019); Cammarota and others (n 13); Benjamin H Mullish and others, 'The Use of Faecal Microbiota Transplant as Treatment for Recurrent or Refractory Clostridium Difficile Infection

superbug'[16] in relation to which antibiotic resistance is a growing concern. In addition, FMT is under investigation for a number of other GI conditions, as well as some non-GI diseases such as diabetes.

In both the rCDI indication, and other areas of investigation, FMT satisfies our criteria for an innovative health technology. While the medicinal use of faeces has been documented as far back as fourth-century China,[17] FMT in its modern form has been used sporadically over the past 50 years, gaining pace in the past decade.[18] However, it fits our criteria of being 'radically new' in the sense that it represents a paradigm shift from the 'germ theory' based therapies, such as antibiotics, which constituted the previous standard of care for rCDI.[19] Instead, FMT engages with the gut microbiota as a 'true organ', one that is 'integral to human physiology,'[20] opening up completely new treatment possibilities. It should be noted that, even in the rCDI indication – i.e. where FMT is best understood – scientists have yet to characterise the precise interactions between the human microbiome and disease and the resultant opportunities and challenges for therapeutic intervention.

Moreover, FMT provides an interesting case study because the question of how it should be regulated is very much still in flux. Around the world, regulation of FMT currently runs the gamut 'from non-existing to strictly regulated'.[21] So far, no jurisdiction has introduced FMT-specific legislation. Instead, the following approaches have been documented:

- FMT is regulated under the existing framework for biologic medicines (e.g. France);
- FMT is regulated under the existing framework for biologic medicines, with some customisation (e.g. Canada, UK, USA);
- No existing regulations apply, and no new regulations are enacted, but 'soft law' in the form of professional guidelines fills the gaps (e.g. Austria); and
- No existing regulations apply, and no new regulations are enacted, leaving gaps and lack of clarity (e.g. Australia, China).

and Other Potential Indications: Joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) Guidelines' (2018) 67 *Gut* 1920.

[16]Rachel E Sachs and Carolyn A Edelstein, 'Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation' (2015) 2 *Journal of Law and the Biosciences* 396.

[17]Kenneth A Young, 'Of Poops and Parasites: Unethical FDA Overregulation' (2014) 69 *Food and Drug Law Journal* 555.

[18]Borody and Khoruts (n 12), Cammarota (n 13).

[19]Alexander Khoruts and Michael J Sadowsky, 'Understanding the Mechanisms of Faecal Microbiota Transplantation' (2016) 13 *Nature Reviews Gastroenterology & Hepatology* 508.

[20]Ibid.

[21]Frederick Verbeke and others, 'Faecal Microbiota Transplantation: A Regulatory Hurdle?' (2017) 17 *BMC Gastroenterology* 128.

3.2. Method

Using the databases MedLine, Web of Science, and HeinOnline, we searched the literature for peer-reviewed publications on FMT, published in or after 2013 (when the first randomised study of FMT in rCDI was published),[22] and which included substantial discussion of legal and regulatory considerations. We used the search terms ***f(a)ecal microbio* transplant* AND [law* OR regulat* OR polic* OR legislat****]. We identified 21 papers that met our inclusion criteria. Most of these (n=14) were published in scientific journals; 5 were published in law journals and two in health policy journals.[23] Eleven papers discussed the USA regulatory context, six related to Europe or individual European countries, there was one paper each on Australia and Canada, and two that compared international approaches.

Using qualitative content analysis methodology,[24] we developed a simple coding framework and extracted data in relation to the following three themes:

- In relation to FMT, how do commentators characterise the goals of regulation?
- What specific regulatory challenges does FMT present?
- How could the regulation of FMT be improved?

3.3. Results

3.3.1. What are the goals of regulation in relation to FMT?

Beyond the general justifications for regulating health technologies, what should regulation seek to achieve specifically in relation to FMT? In this regard, most commentators drew a distinction between FMT for its established indication of rCDI, as compared with other clinical indications.[25] For rCDI, commentators expressed a strong concern that regulation might inappropriately hinder access to a very effective treatment (one paper described this course of action as 'inhumane'),[26] while also stressing the importance of maintaining safety, e.g. through rigorous screening of donors and donated stool. For indications other than rCDI, which are still investigational, most commentators focused on the importance of encouraging responsible research and development, rather than patient access.

[22]Els van Nood and others, 'Duodenal Infusion of Donor Feces for Recurrent Clostridium Difficile' (2013) 368 *New England Journal of Medicine* 407.

[23]Myrisha S Lewis, 'Halted Innovation: The Expansion of Federal Jurisdiction over Medicine and the Human Body' [2018] *Utah Law Review* 1073 (noting that there has been little discussion of FMT in the legal literature).

[24]Margrit Schreier, *Qualitative Content Analysis in Practice* (Sage Publications 2012).

[25]See for example, Carolyn A Edelstein and others, 'The Regulation of Fecal Microbiota for Transplantation: An International Perspective for Policy and Public Health' (2015) 32 *Clinical Research and Regulatory Affairs* 99, 105.

[26]Verbeke and others (n 21) 6.

3.3.2. What regulatory challenges does FMT present?

Three key features of FMT were identified as creating specific regulatory challenges: the nature of the substance itself; the multiple different modes of administration available; and uncertainty regarding the longer-term effects of FMT. First, in terms of the nature of the substance, Sachs and Edelstein note that stool is 'unique for the difficulty of its characterisation and the simplicity of its production, and each of these characteristics raises special safety concerns'.[27] Unlike a conventional medicine, it is easy to manufacture and thus obtain a 'batch' of product, raising the possibility of DIY procedures, carried out outside the auspices of medicine. Yet, also unlike a conventional medicine, each 'batch' – even from the same person – can differ greatly, which presents challenges in its characterisation and therefore for quality control.[28] This difficulty is encapsulated by the fact that almost all commentators raised the spectre of potentially risky 'YouTube FMT' – patients self-administering the procedure on the guidance of online videos.

Secondly, there are multiple different ways to carry out an FMT procedure. Stool may come from a known or an unknown donor, or may be autologous, or synthetic; it may be fresh or frozen; it may be administered via enema, colonoscopy, or other means. This gives rise to multiple variables that may influence the efficacy, safety, and acceptability of FMT, and these have not yet been fully disentangled through clinical trials. While guidelines have been published in several jurisdictions, these have tended to be based on expert opinion, due to the lack of robust evidence.[29] Even in rCDI, most of the available evidence for FMT comes from retrospective case series or systematic reviews,[30] rather than the 'gold standard' of randomised controlled trials. This informs the third feature, which is that little is known about the long-term safety profile of FMT. In particular, the risks of transmitting communicable diseases,[31] as well as non-communicable conditions including psychological illnesses,[32] from the donor to the patient, remain poorly understood.

3.3.3. How could the regulation of FMT be improved?

Commentators suggested a variety of alternatives to the current regulation of FMT, in order to better achieve the identified goals (set out at 3.1) and address

[27]Sachs and Edelstein (n 16) 406.
[28]Diane Hoffmann and others, 'Improving Regulation of Microbiota Transplants' (2017) 358 *Science* 1390. See also Samuel P Costello and Robert V Bryant, 'Faecal Microbiota Transplantation in Australia: Bogged down in Regulatory Uncertainty' (2019) 49 *Internal Medicine Journal* 148, 149.
[29]Cammarota and others (n 13).
[30]SD Goldenberg, 'Faecal Microbiota Transplantation for Recurrent Clostridium Difficile Infection and Beyond: Risks and Regulation' (2016) 92 *Journal of Hospital Infection* 115.
[31]N Kapel and others, 'Practical Implementation of Faecal Transplantation' (2014) 20 *Clinical Microbiology and Infection* 1098, 1099.
[32]Tim Spector and Rob Knight, 'Faecal Transplants Still Need Good Long Term Trials and Monitoring (Editorial)' (2015) 351 *BMJ* h5149.

the identified challenges (set out at 3.2). The regulatory approach advocated by each commentator reflected the priority they gave to these goals and challenges.

Several commentators suggested designating a 'special status' for FMT, similar to that of blood.[33] This was based on a view that the rigorous manufacturing standards applied to drugs would be unduly burdensome for an innately variable substance such as human stool.[34] The blood framework was also considered well suited to addressing the communicable disease risks associated with FMT.[35] Another suggested option was to classify FMT as a gene-, cell-, or tissue-like product for regulatory purposes. This was proposed as a means of addressing FMT risks that fall beyond the risks applicable to blood, including pre-existing risk management frameworks and clear criteria for clinical trial exemptions.[36] However, in their argument *against* regulating FMT as a tissue, Megerlin and colleagues stressed the currently limited understanding of its mechanism of action, likened the healthy donor to a 'bioreactor', and highlighted the substance's topographical rather than cellular origin.[37] Based on these distinctions, Megerlin and colleagues argued that the appropriate regulatory paradigm for FMT was as a *sui generis* biological drug, rather than human tissue.[38]

Others suggested that FMT should be regulated 'like a drug,' but only in certain circumstances. Drawing on the current US system for regulating cord blood, for example, Sachs and Edelstein suggested that while FMT should be regulated as an investigational new drug for its non-approved indications, the cord blood model would be appropriate for the approved indication of rCDI. This model provides differing degrees of oversight based on both the intended recipient (autologous stool and stool donated by close relative, versus banked stool) and the intended use of stool.[39] Responding to the numerous variables in FMT administration, Hoffmann and colleagues proposed a 'three-track regulatory system' for the USA, under which the regulation of FMT would differ depending on the product being used, and its context:[40]

(a) When performed by a physician, using known stool, to treat rCDI, FMT would be regulated as the practice of medicine. In indications other than

[33]JC Lagier, 'Faecal Microbiota Transplantation: From Practice to Legislation before Considering Industrialization' (2014) 20 *Clinical Microbiology and Infection* 1112; Edelstein and others (n 25).
[34]Lagier (n 33); Mark B Smith, Colleen Kelly and Eric J Alm, 'Policy: How to Regulate Faecal Transplants' (2014) 506 *Nature* 290.
[35]Smith, Kelly and Alm (n 34).
[36]Verbeke and others (n 21).
[37]F Megerlin and others, 'Faecal Microbiota Transplantation: A Sui Generis Biological Drug, Not a Tissue' (2014) 72 *Annales Pharmaceutiques Françaises* 217.
[38]Ibid.
[39]Sachs and Edelstein (n 16).
[40]Hoffmann and others (n 28).

rCDI, FMT would be treated as an investigational drug and regulated accordingly, unless the use meets legal requirements for 'clinical innovation'.

(b) When performed by a physician, using banked stool, to treat rCDI, the stool bank would be regulated like a tissue bank, with some additional oversight.

(c) 'Modified stool-based products' would be regulated like biological drugs.

The authors note that the proposed three-track system would not require new legislation, and could be achieved with guidelines.[41] The importance of guidelines, as opposed to 'hard' law, was also notable in the article by Woodworth and colleagues.[42] This article noted the discrepancy between the US FDA's focus on FMT using stool from a known donor, and the empirical trend towards the use of banked stool. In order to address this, they emphasised the importance of rigorous screening protocols and stakeholder collaboration.

4. Discussion

By displacing established scientific and social practices, innovative health technologies create uncertainty[43] and disruption.[44] As a result, they may not fit – or may appear not to fit – into existing legal structures and categories. Innovative health technologies are often deemed, by the public as well as by regulators, to present risks that are qualitatively different from those addressed in existing legislation, and so can prompt calls for new, technology-specific regulations.[45] Yet, as Stokes has observed, it is rare that a new technology arrives 'completely "lawless"'.[46] Rather, on arrival, innovative health technologies are met by complex webs of existing laws and other forms of regulation: the formal and informal rules which include professional norms and guidelines, legislation, regulation, policy directives, funding conditions, and so on, and which govern existing health technologies.

On the basis of our findings regarding FMT, we posit that regulation does not simply react to, or compete with, innovation. While there are many

[41] Ibid.

[42] Michael H Woodworth and others, 'Challenges in Fecal Donor Selection and Screening for Fecal Microbiota Transplantation: A Review' (2017) 8 *Gut Microbes* 225.

[43] Elen Stokes, 'Demand for Command: Responding to Technological Risks and Scientific Uncertainties' (2013) 21 *Medical Law Review* 11.

[44] See for example, Heidi Ledford, 'CRISPR, the Disruptor' (2015) 522 *Nature News* 20.

[45] Bert-Jaap Koops, 'Ten Dimensions of Technology Regulation: Finding Your Bearings in the Research Space of an Emerging Discipline' in MEA Goodwin, BJ Koops and RE Leenes (eds), *Dimensions of Technology Regulation* (Wolf Legal Publishers 2010); Bennett Moses, 'Agents of Change: How the Law "Copes" with Technological Change' (n 1).

[46] Elen Stokes, 'Nanotechnology and the Products of Inherited Regulation' (2012) 39 *Journal of Law and Society* 93, 94.

illustrations which support the existence of a dialectical relationship between innovation and regulation, in the case of FMT our findings instead suggest *dialogical* development.[47] We use this term to describe the relationship between innovation and regulation as dynamic, relational, open-ended, and engaged in a process of constant iteration. Based on our findings above, we make three observations about the encounter between innovative health technologies and the law. We begin by noting that 'innovation' is not, in fact, the object of regulation, and emphasise the importance of specificity. Secondly, we identify the centrality of metaphor in channelling discussion towards one regulatory pathway or another. Finally, we describe the ways in which these metaphors shape the dialogic relationship between innovative health technologies and regulation.

4.1. Regulating 'innovation'

One important observation from our case study of FMT is that, even where an innovative health technology is the object of regulation, 'innovation' *per se* is not the thing being regulated. Rather, the technology's degree of innovation derives from the convergence of other, more specific qualities, and it is these qualities that create any uncertainty, and prompt calls for new or different regulation. So, in the case of FMT, the innovation is the concept of using stool to repopulate the microbiome, as opposed to the previously standard practice of using antibiotics to address the infection. The problem facing scientists, clinicians, and regulators in this space is a specific, rather than a general one: an FMT challenge, not an 'innovation' challenge. This underscores the importance of case-by-case, empirical investigation, to determine whether in fact the specific innovative technology confirms to broader narratives about innovation and regulation.

4.2. The 'channelling' role of metaphor

Our second observation relates to the central role played by metaphor, or reasoning by analogy, in discussions of how FMT should be regulated. We noted at the outset that an innovative health technology is paradigm-shifting: by definition, it is not 'like' any predecessor technology. Yet, whether advocating that FMT should be regulated *like a biological*, *like blood*, or *like an organ*, most suggestions sought to fit FMT within an existing regulatory paradigm, based on the notion that it shares qualities with another product or process. As Megerlin and colleagues note, even the term 'faecal microbiota

[47]The term 'dialogic' is often used in relation to Bakhtin's linguistic theories. According to Bakhtin, dialogic development occurs when language changes in response to how it has been used in the past, and it is also shaped by an understanding of how it may be used in the future: see Bakhtin, *The Dialogic Imagination: Four Essays* (Caryl Emerson ed, Michael Holquist tr, Austin: University of Texas Press 1981).

transplant' is itself a metaphor, and not necessarily an accurate one: rather, its usage reflects the 'lexical disruption' brought about by 'scientific revolution'.[48] Our findings suggest that the decision to compare the innovative health technology to an existing technology is in fact an important regulatory moment. In that moment, the innovative technology is 'channelled' towards an existing regulatory regime based on a prioritisation of identified goals and challenges, and a process begins.

4.3. Dialogical development

Our third observation relates to this process, which – at least in the context of FMT – is better described as a dialogue than as a 'race' in which law lags behind technology. Across jurisdictions, the emergence of FMT has prompted consideration of whether existing regulation applies or is appropriate; adjustments – including in the form of screening protocols, guidelines, and subsidiary legislation – are then made, which in turn inform future developments. As Sachs and Edelstein acknowledged, even the *de novo* legislation option would not be pursed in a vacuum, and 'must be considered in light of decisions that [regulators have] already made in this area'.[49] Noting that the US Food and Drug Administration (***FDA***) had redefined its position on FMT three times, Riley and Olle perceive not regulatory lag, but an iterative process: FDA gaining 'additional experience with the potential technologies before it wades into more formal rulemaking'.[50] As highlighted in multiple papers, FMT is a quickly evolving therapy area, in which the different indications – and their varying strengths of evidence – are as determinative of regulatory choice as the technology itself. In this context, an iterative or dialogic understanding of regulation may in fact be the most appropriate way to 'cope' with innovation.[51]

5. Conclusion

In contrast to the common characterisation of innovative technologies 'leading', while law 'lags' behind, our case study revealed a less oppositional, more fluid and conversational dynamic. Regulatory dynamics, in this study, were shown to be a process rather than a given; involving incremental

[48]Megerlin and others (n 37) 3. Similarly, the UK's National Institute for Health and Care Excellence (NICE) 'recognised that the enteric infusion of donor faeces is not a transplant in the usual sense of transplanting body tissues, but … accepted that faecal microbiota transplant has become an accepted term to describe this procedure': National Institute for Health and Care Excellence (2014) 'Faecal microbiota transplant for recurrent Clostridium difficile infection' (IPG485). Available online at https://www.nice.org.uk/guidance/ipg485 (accessed March 2019).

[49]Sachs and Edelstein (n 16) 413.

[50]Margaret F Riley and Bernat Olle, 'FDA's Pathway for Regulation of FMT: Not so Fraught' (2015) 2 *Journal of Law and the Biosciences* 742.

[51]Bennett Moses, 'Agents of Change: How the Law "Copes" with Technological Change' (n 1).

adjustments, trial-and-error, and mechanisms other than formal law and regulations. The extent to which these findings can be generalised to other innovative health technologies is beyond the scope of this paper. Certainly, and as we noted at the outset, there are many examples that support the traditional, dialectical framing of the relationship between regulation and innovation. However, our research shows that this is not the only possible relationship, and supports an approach which investigates each new regulatory encounter empirically, and on its own merits. Moreover, conceiving of the relationship in dialogic terms has important implications for stakeholders, including scientists, regulators, and the public. In challenging some of the entrenched assumptions about law *versus* innovation, a dialogic framing may open up possibilities for a more collaborative discussion about how best to regulate specific innovative health technologies.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This work was supported by the Australian Research Council under ARC Discovery [grant number DP180101262].

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