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# How do we make sense of chaos? Navigating health research regulation through the liminality of the Brexit process

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## Abstract

This article examines the Brexit process through the anthropological lens of liminality. As a concept that explains the impact of change and transformation on human experience, it is argued that liminality is an especially valuable perspective to understand better the phenomenon of Brexit, particularly as to how this might impact on the regulation of human health research. A central feature of liminality is its attention to process; that is, the identification of milestone thresholds within a series of events involving change. More particularly, liminality has a degree of predictive power about certain influencing factors on transformational processes and their outcomes. In this regard, the pivotal role of law is subjected to close scrutiny in the period leading up to March 29, 2018: one year before the so-called Brexit Day. The European Union (EU) (Notification of Withdrawal) Act 2017 was the threshold trigger for the Brexit process, while the EU Withdrawal Bill 2017–2019 has as its objective the shepherding through of the United Kingdom in its departure from the EU. The argument is made that these events are liminal moments in European legal and human history; moreover, lessons from history are used to identify the specific implications for human health research as an area of human activity that will be profoundly impacted by the Brexit process. This analysis also provides a means to reflect on the broader implications of what a disruptive process such as Brexit means for law generally.

## Keywords

Health, research, regulation, law, liminality, Brexit

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## Introduction

How do we make sense of chaos? How do we navigate our way through—and out of—one of the most complex legal orders ever devised in human history? More particularly, how can we effectively find our way through—and potentially out of—one of the most complex and yet highest-quality human health regulation regimes on the globe? These are the questions that sit at the heart of this article. Normative quandaries aside about why we would wish to set ourselves on such paths, the contribution of this article is to suggest some tentative answers to these questions by invoking the anthropological concept of liminality. Liminality is concerned with in-betweenness. More specifically, it reflects and describes a human quality of being neither one thing nor another. As is outlined below, liminality already offers powerful insights into the human condition as it relates to health and illness, and I have recently written about how liminality can help us to understand the role of law in regulating health and human health research.<sup>1</sup> This article builds on those analytical foundations, not merely by applying the insights to the Brexit process but also by exploring more deeply what liminality teaches us about processes of transition and change, particularly when those processes are shrouded in uncertainty and, at times, chaos.

The article proceeds as follows. The first section considers the landscape of human health research as a suitable area of enquiry and highlights issues and questions that arise for that regulatory space from the Brexit process. The second section outlines the nature and the contribution of liminality to the sphere of health-related human experience, and it identifies key features of that experience that are revealed by the lens of liminality; these include a focus on process, transformation, and change. Here, liminality is offered as a *diagnostic* of what is happening within the Brexit process. The third section uses this analysis as a *prediction* of what might happen for health research regulation as a result of the liminality of Brexit. The last section offers some tentative *solutions* to the challenges of Brexit in the health research context, or, at least, some commentary about what might be expected, and how adverse outcomes might be avoided or their impacts greatly minimized.

## **Brexit and health research regulation: What is the problem (and how does liminality help with the answer)?**

To begin to understand the complexity of the Brexit process, even simply in terms of the sheer number of issues that must be addressed and settled, it is sufficient to have regard to the European Commission position papers published after the United Kingdom's notification of its intention to leave the European Union (EU) on March 29, 2017.<sup>2</sup> It is an understatement of considerable proportions to assert that the Brexit

1. G. Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-between?', *Medical Law Review* 25(1) (2017), pp. 47–72.
2. Commission position papers published after March 29, 2017. Available at: [https://ec.europa.eu/commission/brexit-negotiations\\_en](https://ec.europa.eu/commission/brexit-negotiations_en) (accessed 3 September 2018).

process heaps complexity upon complexity, given that the EU legal order is itself labyrinthine, reaching into every aspect of the lives of EU citizens. This is particularly true in the domain of health, where the sphere of influence of the EU has grown considerably over the years.<sup>3</sup> It is a challenge for lawyers already to navigate the myriad ways in which EU law impacts the health rights and entitlements of EU citizens within and between member states, let alone to understand how these systems might be disentangled without irrevocable damage to those rights and entitlements, for both current and future citizens. When, in addition, we then ask: how do regimes of health research regulation fit into this Gordian knot of laws and regulations, the challenges seem all the more insurmountable.

However, it is legitimate to ask this question because health research regulation is a particularly central feature among the contributions that the EU has made to the quality of human lives in the post–World War II era, both regionally and globally. EU standards represent gold standards for robust scientific and ethical research conduct worldwide. It is therefore a serious concern that in the UK government’s public dialogue to date, the focus of its attentions has been too narrowly concentrated on trade and security matters.<sup>4</sup> Moreover, and as noted by the House of Commons Health and Social Care Committee in its report—*Brexit and Health and Social Care Inquiry: People & Process*—there have been confusing and mixed messages from the government about key future eventualities, including whether the United Kingdom will remain in the European Medicines Agency.<sup>5</sup> The depth of concern was well voiced through evidence from the King’s Fund to the same Committee when it stated:

The UK has its own national regulatory agency, the Medicines and Healthcare products Regulatory Agency (MHRA). However, this deals with national authorisations intended for marketing only in the UK. The inclusion of EEA and EFTA countries for centralised marketing authorisation may mean that, despite leaving the EU, the UK could continue its relationship with the EMA. If this is not the case, however, pharmaceutical companies may need to apply to the MHRA for authorisation for any medicines they wish to supply to the UK. Concerns raised in a recent report from the UK life sciences sector included that no longer being in the EU regulatory system could result in the UK becoming ‘a second priority’ launch market, that ‘there is no appetite to add regulatory bureaucracy by losing European scale and consistency’, and recommending that alignment with the EU

3. T.K. Hervey and J.V. McHale, *European Union Health Law: Themes and Implications* (Cambridge: Cambridge University Press, 2015).
4. Consider, notably, Prime Minister Theresa May’s speech in Florence on September 22, 2017. Available at: <https://www.gov.uk/government/speeches/pms-florence-speech-a-new-era-of-cooperation-and-partnership-between-the-uk-and-the-eu>. Official government documents on the Brexit process (accessed 3 September 2018). Available at: <https://www.gov.uk/government/publications?departments%5B%5D=department-for-exiting-the-european-union> (accessed 3 September 2018).
5. See House of Commons Select Committee on Health and Social Care, *Brexit and Health and Social Care Inquiry: People & Process*, HC 640 (2016–2017), at paras 127–128.

regulatory system be maintained (UK EU Life Sciences Transition Programme Steering Group 2016).<sup>6</sup>

In its response to the Health and Social Care Committee report, the government highlighted that Paul Macnaught, Director of EU, International & Public Health System at the Department of Health, had provided oral evidence to the Health Committee on February 28, 2017, wherein he listed the “. . . biggest issues for the Department arising from the UK’s withdrawal from the EU as including workforce, medicines and devices regulation and the implications for the life sciences sector generally, reciprocal health-care and health protection systems.”<sup>7</sup> However, this response is notable for its silence in failing to clarify the UK government’s position on any future involvement with the European Medicines Agency.

Concerns were compounded because the work of the Health and Social Care Committee was suspended due to the General Election of June 8, 2017.<sup>8</sup> Matters relating to ongoing European research collaborations and funding, including matters of public health, therefore were not addressed.

The report of the successor Committee—*Brexit: Medicines, Medical Devices and Substances of Human Origin*—was published on March 21, 2018. Herein the call was made that “. . . to minimise harm to their citizens both sides should look to secure the closest possible regulatory alignment as a priority in the next round of negotiations.”<sup>9</sup> By this stage, the UK government had also publicly stated its intention to maintain *regulatory alignment* with the European Medicines Agency. Furthermore, the House of Commons (HC) Select Committee also recommended:

The UK should also seek mutual recognition of pharmacovigilance mechanisms by the MHRA and the EMA as a priority in the next round of negotiations. This should include ensuring that all UK pharmacovigilance organisations continue to be members of the

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6. Written Evidence from the King’s Fund (BRE0090), at para 3.7. Available at: <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-committee/brexit-and-health-and-social-care/written/42703.html> (accessed 3 September 2018).

7. Government response to the House of Commons Health and Social Care Committee report *Brexit and Health and Social Care—People & Process*, December 2017, Cm 9469, p. 2.

8. House of Commons Select Committee on Health and Social Care, *Brexit and Health and Social Care Inquiry: People & Process*, at para 142. As the Committee stated:

Questions remain over the UK’s continued participation in health-related EU research programmes such as those investigating rare diseases that rely on large sample populations.<sup>156</sup> The financial support for cross border work such as that provided by the European Investment Bank, Horizon 2020 funding, EU public health programmes, the European Social Fund and the Regional Development Fund is also in question. We believe that these are all areas that will require scrutiny by our successor committee.

9. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, Fourth Report, HC 392 (March 21, 2018). Available at: <https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/392/39202.htm> (accessed 3 September 2018).

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), as the failure to do so could affect patient safety both in the UK and the EU.<sup>10</sup>

Bearing in mind that the political position that overshadows the Brexit negotiations is that “nothing is agreed until everything is agreed” and that there will be no special pleading on a sector-by-sector basis, the HC Select Committee urged the UK government to make this sector a priority in the ongoing negotiations and “. . . to secure . . . the closest possible regulatory alignment with the EU.”<sup>11</sup> These processes of “regulatory alignment” and “mutual recognition” will be unpacked further in the third section.

At the time of writing, the government response to this report is still awaited. Importantly, in a separate letter, the HC Select Committee specifically requested clarity about the details of a transition period and contingency planning in the event of “no deal.”<sup>12</sup> The expectation is that this will be included within the response to the report.

For present purposes, the point should be self-evident that the need to address the complexities of this field of health research regulation as part of Brexit is a matter of crucial importance. This is not only a question of respecting and maintaining world-leading standards and protecting patients but also because of the social and economic benefits that this kind of health-related research brings. It is a long-standing expression of the will of the UK government that the United Kingdom be seen as the “Go To” place to conduct health research.<sup>13</sup> The enduring appeal of the United Kingdom as such a venue in a post-Brexit world must be considered carefully, and the “loss” of the European Medicines Agency from London to Amsterdam<sup>14</sup> is but the start of the process to come.

### Why liminality?

How, then, can we effectively tackle questions of interconnected complexities and processes of disentanglement? This article posits that a crucial starting point is to understand what is happening at the fundamental level of the processes themselves. This is not an empirical question; rather, it is a human experiential question. Whatever one’s political persuasion, Brexit represents a moment in (European) human history of profound seismic transformation and change. What can analysis of other profound processes of

10. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 131.

11. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 18.

12. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 4.

13. See generally information at GOV.UK on *Research and Innovation in Health and Social Care*. Available at: <https://www.gov.uk/government/policies/research-and-innovation-in-health-and-social-care> (accessed 3 September 2018).

14. European Medicines Agency, November 20, 2017. Available at: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2017/11/news\\_detail\\_002857.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/11/news_detail_002857.jsp&mid=WC0b01ac058004d5c1) (accessed 3 September 2018).

change in the human condition possibly teach us about Brexit and its impact on human health research?

This brings us to liminality. Fittingly, we can use a further example of a monumental social—and literally seismic—change to provide an introduction to this concept. In his work, *Liminality and the Modern*,<sup>15</sup> anthropologist Bjørn Thomassen examines the social and political impacts of the 1755 Lisbon earthquake. As one of the worst natural disasters in human history, claiming anything between 10,000 and over 100,000 lives, the ramifications of this event throughout Europe and beyond were profound for the rupture with status quo thinking at the time that the earthquake caused: It transformed how humans saw their relationship with the natural world. The earthquake was changed:

... [from] brutal fact to a complex cultural sign, redirecting material and mental processes in Europe and merging with the complex contemporary scientific and political developments that secured its long-term relevance.<sup>16</sup>

Direct impacts from the event included profound shifts in philosophical and political thinking about the dominance of man's control over social progress.<sup>17</sup> Thomassen identifies this as a liminal moment in human history. The Europe before the Lisbon earthquake was radically different to the Europe that emerged afterward. Citing a series of other social and personal examples, he suggests that liminality "... captures something essential about the *imprecise and unsettled situation of transitoriness*."<sup>18</sup> This mirrors precisely the character of the Brexit negotiations at the time of writing. Anthropological studies and other works show that the liminal—transitional—phase in moments of profound change—the in-betweenness, if you will—has particular characteristics that are addressed in the next section.

## What is liminality anyway?

Thomassen points out that at the heart of an understanding of liminality are two features: experience and transition. Thus:

To experience something means, etymologically, to go through something. Any discussion of liminality must therefore engage with experience. To take liminality seriously means to take experience seriously ...<sup>19</sup>

15. B. Thomassen, *Liminality and the Modern: Living Through the In-Between* (Farnham: Ashgate, 2014).

16. Op. cit., p. 99.

17. There is even evidence of it impacting the works of Kant; the suggestion is that the trope in Kant's work of the struggle of humanity with the chaos of the natural world is attributable to the influence of this event, Thomassen, *Liminality and the Modern: Living Through the In-Between*, p. 99.

18. Thomassen, *Liminality and the Modern: Living Through the In-Between*, p. 5 (emphasis added). Here Thomassen also cites A. Horvarth, *Modernism and Charisma* (Basingstoke: Palgrave MacMillan, 2013), p. 10.

19. Thomassen, *Liminality and the Modern: Living Through the In-Between*, p. 5.

Moreover, as its Latin origins suggest, liminality is about thresholds: the *limen*. With the crossing of a threshold comes a transition arising from the experience. At the macro-societal level of the Lisbon earthquake, this transition was extensive and far-reaching for communities.

The intellectual father of our understandings of liminality is Arnold van Gennep. In his 1908 book, *Rites of Passage*, van Gennep argued that in moments of profound transition in human life, a schema of three distinct stages characterizes the processes involved. Drawing on an extensive range of ethnographic evidence from tribal communities, van Gennep characterized these stages relative to the rites that accompanied them. The paradigm examples to consider are rites of passage from childhood to adulthood. Thus, there are

... the [i] rites of separation from a previous world, *preliminal rites*, those executed during the [ii] transitional stage *liminal (or threshold) rites*, and the [iii] ceremonies of incorporation into the new world *post-liminal rites*.<sup>20</sup>

The crossing of a threshold into the liminal sphere signified change. It represented rupture with the past. It was characterized by uncertainty and was potentially chaotic. Thus, for van Gennep, rituals were important, first, to *manage potential chaos* and, second, to *help those going through a transformation to navigate* the process. In this respect, a key figure to emerge from the ethnographic studies was the Master of Ceremonies who took on this role as steward through the liminal process.

Later writers, notably Turner,<sup>21</sup> Thomassen,<sup>22</sup> and Szokolczai<sup>23</sup> demonstrated extensively that liminality is not only a feature of tribal cultures, it is also a constant feature of modern human societies, and it impacts on the entire phenomenon of human existence. For example, Turner argued persuasively that in liminal moments social structure is

20. A. van Gennep, *The Rites of Passage* (Chicago: University of Chicago Press, 1960), p. 21. Emphasis as in original text.

21. This article cannot do justice to the contributions of Victor Turner to the development of the concept of liminality, but key texts include V. Turner, *The Ritual Process: Structure and Anti-Structure* (Piscataway, New Jersey: Aldine Transaction, 1969) for the direct continuation of van Gennep's work with tribal communities. Beyond the tribal studies context, see V. Turner, *From Ritual to Theatre: The Human Seriousness of Play* (New York: PAJ Books, 1982), V. Turner, *The Anthropology of Performance* (New York: PAJ Books, 1986). Commentaries on the contributions of Turner include B.C. Alexander, *Victor Turner Revisited: Ritual as Social Change* (New York: Oxford University Press, 1991) and G. St. John, *Victor Turner and Contemporary Cultural Performance* (New York: Berghahn Books, 2008).

22. Thomassen, *Liminality and the Modern: Living Through the In-Between* (Ashgate, 2014). See also, A. Horvath, B. Thomassen and H. Wydra (eds), *Breaking Boundaries: Varieties of Liminality* (New York: Berghahn, 2015).

23. A. Szokolczai, 'Liminality and Experience: Structuring Transitory Situations and Transformative Events', *International Political Anthropology* 2(1) (2009), pp. 141–172; A. Szokolczai, 'Permanent (Trickster) Liminality: The Reasons of the Heart and of the Mind', *Theory and Psychology* 27(2) (2017), pp. 231–248.



replaced by anti-structure—that is, there is a breaking down of preexisting norms and the opening up of possibilities in the processes of transformation and change.

A key feature of liminal understanding is the notion of the *processual*. That is, the focus is on the dynamics of human experience toward a particular end point, and the place of liminality is relative to that experience. Ultimately, there is emergence at the other side of a defined process. Thus, in ceremonial liminality involving rites and a Master of Ceremonies such as that described by van Gennep, there is a clear end point to the processual experience; usually, a change of status.

However, liminality is present even if the end point is not known or clear when liminality is triggered by crisis or chaos. From all of this, three important features about liminality emerge: these are the prospect of (i) permanent liminality, (ii) the risk of the rise of the Trickster, and (iii) a tendency toward imitative pattern of behavior in the absence of a clear path to follow out of liminality, also known as mimesis.<sup>24</sup> First, as argued by Szakolczai, if for whatever reasons there is no “leading out” of liminality by a Master of Ceremonies, then the result can be permanent liminality, for which we might read permanent crisis or chaos.<sup>25</sup> Turner also commented on the failure to complete the processual, leading to schism in society, or sectors thereof, and a “splitting off” of groups.<sup>26</sup> This speaks to the importance of having some sense of the telos of the processual, that is, what is the transformation or concrete change that is sought.

Second, as to the rise of the Trickster, numerous writers point out that in times of crisis, the role of Master of Ceremonies—or more generically Representative of Order—is an attractive prospect for actors who would exploit the uncertainty of liminality for their own ends.<sup>27</sup> Finally, as to mimesis, that is, imitative patterns of behavior, liminality itself and certainly sustained periods of, or permanent, liminality can provoke unreflexive copying of action.

I have considered elsewhere the implication of applying liminal analysis to law.<sup>28</sup> Writing on law as process in 1978, Sally Falk Moore put it thus:

Awareness of the limitations on regulation should affect the research objective of those responsible for drawing up rules, predicting their effects, and monitoring their application. A central concern of any rule-maker should be the identification of the social processes which operate outside the rules, or which cause people to use rules, or abandon them, bend them, reinterpret them, side-step them, or replace them. To recognize that such processes

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24. R. Girard, *Violence and the Sacred* (Baltimore, Maryland: Johns Hopkins University Press, 1979) provides a very full account of mimetic affect and behavior in ancient and more recent cultures.
  25. A. Szakolczai, *Reflexive Historical Sociology* (London: Routledge, 2000), p. 220. The author argues that there are, in fact, three types of permanent liminality corresponding to the three phases of rites of passage.
  26. V. Turner, *From Ritual to Theatre: The Human Seriousness of Play* (New York: PAJ Books, 1982), p. 104.
  27. See L. Ellis, ‘Trickster: Shaman of the Liminal’, *Studies in American Indian Literatures* 5(4) (1993), pp. 55–68. For western societal accounts, see also Thomassen, *Liminality and the Modern: Living Through the In-Between*, pp. 103–105.
  28. See Laurie, ‘Liminality and the Limits of Law in Health Research Regulation.

are inescapable aspects of the use of rule-systems and to try to understand as much as possible about the conditions of their operation would probably be far more effective than taking the view that such activities might be fully controlled simply by tighter drafting of ‘loophole-less’ legislation. Social transactions usually take place in the service of objectives to which legal rules are merely ancillary shapers, enablers, or impediments. Conformity to the rules is seldom in itself the central objective.<sup>29</sup>

This is a call to understand the wider social processes and the need for interaction and dynamics in the development of such (legal) processes. In the health research context, these social processes are both ethical and legal processes about fundamental respect for persons as participants throughout the life cycle of human health research, and it is about the processual challenge of bringing about social value from human health research and from the act of participation itself. Liminality—as a processual phenomenon—draws attention to each step of a process; it requires the identification of a telos for the process in question, and it raises our awareness of likely risks if liminality is created spontaneously or from crisis and/or results in chaos itself. Liminality reminds us also of the crucial role of the need for a Representative of Order, and the ever-present threat of the Trickster, or multiple manifestations thereof.

Brexit is quintessentially a liminal moment in (European) human history.<sup>30</sup> Moreover, given the above analysis, liminality raises a number of questions about the Brexit process. On its likely impact on the future of health research regulation, key questions include

- What is the end point of the liminal process created by Brexit?
- How long will the liminality of Brexit last?
- Which process—or indeed processes—are in play?
- Who is the (legitimate) Representation of Order?
- What is the role of law in the Brexit process, seen as an aspect of liminality?
- Overarchingly, can law manage the chaos that is Brexit?

## **What does liminality predict about Brexit?**

This section attempts to answer the above questions, as of the date of writing (March 29, 2018).

### *What is the end point of the liminal process created by Brexit, and for how long will it last?*

Multiple ironies emerged from the United Kingdom General Election of June 8, 2017, held in the attempt “to strengthen the hand” of Prime Minister Theresa May after the

29. S. Falk Moore, *Law as Process: An Anthropological Approach* (Oxford: Oxford University Press for the International African Institute, 1978), p. 4.

30. D. Edward, ‘In Europe History is the Unseen Guest at Every Table’, *Common Market Law Review* 55(2/1) (2018), pp. 251–261.

Conservative government had given notice of its intention to leave the EU on March 29, 2017. Principal among these ironies was the backfire in rhetoric against the Conservative Party that had labeled the Opposition a “Coalition of Chaos.” Significant lack of progress in EU-UK negotiations in phase 1,<sup>31</sup> absence of sectoral impact assessments about the effects of Brexit (first stated to exist, then denied),<sup>32</sup> a defeat in the HC on a decisive parliamentary vote on any final Brexit deal,<sup>33</sup> no fewer than 10 defeats in the House of Lords on key provisions of the Withdrawal Bill,<sup>34</sup> and the ever-present prospect of a “cliff-edge” no-deal outcome,<sup>35</sup> all fed newspaper headlines about the chaotic nature of the Brexit process. While agreement to move to phase 2 negotiations was reached on December 8, 2017,<sup>36</sup> this was but the end of the beginning of the process outlined by Article 50 TEU. This short article itself imposes a hard 2-year deadline as follows in Article 50(3):

The Treaties shall cease to apply to the State in question from the date of entry into force of the withdrawal agreement or, failing that, two years after the notification referred to in paragraph 2, unless the European Council, in agreement with the Member State concerned, unanimously decides to extend this period.

Any discretion to vary this is within the gift of the European Council.<sup>37</sup> There is much discussion, especially within the United Kingdom, of March 29, 2019, as being “Brexit Day” on a literal interpretation of this provision. However, the matter is not so simple, and two examples serve to illustrate this. First, Theresa May’s Florence speech contained

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31. BBC News, *Whatever Happened to the Brexit Talks?*, January 22, 2018. Available at: <http://www.bbc.co.uk/news/uk-politics-42778234> (accessed 3 September 2018).
  32. BBC News, *Impact Assessments of Brexit on the UK “don’t exist,”* December 6, 2017. Available at: <http://www.bbc.co.uk/news/uk-politics-42249854> (accessed 3 September 2018).
  33. BBC News, *‘Brexit Bill: Government Loses Key Vote After Tory Rebellion’*, December 13, 2017. Available at: <http://www.bbc.co.uk/news/uk-politics-42346192> (accessed 3 September 2018).
  34. BBC News, *Brexit: Government Defeat in Lords Over Terms of Meaningful Vote*, April 30, 2018. Available at: <http://www.bbc.co.uk/news/uk-politics-43951405> (accessed 3 September 2018).
  35. See, for example, the sustained concern by the House of Commons Select Committee on Health and Social Care in its most recent report in which it repeatedly calls for the government to share its contingency planning in the event of such an outcome, House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*.
  36. Joint Report from the Negotiators of the European Union (EU) and the United Kingdom Government on Progress during Phase 1 of Negotiations under Article 50 TEU on the United Kingdom’s Orderly Withdrawal from the EU, December 8, 2017, TF50 (2017) 19. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/joint\\_report.pdf](https://ec.europa.eu/commission/sites/beta-political/files/joint_report.pdf) (accessed 3 September 2018).
  37. See further, *Terms of Reference for the Article 50 negotiations*, as agreed on June 19, 2017. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/eu-uk-art-50-terms-reference\\_agreed\\_amends\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/eu-uk-art-50-terms-reference_agreed_amends_en.pdf) (accessed 3 September 2018).

a proposal for an “implementation,” that is, transitional period of around 2 years after withdrawal to determine the nature of the “new future partnership” that the United Kingdom proposes, without details as to what exactly that partnership would entail (nor with explanation of how it would conform to EU law). So, this would extend the Brexit process by double: from 2 years to 4 years. To be clear, the United Kingdom would no longer be a formal member of the EU from March 29, 2019, but its then uncertain status in formulating its partnership with the EU would endure a further 2 years.<sup>38</sup>

Thus, to attempt to answer the first part of the question at hand—what is the end point of the Brexit process?—we currently have only the vaguest of answers from the United Kingdom. Recall from the earlier discussion that the HC Select Committee on Health and Social Care wrote specifically to the government requesting clarification about its contingency planning in the event of a “cliff edge” withdrawal and specifically with respect to matter of medicines, devices, and public health.<sup>39</sup>

Despite extensive and groundless speculation, two points of clarity did, however, emerge from Theresa May’s Florence speech about what is *not* envisioned: (i) seeking membership of the European Economic Area<sup>40</sup> and (ii) seeking an “ambitious” free trade agreement, going further than any existing trade agreements between the EU and third countries. For example, as May pointed out:

As for a Canadian style free trade agreement, we should recognise that this is the most advanced free trade agreement the EU has yet concluded and a breakthrough in trade between Canada and the EU. But, compared with what exists between Britain and the EU today, it would nevertheless represent such a restriction on our mutual market access that it would benefit neither of our economies.

So, if the status of the United Kingdom will not be either of these existing options, what will it be? Even its status as a third country—that is, equivalent simply to a state that has never been a member state of the EU—is not obvious. As a recent Editorial of the Common Market Law Review comments:

There have been many analogies drawn with Brexit and divorce; but perhaps the converse analogy is equally relevant: that a legal obligation extends beyond the date at which the divorce takes effect because of the nature of the marriage that preceded it. At the edges of the legal order, it becomes harder, but not always impossible, to decouple what constitutes a

38. For discussion, see Editorial Comments, ‘Theresa’s Travelling Circus: A Very British Entertainment Trips Its Way from Florence to Brussels’, *Common Market Law Review* 54(6) (2017), pp. 1613–1626, and pp. 1619–1621.

39. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*.

40. On the arguments against this, see HM Government, *Alternatives to Membership: Possible Models for the United Kingdom Outside the European Union*, (2016), pp. 16–21. Available at: <https://www.gov.uk/government/publications/alternatives-to-membership-possible-models-for-the-united-kingdom-outside-the-european-union> (accessed 3 September 2018).

legal obligation and what is instead a choice made for political expediency and/or economic security.<sup>41</sup>

As for the EU, Article 121 of the draft Withdrawal Agreement specifies December 31, 2020, as the end of the *transition* period,<sup>42</sup> but this does not solve anything in that—if agreement cannot be reached on all matters, and especially the complex question of Northern Ireland—the withdrawal agreement negotiations fall apart entirely:

The European Council recalls that other issues still require agreement and negotiations can only progress as long as all commitments undertaken so far are respected in full, and welcomes in this respect Prime Minister May’s written assurances notably regarding Ireland/Northern Ireland.<sup>43</sup>

The end point—the telos—of Brexit is, then, still unclear. This is problematic from a liminality perspective because it means that there is fundamental uncertainty about when, where, how, and by whom UK citizens will be led out of uncertainty and the ensuing chaos. The empty rhetoric of “taking back control” will eventually wear thin when rights and entitlements are more substantively in play: when decisions eventually *have* to be taken. Furthermore, it suggests that the prospect of permanent liminality does not merely arise with a no-deal “cliff-edge” Brexit; unsettled matters may continue indefinitely.<sup>44</sup> Yet further still, liminality predicts social schism in such extended periods of liminality. This could take the form of sporadic civil unrest and/or further breakup of the United Kingdom itself.

Concerns about an extended period of liminality are compounded when we consider that a key provision of the agreed phase 1 negotiations related to the ongoing jurisdiction of the Court of Justice of the European Union (CJEU):

The Agreement should also establish a mechanism enabling UK courts or tribunals to decide, having had due regard to whether relevant case-law exists, to ask the CJEU questions of interpretation of those rights where they consider that a CJEU ruling on the question is necessary for the UK court or tribunal to be able to give judgment in a case before it. This mechanism should be available for UK courts or tribunals for litigation brought within 8 years from the date of application of the citizens’ rights Part.<sup>45</sup>

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41. Editorial, ‘Polar Exploration: Brexit and the Emerging Frontiers of EU Law’, *Common Market Law Review* 55(1) (2018), pp. 1–16.

42. Draft Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, March 19, 2018, TF50 (2018) 35. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/draft\\_agreement\\_coloured.pdf](https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf) (accessed 3 September 2018).

43. See, the European Council Guidelines (Brussels, December 15, 2017 (OR. en) EUCO XT 20011/17). Available at: <http://data.consilium.europa.eu/doc/document/XT-20011-2017-INIT/en/pdf>, at para 1 (accessed 3 September 2018).

44. Hervey, T.K. (2018) The Immediate Futures of EU Health Law in the UK after Brexit. *Medical law International*. Available at: <http://eprints.whiterose.ac.uk/119455/>

45. Joint Report from the Negotiators of the European Union and the United Kingdom Government on Progress during Phase 1 of Negotiations under Article 50 TEU on the United Kingdom’s Orderly

As of March 19, 2018, Article 151 of the draft Agreement on Withdrawal embodied this in the following manner:

1. Where, in a case which has commenced at first instance within 8 years from the end of the transition period before a court or tribunal in the United Kingdom, a question is raised concerning the interpretation of Part Two of this Agreement, and where that court or tribunal considers that a decision on that question is necessary to enable it to give judgment in that case, it may request the CJEU to give a preliminary ruling on that question. However, where the subject matter of the case before a court or tribunal in the United Kingdom is a decision on an application made pursuant to Article 17 paragraphs (1) or (4) or Article 17a, a request for a preliminary ruling may be made only where the case has commenced at first instance within 8 years from the date from which Article 17a applies.
2. The CJEU shall have jurisdiction to give preliminary rulings on requests pursuant to paragraph 1. The legal effects in the United Kingdom of such preliminary rulings shall be the same as the legal effects of preliminary rulings given pursuant to Article 267 TFEU in the Union and its member states.

Thus, the reach and influence of the EU's judicial arm will therefore be felt long after the United Kingdom ceases to be a member state. If this provokes a domestic political rebellion and forces a hard Brexit, then we are back to a position of permanent liminality for the United Kingdom and the prospect of continued chaos. As to what will happen internally in the United Kingdom with respect to law and governance, this question is picked up again in section "What is the role of law in managing the chaos of the Brexit process, seen as an aspect of liminality?"<sup>46</sup>

### *Which process—or indeed processes—are in play?*

It is all too easily forgotten that Brexit is also a process for the Union institutions and the EU27—it is virgin territory for the EU to lose a member state. Current indicators suggest, however, that rather than causing chaos within EU27 leading to further disintegration, Brexit is actually promoting better integration.<sup>47</sup> And, when we begin to examine the myriad areas where EU law has reach into member state laws, including the multiple institutions, governance and regulatory mechanisms, reporting processes, and

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Withdrawal from the European Union, December 8, 2017, at para 38. Available at: [https://ec.europa.eu/commission/sites/beta-political/files/joint\\_report.pdf](https://ec.europa.eu/commission/sites/beta-political/files/joint_report.pdf) (accessed 3 September 2018).

46. See generally on UK courts post-Brexit, T. Horsley 'Brexit and UK Courts: Awaiting Fresh Instruction', in M. Dougan ed., *The UK after Brexit: Legal and Policy Challenges*, chapter 4, (Cambridge: Intersentia, 2017), pp. 73–94.

47. See C. Hillion 'Withdrawal under Article 50 TEU: An Integration-friendly Process', *Common Market Law Review* 54(2/1) (2018), pp. 29–56.

enforcement procedures that are involved, we appreciate that “liminal hotspots”<sup>48</sup> are appearing across the EU’s legal and political domain. It is apposite, then, to consider the domain of health research regulation as a particular exemplar.

The editors of the *Common Market Law Review* have recently reminded us of a truism about law that echoes the earlier quote in this article from Falk Moore about law as process:

... cooperation is not built merely on rules and regulations; it is also built on a complex network of institutions and processes—political, administrative and judicial—which make the whole system work in practice.<sup>49</sup>

Mention has already been made of the move of the European Medicines Agency from London to Amsterdam. In the realm of health research regulation within which the EU currently has influence with respect to the United Kingdom, there are multiple other agencies and relationships whose future will have to be negotiated covering not just pharmaceuticals but clinical trials,<sup>50</sup> medical devices,<sup>51</sup> advanced therapy medicinal products,<sup>52</sup> and data protection<sup>53</sup> that underpins all of these fields. In respect of the first and the last of the examples, we can speculate what Brexit might mean, and this is addressed below in the third section of this article.

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48. I am grateful to the insights of Paul Stenner for this expression used at a workshop of our Liminal Spaces project, held in Edinburgh in May 2015, details here. Available at: <http://www.liminalspaces.ed.ac.uk/2015/07/01/190/> (accessed December 21, 2017). The event was held as part of the Wellcome funded project ‘Confronting the Liminal Spaces of Health Research Regulation’, Award No: WT103360MA. See, more recently, Szakolczai (2017), *Liminality and Experience: Structuring Transitory Situations and Transformative Events*.
  49. Polar Exploration: Brexit and the Emerging Frontiers of EU Law, *Common Market Law Review*, p. 1620.
  50. Council Regulation (EU) 536/2014 of April 16, 2014, on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L158/1.
  51. Council Directive 90/385/EEC of June 20, 1990, on the approximation of the laws of the Member States relating to active implantable medical devices [1990] OJ L189/17; Council Directive of 93/42/EEC concerning medical devices [1993] OJ L169/1; and Council Directive of October 27, 1998, on in vitro diagnostic medical devices [1998] OJ L331/1. Proposals for reform can be followed here. Available at: [https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework\\_en](https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en) (accessed 3 September 2018).
  52. Council Regulation 1394/2007 of November 13, 2007, on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 [2007] OJ L324/121. Proposals for reform can be followed here. Available at: [http://ec.europa.eu/health/human-use/advanced-therapies/index\\_en.htm](http://ec.europa.eu/health/human-use/advanced-therapies/index_en.htm) (accessed 3 September 2018).
  53. Council Directive 95/46/EC of October 24, 1995, on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31. The General Data Protection Regulation was adopted by the Council of the EU on April 8, 2016, and by the European Parliament on April 14, 2016. Content and legislative history here. Available at: [http://ec.europa.eu/justice/data-protection/reform/index\\_en.htm](http://ec.europa.eu/justice/data-protection/reform/index_en.htm) (accessed 3 September 2018).

As a precursor to this discussion, it will be recalled that the UK government is yet to respond formally to the HC Select Committee on Health and Social Care report on *Brexit: Medicines, Medical Devices and Substances of Human Origin* from March 2018. A clear message from that report, however, is the imperative to seek regulatory alignment between the post-Brexit UK regime and the EU models with respect to agencies, standards, processes, and procedures impacting on all aspects of health research regulation.<sup>54</sup> This is both a metaphor for seeking some degree of continued certainty from the Brexit chaos and a measure of faith in the legal models that have been in operation to date in the health research context, at least for providing adequate and acceptable degrees of safety, efficacy, and performance about the products of health research, notably medicines and medical devices. As the Select Committee noted:

The UK's absence from European decision-making could shift the regulatory environment in Europe towards a more precautionary environment. Such a move could create both opportunities and risks for the UK. However, the worst outcome would be for the UK to become an isolated rule-taker in a more precautionary environment which is less supportive of innovation.<sup>55</sup>

This led it to recommend the following:

We support the Government's intention to negotiate a close relationship with the European Union, including associate membership of the EMA. The UK, with the expertise and capacity of the MHRA, has a great deal to offer its European partners. We believe this is in the interests of citizens and governments on both sides of the negotiations and should be prioritised in the next phase. Failure to achieve an ongoing collaboration would signal the triumph of political ideology over patient care. In the context of continued collaboration with the EMA and maintaining regulatory alignment, it will be in the interests of both sides for the EMA to benefit from the expertise of the MHRA and to continue to allow participation of UK representatives in decision making.<sup>56</sup>

Fears about the implications of unspecified temporal chaos for health research regulation include concerns that laboratories and industrial operations will relocate, that researchers might stop coming to the United Kingdom, and that talent might flee. Without a sense of status quo, there might also be implications within the United Kingdom from a much more deregulated health research sector—equally for life sciences researchers, clinicians, the NHS, and patients alike.

This kind of low-level panic about the unknown, and a desire to hold on to certainty (irrespective of its foibles), is precisely what liminality is. A liminal perspective can hope

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54. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*.

55. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 41.

56. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 45.



neither to address the above concerns in terms of concrete responses nor to answer the myriad of questions that arise from them. However, to the extent that law is often called upon and relied upon to bring certainty from chaos, the liminal lens can be focused on what expectations arise from these processes and what can reasonably be expected of law and its actors as a result. This discussion occurs at a time when anxiety is mounting because there are only questions—multiplying questions—and too few answers. Law is but an instrument to put answers into effect, but it is a substitute for neither the political will nor the social values that drive the processes of change. Brexit shows that we are perhaps overestimating what law can resolve about these profound social shifts. In the language of liminality, can law be the Representative of Order that liminality predicts we require to lead us from chaos?

### *Who is the (legitimate) Representative of Order?*

Manifestly, the specter of chaos is a recurrent theme in this article. One might reasonably hold to the view that the architect of the chaos that is Brexit is former UK Prime Minister David Cameron. He put the United Kingdom on the current path by announcing a referendum to appease hard-liners within his own party. That decision was soon exploited by various individuals, including Boris Johnston, Michael Gove, and Nigel Farage—each manifestly acting in his or her own political self-interest under the guise of seeking a return of sovereignty to the United Kingdom and a clarion call to “take back control.”

Liminality warns us about the risk of the rise of the Trickster. As Thomassen comments:

Tricksters are trained in upsetting the social order by reversing values, and via their rhetorical and theatrical skills. As weber recognized, in moments of radical social or political change, in ‘out-of-the-ordinary-moments’, we see the emergence of charismatic leadership . . . the trickster mimics charisma (Hovarth 2013: 9),<sup>57</sup> and his magnetic powers must certainly not be underestimated, hollow as they are . . . The analysis of the trickster as a particularly dangerous type of political leader that may emerge in liminal situations, as proposed by Hovarth (1998),<sup>58</sup> may well represent a breakthrough in our understanding of how liminal moments or period may be carried in dangerous directions.<sup>59</sup>

An almost instinctual understanding of this phenomenon has arisen precisely in the context of Brexit. A 2017 Editorial from the Common Market Law Review commentary on Theresa May’s Florence speech finishes thus:

. . . the Brexit circus continues to rattle along its merry way. And its most bizarre joke? It is the clowns who are asking to see magic conjuring tricks from the bemused spectators—the

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57. Horvarth, *Modernism and Charisma*.

58. A. Hovarth, ‘Tricking into the Position of the Outcast: A Case Study in the Emergence and Effects of Communist Power’, *Political Psychology* 19(2) (1998), pp. 331–347.

59. Thomassen, *Liminality and the Modern: Living Through the In-Between*, p. 105.

same spectators who never even wanted to watch this grotesque carnival in the first place. Oh, those British—so *drôles* . . . .<sup>60</sup>

It would be too easy to dismiss these comments as political sour grapes. The anthropological point is that this phenomenon is predicted by liminality, and when tricksters emerge, they take advantage of liminality. We must seek to counter this by various practical measures at the highest political levels. However, in the context of this article, the important point is that this trickster phenomenon might also occur within and across the multiple liminal hotspots identified above within health research regulation. There is therefore all the more need for representatives of order to lead stakeholders through the liminal moment as an obvious counterpoint to this.

Thus, even if we cannot yet say what is the end point of the Brexit process for the United Kingdom as an international state actor, we can still recognize micolevel liminal spaces and seek to identify appropriate end points and telos of the associated liminal processes that are being created as a direct and indirect result of Brexit. For example, I have argued elsewhere with colleagues that there is an important role for regulatory stewardship in health research regulation, that is, the need for identified actors to work with researchers to help guide them through the regulatory landscape.<sup>61</sup> I suggest here that this becomes all the more crucial in the liminal periods of transition as the United Kingdom leaves the EU. This might mean, for example, an increased role for regulators such as the Health Research Authority, the agents of the Medicines & Healthcare products Regulatory Agency, the Human Tissue Authority, and the Information Commissioner's Office in navigating particular hotspot areas of health research regulation with respect to their specific fields of competence and influence. This is both a regulatory and a political issue. It is self-evident that the regulators ought to act proactively within their own sectors to ensure compliance and to promote sound research; the less obvious role is where and how they might assume increased roles as political actors. Consider, however, that this tacit assumption is already emerging. A key recommendation from the Health and Social Care Committee report in March 2018 sought to place the MHRA in a crucial position with respect to ongoing negotiations and future influence in the formation and implementation of EU medicines policy:

In the context of continued collaboration with the EMA and maintaining regulatory alignment, it will be in the interests of both sides for the EMA to benefit from the expertise of the MHRA and to continue to allow participation of UK representatives in decision making.<sup>62</sup>

And what of the law in all of this? As asked previously, can the law be the Representative of Order that we require, or might it assume the mantle of Trickster that is also predicted by liminality?

60. Editorial, 'Polar Exploration: Brexit and the Emerging Frontiers of EU Law', pp. 1624–1625.

61. G. Laurie, et al., 'Charting Regulatory Stewardship in Health Research: Making the Invisible Visible', *Cambridge Quarterly of Healthcare Ethics* 27(2) (2018), pp. 333–347.

62. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 45.

Two examples from health research regulation unpack these ideas more fully. These are data protection and clinical trials regulation. In both sectors, the reach and influence of European law has been significant and subject to ongoing reform in the lead up to the Brexit process.

### *Data protection*

The General Data Protection Regulation (GDPR)<sup>63</sup> applied in all 28 member states of the EU from May 28, 2018. Manifestly, this date was before any formal departure of the United Kingdom from the EU, and the United Kingdom must comply fully with EU law for now. The Data Protection Bill 2017–2019 is proceeding through Westminster at the time of writing, and it serves as a source for various lessons that arise from this liminal legislative period. For health research regulation, the GDPR will have a range of impacts. For example, the regulation now makes processing of personal data on the grounds of consent a more onerous exercise for those seeking to reply on this provision. Thus, Article 4 provides:

(11) ‘consent’ of the data subject means any *freely given, specific, informed and unambiguous indication* of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her [emphasis added].

This represents a very specific, legalistic view of the role of consent that focuses on the nature of degree of informedness of the data subject. Given that health research is determinedly open-ended, it will be increasingly difficult to meet this criterion in a health research context. Moreover, the tradition backstop measure—relying on anonymized information—is also potentially rendered more problematic because the GDPR now makes pseudonymized data also part of the definition of “personal data” (Article 4(5)). In short, processing on the basis of public interest becomes a far more viable option for the research community when “personal data” are being used for research.

At present, however, “public interest” is defined very narrowly in the Data Protection Bill 2017–2019:

In Article 6(1) of the GDPR (lawfulness of processing), the reference in point (e) to processing of personal data that is necessary for the performance of a task carried out in the public interest or in the exercise of the controller’s official authority includes processing of personal data that is necessary for—

- (a) the administration of justice,
- (b) the exercise of a function of either House of Parliament,
- (c) the exercise of a function conferred on a person by an enactment or rule of law,

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63. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 45.

- (d) the exercise of a function of the Crown, a Minister of the Crown, or a government department, or
- (e) an activity that supports or promotes democratic engagement. (Clause 8)

Not only is there no mention of research in this context, but the list refers to actors and matters of the same kind (*eiusdem generis*); thus, as a matter of standard legislative interpretation and even if this list is nonexhaustive, other examples will also have to be of the same kind to qualify. On the face of the current draft Bill, it is not at all obvious that health research would qualify.

So, what does liminality tell us about these processes? The GDPR does not mandate any particular view of public interest. Moreover, with the prospect of Brexit, it becomes all the more incumbent on health research stakeholders to lobby Westminster for clearer explicit mandate within the United Kingdom with respect to processing of data for research purposes in a proven public interest. More specifically, however, the call for regulatory alignment itself must be subjected to scrutiny. In the first instance, it clearly suggests that law—as text—ought to reflect as closely as possible a common position between the United Kingdom and the EU law. But if we adopt the processual analysis that liminality encourages, regulatory alignment must be something that itself is seen as *process*. This is particularly important with a concept as amorphous as public interest that is subject to myriad variations of influence and interpretation. How can we ensure that what counts as public interest (in health research) will align with Continental European interpretations and values over time? Without the longer-timer oversight of the CJEU, will “public interest” be determined differently? Who might take advantage of the removal of one possible avenue of scrutiny of domestic implementation, that is, a reference to the CJEU?

Notwithstanding, the HC Select Committee signaled its satisfaction with a statement from Theresa May on March 2, 2018, to the effect:

... The free flow of data is also critical for both sides in any modern trading relationship too. The UK has exceptionally high standards of data protection. And we want to secure an agreement with the EU that provides the stability and confidence for EU and UK business and individuals to achieve our aims in maintaining and developing the UK’s strong trading and economic links with the EU... [t]hat is why we will be seeking more than just an adequacy arrangement and want to see an appropriate ongoing role for the UK’s Information Commissioner’s Office. This will ensure UK businesses are effectively represented under the EU’s new ‘one stop shop’ mechanism for resolving data protection disputes.<sup>64</sup>

Note, as above, there is subtle yet emphatic regulatory realignment here with respect to the role of the regulator. Its task becomes not simply one of ensuring stakeholder compliance with the law but also of acting as our watchdog with respect to the enduring

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64. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 109, quoting PM Speech. Available at: <https://www.gov.uk/government/speeches/pm-speech-on-our-future-economic-partnership-with-the-european-union> (accessed 3 September 2018).

regulatory alignment of domestic law with its European legal counterpart. This is neither a neutral nor an apolitical exercise. The Information Commissioner's Office is being tasked with the Role of Representative of Order here, both legally and politically. For a concept as vague and malleable as "public interest"—both generally and in the context of what it might mean for health research regulation—there will be introduced varying and potentially competing views about what counts as important. The spectrum of political and social values that led to Brexit—as manifestly divergent with common values underpinning the EU project—might equally come to bear on how "public interest" is interpreted in the future. The role, then, of our Representative of Order cannot be the bare text of law; it will become the context of the regulator interpreting the law.

### *Clinical trials*

This links to the second example in this section: clinical trials. The Clinical Trials Regulation<sup>65</sup> is due to apply in 2019, albeit that a precise date is not yet fixed. This particular legislative instrument therefore might—or might not—fall within the formal membership period of the United Kingdom. Other authors in this volume explore the specifics of the Regulation itself; for present purposes, the example raises a number of points also predicted by liminality.

Liminality predicts potential social schism, the rise of the trickster, and also mimesis: copying of behavior. Copying, per se, is not necessarily problematic. There are very good reasons why the form and function of the Clinical Trials Regulation ought to apply in the United Kingdom, not least to ensure the continuation of high standards and approximation with near-markets on the European continent. This was the "almost unanimous"<sup>66</sup> view in the evidence to the HC Select Committee on Health and Social Care with respect to Brexit: medicines, medical devices, and substances of human origin. This is no surprise. Liminality also suggests that this "copying" will happen, at least in the first instance. As with the previous example, this phenomenon is captured in the phrase "regulatory alignment," and the call is as strong in the clinical trials section as with data protection.

Equally, because liminality is typified by anti-structure, that is, the upending of the existing norms and structures—we must be alert to the possibility that any initial alignment might not hold. For clinical trials, for example, the prospect of Brexit might be seen in some quarters as an opportunity to reject the Sudden Unexplained Serious Adverse Reaction (SUSARs) regime (seen by some as generating unnecessary white noise in data reporting)<sup>67</sup> or as a chance to decouple the clinical trials regime from links with

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65. Council Directive 95/46/EC of October 24, 1995, on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995].

66. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 18.

67. For discussion, see A. Mascolo, et al., 'Can Causality Assessment Fulfill the New European Definition of Adverse Drug Reaction? A Review of Methods Used in Spontaneous Reporting', *Pharmacological Research* 123 (2017), pp. 122–129; S. Wallace, et al.,

Good Clinical Practice Guidelines.<sup>68</sup> This would fit with the narratives of “taking back control” that were so influential in the lead up to the Brexit referendum. In contrast, the HC Select Committee has recommended that

The UK should aim to have a seat at the International Council on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) in its own right. We call on the Government to confirm that it will apply for full membership of the ICH at the earliest possible opportunity and to set out its timeline for doing so.<sup>69</sup>

This, however, is a soft option that would carry neither full political weight nor any legal basis for automatic entry for the United Kingdom. As a further liminal process to be navigated, the opportunities to influence and derail such efforts are considerable.

We can only speculate as to the processes by which the UK government might seek regulatory alignment on clinical trials; this might be treated as retained EU law or the United Kingdom might pursue primary legislation. Pragmatically, the operational downstream implications are considerable, including ongoing access to the European database on SUSARs and to demonstrate compliance more generally. Insufficient alignment by the United Kingdom on its chosen path of clinical trials regulation might rapidly and devastatingly impact on patient health and access to medicines. As with data protection, an overt role for a Representative of Order here to police effective alignment will be crucial. Specifically in this sector this is likely to be the MHRA. More broadly, however, given that the actual path to regulatory alignment will require further legislative action, it will also put increased responsibility on Parliament to police the constitutional dimensions of the process—raising important questions about the relationship between Parliament and the post-Brexit Government, including whether and how the Westminster Parliament might have more direct relationship with European institutions in discharge of its oversight function with respect to the robustness of any alignment exercise that is sought through domestic legislation.<sup>70</sup>

As this section demonstrates, because liminality predicts the potential rise of trickster in all liminal moments, there is a need to be alert to this at each of the macro-, meso-, and micro-level of regulation. While there might be valid reasons to advocate the United Kingdom pursuing an evermore divergent path from the EU, these reasons must be subjected to extremely careful scrutiny. Their telos must be clearly identified and justified, and proponents must be able to demonstrate the integrity of their motives. This is

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‘Serious Adverse Event Reporting in Investigator-Initiated Clinical Trials’, *Medical Journal of Australia* 204(6) (2016), pp. 231–233.

68. See Academy of Medical Sciences, *Regulation and Governance of Health Research: Five Years On* (2017). Available at: <https://acmedsci.ac.uk/publications> (accessed 3 September 2018).

69. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 35.

70. See further, M. Gordon, ‘Brexit: The Relationship Between the UK Parliament and the UK Government’ in Dougan (2017), *Polar Exploration: Brexit and the Emerging Frontiers of EU Law*, *Common Market Law Review*, pp. 15–33.

not to belie the motives of those who have criticized the EU regimes to date, and the advent of both the General Data Protection Regulation (GDPR) and the Clinical Trials Regulation (CTR) are both explicit acknowledgements of serious weaknesses in the predecessor Directives. Notwithstanding, the EU regimes to date are largely tried and tested. When it comes both to the context of the enduring liminality of Brexit for the whole of the UK economy and social structure, we must not be naive to imagine that political and economic pressure will not be brought to bear also on the health research sector.

### *What is the role of law in managing the chaos of the Brexit process, seen as an aspect of liminality?*

The legal regimes represented by data protection and clinical trials are among the most complex within the EU system. In terms of Brexit, however, they represent a mere tiny fraction of the myriad ways that EU laws and regulations permeate the legal systems of the United Kingdom. While it is understandable, then, that the EU Withdrawal Bill 2017 provides that: “[d]irect EU legislation, so far as operative immediately before exit day, forms part of domestic law on and after exit day” (Clause 31), once again, a liminal analysis offers some insights on what this legislative action represents.

As stated above, liminality—in the face of uncertainty—often results in mimesis (copying). The Withdrawal Bill must go down as the most manifest example of this in history. But, so what? The reader might ask. Well, mimesis in a strict anthropological and sociological sense is also characterized by *unreflexive* behavior.<sup>71</sup> For this reason, one of the most important recommendations of the HC Select Committee on Health and Social Care bears repeating:

We recommend that the nature and level of UK ‘regulatory drift’ in the life science sector from the EU be systematically assessed at regular intervals by current and future UK Governments, in order to prevent issues over a lack of harmonisation occurring in the future.<sup>72</sup>

This is all the more important for the Withdrawal Bill. Liminality requires us to follow the process through and out of the other side. And so, where will the Withdrawal Bill lead? Two core concerns in this regard emerge.

First, consider a subsequent clause in the 2017 Bill. Clause 6(3) states:

Any question as to the validity, meaning, or effect of any retained EU law is to be decided, so far as that law is unmodified on or after exit day and so far as they are relevant to it—

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71. Thomassen, *Liminality and the Modern: Living Through the In-Between*, pp. 102–103.

72. House of Commons Select Committee on Health and Social Care, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, at para 73.

- (a) in accordance with any retained case law and any retained general principles of EU law and
- (b) having regard (among other things) to the limits, immediately before exit day, of EU competences.

In other words, the United Kingdom's interpretation of the legacy of EU law will be fixed—frozen in permanent liminality—at the date of exit. UK courts will not be required to follow the evolution of EU law over time, although equally they are at liberty to do so. In areas as important, sensitive and highly dynamic such as health and health research regulation, the chasms might soon appear and could quickly grow. This Bill ossifies EU law at a particular moment in time, leaving the United Kingdom at the same time both part of the history of the EU, while potentially bearing less and less similarity to what the EU will inevitably evolve to become. Everything will depend on the future UK-EU relationship. One answer to a concern about divergence might be to refer to the Norwegian-EU relationship: bluntly, courts in Norway have to follow the *acquis communautaire*. However, at the time of writing a Norway-type model seems increasingly unlikely, and the kind of European Court of Justice oversight that flows from this close relationship remains a very red line for the United Kingdom, as demonstrated by repeated official announcements.<sup>73</sup>

The “discretion” to be afforded to UK courts—possibly to follow EU law in some areas and maybe not in others—simply strengthens the charge here that significant areas of the Brexit process run a risk of permanent liminality or at least enduring chaos for a considerable time.

A possible answer to this point might be to refer to Clause 7(1):

A Minister of the Crown may by regulations make such provision as the Minister considers appropriate to prevent, remedy, or mitigate—

- (a) any failure of retained EU law to operate effectively, or
- (b) any other deficiency in retained EU law, arising from the withdrawal of the United Kingdom from the EU.

However, quite apart from the considerable ambiguity, uncertainty, and potential constitutional crisis that looms at the prospect of such draconian powers, this provision merely legislates for future liminal hotspots. The same risks as identified above will reemerge. The unfettered discretion embodied in this provision suggests that there is little knowable *telos* for Ministerial actions; it is unknowable who might be affected by the said actions—and so who will be thrust into liminality; there is no mention or reference to rights (rites?) to protect citizens subjected to such powers; and there is the ever-present concern about abuse by trickster figures.

Such poorly drafted law can itself be seen as a trickster in the Brexit process. Law, at its best, acts as the consummate representative of order—standing objectively outside of

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73. UK government official documentation can be found here. Available at: <https://www.gov.uk/government/publications?departments%5B%5D=department-for-exiting-the-european-union> (accessed 3 September 2018).



social processes affecting individuals and guiding them dispassionately toward socially valued ends. The EU Withdrawal Bill has none of these traits.

### **Conclusion: Does liminality help us to deal with Brexit?**

Matters that profoundly affect human values such as health and human health research move forward rapidly, unceasingly, and unevenly. Health research regulation is among some of the most tightly regulated areas of human activity and for good reason. The EU has instigated, and maintains, one of the most robust and high-quality regimes that exists anywhere in the world. While far from perfect, these regimes consistently deliver research within the highest ethical parameters.

The impact of the Brexit process on health research in the United Kingdom, and more particularly on its regulation, is necessarily uncertain. This must be a cause for concern. This article has offered the perspective of liminality to suggest that it is nonetheless possible to anticipate and prepare for possible features that will emerge from this uncertain Brexit process as a quintessential liminal moment in (European) human history. Liminality—typified by transition and change—is a universal human experience; as such there are good reasons to expect that these predictions have some basis. Liminality is often chaotic, and the purpose is to lead people out of liminality. To do this—whether at the macro level of the future status of the United Kingdom or at the micro level of particular regulatory regimes—a clear end point (telos) must be identified. Liminality is also typified by mimetic behavior, and while this explains the wholesale adoption of EU law into domestic law by the EU Withdrawal Bill 2017, this particular legislative move signally fails to reflect the processual element in these dynamics. Rather, it ossifies EU law within the United Kingdom's future legal framework; the solution to move beyond this is arguably worse: the 2017 Bill offers unspecified, obscure, and undemocratic powers to faceless bureaucrats. For citizens facing the liminality of the Brexit process, this suggests that the need for a representative of order has never been greater. Moreover, liminal processes predict the emergence of tricksters who seek to take advantage of uncertainty and emerging chaos. In the health research context, this means that it is all the more incumbent on local agents and actors—such as current regulators—to assume the role of representatives of order. The task is to protect citizens and promote health research in the future United Kingdom in ways that do justice to its history as a member state of the EU and which will represent a fitting regime for whatever partnership emerges from the Brexit process.

As to the role of law itself in these processes, liminality predicts that it will not deliver salvation or even much clarity from the chaos. Liminality is an essential human experience, and we will have to learn to live with extended periods of time where we only have questions and too few answers. Law cannot predict or determine the future as much as we would like; indeed, as demonstrated by various examples from the Withdrawal Bill itself, the law might be cast in the role of trickster. Equally, a liminal lens does not reveal a clear path forward in our desperate desire to understand. Liminality does, however, alert us to the nature of the processes ahead and remind us that a reversion to law for comfort is a misguided step. This is a mess of our own making.

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