



Expectations as techniques of legitimation? Imagined futures through global bioethics standards for health research

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ABSTRACT

I argue that expectations or strong beliefs about what can occur, and the imaginaries they construct, can be shaped by organizations and used by them as techniques for public legitimation of their governance and regulatory activities. I advance this argument by reference to the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The expectations and imaginary flowing from the ICH's mission and framing, 'harmonisation for better health', support a focus on technological development for the production of safe, quality, and effective pharmaceuticals and individual ethical conduct to achieve it. The expectations also marginalize wider systemic issues relating to social justice, particularly those affecting the global South. The central role of scientific-technical knowledge and expertise to harmonization abets the latter by minimizing the value to governance of public knowledges on systemic issues. Instead of ensuring the contribution of these knowledges to governance through public participation, there is an attempt to bolster legitimation through communication of expectations and transparency to show practices are in accordance with them (ie expectations are met).

KEYWORDS: expectations, imaginaries, legitimation, bioethics, social justice, risk

I. INTRODUCTION

Expectations or strong beliefs about what biomedical science can deliver for public health have, it seems, reached new heights with coronavirus disease 2019 (COVID-19).

According to the Director of the Wellcome Trust, Jeremy Farrar, ‘To dream of imminent solutions [to COVID-19] is only human. *But progress will come from controlled expectations.*’¹ These expectations are already being met through the development and deployment of vaccines and treatments against COVID-19. Expectations are seen to play a key role in making this happen. Delivering on these expectations occurs, in part, through flexible and adaptive governance and regulation of the development process,² and intensive research by the industry.³

Notwithstanding the obvious contemporary importance of expectations and related concepts for biomedical governance and regulation, their roles receive little attention within legal and regulatory studies.⁴ Expectations and related concepts do feature as part of other discussions. For instance, the benefits and value of new science and technology can constitute positive expectations about what they may deliver. These are weighed against negative expectations about concerns and risks, and together provide reasons for regulation (or none), and in turn a basis for its legitimation.⁵ The weighing of these positive and negative expectations, with an outcome in favor of the former, is also central to informed consent to treatment and the justification of human participation in health research (as I detail further below).⁶ More broadly, expectations also feature in the ‘reasonable expectation of privacy’, including within health research,⁷

1 Jeremy Farrar, *Let us Get Real. No Vaccine Will Work as if by Magic, Returning Us to ‘Normal’*, THE GUARDIAN, Sept. 6, 2020 (emphasis added).

2 For discussion, see: Wellcome Trust, *A Blueprint for Dynamic Oversight. How the UK Can Take a Global Lead in Emerging Science and Technologies* (2019). Also see: Nuffield Council on Bioethics, *Emerging Biotechnologies: Technology, Choice and the Public Good* (2012). <http://nuffieldbioethics.org/project/emerging-biotechnologies> (accessed Sept. 1, 2020).

3 This may lead to ‘blockbusters’ for an industry struggling to innovate—see: Forbes, *Pharma’s Innovation Crisis, Part 1: Why the Experts Cannot Fix It and What To Do About It Part 2*. <https://www.forbes.com/sites/stanfleming/2018/09/06/why-experts-cant-fix-pharmas-innovation-crisis-part-1-and-what-to-do-about-it-part-2/#563430fc16fe> (accessed Sept. 1, 2020).

4 For one recent notable exception, see: Mark Hanna, *Between Law and Transnational Social Movement Organizations: Stabilizing Expectations of Global Public Goods*, 44 J. L. SOC. 345 (2017). In the context of health research some have discussed imaginations, imaginaries or imagined futures, see: Graeme Laurie, *Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-Between?*, 25(1) MED. L. REV. 47 (2016), 68–71 on ‘imagining liminal regulatory spaces’. Also see: Jan Komárek, *Europe’s Democratic Imaginary: Government by the People, for the People and of the People?*, 22(6) MAAS. J. EURO. COMP. L. 784 (2015); Jiří Příbáň, *Constitutional Imaginaries and Legitimation: On Potentia, Potestas, and Auctoritas in Societal Constitutionalism*, 45(1) J. L. SOC. S30.

5 For discussion in the context of EU regulation in the public health domain, see: MARK L. FLEAR, *GOVERNING PUBLIC HEALTH* (hardback 2015; paperback 2018), chapter 2 ‘EU Public Health Governance’.

6 In relation to informed consent in the context of treatment and research respectively, see: EMILY JACKSON, *MEDICAL LAW: TEXT, CASES AND MATERIALS* (5th ed., 2019), chapters 4 and 10; GRAEME T. LAURIE ET AL., *MASON AND MCCALL SMITH’S LAW AND MEDICAL ETHICS* (11th ed., 2019), chapters 4 and 20. In Scottish case of *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 the United Kingdom Supreme Court was highly attentive to patient expectations of ‘material risks’ in the doctor’s duty, ie ‘to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments’ (Para. 87).

7 This is the legal test for determining in which places and in which activities a person has a legal right to privacy and is especially relevant in US law—see: Matthew B. Kugler and Lior Jacob Strahilevitz, *Actual Expectations of Privacy, Fourth Amendment Doctrine, and the Mosaic Theory*, 2015 SUP. COURT REV., 205 (2016). In the context of health research, see: Mark J. Taylor and James Wilson, *Reasonable Expectations of Privacy and Disclosure of Health Data*, 27(3) MED. L. REV. 432 (2019).

the connected principles of legal certainty and legitimate expectations,⁸ and relate to legal doctrine on promises.⁹

Within socio-legal studies, Riles' influential work is noteworthy in that it relates to expectations by exploring how legal technicality includes the 'hopes, ambitions, fantasies and day-dreams of armies of legal engineers'.¹⁰ Elsewhere, in science and technology studies (STS), the sociology of expectations, and cognate disciplines such as economics and anthropology, scholars refer to expectations, regimes of hope, promises, visions, imaginaries, narratives, and more.¹¹ These terms, each in their own way, express the basic idea that technological innovations preexist in individual and collective imaginations and that it is necessary to perform them into being. These terms amount to 'temporal trajectories'¹² that provide the rhetorical resources to make this happen. This point resonates with Ferrar's claim about the role of expectations, and links to discussion on the performative nature of language, such as that of promises.¹³

I understand expectations as one such temporal trajectory. Expectations provide 'prospective structures' that are 'put forward and taken up in statements, brief stories

8 Legal certainty and legitimate expectations are closely connected concepts found in many legal orders. For discussion of these concepts in one legal order, see: PAUL CRAIG, *EU ADMINISTRATIVE LAW* (2012), chapter 18 'Legal Certainty and Legitimate Expectations'. Also see: Lord Mance, *Should the Law Be Certain?*, THE OXFORD SHRIEVAL LECTURE (2011), https://www.supremecourt.uk/docs/speech_111011.pdf (accessed Sept. 1, 2020). Legitimate expectations are a key ground for judicial review of the decisions of public authorities, in particular relating to use of their procedures. In general, see: MATTHEW GROVES AND GREG WEEKS EDS, *LEGITIMATE EXPECTATIONS IN THE COMMON LAW WORLD* (2017).

9 Contracts have long been theorized and understood as a mechanism for enforcing promises, see: DORI KIMEL, *FROM PROMISE TO CONTRACT: TOWARDS A LIBERAL THEORY OF CONTRACT* (2003). Promise is also relevant to the doctrine of promissory estoppel and expectation losses in relation to damages in contract law, see: EWAN MCKENDRICK, *CONTRACT LAW: TEXT, CASES, AND MATERIALS* (8th ed., 2018), chapter 5.

10 Annalise Riles, *A New Agenda for the Cultural Study of Law: Taking on the Technicalities*, 53 *BUFF. L. R.* 973, 975 (2005). One application of this looks at metaphors in the law and how they communicate 'stories and myths; even dreams, hopes and fears'—Paul James Cardwell and Tamara Hervey, *Bringing the Technical into the Socio-legal: Metaphors of Law and Legal Scholarship of a Twenty-First Century European Union*, in *EXPLORING THE 'LEGAL' IN SOCIO-LEGAL STUDIES* (David Cowan and Daniel Wincott, eds., 2016), at 159. All of this work is essentially related to or about the future or futures, and how they are imagined—also see: SÍAN BEYNON-JONES AND EMILY GRABHAM EDS., *LAW AND TIME* (2018); Roxanne Mykitiuk and Isabel Karpin, *Fit or Fitting In: Deciding Against Normal When Reproducing the Future*, 31(3) *CONTINUUM* 341 (2017); Carla Rice et al., *Imagining Disability Futurities*, 32(2) *HYPATIA* 213 (2017).

11 Kornelia Konrad et al., *Performing and Governing the Future in Science and Technology*, in *THE HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES* 467 (Ulrika Felt et al. eds., 4th ed., 2017); Maureen C. McNeil et al., *Conceptualising Imaginaries of Science, Technology, and Society*, in *THE HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES* (Ulrika Felt et al. eds., 4th ed., 2017).

12 REBECCA BRYANT AND DANIEL M. KNIGHT, *THE ANTHROPOLOGY OF THE FUTURE* (2019), at 2. The specific focus in this work is on distinguishing expectations and related concepts including anticipation and hope. There is limited legal or law-related scholarship on imaginaries: see the introduction to this special issue.

13 See the foundational work: JOHN L. AUSTIN, *HOW TO DO THINGS WITH WORDS* (ED., 2018); JOHN R. SEARLE, *SPEECH ACTS: AN ESSAY IN THE PHILOSOPHY OF LANGUAGE* (1969).

and scenarios¹⁴ to construct and engender ‘imagined futures’,¹⁵ engage investors, and build social and institutional support for innovation and the implementation of science and technology. Legitimation is a generally overlooked aspect of the resources provided by rhetorical terms within these various literatures. I bring these literatures into conversation to illuminate how expectations may be set and shaped by organizations, and used by them to legitimate their governance and activities. In doing so, I reveal how expectations provide a key resource for performing imagined futures into being.

My case study for this analysis is the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).¹⁶ The ICH is a key standard setter for global bioethics standards on the development of pharmaceuticals. ICH guidelines are de facto regulatory requirements that shape the pathway to market authorization of pharmaceuticals, including vaccines (hereinafter, for simplicity only the former is usually mentioned). These include for COVID-19 as well as other health scourges in ICH Members and non-ICH countries. I draw information about the ICH from its website,¹⁷ including statements made there, ICH Articles of Association, Rules of Procedure of the ICH Assembly,¹⁸ and the ICH’s guidelines.¹⁹ The European Union (EU),²⁰ Japan and the United States (US) are the ICH’s Founding Members, and there are also corresponding Founding Industry Members from their respective industry associations. The ICH is apt for this study, since, as with other examples of global governance, its importance for law and regulation tends to be masked by geographic distance and reliance on (supra)national legal and regulatory orders for implementation of its global norms.²¹ The ICH is hardly touched

14 Harro van Lente and Arie Rip, *Expectations in Technological Developments: An Example of Prospective Structures to Be Filled in by Agency*, in GETTING NEW TECHNOLOGIES TOGETHER: STUDIES IN MAKING SOCIOTECHNICAL ORDER (Cornelis Disco and Barend van der Meulen eds., 1998), at 205. Also see: HARRO VAN LENTE, PROMISING TECHNOLOGY: THE DYNAMICS OF EXPECTATIONS IN TECHNOLOGICAL DEVELOPMENT (1993).

15 JENS BECKERT, IMAGINED FUTURES: FICTIONAL EXPECTATIONS AND CAPITALIST DYNAMICS (2016).

16 The discussion looks at the ICH level of multi-level governance of health research, rather than at the level of individual ICH Members. On multi-level governance and the EU in particular, see: LIESBET HOOGHE AND GARY MARKS, MULTILEVEL GOVERNANCE AND EUROPEAN INTEGRATION (2001). Black’s definition of regulation encompasses the focus of this article, in that it is ‘the intentional use of authority to affect behaviour of a different party *according to set standards*, involving instruments of information-gathering and behaviour modification’—see: Julia Black, *Critical Reflections on Regulation*, 27 *AUS. J. LEGAL PHIL.* 1 (2002) (emphasis added). This understanding of regulation includes ‘hard law’, ‘soft law’, social norms, standards and the market. See further: Robert Baldwin et al., *Regulation, the Field and the Developing Agenda*, in THE OXFORD HANDBOOK OF REGULATION (Robert Baldwin et al. eds., 2011); ROBERT BALDWIN ET AL., UNDERSTANDING REGULATION: THEORY, STRATEGY, AND PRACTICE (2nd ed., 2012). On the distinction (or not) between ‘governance’ and ‘regulation’, see: Christel Koop and Martin Lodge, *What is Regulation? An Interdisciplinary Concept Analysis*, 11(1) *GOV. REG.* 95 (2017).

17 ICH, *Introduction to ICH*, http://www.ich.org/fileadmin/Public_Web_Site/ABOUT_ICH/Vision/Introduction_to_ICH_24Jun2014.pdf (accessed Sept. 1, 2020).

18 Especially 3.6 Assembly Decision-Making Process, Rules of Procedure of the ICH Assembly (2019).

19 ‘Harmonisation’ is the British rather than the American English spelling of the word. This might not be a point of normative significance. Although the choice of spelling might not be accidental, further discussion of this point is not relevant to the present argument.

20 For discussion, see: Flear, *supra* note 5.

21 David Kennedy, *The Mystery of Global Governance*, 34 *OHIO NORTH. UNI. L. REV.* 827 (2008); Thomas Weiss and Rorden Wilkinson, *Rethinking Global Governance? Complexity, Authority, Power, Change*, 58 *INT. STUD. Q.* 207 (2014).

upon in the literatures on medical and health law²²—or indeed global governance and international organizations.²³

The analysis in this article makes visible the way in which the expectations within the ICH's mission of 'harmonisation for better health'²⁴ set and shape an imaginary of the future. The expectations and imaginary concern the outcome of the harmonization process: producing safe, quality, and effective pharmaceuticals. This outcome focuses on technological development and its achievement in line with principles of individual ethical conduct²⁵ or so-called 'quandary ethics'.²⁶ I argue that the expectations and imaginary of this outcome may be used by the ICH to generate public legitimation for itself and its global bioethics standards, especially among its stakeholders, non-ICH countries who conform to ICH standards, and wider publics (those individuals and people subject to ICH governance and standards – sometimes referred to in the following simply as 'publics' or in references to 'public participation'). The legitimation the expectations provide amounts to a resource to perform the ICH's mission into being. I advance this argument in two steps. First, in the next (second) section, by looking at the technological framing of the ICH and its governance structures by the mission. Second, in the third section, by examining the further implementation of the mission through health research regulation.

Throughout I explain how in legitimating the ICH's technological focus, the expectations flowing from the mission may also mask the privileging of market aims that benefit ICH Members and their industries, which are usually in the global North. This focus may also sideline wider systemic issues relating to social justice, especially those affecting non-ICH countries in the global South. There poverty is often a particular issue and non-pharmaceutical interventions are even more important for overall public health, not least because they may be cheaper than pharmaceuticals.

The central role of scientific-technical knowledge and expertise to delivering safe, quality, and effective pharmaceuticals abets the marginalization of wider issues relating to social justice. It does so by minimizing the value of the knowledge and experience held by the ICH's wider publics, and limiting their participation and contribution

22 For instance: Jackson, *supra* note 6; Laurie et al., *supra* note 6.

23 For instance: Jonas Tallberg and Michael Zürn, *The Legitimacy and Legitimation of International Organizations: Introduction and Framework*, 14(4) REV. INT. ORG. 581 (2019), part of the special issue: Jonas Tallberg and Michael Zürn eds., *The Legitimacy and Legitimation of International Organizations*, (Special Issue) 14(4) REV. INT. ORG. 581 (2019). More generally, see: AUGUSTO LOPEZ-CLAROS ET AL., GLOBAL GOVERNANCE AND THE EMERGENCE OF GLOBAL INSTITUTIONS FOR THE 21ST CENTURY (2020); THOMAS G. WEISS AND RORDEN WILKINSON, INTERNATIONAL ORGANIZATION AND GLOBAL GOVERNANCE (2nd ed., 2018). However, there is recent interest in the ICH within legal studies: Mark L. Flear, *Charting a Roadmap Towards Membership and Formal Voice in Global Bioethics Standard-Setting: Health Research and the Case of the International Council on Harmonisation*, 18(2)–(3) MED. L. INT. 157 (2018); Sabrina Röttger-Wirtz, *Independence Under Threat: The Role of Private Actors in the Setting of Global Pharmaceutical Standards and Resulting Challenges for European Public Law*, 24(3) EUR. PUB. L. 433 (2018).

24 ICH, *Mission*, www.ich.org/about/mission.html (accessed Sept. 1, 2020) (emphasis added).

25 Daniel Callaghan, *The Social Sciences and the Task of Bioethics*, 128(4) DAEDALUS 275 (1999), 276.

26 PAUL FARMER, *PATHOLOGIES OF POWER: HEALTH, HUMAN RIGHTS, AND THE NEW WAR ON THE POOR* (2003), 204–205. For recent discussion, see: Michael Thomson, *Bioethics & Vulnerability: Recasting the Objects of Ethical Concern*, 67(6) EMORY L. J. 1207 (2018). Using the outcome of the harmonization process—'better health'—for legitimation can be understood as focusing on 'output legitimacy', rather than 'input legitimacy', in the vein of Scharpf—see: FRITZ SCHARPF, *GOVERNING IN EUROPE. EFFECTIVE AND DEMOCRATIC?* (1999).

toward governance. Instead, there is an attempt to shape public perceptions and generate legitimation through the communication of expectations and transparency to demonstrate practices are in accordance with them (ie expectations are met).

Overall, then, in this article I underline the centrality of law-led interdisciplinary analysis of expectations and imaginaries to revealing their role as techniques for the public legitimation of governance and regulation. Through this, I aim to stimulate discussion on this overlooked issue, both within legal and regulatory studies and between them and cognate disciplines.

II. EXPECTATIONS OF HEALTH INNOVATION THROUGH GLOBAL HARMONIZATION

II.A. Starting Points for an Imaginary

The EU, Japan, and the US founded the ICH in 1990 at a meeting in Brussels organized by the European Federation of Pharmaceutical Industries and Associations (EFPIA).²⁷ On Oct. 23, 2015, the ICH was placed on a more formal footing through its establishment as an international association under Swiss law.²⁸ The ICH Membership comprises representatives from regulators and industry. In addition to the Founding Regulatory Members from the EU, Japan and the US,²⁹ the other Members³⁰ comprise: Standing Regulatory Members from Canada and Switzerland;³¹ and Regulatory Members from, *inter alia*, Brazil, Korea and most recently China.³² There are also representatives from industry: Founding Industry Members that comprise the EFPIA and industry associations of Japan and the US;³³ and other Industry Members.³⁴ Since 2018, all ICH Members pay a membership fee, ranging from CHF 233,000 for all Founding Members, CHF 96,000 for Standing Regulatory Members and CHF 20,000 for all other Members.³⁵

The ICH's mission, 'harmonisation for better health,' amounts to a programmatic statement ie it summarizes a program of work for the ICH. Such statements are significant for present purposes because, as Jasanoff explains, 'actors with authority to shape the public imagination . . . blend into these [statements] their expectations of science

27 For discussion of the inner workings of the ICH before the recent organizational changes, see: Ayelet Berman, *The Role of Domestic Administrative Law in the Accountability of IN-LAW: The Case of the ICH*, in *INFORMAL INTERNATIONAL LAWMAKING* (Joost Pauwelyn et al. eds., 2012).

28 Before which the ICH was the International Committee on Harmonisation.

29 European Commission; Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; US Food and Drug Administration—see: Article 8(1) ICH Articles of Association (2019).

30 Article 7(1) and Article 7(2) ICH Articles of Association (2019) respectively relate to the five categories and specification of their naming as 'Members'.

31 Health Canada; Swissmedic—see: Article 10(1) ICH Articles of Association (2019).

32 Agência Nacional de Vigilância Sanitária, Brazil; Ministry of Food and Drug Safety, Korea; Chinese Food and Drug Administration, China—see: Articles 11(1) and 11(2) ICH Articles of Association (2019). Other Regulatory Members come from South Africa, Armenia, Singapore, Australia, Turkey, and Taiwan.

33 EFPIA; Japan Pharmaceutical Manufacturers Association; Pharmaceutical Research and Manufacturers of America—see: Article 9(1) ICH Articles of Association (2019).

34 Biotechnology Innovation Organization; International Generic and Biosimilar Medicines Association; World Self-Medication Industry—see: Article 12(1) ICH Articles of Association (2019).

35 ICH, *Funding*, <https://www.ich.org/page/funding>.

and technology'.³⁶ The ICH's mission statement distils expectations to construct an imaginary. What makes the latter consequential is, as Ezrahi explains, the 'capacity [of imaginaries] to generate performative scripts that orient political behaviour and the making and unmaking of political institutions'.³⁷ The expectations and imaginary frame the ICH's work and this is 'embodied'³⁸ in its Articles of Association.

At the broadest level, the ICH's mission statement projects the central expectation: harmonization of bioethics standards relating to pharmaceuticals will lead to improvements in health. Harmonization occurs through guidelines on quality, safety and efficacy, as well as multidisciplinary or cross-cutting guidelines on topics such as ICH medical terminology.³⁹ 'Harmonization' thus evokes a purely technical and value-neutral exercise and provides a technological framing of the ICH. However, 'better' or improved 'health', a key value, provides the purpose and rationale for harmonization. Implicit in the idea of 'better health' is a judgment on the present state of health; there is something lacking and it is possible to make it *better* through harmonization. As part of the technological framing of the ICH's mission by this statement, the expectations and imaginary not only help to organize what the ICH does, and how it does it, but also attempt to produce public legitimation of them.⁴⁰

Elsewhere, the meaning of 'health' and the expectations of what harmonization is to deliver become clearer and more precise. The ICH's 'mission is to achieve *greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner*'.⁴¹ The expectations and imaginary of global 'harmonisation for better health' are narrowed through this clarification of the meaning and content of the technological framing. The safety, quality, and effectiveness of pharmaceuticals, including vaccines, are central to the ICH's clarification of what harmonization is actually about: technological development and individual ethical conduct to achieve it. This is far from the World Health Organization's (WHO) expan-

36 Sheila Jasanoff, *Future Imperfect: Science, Technology, and the Imaginations of Modernity*, in DREAMSCAPES OF MODERNITY. SOCIOTECHNICAL IMAGINARIES AND THE FABRICATION OF POWER (Sheila Jasanoff and Sang-Hung Kim ed., 2015), at 25 (emphasis added).

37 YARON EZRAHI, *IMAGINED DEMOCRACIES* (2012), at 38 (emphasis added). On performativity, see further: Mads Borup et al., *The Sociology of Expectations in Science and Technology*, 18(3–4) *TECH. ANAL. STRA. MAN.* 285 (2006), at 289; Nik Brown and Mike Michael, *A Sociology of Expectations: Retrospecting Prospects and Prospecting Retrospects*, 15(1) *TECH. ANAL. STRA. MAN.* 3 (2003); John Gardner et al., *Sociology of Low Expectations: Recalibration as Innovation Work in Biomedicine*, 40(6) *SCI. TECH. HUM. VAL.* 998 (2015).

38 ICH, *Mission*, *supra* note 24 (accessed Sept. 1, 2020).

39 ICH, *ICH Guidelines*, <https://www.ich.org/page/ich-guidelines> (accessed Sept. 1, 2020).

40 ERVING GOFFMAN, *FRAME ANALYSIS: AN ESSAY ON THE ORGANIZATION OF EXPERIENCE* (1974); Maarten Hajer and David Laws, *Ordering through Discourse*, in *THE OXFORD HANDBOOK OF PUBLIC POLICY* (Michael Moran et al. eds., 2006); Vivien A. Schmidt, *Discursive Institutionalism: The Explanatory Power of Ideas and Discourse*, 11 *AMER. REV. POL. SCI.* 303 (2008).

41 ICH, *Mission*, *supra* note 24 (accessed Sept. 1, 2020) (emphasis added). The ICH's guidelines relate specifically to quality, safety and efficacy, as well as cross-cutting matters (explained further below). Here and elsewhere the ICH refers to 'effective' pharmaceuticals. In most of what follows, I refer to 'effective' pharmaceuticals or their 'effectiveness'. However, in relation to clinical trials for the development and initial marketing of pharmaceuticals, I refer to 'efficacy'. These clinical trials are for determining efficacy ie 'the performance of an intervention under ideal and controlled circumstances, whereas effectiveness refers to its performance under "real-world" conditions'—see: Amit G. Singal, *A Primer on Effectiveness and Efficacy Trials*, 5(1) *CLIN. TRANSL. GASTROENTEROL.* e45 (2014), at 1.

sive understanding of health as a ‘state of complete physical, mental and social well-being and not merely the absence of infirmity.’⁴²

The key benefits of harmonization accrue to ‘both regulatory authorities and the pharmaceutical industry *with beneficial impact for the protection of public health*’. Harmonization presents a win-win for the ICH’s Regulatory Members and Industry Members. Benefits include:

‘preventing duplication of clinical trials in humans and minimising the use of animal testing without compromising safety and effectiveness; streamlining the regulatory assessment process for new drug applications; and reducing the development times and resources for drug development.’⁴³

These benefits are also about markets: making the development pipeline more favorable to enterprise, risk-taking and innovation by industry (who essentially define ‘innovation’ for themselves).

A societal level presumption that it ought to be possible to use technical solutions (harmonization) to control risk and fix social problems (the present state of health), and ensure progress (better health), appears to operate here.⁴⁴ Indeed, the expectations and imaginary flowing from the ICH’s mission derive some of their power as techniques of legitimation from their apparent fulfilment of this presumption. This broader expectation is derived, at least in part, from past experience of success or promissory pasts of pharmaceuticals.⁴⁵ These structure expectations of the future.⁴⁶ In short, imagined futures ‘are also built from imaginaries of the past.’⁴⁷

The expectations built into the mission and frame for the ICH are part of what Power describes as the wider ‘*web of expectations*’ about management and actor responsibility.⁴⁸ As such, these expectations limit responsibility and accountability

42 WHO, *Constitution of the World Health Organization* (1948) 14 U.N.T.S. 185.

43 ICH, *Transparency*, <http://www.ich.org/about/transparency.html> (accessed Sept. 1, 2020) (emphasis added). See further: John Abraham and Tim Reed, *Progress, Innovation and Regulatory Science in Drug Development: The Politics of International Standard-Setting*, 32(3) SOC. STUD. SCI. 337 (2002); Hironobu Saito, *ICH Culture: Its Maintenance and Development*, 51(1) THERAP. INN. REG. SCI. 9 (2017).

44 MICHAEL POWER, *THE RISK MANAGEMENT OF EVERYTHING: RETHINKING THE POLITICS OF UNCERTAINTY* (2004). For application of this thinking see: ROGER BROWNSWORD AND KAREN YEUNG EDS., *REGULATING TECHNOLOGIES: LEGAL FUTURES, REGULATORY FRAMES AND TECHNOLOGICAL FIXES* (2008). As regards the turn to pharmaceuticals see: Susan E. Bell and Anne E. Figert, *Medicalization and Pharmaceuticalization at the Intersections: Looking Backward, Sideways and Forward*, 75(5) SOC. SCI. MED. 775 (2012); Simon J. Williams et al., *The Pharmaceuticalization of Society? A Framework for Analysis*, 33 SOC. HEAL. ILL. 710 (2011).

45 See: Jonathan Gabe et al., *Pharmaceuticals and Society: Power, Promises and Prospects*, 131 SOC. SCI. MED. 193 (2015)—the introduction to a special issue. Also see: Susan E. Bell and Anne E. Figert, *Medicalisation and Pharmaceuticalisation at the Intersections: Looking Backward, Sideways and Forward*, 75(5) SOC. SCI. MED. 775 (2012); Simon Williams et al., *The Pharmaceuticalisation of Society? A Framework for Analysis*, 33 SOC. HEAL. ILL. 710 (2011).

46 Paul Martin et al., *Commercial Development of Stem Cell Technology: Lessons from the Past, Strategies for the Future*, 1(6) REGEN. MED. 801 (2006).

47 For discussion, see: Beckert, *supra* note 15, at 91. The importance of imaginaries of the past is perhaps most striking in the idea of ‘imagined communities’—see: BENEDICT ANDERSON, *IMAGINED COMMUNITIES* (2016).

48 MICHAEL POWER, *ORGANIZED UNCERTAINTY: DESIGNING A WORLD OF RISK MANAGEMENT* (2007), at 6 (emphasis added).

in the event of a failure to fulfill them. As Bryant and Knight explain, expectations provide ‘a standard for evaluation, for saying whether certain outcomes are good or bad, desirable or undesirable . . .’⁴⁹ A determination that there has been a failure to fulfill responsibilities, and the expectations they reflect, is one possible outcome of this evaluation.⁵⁰ Due in part to the role of expectations in limiting the boundaries of responsibility and accountability, therefore, the narrow framing of the ICH and its global bioethics standards might also facilitate consensus around their development. This is not least because a focus on the safety, quality, and effectiveness of pharmaceuticals narrows expectations of the ICH, limits its responsibility and accountability, and sidelines larger questions about what is within the legitimate purview of global harmonization efforts.

However, the focus of the expectations of global harmonization, and the imaginary they construct, is not without problematic consequences for social justice. Luhmann points out how expectations reduce complexity, and limit perceptions of the environment, and in doing so they are ‘[preparing the] possibilities of future events.’⁵¹ In legitimating a technological framing of governance as ‘harmonisation for better health’, the expectations and imaginary flowing from this mission statement also centralize scientific-technical knowledge and expertise. At the same time, the expectations and imaginary also marginalize ‘the social,’⁵² which includes knowledge—the “know how” that makes government possible⁵³—that could form the basis for alternative expectations and imagined futures. The focus on technological development, and principles of individual ethical conduct to achieve it, and the marginalization of wider social knowledge and concerns, reflects the dominant tendency in mainstream bioethics.⁵⁴

In the present instance, focusing global harmonization on safety, quality, and effectiveness—technical matters—not only marginalizes other kinds of harm (social, political, environmental) to which risk might pertain, but also a whole range of other normative issues. These include the points I summarized in the introduction: the ICH’s market orientation and adverse consequences of ICH guidelines for non-ICH countries. For instance, pressure to follow ICH guidelines applied to the latter countries, which are often in the global South, may not be justified by additional safety bene-

49 Bryant and Knight, *supra* note 12, at 63.

50 On the link between expectations and failure, see: Timothy Carroll et al., *Introduction: Towards a General Theory of Failure*, in *THE MATERIAL CULTURE OF FAILURE* 15 (Timothy Carroll et al. eds., 2018) (emphasis added). Kurunmäki and Miller explain how failure is ‘undeniably constructed through the *multiple ideas and instruments* that set the parameters within which open-ended yet not limitless negotiation and judgment takes place, as the moment of failure is either predicted or pronounced’—see: Liisa Kurunmäki and Peter Miller, *Calculating Failure: The Making of a Calculative Infrastructure for Forgiving and Forecasting Failure*, 55(7) *BUS. HIST.* 1100 (2013), at 1101 (emphasis added).

51 NIKLAS LUHMANN, *DIE WIRTSCHAFT DER GESELLSCHAFT* (1988).

52 On the underlying process of coproduction that makes this possible, see: Sheila Jasanoff, *The Idiom of Co-Production*, in *STATES OF KNOWLEDGE* (Sheila Jasanoff ed., 2004); Sheila Jasanoff and Brian Wynne, *Science and Decision-Making*, in *HUMAN CHOICE AND CLIMATE CHANGE, VOLUME 1: THE SOCIETAL FRAMEWORK* (Steve Rayner and Elizabeth L. Malone eds., 1998).

53 Nikolas Rose and Peter Miller, *Political Power Beyond the State: Problematics of Government*, 43(2) *BRIT. J. SOC.* 172, 178 (1992). For discussion on scientific knowledge, see: MICHAEL LYNCH AND STEVE WOOLGAR EDS., *REPRESENTATION IN SCIENTIFIC PRACTICE* (1990); ANDREW PICKERING ED., *SCIENCE AS PRACTICE AND CULTURE* (1992).

54 See references *supra* notes 25 and 26.

fits for them.⁵⁵ Moreover, following ICH guidelines might prove costly and impede the development of domestic biomedical industries in those countries.⁵⁶ The reduction of ‘better health’ to ‘safe, quality and effective pharmaceuticals’ may also shift attention and resources toward them, and away from non-pharmaceutical interventions.

The focus on safety, quality, and effectiveness, as ‘the’ risks for the purposes of the ICH’s mission, may engender a distortion of attention and resources toward the management of consequences through technical solutions ie treatment using pharmaceutical responses. The COVID-19 pandemic only underscores how the latter operates: the wider social conditions that cause the virus’ spread seem marginal in the midst of attempts to grapple with the health emergency. The distortion of priorities may undermine the social infrastructures needed to address all public health problems. The latter may actually be cheaper, more effective, and beneficial for preventing not only communicable diseases, but also non-communicable diseases. The latter usually cause far more mortalities and morbidities than communicable diseases; and that may continue to be the case despite the growing toll wrought by COVID-19.⁵⁷ A shift of attention and resources away from non-technological interventions would be inimical to overall public health and inconsistent with the WHO’s far wider understanding of ‘health.’⁵⁸

Yet, the expectations and imaginary that flow from the ICH’s mission provide legitimation that may in turn mask these kinds of consequences, especially from the ICH’s wider publics. A key aspect of the legitimating function of the expectations and imaginary, then, thus relates to the shaping of public perceptions of ‘what to expect’ of the ICH, its guidelines and those who make use of them in health regulation. In other words, there is a pedagogical component to communication—which here amounts to ‘innovation communication’⁵⁹ and wider ‘organizational communication.’⁶⁰ Such communication attempts to inculcate wider publics by shaping their perceptions and understanding of the ICH’s work. This is partly about managing risks to the ICH’s standing and reputation—a key institutional risk—to bolster legitimation. According

55 WHO, *The Impact of the Implementation of ICH Guidelines in Non-ICH Countries*, Regulatory Support Series, No. 9 (2002).

56 Trudie Lang and Sisira Siribaddana, *Clinical Trials Have Gone Global: Is This a Good Thing?*, 9(6) PLOS MED. e1001228 (2012); Alex D. McMahon et al., *The Unintended Consequences of Clinical Trials Regulations*, 6(11) PLoS MED. e10000131 (2009); Nicholas J. White, *Clinical Trials in Tropical Diseases: A Politically Incorrect View*, 11(10) TROP. MED. INT. HEAL. 1483 (2006).

57 For discussion, see: Flear, *supra* note 5, especially chapter 7 ‘Querying Framing and Knowledge Production’ and chapter 8 ‘Querying Interventions’.

58 In addition to vulnerability theory *supra* note 26, there are a range of other perspectives that encompass wider understandings of health as including ‘the social’. These include precarity (Judith Butler, *PRECARIOUS LIFE: THE POWER OF MOURNING AND VIOLENCE* (2005)); the capabilities approach (MARTHA NUSSBAUM, *CREATING CAPABILITIES* (2011); Amartya Sen, *Equality of What?*, in TANNER LECTURES ON HUMAN VALUES, VOLUME 1 (Sterling M. McMurrin ed., 1980)); and the social body (Sam Lewis and Michael Thomson, *Social Bodies and Social Justice*, 15(3) INT. J. L. CONT. 344 (2019)).

59 C.f. the roles of strategic reports—Harro van Lente and Arie Rip, *The Rise of Membrane Technology: From Rhetorics to Social Reality*, 28(2) SOC. STUD. SCI. 221 (1998)—and patents—Kathryn Packer and Andrew Webster, *Patenting Culture in Science: Reinventing the Scientific Wheel of Credibility*, 21(4) SCI. TECH. HUM. VAL. 427 (1996). In general see: Ursula Plesner and Maja Horst, *Before Stabilization*, 16(7) INF. COMM. SOC. 1115 (2013).

60 Maja Horst et al., *Reframing Science Communication* in, *THE HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES* (Ulrika Felt et al. eds., 4th ed., 2017), at 893.

to Power, managing ‘unruly perceptions’, and hence the risk to standing and reputation, is central to risk management and maintaining the ‘production of legitimacy in the face of these perceptions.’⁶¹

Alongside communication, transparency is a key way of shaping public perceptions. The ICH notes the ‘obvious rise in public demand for more openness’ and the idea that ‘transparency builds trust’. The latter links to the ICH’s attempts to reform and transform itself into ‘a truly global initiative’. These attempts offer ‘the opportunity to *increase transparency and allow a wider audience to better understand and share in the success of the ICH initiative*.’⁶² Particularly since the ICH’s establishment as an international association in 2015, there has been an increase in information published on the ICH website. This information includes the agendas, records, and minutes of meetings, membership of governance bodies and engagement via social media (ie on Twitter via @ICH_news). Documents containing information that is commercially sensitive remain confidential.

Communication and transparency appear to work in tandem to inculcate expectations of the ICH among its publics, demonstrate practices are in accordance with them (ie expectations are met), and through it produce legitimation. Moreover, the legitimation derived from communication and transparency draws upon and aligns with the wider cultural resonance of transparency and widespread societal demands and expectations relating to it. Gommers and Mullin explain how:

‘There is no doubt that *expectations for transparency and disclosure* had changed dramatically over the years since ICH first began...improving the transparency of ICH’s activities and its decision making [is] thus one of the cornerstones of the [recent] reform.’⁶³

As is apparent, the expectations and imaginary built into and flowing from the ICH’s mission are actually far narrower than ‘harmonisation for better health’ may suggest. The expectations and imaginary help to legitimate this mission and framing. The narrowness of the expectations and imagined future they construct, delimits the ICH’s responsibility and accountability to the safety, quality, and effectiveness of pharmaceuticals, and masks the implications for social justice. The ICH’s mission, and its focus on technological development and individual ethical conduct to achieve it, are not simply technical and neutral, but embed judgments and choices about the meanings of health and harmonization. This becomes even clearer through the vision for global governance that the expectations construct as part of the imaginary.

II.B. Envisioning a (Particular) Future for Global Governance

Meeting the expectations of ‘harmonisation for better health’, and building an imagined future along those lines, also implies and legitimates a vision. Konrad and others explain how a vision relays ‘a fuller portrait of an alternative world that includes revised social

61 Power, *supra* note 48, at 21.

62 ICH, *Transparency*, *supra* note 43 (emphasis added). For discussion of transparency, see: Power, *supra* note 48, at 18.

63 Lenita Lindström-Gommers and Theresa Mullin, *International Conference on Harmonization: Recent Reforms as a Driver of Global Regulatory Harmonization and Innovation in Medical Products*, 10S(4) CLJ. PHAR. THE. 927 (2019), at 930 (emphasis added).

orders, governance structures, and societal values.⁶⁴ Expectations contribute to the building of this vision. As Bryant and Knight put it, ‘expectation is the ground on which practices, orders, and hence the normative emerge . . .’⁶⁵ In the case of the ICH, the central expectation is of a more harmonized global order for the development of safe, quality and effective pharmaceuticals. Implicit to the vision of the ICH is its converse—a more fragmented global order that may be less safe and worse for health. The latter further grounds and legitimates harmonization governance and ICH Membership. These are particularly revealing of the revised structures, practices, and values constitutive of the ICH’s vision as part of the wider imagined future.

As for the ICH’s governance frameworks, the focus on technological development for the production of pharmaceuticals is readily apparent in the description of the ICH as ‘*unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.*’⁶⁶ Guidelines are developed ‘*via a process of scientific consensus with regulatory and industry experts working side-by-side.*’⁶⁷ By providing the basis for the authority and legitimation of ICH guidelines, scientific knowledge and the involvement of industry support the vision of global harmonization. The default position is for consensus in decisions on ICH guidelines in *inter alia* the ICH Management Committee, the Expert Working Groups that develop the fine detail, and the ICH Assembly.⁶⁸

The latter was established when the ICH became an Association in 2015 and it involves all ICH Members and Observers. The role and description of the ICH Assembly echoes the technological framing of the ICH in the mission. The ICH Assembly is:

‘the over-arching governing body with the *aim of focusing global pharmaceutical regulatory harmonization work in one venue* that allows pharmaceutical regulatory authorities and notably concerned industry organizations to be more actively involved in ICH’s harmonization work.’⁶⁹

There has been an increase in the number of Regulatory Members to include regulators from emerging markets in the global South, such as the National Medical Products Administration (NMPA) (formerly the Chinese Food and Drug Administration), which became a Regulatory Member in June 2017. Technical standard setting through the ICH Assembly thereby leverages ideas of democratic accountability and legitimacy (regardless of the democratic credentials of individual ICH Members). It is, however,

64 Konrad et al., *supra* note 11. Visions also form part of Jasanoff’s definition of sociotechnical imaginaries: ‘collectively held, institutionally stabilized, and publicly performed visions of desirable futures . . . supportive of, advances in science and technology’—see Sheila Jasanoff, *Future Imperfect: Science, Technology, and the Imaginations of Modernity*, in *DREAMSCAPES OF MODERNITY. SOCIOTECHNICAL IMAGINARIES AND THE FABRICATION OF POWER* (Sheila Jasanoff and Sang-Hung Kim ed., 2015), at 4 (emphasis added).

65 Bryant and Knight, *supra* note 12, at 63. Also see: ARJUN APPADURAI, *THE FUTURE AS CULTURAL FACT* (2013); JUAN FRANCISCO SALAZAR ET AL. EDS., *ANTHROPOLOGIES AND FUTURES: RESEARCHING EMERGING AND UNCERTAIN WORLDS* (2017).

66 ICH, *Mission*, *supra* note 24 (accessed Sept. 1, 2020) (emphasis added).

67 *Id* (emphasis added).

68 In relation to the ICH Management Committee, see Article 38(4) ICH Articles of Association (2019) and in relation to the ICH Assembly, see Article 26(2) ICH Articles of Association (2019).

69 ICH, *History*, <http://www.ich.org/about/history.html> (accessed Sept. 1, 2020) (emphasis added).

notable that where it is not possible to reach a consensus, a decision may be made using alternative voting arrangements, and these effectively give the pivotal role to the Founding Regulatory Members (the EU, Japan, and US).⁷⁰

There has also been more concerted dialogue between the ICH and non-Members, including Observers. The Global Cooperation Group is one forum for this kind of dialogue.⁷¹ The vision built through the ICH's governance frameworks, thus brings the places where clinical trials are increasingly carried out (the global South), into concert with the most powerful global regulators and industry (in the global North). These structures are an attempt to realize the expectations and imaginary of technological development through global harmonization. The expectations and imaginary flowing from the ICH's mission legitimate these governance structures and thus help to bring them into being.

Turning to ICH Membership, this links directly to the vision's construction and through it the future global sociotechnical order. ICH Membership is thus key to realizing the limited expectations and imaginary of what harmonization is to achieve in terms of technological development with a focus on safe, quality, and effective pharmaceuticals. These expectations and imaginary, although oriented towards the future, legitimate Membership in the present. Indeed, ICH Membership provides 'a *say* on the technical and policy environment of the *future*.'⁷² The 'value and advantages' of ICH Membership provide further insights into how the ICH's vision of its alternative global order revises values. ICH Membership 'sends a clear message that the regulatory authority and the regulated industry are *committed to align with the highest global standards for the quality, efficacy and safety of medicinal products*'. Moreover, ICH Membership confers '*integrity and recognition* as ICH guidelines are widely recognized and are increasingly applied worldwide.'⁷³

The expectations and imaginary flowing from the ICH's mission contribute towards the shaping of public perceptions and understanding of ICH Membership, and its value and advantages. This in turn provides a motivation for joining the ICH in the first place. ICH Membership may itself become a form of virtue signaling that facilitates the performance of the vision of global harmonization. Expectations thus become, as Brown and Michael observe, 'crucial to providing the *dynamism and momentum* upon which so many ventures in science and technology depend.'⁷⁴ In a virtuous cycle, ICH Membership adds to the authority and value of ICH governance and guidelines—and in turn supports their legitimation. This also increases the normative status and weight

70 For example, the ICH Management Committee submits proposals to the ICH Assembly for the adoption, amendment or withdrawal of ICH guidelines. Where a consensus cannot be reached, decisions on the adoption, amendment or withdrawal of ICH Guidelines are taken by a simple majority of the votes cast of the Founding Regulatory Members, Standing Regulatory Members and Regulatory Members. The majority must include the votes of each Founding Regulatory Member—see: Article 26(6) ICH Articles of Association (2019).

71 This was formed on Mar. 11, 1999 as a subcommittee of the then ICH Steering Committee, what is now the ICH Management Committee. The Global Cooperation Group is specifically designed to develop cooperation between ICH regions (EU, Japan and US) and non-ICH countries and regions.

72 ICH, *Value of Membership*, www.ich.org/about/value-of-membership.html (accessed Sept. 1, 2020) (emphasis added).

73 *Id* (emphasis added).

74 Brown and Michael, *supra* note 37.

of ICH guidelines, and makes ICH Membership, and participation in ICH governance, even more attractive.

For instance, in relation to the NMPA:⁷⁵

‘[ICH Regulatory Membership] is a key milestone . . . [NMPA] will actively participate in the design and enacting of international rules, to speed up the international innovative products to China and to fulfil the unmet medical needs of China, at the same time, to improve the innovation ability and international competitiveness of the Chinese pharmaceutical industry.’⁷⁶

This makes clear how the attractiveness of ICH Membership is also bound-up with its capacity to generate enterprise and increase global competitiveness through the production and consumption of safe, quality, and effective pharmaceuticals. In the case of the ICH, at least, the expectations and imaginary that flow from its mission, and produce a vision of global bioethics governance, also service broadly market-oriented aims. This orientation towards markets provides the shared understanding of social life and values that undergirds the vision to realize ‘better health’ through governance for pharmaceutical technoscience.

The vision is realized ‘at a distance’⁷⁷—the hallmark of market-based thinking under neoliberalism—through the creation of more favorable (ie harmonized) global governance conditions for profit-making by the pharmaceutical industry. These conditions reconfigure several key relationships that underpin governance. For instance, the reconfiguration of sovereignty and territoriality occurs through the widening global reach of the ICH’s standards, including through take-up beyond the ICH Membership. The standards apply in non-ICH countries and markets beyond ICH Members in the global North (and the countries joining these powerful ranks, such as China).⁷⁸ At the same time, the reconfiguration of governance and the governed occurs through the widening pool of available biomedical labor the latter makes possible.

The expectations and imaginary help to legitimate these reconfigurations in global biomedical governance to deliver ‘better health’ are understood as being about harmonization for technological development of safe, quality and effective pharmaceuticals. Governance to deliver the latter reiterates the tendency in wider bioethics to marginalize systemic issues relating to social justice. In particular, the narrow expectations of global harmonization legitimate and support the reach of bioethical standards for the development of pharmaceuticals, which as noted are co-authored by

75 Final Minutes ICH Assembly May 31 and June 1, 2017, Montreal, Canada, Sept. 1 2017, ICH2017/04F.

76 See: NMPA [formerly CFDA]/DIA Joint ICH Day, May 22, 2018. www.ich.org/fileadmin/Public_Web_Site/Training/2018/ICH_Day_Program_Eng_0423.pdf (accessed Sept. 1, 2020).

77 MITCHELL DEAN, *GOVERNMENTALITY: POWER AND RULE IN MODERN SOCIETY* (2nd ed., 2009). Also see: P. O’MALLEY, *RISK, UNCERTAINTY AND GOVERNMENT* (2004); Niklas Rose et al., *Governmentality*, 2 AN. REV. L. SOC. SCI. 83, 84 (2006).

78 World Trade Organization (WTO) law can provide another driver for national compliance with ICH guidelines as ‘international standards’. For discussion see: Markus Wagner, *International Standards*, in *RESEARCH HANDBOOK ON THE WTO AND TECHNICAL BARRIERS TO TRADE* (Tracey Epps and Michael J. Trebilcock eds., 2013). For discussion on the exclusionary effects of these rules on producers of generics in the global South, see: Karin Timmermans, *Harmonization, Regulation and Trade: Interactions in the Pharmaceutical Field*, 34 INT. J. HEAL. SER. 651 (2004).

regulators and industry based primarily in the global North, and those that join these powerful ranks, such as the NMPA.⁷⁹

Another key concern builds on one noted above, that is, the way in which the ICH's focus on pharmaceuticals may contribute toward a distortion of attention and resources in public health priorities away from non-pharmaceutical responses, and the negative effects of that, especially in the global South. ICH guidelines have further implications that derive from the link between their status as being de facto binding for the marketing of new pharmaceuticals, and the potential for global patent protection for the latter under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).⁸⁰ Pharmaceuticals, including those for COVID-19, produced in accordance with ICH guidelines are more likely to meet regulatory requirements for marketing ie within the ICH Membership and elsewhere. Marketable (ICH-compliant) pharmaceuticals are also generally subject to patents globally. All technologies including medicines are patentable under the TRIPS agreement in all WTO states ie globally. Under TRIPS, the patent holder (who is usually also the marketer) is able to prevent generic equivalents from entering the market for the duration of the patent grant (20 years).

The market exclusivity afforded by patent protection thus allows the patent holder to prevent competition from producers of generic versions of patented pharmaceuticals, who will usually have to wait until a pharmaceutical is 'off patent' before generics can be made and/or marketed. Many of these producers have been based in China and Brazil (now both ICH Regulatory Members), and India and South Africa (now both Observers). Consequently, countries in the industrialized global North, the usual base for the biggest producers of pharmaceuticals, are effectively able to apply for and utilize their patent protections worldwide.

This is not without deleterious effects for access to pharmaceuticals, including vaccines, especially in the global South where the foundational assumptions for patents do not necessarily apply. Indeed, the global North provides the vast majority of profits for ICH Industry Members, since the markets there are the largest and it is possible to charge higher prices to wealthier customers. However, many of the pharmaceuticals sold in the global North do not tackle diseases of the poor in the global South. As the WHO Commission on Intellectual Property Rights found, 'patents are not a relevant factor or effective in stimulating R&D and bringing new products to market'⁸¹ in respect of low and middle income countries.⁸² Such countries often have little or

79 For discussion, see: JOHN ABRAHAM AND GRAHAM LEWIS, *REGULATING MEDICINES IN EUROPE: COMPETITION, EXPERTISE AND PUBLIC HEALTH* (2000); ARTHUR A. DAEMMRICH, *PHARMACOPOLITICS: DRUG REGULATION IN THE US AND GERMANY* (2004).

80 Marrakesh Agreement Establishing the World Trade Organization, opened for signature Apr. 15, 1994, 1867 UNTS 3, annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) (entered into force Jan. 1, 1995) (TRIPS). This agreement is enforceable via the WTO's Understanding on Dispute Settlement. Least developed countries did not have to implement TRIPS until 2016.

81 WHO Commission on Intellectual Property Rights, *Innovation and Public Health, Public Health Innovation and Intellectual Property Rights* (2006).

82 On the more specific issue of patents and vaccines for COVID-19, see: Aisling McMahon, *Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance*, J. MED. ETHICS (2020) DOI: [10.1136/medethics-2020-106795](https://doi.org/10.1136/medethics-2020-106795); KAUSHIK SUNDER RAJAN, *PHARMOCRACY: VALUE, POLITICS, AND KNOWLEDGE IN GLOBAL BIOMEDICINE* (2017). Also see: MELINDA COOPER, *LIFE AS SURPLUS: BIOTECHNOLOGY AND CAPITALISM IN THE NEOLIBERAL ERA* (2008); KAUSHIK SUNDER RAJAN, *BIOCAPITAL: THE CONSTITUTION OF POSTGENOMIC LIFE* (2006).

no manufacturing capacity and become reliant on imports of (more costly) patented pharmaceuticals instead of cheaper generic versions.⁸³

Overall, the vision of ICH governance, including reconfigurations of several of its underpinning relationships, emerges from the expectations of the ICH and becomes integral to the imagined future they construct. This is of a more harmonized future to realize the expectations and imaginary of ‘better health’. The vision of ICH governance derives purpose, meaning, and legitimation from the limited expectations. A whole network hinges on the legitimation of the vision of global harmonization for clinical trials and pharmaceuticals. These include the ‘promissory identities’⁸⁴ of the ICH itself, its Membership, and those others with whom the ICH engages; the self-understanding and narrative about themselves; and the value, authority, and significance of the ICH’s mission and guidelines within regulation.

More broadly, the discussion across this section shows that harmonization is not simply ‘for better health’, but instead limits the ICH’s responsibility and accountability to technological development, ie of safe, quality, and effective pharmaceuticals, and shaping individual ethical conduct to facilitate it. This is, as well noted by now, the dominant tendency seen across bioethics. A key goal of harmonization is to widen the pool of biomedical labor for clinical trials to generate data demonstrating the safety, quality, and effectiveness of pharmaceuticals. Another goal is to expand markets for the resulting pharmaceuticals by extending the reach of ICH guidelines as de facto requirements for market authorization (in new ICH Members and other countries). The tacit mission of the ICH, then, is creating conditions for increasing the profitability and competitiveness of the global pharmaceutical industry-based primarily in the global North. The expectations and imaginary flowing from the mission help to legitimate this, and in turn to mask the marginalization of wider systemic issues relating to social justice, particularly those affecting the global South.

The marginalization of these kinds of issues links to the two main ways in which the ICH generates public legitimation: one-way communication of the expectations flowing from its mission, and reliance on transparency to show practices are in accordance with them (ie that expectations are met). Underpinning both of these is an assumption that derives from the technological framing of the ICH and its centering of scientific-technical knowledge and expertise in governance. As Leach and others explain, because of this framing:

‘questions about the setting of science and technology agendas in the first place, about processes of innovation, and about whose priorities or visions of development or the good society these are to address, are left begging. The assumption is that public concerns are focused on risks and consequences *rather on the unstated and unaccountable human purposes, aspirations, priorities, expectations and aims that drive innovation-oriented scientific knowledge*.’⁸⁵

83 For discussion, including TRIPS and subsequent clarifications of its scope and flexibilities, see: Flear, *supra* note 5, at 257–265; EMILIE CLOATRE, *PILLS FOR THE POOREST* (2013).

84 C.f. John G. Gardner et al., Promissory Identities: Socio-technical Representations and Innovation in Regenerative Medicine, 174 *SOC. SCI. MED.* 70 (2016).

85 MELISSA LEACH ET AL. EDS., *SCIENCE AND CITIZENS: GLOBALIZATION AND THE CHALLENGE OF ENGAGEMENT* (2005), at 10 (emphasis added).

In short, the ICH's mission and framing marginalize broader expectations of technoscientific innovation, and the wider publics who may be able to contribute their perspectives on them.

This underscores the pedagogical dimension of the ICH's communications with its wider publics, noted above, and its use for legitimation purposes. It seems these publics are to be educated into providing legitimation. At the same time, this implies the ICH's wider publics have little to contribute toward governance, ie their knowledges and experiences are merely part of 'the social'. One-way communication between the ICH and its publics appears to be about encoding understanding of the ICH and its technical guidelines in public epistemologies or ways of knowing.⁸⁶ Such communication therefore appears aimed at further shaping wider public perceptions of scientific and ethical credibility to legitimate global harmonization.

I turn now to consider how the expectations flowing from the ICH's mission also engender and legitimate specific aspects of risk regulation: anticipatory techniques, especially those relating to knowledge creation, and risk management. These further implement the technological focus of ICH governance, while continuing to marginalize systemic matters relating to social justice.

III. PERFORMING EXPECTATIONS THROUGH HEALTH RESEARCH REGULATION

III.A. Anticipatory Practices for the Harmonization of Knowledge Creation

Particularly important to the realization of the expectations and construction of the imaginary of the ICH, and its governance, is the fashioning and legitimation of supporting practices that seek to anticipate and respond to improvements and changes in knowledge creation for the development of pharmaceuticals. Bryant and Knight explain how anticipation 'is more than simply expecting something to happen; it is the act of looking forward that also pulls [us] in the direction of the future and *prepares the groundwork for that future to occur*'.⁸⁷ Anticipation is apparent in a key task under the ICH's mission, to 'facilitate the adoption of new or improved technical research and development approaches which update or replace current practices'.⁸⁸

Anticipatory practices for biomedical research and pharmaceutical development gain legitimation from the ICH's mission. Such practices fall within the boundaries of the ICH's responsibility and accountability, and enable the ICH to realize the expectations flowing from the mission. In particular, '[t]o avoid divergent future requirements through harmonization of selected topics *needed as a result of therapeutic advances and the development of new technologies* for the production of medicinal products'.⁸⁹ As Douglas explains, 'institutions encode expectations' and the more they achieve this, here through anticipatory practices, 'the more they put uncertainty under control, with the further effect that behaviour tends to conform to the institutional matrix'.⁹⁰ The

86 SHEILA JASANOFF, *DESIGNS ON NATURE* (2007), chapter 10 'Civic Epistemology'.

87 Bryant and Knight, *supra* note 12, 28 (emphasis added). For discussion in the context of biomedicine, see: Martyn Pickersgill, *Connecting Neuroscience and Law: Anticipatory Discourse and the Role of Sociotechnical Imaginaries*, 30(1) *NEW GEN. SOC.* 27 (2011).

88 ICH, *Mission*, *supra* note 24 (accessed Sept. 1, 2020); Article 3(f) ICH Articles of Association (2019).

89 ICH, *Mission*, *supra* note 24 (accessed Sept. 1, 2020) (emphasis added).

90 MARY DOUGLAS, *HOW INSTITUTIONS THINK* (1986), at 48.

twist here is that the expectations and imaginary legitimate and engender anticipatory practices that pull governance into the future, and in doing so further encode them.

Legitimizing anticipatory practices to avoid divergence within the ICH Membership and those countries involved in clinical trials, becomes even more urgent in light of globalization. Hence, '[s]ince its inception in 1990, ICH [sic] has *gradually evolved, to respond to the increasingly global face of drug development*.'⁹¹ A key response is through the focus on 'extending the benefits of harmonization'—integral to realizing the expectations and vision described above—'*beyond the founding ICH regions*.'⁹² This is at the heart of the reconfiguration of sovereignty and territoriality, and governance and the governed, which as noted above are two key relationships underpinning governance. Efforts to extend ICH governance and guidelines beyond the Founding Regulatory Members help to increase the places and populations subject to them, especially in the global South. These trials increase the amount and type of data submitted to the pharmaceutical market authorization processes of the ICH's Regulatory Members.⁹³ In particular, scientific developments make it possible to generate data on more specific population groups and improve the development of safe, quality, and effective pharmaceuticals for them.

Delivering on the potential of these developments necessitates anticipation of changes in knowledge creation through updating or replacing regulatory terminology, methodologies, and guidelines. Without these anticipatory practices, and the tightening relations between governance (and regulation) and knowledge they represent, it would be hard if not impossible to fully realize the expectations and imaginary that flow from the ICH's mission. These anticipatory practices signify another reconfiguration in the key relationships underpinning governance, which are an outworking of the focus of ICH governance on technical issues. Three examples, on the harmonization of medical terminology, ICH GCP and, briefly, training on ICH guidelines, underscore the role of the expectations and imaginary flowing from the ICH's mission in legitimating and realizing anticipatory practices.

The ICH Medical Dictionary for Regulatory Activities Terminology (or MedDRA), a multidisciplinary or cross-cutting guideline, is a key example of an anticipatory practice for future harmonization. The ICH adopted version 1.0 of MedDRA in 1994 and last updated it to version 23.0 in 2020. The expectations and imaginary that flow from the ICH's missions legitimate and strongly imply a need for MedDRA. Indeed, a common regulatory dictionary became essential since use of different terminologies at different stages in the process of developing pharmaceuticals led to difficulties in cross-referencing and analyzing data produced around the globe. The increasing globalization of clinical trials and pharmaceutical development, which the ICH facilitates, only exacerbates this problem. As such, MedDRA is a top priority for the ICH and its delivery of 'harmonisation for better health' understood as limited to producing safe, quality and effective pharmaceuticals. This is apparent in the Articles of Association, which provide MedDRA's purpose is:

91 ICH, *Mission*, *supra* note 24 (accessed Sept. 1, 2020) (emphasis added).

92 ICH, *History*, *supra* note 69 (accessed Sept. 1, 2020) (emphasis added).

93 For discussion, see: ADREANA PETRYNA, *WHEN EXPERIMENTS TRAVEL* (2009).

‘ensuring the scientific and technical maintenance, development and dissemination of MedDRA as a *standardized dictionary which facilitates the sharing of regulatory information internationally for medicinal products used by humans*.’⁹⁴

The Maintenance and Support Services Organization (MSSO) keeps MedDRA up-to-date under the supervision of the MedDRA Management Committee, to ‘*meet the evolving needs of regulators and industry around the world*.’⁹⁵ In total MedDRA is available in 14 languages. Besides the English master, the other languages include Japanese, Chinese, French, German, Brazilian Portuguese, Russian, and Spanish. Irrespective of the language, each MedDRA term has an eight-digit numerical code to facilitate information sharing.

The sharing of information MedDRA makes possible through this harmonized code is important throughout the pharmaceutical development and marketing process. Indeed, MedDRA is:

‘*used for registration, documentation and safety monitoring of medical products both before and after a product has been authorized for sale. Products covered by the scope of MedDRA include pharmaceuticals, vaccines and drug-device combination products*.’⁹⁶

ICH Members, regulators, pharmaceutical companies, clinical research organizations, and healthcare providers, use MedDRA. MedDRA’s terminology is free to regulators, academics, and healthcare providers, but companies must pay subscriptions based on their annual turnover. The ICH notes how the wide usage of MedDRA ‘allows better global protection of patient health.’⁹⁷ According to the ICH, a standardized terminology provides several advantages for regulators, industry, and other stakeholders. These advantages include:

‘*Removal of the need to convert data from one terminology to another preventing the loss and/or distortion of data and allowing savings in resources*’ and ‘*Improvements in the ease, quality and timeliness of data available for effective analysis, exchange and decision making*.’⁹⁸

The updating of MedDRA in light of the COVID-19 pandemic health emergency only underscores the vital importance of anticipating which terms require harmonization, so as to realize these advantages—and in turn the ICH’s mission. Indeed, the pandemic:

‘*has prompted an urgent need for a harmonized, standardized approach to coding and reporting the infection as a global health issue*. The ICH M1 Points to Consider Working Group and the MedDRA MSSO, with the approval of the MedDRA Management Committee,

94 ICH, *Mission*, *supra* note 24; Article 3(h) ICH Articles of Association (2019) (emphasis added).

95 ICH, *MedDRA*, <https://www.ich.org/page/meddra> (accessed Sept. 1, 2020) (emphasis added).

96 *Id* (emphasis added).

97 *Id*.

98 *MedDRA, Vision for MedDRA*, <https://www.meddra.org/about-meddra/vision> (accessed Sept. 1, 2020) (emphasis added).

are issuing this notification for MedDRA users regarding existing and new terms for *coronavirus concepts*.⁹⁹

The expectations and imaginary that flow from the ICH's mission also legitimate and mandate the modification of ICH guidelines on quality, safety, and efficacy. This provides the second key example of anticipatory practices. Without up-to-date guidelines global harmonization would grind to a halt. By way of introduction, each type of ICH guideline aims to ensure product safety.¹⁰⁰ The ICH guideline on good clinical practice for clinical trials (ICH GCP¹⁰¹) is a key example. All efficacy guidelines are:

*'concerned with the design, conduct, safety and reporting of clinical trials. [Work on these guidelines] also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/genomics techniques to produce better targeted medicines.'*¹⁰²

ICH GCP, in particular, aims to 'provide a unified standard' for the EU,¹⁰³ Japan, and the US 'to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions'.¹⁰⁴ Consideration of GCP practices in the latter and those of Australia, Canada, the Nordic countries and the WHO is integral to the construction of ICH GCP.

ICH GCP seeks to produce credible scientific data in a way that is compliant with its first principle,¹⁰⁵ which is the ethical standards originating in the Declaration of

99 ICH, *ICH M1 Points to Consider Working Group and MedDRA MSSO Communication on Coronavirus* (2020). Available via ICH, *Notification on MedDRA Terms for Coronavirus Concepts Now Available*, <https://www.ich.org/news/notification-meddra-terms-coronavirus-concepts-now-available> (accessed Sept. 1, 2020) (emphasis added).

100 Regulatory science is a topic of growing importance, and European Medicines Agency (EMA) has recently closed a consultation on its strategy—see: EMA, *Regulatory Science to 2025. Strategic Reflection* (2018). More generally see the 'regulatory science' section of the journal *Frontiers in Medicine*, <https://www.frontiersin.org/journals/medicine/sections/regulatory-science> (accessed Sept. 1, 2020).

101 ICH, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2), Current Step 4 Version Dated 9 November 2016 (ICH GCP). ICH, *E6(R2)*, http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf (accessed Sept. 1, 2020). This version amends that finalized and adopted in 1996. Note the use of 'efficacy' here and below in relation to specific kinds of clinical trials. For an explanation of the difference between 'efficacy' and 'effectiveness' (as used throughout this article), see *supra* note 41.

102 ICH, *Efficacy Guidelines*, <https://www.ich.org/page/efficacy-guidelines> (accessed Sept. 1, 2020) (emphasis added).

103 ICH GCP is the only ICH guideline to be the subject of specific legislation at the EU level, currently: Regulation (EU) 536/2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC [2014] O.J.L. 158/1. The Regulation is planned to apply from 2021. For discussion of the EU level, see: Flear, *supra* note 5.

104 ICH, *ICH GCP*, *supra* note 101, at 1.

105 *Id.*, at 9, Point 2.1.

Helsinki (Helsinki),¹⁰⁶ and the rights inflected through them.¹⁰⁷ Adherence to these standards is instrumentalized for regulatory science ie data production for regulatory purposes.¹⁰⁸ In respect of ICH GCP, it *should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities*.¹⁰⁹ In practice, ICH GCP often applies to pharmaceuticals not intended for marketing,¹¹⁰ and medical devices.¹¹¹ As such, ICH GCP is likely to have implications beyond the development of pharmaceuticals. This in turn means that the unequal burden of following ICH GCP in the global South is likely to be felt beyond the pharmaceuticals sector and across technoscience for health products more generally.

In terms of anticipation, the expectations and imaginary of the ICH legitimate and require foresight in the identification of topics for harmonization¹¹² to prevent future divergence in technical requirements.¹¹³ Year 2016 saw the updating of ICH GCP (and

106 Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. Helsinki is produced by the World Medical Association (WMA) and has been modified many times, the last time in 2013 by the 64th WMA General Assembly. Helsinki echoes the Nuremberg Code: GEORGE J. ANNAS AND MICHAEL A. GRODIN EDS., *THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION* (1992). Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects (1964, as revised, the last time in 2013). The Helsinki Declaration is an instrument of the World Medical Association. There is also the WHO, *Guidelines for Good Clinical Practices for trials on Pharmaceutical Products, WHO Technical Report Series No. 850, Annex 3* (1995). The International Ethical Guidelines for Biomedical Research Involving Human Subjects is produced by the WHO and the Council for International Organizations of Medical Sciences (CIOMS—hence, these are often referred to as the CIOMS guidelines) and aimed at applying Helsinki in developing countries.

107 Declaration of Helsinki, *Id.*, Para. 10, states that ‘Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards’ (emphasis added). The latter include Universal Declaration of Human Rights (Dec. 10, 1948) U.N.G.A. Res. 217A (III), U.N. Doc. A/810, itself highly influenced by the Nuremberg Code; International Covenant on Civil and Political Rights (Dec. 16, 1966, entered into force 23 Mar., 1976) 999 U.N.T.S. 171; International Covenant on Economic, Social and Cultural Rights (Dec. 16, 1966, entered into force Jan. 3, 1976) 993 U.N.T.S. 3; Convention on the Elimination of All Forms of Discrimination against Women (Dec. 18, 1979, entered into force Sept. 3, 1981) 1249 U.N.T.S. 13; Convention on the Rights of the Child (Nov. 20, 1989, entered into force Sept. 2, 1990) 1577 U.N.T.S. 3.

108 John Abraham and Tim Reed, *Trading Risks for Markets: the International Harmonization of Pharmaceutical Regulation*, 3 HEAL. RISK SOC. (2001) 113.

109 ICH, *ICH GCP*, *supra* note 101, at 1 (emphasis added).

110 Although this is a consequence of decisions on its practical application by funders, researchers and regulators: the ‘principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects’—ICH GCP, *ICH GCP*, *supra* note 101, 1 (emphasis added).

111 There is also the International Standards Organization (ISO): ISO 14155 on GCP for the design, conduct, recording, and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

112 As Power explains, ‘social and economic institutions . . . shape and frame knowledge of, and management strategies for, risk, including the definition of specific “risk objects”’—Power, *supra* note 48, at 3–4. See further: François Ewald and Stephen Utz, *The Return of Descartes’ Malicious Demon: An outline of a philosophy of precaution*, in *EMBRACING RISK: THE CHANGING CULTURE OF INSURANCE AND RESPONSIBILITY* (Tom Baker and Jonathan Simon eds., 2002). More generally see: RICHARD V. ERICSON, *CRIME IN AN INSECURE WORLD* (2007); Lucia Zedner, *Fixing the Future? The Pre-emptive Turn in Criminal Justice, in REGULATING DEVIANCE: THE REDIRECTION OF CRIMINALIZATION AND THE FUTURES OF CRIMINAL LAW* (Bernadette McSherry et al. eds., 2009).

113 On anticipatory governance, see: Leon S. Fuerth, *Foresight and Anticipatory Governance*, 11(4) FORESIGHT 14 (2009); David H. Guston, *Understanding ‘Anticipatory Governance’*, 44(2) SOC. STUD. SCI. 218 (2014).

other guidelines). This amendment takes into account developments in data science, so-called ‘datafication.’¹¹⁴ For instance, these developments make possible the use of electronic data to construct different and more specific population groups for clinical trials, and enable improvements in the quality, safety and efficacy of pharmaceuticals for those groups. The 2016 amendment essentially updated quality management of recording, reporting, and monitoring of clinical trials to facilitate the use of electronic data for these kinds of purposes. The 2016 amendment was also consistent with the key task within the ICH’s mission, ‘[t]o monitor and update harmonized technical requirements leading to a greater mutual acceptance of research and development data.’¹¹⁵

Training for users of MedDRA and other ICH guidelines is a cross-cutting supplementary anticipatory practice, and it provides the third example for the present discussion. The expectations and imaginary flowing from the ICH’s mission are also legitimate and necessitate these practices. The dissemination of MedDRA and the ICH’s guidelines through training,¹¹⁶ including through ‘bilateral regulatory cooperation . . . on the exchange of information, training and reliance practices,’¹¹⁷ is central to their implementation and in turn realization of the expectations. Training lends further normative weight to MedDRA and ICH guidelines, and strengthens the latter’s status as de facto binding.¹¹⁸

In summary, these anticipatory practices for the harmonization of knowledge creation are key attempts to furnish governance with future-ready regulatory tools. These tools fall within the boundaries of the ICH’s responsibility and accountability. The expectations and imaginary flowing from the ICH’s mission legitimate and thus help to perform these future-oriented practices into being. This in turn facilitates the legitimation of ICH governance, both in the present and into the future, in light of developments in science and technology.

Anticipatory practices further encode and realize the expectations and imaginary flowing from the ICH’s mission. These practices help to ensure the development of ‘safe, effective, and high quality medicines’ is achieved ‘in the most resource-efficient manner.’¹¹⁹ At the same time, the expectations and imaginary help to legitimate these anticipatory practices and their reshaping of the ICH’s regulatory tools in response to changes in knowledge production, including those prompted by health emergencies like COVID-19. The latter in turn makes it possible to maintain legitimation into the future. Indeed, further legitimation occurs through the ongoing sanctioning of

114 Harcourt explains this is ‘the idea that amassing large data sets, mining and analyzing them will reveal new truths about society and ourselves that we would never have known before and which will allow us to find solutions to problems that we might never have discovered’—see: BERNARD E. HARCOURT, *EXPOSED: DESIRE AND DISOBEDIENCE IN THE DIGITAL AGE* (2015), 21. Also see: ANJA BECHMANN AND STINE LOMBERG EDS., *THE UBIQUITOUS INTERNET: USER AND INDUSTRY PERSPECTIVES* (2015); José van Dijck, *Datafication, Dataism and Dataveillance: Big Data between Scientific Paradigm and Ideology*, 12 *SURV. SOC.* 197 (2014).

115 ICH, *Mission*, *supra* note 24; Article 3(d) ICH Articles of Association (2019).

116 ICH, *Id.*; Article 3(g) ICH Articles of Association (2019).

117 ICH, *Value of Membership*, *supra* note 72.

118 In general, see: Dean, *supra* note 77. On the importance of looking at training and other instruments, see: Pierre Lascombes and Patrick Le Gales, *Introduction: Understanding Public Policy through its Instruments—From the Nature of Instruments to the Sociology of Public Policy Instrumentation*, 20(1) *GOV.* 1 (2007).

119 ICH, *Mission*, *supra* note 24 (accessed Sept. 1, 2020) (emphasis added).

new scientific methods and updating of existing practices.¹²⁰ This affirms Harvey and Salter's more general point about how novel science 'gives bioethical expertise access to new governance territory; *bioethical expertise gives sciences access to political acceptability*'.¹²¹

Anticipatory practices for the shaping of knowledge support the technological framing of the ICH's governance structures and regulatory practices. The expectations and imaginary that flow from the ICH's mission legitimate these practices. These practices also make possible the key matters discussed above: the marginalization of systemic implications relating to social justice and the narrow space for public participation to highlight them.

III.B. Engaging with Risk Management

The expectations and imaginary of the ICH, and its governance, also legitimate and perform into being techniques of risk management. These are relevant to the ICH's guidelines. In respect of quality guidelines, they include:

'pivotal milestones such as the conduct of stability studies [for pharmaceuticals], defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice . . . risk management'

Safety guidelines also relate to risk management in that they aim to '*uncover potential risks like carcinogenicity, genotoxicity, and reprotoxicity*'.¹²² The safety, quality, and effectiveness of pharmaceuticals are the overriding focus of risk-management techniques.

ICH GCP, already mentioned as a key efficacy guideline and anticipatory practice, also exemplifies the ICH's engagement with risk management. The ICH describes ICH GCP as '*an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects*'.¹²³ While the technological framing of the ICH centers on safety, quality, and effectiveness, and risk management pertains to these as 'risks',¹²⁴ within ICH GCP this manifests in a management system encompassing risk identification (including 'risks to critical trial

120 Lena Eriksson and Andrew Webster, *Standardizing Work as a Recursive Process: Shaping the Embryonic Stem Cell Field*, 34(1) NEW GEN. SOC. 72 (2015). For related examples, see: Martyn Pickersgill, *Neuroscience, Epigenetics and the Intergenerational Transmission of Social Life: Exploring Expectations and Engagements*, 3(3) FAM., REL. SOC. 481 (2014); NIKOLAS ROSE AND JOELLE M. ABI-RACHED, *NEURO: THE NEW BRAIN SCIENCES AND THE MANAGEMENT OF THE MIND* (2013); D WASTELL AND S WHITE, *BLINDED BY SCIENCE: THE SOCIAL IMPLICATIONS OF EPIGENETICS AND NEUROSCIENCE* (2017).

121 Alison Harvey and Brian Salter, *Anticipatory Governance: Bioethical Expertize for Human/Animal Chimeras*, 21(2) SCI. AS CUL. 291 (2012) (emphasis added).

122 ICH, *Safety Guidelines*, <https://www.ich.org/page/safety-guidelines> (emphasis added).

123 *Id.*, at 1 (emphasis added).

124 For discussion on the prioritization of risks, see: MARY DOUGLAS AND AARON WILDAVSKY, *RISK AND CULTURE: AN ESSAY ON THE SELECTION OF TECHNICAL AND ENVIRONMENTAL DANGERS* (1982); NIKOLAS LUHMANN, *RISK: A SOCIOLOGICAL THEORY* (1993).

processes and data¹²⁵), risk evaluation, risk control, risk communication, risk review, and risk reporting.¹²⁶ In short, ICH GCP is ‘risk-based’.¹²⁷

Under Helsinki the creation, refinement, and advancement of scientific knowledge—the scientific enterprise¹²⁸—is central to ethics. Research involving human subjects must seek to produce generalizable knowledge and ‘improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments)’.¹²⁹ The interests of society, ie the generation of new biomedical knowledge and products, must not prevail over the interests of trial subjects.¹³⁰ In terms of the relationship between ICH GCP and Helsinki:

‘Compliance with this standard *provides public assurance that the rights, safety and well-being of trial subjects are protected*, consistent with the principles that have their origin in the Declaration of Helsinki, *and that the clinical trial data are credible*’.¹³¹

Drawing on Helsinki, ICH GCP further encodes and implements expectations that ICH guidelines will produce technological development of pharmaceuticals and individual ethical conduct centered on safety, quality and effectiveness.

The main way in which this occurs is through a weighing of the expected benefits and risks, or positive and negative expectations respectively, of research involving human subjects.¹³² This calculus must show that the research subject’s participation in the clinical trial has not left her worse off than she would have otherwise been.¹³³ The involvement of human research subjects in trials is justified to Research Ethics Committees based on the balance being on the side of benefits or positive expectations.¹³⁴ Research participants grant their informed consent based on the expected benefits and risks. The ‘methods used to assure and control the quality of the trial’ provide participants with further protection by providing they ‘should be *proportionate to the risks* inherent in the trial and the importance of the information collected’.¹³⁵

As tools of risk management, ICH GCP and other guidelines focus on safety, quality and effectiveness, as the key technical matters, and draw upon ethics and rights to present the ICH as a legitimate, accountable body that is an international leader in socially robust innovation. This chimes with Power’s assertion that risk management

125 ICH, *ICH GCP*, *supra* note 101, at 21, Point 5.0.2.

126 *Id.*, 21–22, Point 5.0.2–Point 5.0.7.

127 *Id.* For discussion, see: Lindström-Gommers and Mullin, *supra* note 63, at 930.

128 HARRY M. MARKS, *THE PROGRESS OF EXPERIMENT: SCIENCE AND THERAPEUTIC REFORM IN THE UNITED STATES, 1900–1990* (1997).

129 Declaration of Helsinki, *supra* note 106, Para. 6 (emphasis added).

130 ICH, *ICH GCP*, *supra* note 101, at 9, Point 2.3; Declaration of Helsinki, *supra* note 106, Para. 8.

131 *Id.*, at 1 (emphasis added).

132 John Abraham and Tim Reed, *Reshaping the Carcinogenic Risk Assessment of Medicines: International Harmonization for Drug Safety, Industry/Regulator Efficiency or Both?*, 57 *SOC. SCI. MED.* (2003) 195.

133 ICH, *ICH GCP*, *supra* note 101, at 9, Point 2.2; Declaration of Helsinki, *supra* note 106, Paras. 16–18.

134 *Id.*, at 9, Point 2.6; Declaration of Helsinki, Para. 23. In the US, these are known as institutional review boards. See further: Charles L. Bosk, *Professional Ethicist Available: Logical, Secular, Friendly. Bioethics and Beyond*, 128(4) *DAEDALUS* 47 (1999); Charles L. Bosk and Raymond G. de Vries, *Bureaucracies of Mass Deception: Institutional Review Boards and the Ethics of Ethnographic Research*, 595(1) *ANN. AMER. AC. POL. SOC. SCI.* 249 (2004); EDWARD S. DOVE, *REGULATORY STEWARDSHIP OF HEALTH RESEARCH: NAVIGATING PARTICIPANT PROTECTION AND RESEARCH PROMOTION* (2020).

135 ICH, *ICH GCP*, *supra* note 101, at 21, Point 5.0 (emphasis added).

‘embodies ideas about purpose’, here technical matters, which also ‘embeds [its] practices in larger systems of value and belief’,¹³⁶ here those relating to ethics and rights. This is an instance of how, according to Sparks, drawing on Garland, risk has ‘moral, emotive and political as well as calculative’ dimensions and is a ‘mixed discourse.’¹³⁷

The expectations and imaginary that flow from the ICH’s mission legitimate and help to perform ICH guidelines into being. The risk-based nature of ICH guidelines expedites the performance and realization of the expectations and imaginary that flow from the mission.¹³⁸ This is because the legitimation the expectations provide gains additional support from that bestowed by risk discourse.¹³⁹ As such, the expectations and imaginary ultimately enable ICH guidelines, including MedDRA, to become, in Power’s terms, ‘visionary documents and designs . . . for individuals and organizations.’ These documents are among ‘the recipes and recommendations’ that ‘constitute a new normativity for risk management.’¹⁴⁰ As visionary documents, ICH guidelines further encode the expectations and imaginary flowing from the ICH’s mission. In doing so, ICH guidelines are another example, to paraphrase Douglas, of the ICH putting risk and uncertainty under control, here, by providing a common regulatory roadmap for regulators and industry worldwide.

The ICH’s guidelines implement the focus on technological development and individual ethical conduct for the production of pharmaceuticals found in the mission. By reflecting the dominant approach in bioethics, ICH guidelines perpetuate the marginalization of wider normative issues, discussed above, within the very practices of risk management. In particular, as Flear explains:

‘The focus on consent and GCP also abstracts the research subject from social context while also freighting it with responsibility [through consent]. This in turn limits the responsibilities and accountabilities of those carrying out trials...the regulator[s] that [use] the data produced in order to authorize the marketing of products on safety grounds, and the corporations who ultimately profit.’¹⁴¹

136 Power, *supra* note 48, at 25 (emphasis added).

137 Richard Sparks, *Degrees of Estrangement: The Cultural Theory of Risk and Comparative Penology*, 5(2) THEO. CRIM. 159, 169 (2001), drawing on DAVID GARLAND, *PUNISHMENT AND MODERN SOCIETY: A STUDY IN SOCIAL THEORY* (1990) (emphasis added). For related discussion on the relationship between risk, ethics, and rights, in health regulation, see: MARK L. FLEAR ET AL. EDs., *EUROPEAN LAW AND NEW HEALTH TECHNOLOGIES* (2013).

138 Adam Hedgecoe and Paul Martin, *The Drugs Do not Work: Expectations and the Shaping of Pharmacogenetics*, 33 SOC. STUD. SCI. 327 (2003).

139 Black notes that the rhetoric of risk is a ‘useful legitimating device’—see: Julia Black, *The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom*, 512, 519 PUB. L. (2005). On calculative devices as tools to justify and legitimate action, see: JENS BECKERT AND RICHARD BRONK EDs., *UNCERTAIN FUTURES: IMAGINARIES, NARRATIVES, AND CALCULATION IN THE ECONOMY* (2019), at 18–20.

140 Power, *supra* note 48, at 5 (emphasis added). More generally, see: LAWRENCE BUSCH, *STANDARDS: RECIPES FOR REALITY* (2011); KEVIN DAVIS ET AL. EDs., *GOVERNANCE BY INDICATORS: GLOBAL POWER THROUGH QUANTIFICATION AND RANKINGS* (2012).

141 Flear, *supra* note 5, at 230, citing: Marie-Andrée Jacob, *Form-Made Persons: Consent Forms as Consent’s Blind Spot*, 30(2) POL. L. ANTH. REV. 249 (2007). See further: Marie-Andrée Jacob and Annalise Riles, *The New Bureaucracies of Virtue: Introduction*, 30(2) POL. L. ANTH. REV. 181 (2007).

Risk management of clinical trials centered on the technical matters of safety, quality and efficacy, may actually further militate against public questioning and reinforce the marginalization of ‘the social’. This is due to the way in which risk discourse shifts attention to consequences, and thus obscures the sorts of normative matters noted above. The central roles of utilitarian-based (ie consequence-oriented) ethics and human rights in building ICH guidelines supports, and thus may exacerbate, this shift of attention away from wider issues of social justice.

Further, the reliance within risk management, as with wider ICH governance, on scientific-technical knowledge and expertise on technical matters can marginalize other kinds of knowledge and expertise, including those held by the ICH’s wider publics. Commenting on the regulation of new technologies more generally, Brownsword remarks, once a ‘technology has been pronounced safe, or at any rate not demonstrably unsafe, the weight of “expert” scientific opinion makes it difficult for dissenting voices to be heard’.¹⁴² Moreover, in the context of the ICH, the focus on safety, quality, and effectiveness as benefits or positive expectations of pharmaceuticals, might support and privilege certain voices and publics. These groups may become central to the legitimation of the ICH and its global bioethics guidelines. In particular, the focus on positive expectations might prioritize the voicing of support by those individuals and groups who actively campaign towards, for example, research and public funding that addresses their concerns and supports the development of pharmaceutical-enabled ‘hope technologies’.¹⁴³

It is in their relation to responsibility and accountability that more becomes apparent about how the expectations and imaginary flowing from the ICH’s mission and framing support the legitimation of risk management.¹⁴⁴ Not meeting expectations relating to the safety, quality, and effectiveness of pharmaceuticals, the primary risk, through ICH guidelines may amount to a failure and give rise to adverse public perceptions—and calls for accountability. The latter is a risk to standing and reputation, an institutional risk, that is, a key secondary risk. However, this risk may undermine legitimation of the ICH’s aims, governance, and the identity of the ICH, its Membership, and those that implement the ICH’s regulatory instruments.¹⁴⁵ In short, adverse public perceptions may undermine the very project of global harmonization.

Nevertheless, the performance of expectations through activities ‘for better health’ may help to manage public perceptions, ie that expectations are being met. Key activities, such as revising ICH GCP and other guidelines in response to developments in data science, and the updating of MedDRA in light of COVID-19, may produce the perception that the ICH is helping to realize ‘better health’ through them. These attempts to meet the expectations, and fulfil the responsibilities, flowing from the ICH’s mission, not only drive harmonization forward—they may also inform public views

142 ROGER BROWNSWORD, *RIGHTS, REGULATION AND THE TECHNOLOGICAL REVOLUTION* (2008), at 119.

143 SARAH FRANKLIN, *EMBODIED PROGRESS: A CULTURAL ACCOUNT OF ASSISTED CONCEPTION* (1997).

144 For discussion, see: Anthony Giddens, *Risk and Responsibility*, 62(1) *MOD. L. REV.* 1 (1999).

145 Institutional and organizational risks are sometimes used interchangeably. For discussion of this secondary risk, see Flear, *supra* note 5, at 8–9, who develops insights from Henry Rothstein et al., *A Theory of Risk Colonization: The Spiralling Regulatory Logics of Societal and Institutional Risk*, 35 *EC. SOC.* 91 (2006). For discussion of failure as a risk, see: BRIDGET M. HUTTER AND SALLY LLOYD-BOSTOCK, *REGULATORY CRISIS: NEGOTIATING THE CONSEQUENCES OF RISK, DISASTERS AND CRISES* (2017).

of regulatory effectiveness, forestall adverse public perceptions, and produce ongoing legitimation.¹⁴⁶

The importance of governance and regulatory activity to legitimation links to the emphasis on public communication of expectations and transparency to demonstrate practices are in accordance with them. In relation to risk management, public communication and transparency can be understood as part of what Power describes as the growing attention ‘on the *process* of risk management rather than on its content’¹⁴⁷ amidst more general attentiveness to ‘political perceptions of effectiveness and the possibility of blame’¹⁴⁸ in the event of failure (ie not meeting expectations).

However, reliance on one-way communication and transparency to shape public perceptions of the ICH, and generate legitimation among the ICH’s wider publics, is becoming increasingly problematic given changes in the very production of knowledge, which relate to those already discussed. Scholarship within STS, and the broader social studies of science, in particular, emphasizes the epistemic capacities of the publics of novel technoscience. Individuals know about diverse things in different ways, have a range of expertise, and are often reflexively aware of limitations to their comprehension of particular sociotechnical developments that they may actively seek to address. Relying on ‘better health’, the outcome of the harmonization process, to produce legitimation for the ICH and its global bioethics standards no longer appears sustainable. Input from the ICH’s wider publics is, therefore, now a pressing concern.¹⁴⁹

The ICH’s wider publics could organize to inform discussion on the purpose and framing of risk governance and regulation, including what falls within the legitimate purview of global harmonization efforts. The ICH’s wider publics could also underline the kinds of issues relating to social justice noted throughout. In particular, whom global harmonization tends to make vulnerable (usually people in the global South), and whom it tends to benefit (often industry in the global North).¹⁵⁰ Finally, the ICH’s wider publics could provide insights on how we might know these largely overlooked

146 On governance activity and legitimation, see Flear, *supra* note 5, at 204, citing the concept of ‘output legitimacy’ discussed by Scharpf, *supra* note 26.

147 Power, *supra* note 48, at 18. Original emphasis.

148 *Id.* Original emphasis.

149 For discussion of public participation in risk-based decision making, see: Flear, *supra* note 5. This cites and summarizes the key scholarship in STS and cognate disciplines, including: ALAN IRWIN AND MIKE MICHAEL, *SCIENCE, SOCIAL THEORY AND PUBLIC KNOWLEDGE* (2003). This work is also informed by: ULRICH BECK, *RISK SOCIETY: TOWARDS A NEW MODERNITY* (1986); ANTHONY GIDDENS, *MODERNITY AND SELF-IDENTITY: SELF AND SOCIETY IN THE LATE MODERN AGE* (1991); NIKLAS LUHMANN, *OBSERVATIONS ON MODERNITY* (1998); GABE MYTHEN AND SANDRA WALKLATE EDs., *BEYOND THE RISK SOCIETY* (2006).

150 The ICH’s publics could organize to make demands and contest decisions relating to social justice, such as those affecting their biology, conditions, and lived experiences. See further: PAUL RABINOW, *ESSAYS ON THE ANTHROPOLOGY OF REASON* (1996); SAHRA GIBBON AND CARLOS NOVAS EDs., *BIOSOCIALITIE, GENETICS AND THE SOCIAL SCIENCES* (2007). A key example is activism around global patents on antiretroviral medicine for AIDS and access for poorer people, who are usually in the global South. For discussion, see: JOÃO BIEHL, *WILL TO LIVE: AIDS THERAPIES AND THE POLITICS OF SURVIVAL* (2007); Vinh-Kim Nguyen, *Antiretroviral Globalism, Biopolitics, and Therapeutic Citizenship*, in *GLOBAL ASSEMBLAGES: TECHNOLOGY, POLITICS, AND ETHICS AS ANTHROPOLOGICAL PROBLEMS* (Aihwa Ong and Stephen J. Collier eds., 2005). See further: NIKOLAS ROSE AND CARLOS NOVAS, *Biological Citizenship* in, *GLOBAL ASSEMBLAGES: TECHNOLOGY, POLITICS, AND ETHICS AS ANTHROPOLOGICAL PROBLEMS* (Aihwa Ong and Stephen J. Collier eds., 2005).

aspects of ‘the social’ and adjust governance and regulation accordingly.¹⁵¹ The European Medicines Agency (EMA), for example, has since its foundation in 1995 been gradually developing ways of collaborating with its own publics around these sorts of issues, including within its predominantly risk-based processes.¹⁵² Public participation within the EMA is seen as enhancing transparency and the regulatory process itself, leading to improvements in the quality, safety, and efficacy of pharmaceuticals, and thus providing additional legitimation, perhaps especially at the EU level of governance.¹⁵³

Changes in knowledge production unsettle the foundations for the technological framing of ICH governance and its regulatory instruments, including anticipatory practices and risk management. Nevertheless, such discussion remains largely ignored within the ICH, where wider publics figure in efforts at communication and transparency to educate them into conferring legitimation. Despite attempts to facilitate public participation among the regulatory authorities of ICH Members, it seems likely limitations in public participation in ICH governance, and the marginalization of systemic matters relating to social justice that it abets, will continue. Yet, again, this mirrors the general position across bioethics, which largely remains separate from discussion on public participation.¹⁵⁴

IV. CONCLUSION

In this article, I drew upon insights from STS and closely related disciplines, and brought them into discourse with others from socio-legal studies. I did so to illuminate how expectations and imaginaries set and shaped by the ICH help to legitimate and perform into being its governance and regulatory instruments. The law-led analysis in this article adds to extant scholarship across these disciplines.

Measuring the impact of expectations in the legitimation of regulation and technoscience is, of course, an empirical question of the kind that is outside the scope of the more normative analysis this article has sought to advance. What does this analysis demonstrate about what expectations actually do in respect of legitimation? In terms of health research governance and regulation, expectations appear to do a great deal.

151 Sheila Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 *MINERVA* 223 (2003). Also see: Brian E. Wynne, *Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm*, 2(2) *GL. ENV. CH.* 111 (1992).

152 In general, see: David Haerry et al., *EUPATI and Patients in Medicines Research and Development: Guidance for Patient Involvement in Regulatory Processes*, 5(230) *FRONT. MED.* DOI: 10.3389/FMED.2018.00230 (2018). On public participation in risk-based processes at the EU level, see: Michael Berntgen et al., *Improving the Contribution of Regulatory Assessment Reports to Health Technology Assessments—A Collaboration Between the European Medicines Agency and the European Network for Health Technology Assessment*, 17 *VAL. HEAL.* 634 (2014); Axel C. Mühlbacher et al., *Patient-Focused Benefit–Risk Analysis to Inform Regulatory Decisions: The European Union Perspective*, 19 *VAL. HEAL.* 734 (2016).

153 EMA, *Patients and Consumers*, <https://www.ema.europa.eu/en/partners-networks/patients-consumers> (accessed Sept. 1, 2020). For recent theorizations of techniques of legitimation at the EU level of governance, see: Vivien Schmidt and Matthew Wood, *Conceptualizing Throughput Legitimacy: Procedural Mechanisms of Accountability, Transparency, Inclusiveness and Openness in EU Governance*, 97(4) *PUB. AD.* 727 (2019). This is part of the special issue: Vivian Schmidt and Matthew Wood eds., *Throughput Legitimacy in the European Union (Special Issue)* 97(4) *PUB. AD.* (2019).

154 For discussion on this, and the idea that ‘the technical is potentially political’ and public participation makes sense only where there is injustice—see: Alfred Moore, *Beyond Participation: Opening-Up Political Theory in STS*, 40(5) *SOC. STUD. SCI.* 793 (2010).

The expectations flowing from the ICH's mission construct an imaginary of global harmonization centered on safe, quality, and effective pharmaceuticals. The ICH's governance structures and regulatory instruments encode the expectations and imaginary, and delimit responsibility and accountability in the event of failure (ie not meeting expectations). At the same time, the expectations and imaginary help to legitimate this performance.

The legitimation these expectations provide further animates governance and its regulatory instruments, and propels attempts to support pharmaceutical development, innovation, and profit making. Employing expectations to produce support for pharmaceutical innovation aligns regulatory strategies with the broader global attempt to widen research populations, and integrate markets into the wider global circuits of clinical trials data and patented pharmaceuticals. For the ICH, ICH Members, and those states that implement ICH guidelines through their law and policy, the expectations framing ICH guidelines are important to their identities and legitimation. Expectations support a view on the potential of harmonizing technical standards to improve health, albeit reduced to safe, quality, and effective pharmaceuticals, which sets the conditions for possible innovation.

However, the main focus of the expectations on these technical matters perpetuates the dominant approach in bioethics. This tends to centralize matters relating to technological development and its achievement through individual ethical conduct, while marginalizing other normative matters as part of 'the social' or mere context. These include the potential for the distortion of attention and resources toward pharmaceuticals, especially those to tackle pandemic health emergencies, and away from non-pharmaceutical responses that are not only often cheaper, but also key to prevention of both communicable and non-communicable diseases in the first place, including those relating to poverty. The central role of scientific-technical knowledge and expertise to delivering safe, quality, and effective pharmaceuticals abets the latter. It does so by minimizing the value of the knowledge and experience held by the ICH's publics (those individuals and people subject to ICH governance and standards), and limiting their participation and contribution toward governance. Instead, there is an attempt to shape public perceptions and generate legitimation through one-way communication of expectations and transparency to demonstrate practices are consistent with them (ie that expectations are met).

Since it is largely for the ICH, regulators and industry to define expectations of innovation,¹⁵⁵ and the definition itself is not without normative consequences, this raises the question: how can the expectations themselves be legitimate? In raising this question, and making my broader claims, I do not deny that there may be significant benefits to the shaping and use of expectations in legitimating and propelling innovation and risk-taking for new technoscience. Indeed, it is precisely because of this that I feel it is necessary to explain the limitations of expectations as techniques of legitimation. Thus, my goal here is to suggest that those who set and shape expectations, and create imaginaries, need to be more reflexive about whose interests their efforts actually prioritize.

155 For discussion on the influence of short-term results, including making a profit and commercial advantage, and the utility of peer review for scientific progress, see: DONALD BRABEN, *SCIENTIFIC FREEDOM* (2008).

This article provides a basis upon which further discussions about the role of expectations in legitimating governance and regulation can develop. These discussions will be disruptive to the current means of propelling innovation. In respect of the ICH, the expectations and imaginary flowing from its mission are gradually narrowed through a restrictive regime. This regime narrows the expectations and imagined future they construct precisely to generate public legitimation on the basis of outcomes, but with limited possibilities for public participation to enhance them and legitimate the whole project of global harmonization.

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