Recognizing and Legitimizing the Transnational Scientific Governance of Human Gene Editing

*Liam W Harris**

The development of the CRISPR-Cas9 gene editing technique has provoked an international conversation regarding the regulation of human gene editing and the stewardship of humanity's genetic heritage. In the absence of coherent national regulation, non-legal actors at the transnational level may play a key role in regulating the ethical and biological risks raised by these advancements. However, the transnational governance of biotechnology is poorly understood. To further this understanding, the important role played by scientific organizations in transnational governance of these technologies must be examined in greater detail. While a growing literature has examined transnational governance processes and the role of science in these processes, the role of scientific organizations in the transnational governance of science itself has not yet been characterized in depth This paper seeks to understand the role of scientific organizations in the global regulation of scientific practice, by examining the role of the host organizations of the Inter-

Le développement de la technique d'édition génétique CRISPR-Cas9 a provoqué une conversation internationale sur la réglementation de l'édition des gènes humains et la sauvegarde du patrimoine génétique de l'humanité. Dans l'absence de réglementation nationale cohérente, les acteurs non juridiques au niveau transnational peuvent jouer un rôle important dans la réglementation des risques éthiques et biologiques soulevées par ces technologies. Cependant, la gouvernance transnationale de la biotechnologie n'est pas bien comprise. Pour approfondir cette compréhension, le rôle important joué par des organisations scientifiques dans la gouvernance transnationale de ces technologies doit être examiné. Une littérature croissante examine les processus de gouvernance transnationale et le rôle de la science dans ces processus, mais le rôle des organisations scientifiques dans la gouvernance transnationale de la science elle-même n'a pas encore été caractérisé en profondeur. Cet article cherche à comprendre le rôle des organisations scientifiques dans

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* B.C.L./LL.B. Candidate, McGill University Faculty of Law; B.Sc. I wish to express my gratitude to Prof. Jaye Ellis who supervised this work and provided invaluable insight, as well as to the three anonymous reviewers for their very helpful comments.

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national Summit on Human Gene Editing in the regulation of gene editing in humans. This paper argues that the host organizations are in a better position to regulate these technologies than formal legal actors due to the dynamic, transnational, and technical nature of this regulatory task. In addition, this paper examines the inherent legitimacy challenges faced by the host organizations and highlights strengthened discourse between scientific organizations and the public with regards to their policy role as a possible solution.

la réglementation globale de la pratique scientifique en examinant le rôle des organisations hôtes du *International Summit on Human Gene Editing* dans la réglementation de l'édition des gènes humains. Cet article fait valoir que les organisations hôtes sont mieux placées pour réglementer ces technologies que les acteurs étatiques en raison de la nature dynamique, transnationale et technique de cette tâche. En outre, cet article examine les défis de légitimité rencontrés par les organisations hôtes et suggère le renforcement du discours entre les organisations scientifiques et le public concernant leur rôle juridique comme solution.

Introduction

The development and widespread adoption of the CRISPR-Cas9 technique has reinvigorated the international conversation concerning human gene editing. CRISPR[1] allows scientists to manipulate the genome with unprecedented ease and precision, and its low cost and relative simplicity have made it a fixture in laboratories worldwide.[2] There is significant hope that this development will not only fuel better understandings of basic biology but will also lead to a revolution in genetic medicine. However, the power CRISPR offers to edit the genome is accompanied by significant risks, notably the prospect that the genetic makeup of the human species could be altered through inheritable genetic changes.[3] Given its significant potential benefits and risks, CRISPR has revived policy debates about the acceptable limits of scientific research and how to manage humanity's genetic heritage.

This most recent policy challenge builds on previous debates regarding the scientific manipulation of life. Stem cell, cloning, and assisted reproductive technologies have generated significant controversy in preceding decades, leading to the adoption of policies at the national and international levels to manage risks and ethical concerns while minimizing impediments to scientific discovery.[4] The legacy of these debates is a patchwork of highly divergent national laws,[5] coupled with vague and toothless instruments at the international level.[6] The development of CRISPR has revealed that the area of gene editing regulation is characterized by inconsistency and uncertainty.

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1 In the interests of brevity, the term CRISPR will be used in place of the CRISPR-Cas9 technique. CRISPR refers to the family of DNA sequences used in the technique that, in conjunction with the Cas9 enzyme, can be used to edit genomes.

2 See Jennifer A Doudna & Emmanuelle Charpentier, "The New Frontier of Genome Engineering with CRISPR-Cas9" (2014) 346:6213 Science 1258096 at 1258096-1.

3 See Edward Lanphier et al, "Don't Edit the Human Germ Line" (2015) 519 Nature 410 at 410.

4 See e.g. Heidi Ledford, "The Landscape for Human Genome Editing" (2015) 526 Nature 310 at 311.

5 See *ibid* at 310.

6 See e.g. Carol A Tauer, "International Policy Failures: Cloning and Stem-Cell Research" (2004) 346 Lancet 209 at 210.

It was in the context of this regulatory uncertainty that the leading scientific bodies from the United States, the United Kingdom, and China convened the International Summit on Human Gene Editing (Summit). It brought together hundreds of thinkers from various disciplines to discuss the appropriate uses of CRISPR. The Organizing Committee's conclusions call for a ban on some clinical applications of the technique while approving its relatively unfettered use in basic scientific applications.[7] In addition, an ongoing process set up by the hosts of the Summit (hereafter, collectively referred to as the ISHGE) aims to monitor the technology's development and construct a more detailed guidance framework.[8]

The ISHGE process raises questions about the role of networks of non-state actors in the governance of transnational issues. There is increasing recognition that focusing on states to the exclusion of non-state actors leads to an incomplete understanding of regulation at the international level. National systems of law are complemented by processes occurring across borders, which shape people's behaviour and can therefore be characterized as modes of transnational governance. A growing literature seeks to characterize the role of non-state actors in transnational governance and to examine the consequences of this role on the legitimacy and democratic processes of the governance system.[9] This literature originated in and has largely focused on the regulation of the global economic system. While the role of science in transnational governance processes has been studied in depth, especially in the context of environmental issues, the role of scientific organizations in the transnational governance of science itself is poorly understood.

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7 Steven Olson, *International Summit on Human Gene Editing: A Global Discussion; Meeting in Brief, 2015* (Washington, DC: National Academies Press, 2016) at 6–7; Andrew R LaBarbera, "Proceedings of the International Summit on Human Gene Editing: A Global Discussion – Washington, D.C., December 1–3, 2015" (2016) 33 J Assist Reprod Genet 1123 at 1126.

8 Olson, *supra* note 7 at 7.

9 See e.g. Alan Brouder, "Introduction" in Christian Tietje & Alan Brouder, eds, *Handbook of Transnational Economic Governance Regimes* (Leiden: Martinus Nijhoff Publishers, 2009) 1 at 5–6; Paul Wapner, "Politics Beyond the State: Environmental Activism and World Civic Politics" (1995) 47:3 World Politics 311; Gregory H Fox & Brad R Roth, eds, *Democratic Governance and International Law* (New York: Cambridge University Press, 2000); Marie-Laure Djelic & Kerstin Sahlin-Andersson, eds, *Transnational Governance: Institutional Dynamics of Regulation* (New York: Cambridge University Press, 2006).

This paper uses the ISHGE process and the regulation of CRISPR gene editing technology as a case study for determining the potential role of transnational scientific networks in the governance of science. This paper also asks how these processes could be optimized, with the goal of more legitimate scientific regulation. I argue that the ISHGE has the potential to play a key role in the regulation of emerging gene editing technology where state-based regulation may be relatively ill-suited. I further argue that the ISHGE, as a private governance actor, faces inherent legitimacy challenges that could be addressed by drawing on the principles of Open Science. Overall, the aim of this paper is to present a framework for understanding transnational scientific governance by examining the significant contemporary regulatory challenge posed by CRISPR.

In Part I, I provide background on the regulatory challenge posed by CRISPR and the details of the ISHGE process. In Part II, I draw on the transnational economic governance literature and the metaphor of regulatory space to conceptualize the challenge of regulating gene editing on a global scale. In Part III, I characterize the ISHGE as a regulatory actor, assess its sources of power, and illustrate how it leverages these resources to affect regulatory outcomes. In Part IV, I survey literature on the legitimacy of non-state governance to assess challenges to the ISHGE's legitimacy and the sources of legitimacy upon which the ISHGE may draw. Finally, in Part V, I consider the relative merits of different mechanisms by which the ISHGE and future transnational scientific governance processes could enhance their legitimacy.

I. Background on CRISPR-Cas9 and the Subsequent International Response

A. CRISPR-Cas9 and the renewed debate on gene editing

Despite deep understanding of the molecular mechanisms of genetics, scientists have struggled to find a way to easily and reliably effect precise point modifications to the genetic code.[10] The power to modify the genome in this way holds immense promise for understanding biological processes, engineering plant and animal species, and developing treatments for genetic diseases.[11]

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[10] See Doudna & Charpentier, *supra* note 2 at 1258096-5 to 1258096-6.

[11] See *ibid* at 1258096-6.

The CRISPR technique represents a massive improvement over previous gene editing techniques and provides a heightened level of precision and simplicity.[12] The technique is based on a bacterial defence system against viral infection that was first described in 2007.[13] CRISPRs – short pieces of repeating DNA punctuated by sequences obtained from previous viral infections – are transcribed and form complexes with the Cas9 enzyme that cut the foreign DNA at precise locations defined by the DNA sequence of the CRISPR.[14] By combining knowledge of this technique with new understandings of the gene editing potential of transcription activator-like effector nucleases (TALENs), scientists were able to identify the gene editing potential of CRISPR in 2012.[15] By January 2013, at least two separate teams of scientists from Harvard and Massachusetts Institute of Technology had carried out gene modification in cells, including human cells.[16] This discovery stimulated the widespread adoption of the technique, along with a huge volume of study on its applications. Despite some remaining practical challenges, scientists are hopeful that this technique or a related approach to gene editing will revolutionize scientific fields involving genetics, from cell and molecular biology to medicine.[17]

Rumours in early 2015 that a Chinese team from Guangzhou had modified the genome of human zygotes sparked intense debates among scientists and attracted widespread public attention to the technique.[18] The experiment

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12 See *ibid* at 1258096-5 to 1258096-6.

13 See Rodolphe Barrangou et al, "CRISPR Provides Acquired Resistance Against Viruses in Prokaryotes" (2007) 315 Science 1709 at 1709.

14 See Doudna & Charpentier, *supra* note 2 at 1258096-1 to 1258096-3.

15 See Martin Jinek et al, "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity" (2012) 337 Science 816 at 816.

16 See Le Cong et al, "Multiplex Genome Engineering Using CRISPR/Cas Systems" (2013) 339:6121 Science 819 at 819; Martin Jinek et al, "RNA-Programmed Genome Editing in Human Cells", online: (2013) 2 eLife e00471 at 1 <https://elifesciences.org/articles/00471>; Prashant Mali et al, "RNA-Guided Human Genome Engineering via Cas9" (2013) 339:6121 Science 823 at 823.

17 See e.g. Olson, *supra* note 7 at 1.

18 See Jocelyn Kaiser & Dennis Normile, "Chinese Paper on Embryo Engineering Splits Scientific Community", *Science* (24 April 2015), online: <www.sciencemag.org/news/2015/04/chinese-paper-embryo-engineering-splits-scientific-community>.

was confirmed in an April 2015 publication[19] and, despite designing the study in such a way as to minimize the ethical implications,[20] it generated significant controversy.[21]

The CRISPR technique has the potential to greatly advance our understanding of cellular and developmental processes in humans, which could lead to the treatment of certain diseases. For example, editing the genetic information in a person's cells could alter the receptors that allow the progression of HIV.[22] It could also in theory remove mutations that cause genetic diseases like sickle cell anemia, immune disorders, or cancer.[23] This could be carried out by simply modifying the affected cells ofthe human body.

More controversial is the use of CRISPR for modifying the DNA sequences in germ cells that form human sperm and eggs, thereby affecting the genetics of future generations. In theory, this could completely and permanently remove genes that predispose humans to disease and infertility.[24] In the more distant future, the technique could be applied to enhance human traits; for example, it could be used to make humans more tolerant of certain environments, increase the robustness of the human body, or increase brain function.[25] Germ cell applications are most controversial because they would result in a change to the pool of human genetic information, thereby altering the course of our evolution as a species.[26]

Ethical objections to gene editing range widely. Those who see the modification of natural human reproductive processes as inherently wrong

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19 Puping Liang et al, "CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes" (2015) 6:5 Protein Cell 363.

20 *Ibid* at 364 (specifically, the authors point out that they use tripronuclear zygotes instead of viable embryos and conclude that clinical applications at this stage would be premature).

21 See e.g. Christopher Scott, "Treading the Line Between Sensational and Groundbreaking Science" (2015) 15:12 Am J Bioeth 1 at 1.

22 See Olson, *supra* note 7 at 2.

23 See *ibid*.

24 See *ibid*.

25 See *ibid*.

26 See Lanphier et al, *supra* note 3 at 410.

categorically oppose germ line editing,[27] echoing concerns expressed in the debates around abortion and artificial reproductive technologies regarding the moral status of the human embryo. Others fear that gene editing technology will exacerbate social inequality.[28] The spectre of eugenics is raised by those who see gene editing as setting us on course to permanently eliminating undesirable features from the human species through the phenomenon of "designer babies."[29] Further, some feel that not enough is known about the technique to proceed without risking significant harm to individuals and the public.[30] Conversely, the strongest proponents argue that the potential to move beyond Darwinian modes of evolution offers considerable benefits, especially as we currently confront the consequences of an increasingly fragile environmental system.[31] Like preceding issues such as stem cell and assisted reproductive technologies, gene editing presents a significant regulatory challenge in balancing uncertain risks and rewards in an area currently devoid of precise legal regulation.

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27 See e.g. Olson, *supra* note 7 at 4 (contribution of Hille Haker); CBC Radio, The 180 with Jim Brown, "Debating the Ethics of Gene Editing" (6 December 2015), online: <www.cbc.ca/radio/the180/gene-editing-debating-the-usefulness-of-sci-fi-analogies-and-does-more-parental-leave-actually-help-women-1.3351174/debating-the-ethics-of-gene-editing-1.3351261> (position of Margaret Somerville). See also Julian Salvescu, "Gene Editing: A CBC Interview of Margaret Somerville and Julian Salvescu" (7 December 2015), *Practical Ethics* (blog), online: <blog.practicalethics.ox.ac.uk/2015/12/gene-editing-a-cbc-interview-of-margaret-somerville-and-julian-savulescu>.

28 See e.g. *ibid* (contribution of Ruha Benjamin, Françoise Baylis, and Catherine Bliss).

29 Daniel J Kevles, "If You Could Design Your Baby's Genes, Would You?", *Politico* (9 December 2015), online: <www.politico.com/magazine/story/2015/12/crispr-gene-editing-213425>; David King "Editing the Human Genome Brings Us One Step Closer to Consumer Eugenics", Opinion, *The Guardian* (4 August 2017), online: <www.theguardian.com/commentisfree/2017/aug/04/editing-human-genome-consumer-eugenics-designer-babies>.

30 See e.g. Olson, *supra* note 7 at 4 (contribution of Hille Haker).

31 See e.g. *ibid* (contribution of John Harris); John Harris, "Why Human Gene Editing Must Not Be Stopped", *The Guardian* (2 December 2015), online: <www.theguardian.com/science/2015/dec/02/why-human-gene-editing-must-not-be-stopped>.

B. The International Summit on Human Gene Editing

It was in the context of proliferating ethical concern generated by the Chinese human embryo study that the United States National Academy of Sciences and National Academy of Medicine (US National Academies), the United Kingdom-based Royal Society, and the Chinese Academy of Sciences convened the Summit in December of 2015. The aim of the Summit was to begin a conversation about the "scientific, ethical, legal, social, and governance issues" associated with the use of gene editing in humans.[32] Attendees and presenters spanned disciplines and offered a range of perspectives.[33] The Summit itself was video-recorded and broadcast live over the Internet; these videos have now been archived to enhance transparency.[34] Though previous meetings had been held to address the ethical challenges posed by CRISPR,[35] the Summit was unique in that it was hosted by a transnational network of professional organizations and in its unprecedented size and scope.

The Summit was a transnational extension of efforts already undertaken by the US National Academies and other national academies to study and inform lawmakers and the public about human gene editing. The mandate of the US National Academies, a private non-profit organization, is to advise the American government and the public on pressing policy developments in science and medicine.[36] The Royal Society plays an analogous role in the

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[32] Olson, *supra* note 7 at 1.

[33] See generally LaBarbera, *supra* note 7.

[34] The National Academies of Sciences, Engineering and Medicine, "International Summit on Gene Editing", online: <www.nationalacademies.org/gene-editing/Gene-Edit-Summit> [National Academies, "Summit"].

[35] See e.g. The Netherlands Commission on Genetic Modification, *Symposium Genome on Demand in Retrospect*, (2015), online: <www.cogem.net/index.cfm/en/news/item/symposium-genome-on-demand-in-retrospect>; United Nations Educational, Scientific and Cultural Organization, Press Release, "UNESCO Panel of Experts Calls for Ban on 'Editing' of Human DNA to Avoid Unethical Tampering with Hereditary Traits" (5 October 2015), online: <https://en.unesco.org/news/unesco-panel-experts-calls-ban-editing-human-dna-avoid-unethical-tampering-hereditary-traits>.

[36] The National Academies of Sciences Engineering and Medicine, "Who We Are" (2017), online: <www.nationalacademies.org/about/whoweare/index.html> [National Academies, "Who We Are"].

UK and the Commonwealth.[37] Though the Chinese Academy of Sciences fulfills a similar role in the People's Republic, it is not a private entity but rather an arm of the Chinese government and reports to the State Council.[38] The ISHGE represents the latest effort of these organizations to move beyond their national mandates and address scientific issues at the transnational level.

The Summit itself was organized and overseen by the Organizing Committee, appointed by the host organizations. The Organizing Committee was made up of twelve scientists: six from the United States, two from each of the United Kingdom and China, and one from each of Canada and Germany.[39] At the close of the Summit, the Organizing Committee delivered a consensus statement of four conclusions that were endorsed by the presidents of the hosting academies.[40] First, basic preclinical research should proceed relatively unhindered in order to learn more about the technique and its applications, including experimentation on human embryos and germ line modifications. Second, clinical uses of gene editing on somatic (non-germ line) cells should be allowed, since the risks involve only the individual being treated and can therefore be evaluated through existing systems. Third, clinical use of germ line editing should not proceed until the risks are better understood, there is broader societal consensus on its appropriateness, and regulation is in place to oversee developments. Finally, in recognizing the transnational nature of the problem, the Organizing Committee called upon the organizing academies to create an ongoing international body to study the issue further and promote transnational coordination.

In response to the need for more in-depth engagement and recommendations, a 22-member Expert Committee with representatives

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37 See The Royal Society, "History of the Royal Society", online: <https://royalsociety.org/about-us/history> [Royal Society, "History"].

38 See Chinese Academy of Sciences, "Introduction" (1 March 2016), online: <english.cas.cn/about_us/introduction>; People's Republic of China, "State Council Organization", online: <english.gov.cn/state_council/2014/09/03/content_281474985533579.htm>.

39 See The National Academies of Sciences, Engineering, and Medicine, "International Summit on Human Gene Editing: Statement of Task and Planning Committee", online: <www.nationalacademies.org/gene-editing/gene_167925> [National Academies, "Statement"].

40 Olson, *supra* note 7 at 6–8; LaBarbera, *supra* note 7 at 1126–27.

from eight countries was formed to undertake consultations and author a report.[41]

C. Subsequent events

Meanwhile, research into CRISPR continues at a furious pace. In the months immediately following the Summit, two experiments involving embryonic gene editing received approval. On 14 January 2016, the lab of Dr. Kathy Niakan received approval from the Human Fertilisation and Embryology Authority (HFEA), the UK's regulator of research involving human embryos, to modify human embryos using CRISPR.[42] In approving the study proposal, the HFEA noted the desirable insights to be gained into the development of human embryos and the potential application in treating genetic disease.[43] In the spring of 2015, Fredrik Lanner received institutional review board approval at the Karolinska Institute for a similar project that had already been approved by the Swedish Regional Ethics Board.[44] Meanwhile, another Chinese study in Guangzhou introduced gene edits in non-viable embryos,[45] and in March 2017, a separate team published the first study using CRIPSR in viable human embryos.[46] Interestingly, these studies attracted much less controversy than Liang et al. had in 2015, signal-

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41 Committee on Human Gene Editing: Science, Medical, and Ethical Considerations, *Human Genome Editing: Science, Ethics, and Governance* (Washington, DC: The National Academies Press, 2017) [Expert Committee].

42 Human Fertilisation & Embryology Authority, *Application for Research License Renewal for Research Project R0162*, License Committee Minutes (14 January 2016), online: Bioetica Web <https://www.bioeticaweb.com/wp-content/uploads/2016/03/33980_ReinoUnido-HFEA_Licence-14012016.pdf>.

43 *Ibid* at 5.

44 See Paul Knoepfler, "Interview with Fredrik Lanner Who Is CRISPR'ing Healthy Human Embryos" (26 September 2016), *The Niche* (blog), online: <https://ipscell.com/2016/09/interview-with-fredrik-lanner-who-is-crispring-healthy-human-embryos>.

45 Xiangjin Kang et al, "Introducing Precise Genetic Modifications into Human 3PN Embryos by CRISPR/Cas-Mediated Genome Editing" (2016) 33:5 J Assist Reprod Genet 581.

46 Lichun Tang et al, "CRISPR/Cas9-Mediated Gene Editing in Human Zygotes Using Cas9 Protein" (2017) 292:3 Mol Genet Genomics 525 at 1.

ling a potential change in attitudes regarding the basic research applications of heritable gene edits following the Summit.

In February 2017, the Expert Committee formed at the close of the Summit released a 200-page report that restated the key conclusions from the event.[47] The report arguably goes even further than the conclusions of the Organizing Committee in stating that clinical application of germ line editing can proceed subject to the restrictions that (1) the research is for a compelling purpose of treating disease and (2) there is stringent oversight in place, among other safeguards.[48] Overall, it seems that the use of human gene editing to treat disease has, at least within the scientific community, become more plausible and more widely accepted since the Summit.

II. Conceptualizing the Regulatory Space

The aim of this Part is to conceptualize the unique challenge posed by the governance of emerging gene editing technology such as CRISPR. First, I will introduce the metaphor of regulatory space from economic governance literature as a conceptual aid to understanding transnational regulation outside the state. I will then consider the particularities of emerging gene editing technology as a regulatory challenge and how this affects the dynamics of the regulatory space. In the final Sub-Parts, I ask how formal legal actors can be expected to act within the defined regulatory space, with reference to the current paucity of regulation in this area. I conclude that state governance structures are poorly situated to regulate emerging gene editing technology, leaving space for informal regulatory actors to wield disproportionate influence.

A. The regulatory space metaphor

Regulation involves the design, implementation, and enforcement of rules through which we organize ourselves as a society.[49] Historically, our thinking about regulation has been focused on the legal rules created by

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47 *Supra* note 41.

48 *Ibid* at 134–35.

49 See L Hancher & M Moran, "Organizing Regulatory Space" in Robert Baldwin, Colin Scott & Christopher Hood, eds, *A Reader on Regulation* (New York: Oxford University Press, 1998) 148 at 148.

states to tackle problems of public concern, with legislative governance among the most apparent forms of social regulation.[50] In recent years, however, it has become increasingly apparent that formal law is but one of many ways behaviour is regulated within a society. Early work framed the regulatory influence of private institutions as an inherently illegitimate "capture" of the regulatory process.[51] However, institutionalist theories of law have emphasized the blurring of "boundaries between voluntary and mandatory regulations, state and non-state regulations, private and public law, and hard and soft law."[52] Especially in a transnational sphere characterized by an absence of centralized authority, these boundaries become more porous and less important for understanding regulation.

The metaphor of regulatory space, developed as an analytical tool by Hancher and Moran in the context of economic regulation, is useful for understanding the morass of transnational regulation.[53] A regulatory space is defined "by the range of regulatory issues subject to public decision" and is occupied by a wide range of competing regulatory actors.[54] The boundaries of a regulatory space are defined by the particular regulated subject matter at issue and within these different spaces the distribution of resources used by actors to compete with each other varies.[55] Importantly, these actors include not just formal legal actors, but also various sources of authority outside of formal legal structures.[56] Ultimately, the metaphor of regulatory space prompts us to reflect on a power struggle between various actors, both public and private, to "occupy" a space defined by the particular set of regulatory issues and the resources that fuel this struggle.

Key to this model is the idea that actors within a regulatory space possess unequal levels of power due to the uneven distribution of regulatory

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50 See *ibid* at 150.

51 *Ibid*.

52 Brouder, *supra* note 9 at 19, citing David Vogel, "Private Global Business Regulation" (2008) 11 Annual Rev Political Science 261 at 265.

53 *Supra* note 49.

54 *Ibid* at 153, citing C Crouch, "Sharing Public Space: States and Organised Interests in Western Europe" in J Hall, ed, *States in History* (Oxford: Basil Blackwell, 1986) 177 at 180.

55 See Hancher & Moran, *supra* note 49 at 154–55.

56 See *ibid* at 152.

resources. Scott has identified four key resources: (1) formal legal authority, (2) possession and control of information, (3) possession of wealth, and (4) organizational capacities.[57] Others have added to this list in the context of particular regulatory issues. Of note is work done by Gibbons on the regulation of biobanks, another biomedical regulatory dilemma. She identified (5) the ability to effectively and authoritatively communicate preferences and (6) control over professional education and culture as important resources in this context.[58] These six resources will inform the assessment of the regulatory capacities of formal legal actors later in this Part, as well as the characterization of the ISHGE as a regulatory actor in Part III.

Applying the regulatory space metaphor to emerging gene editing technology requires integrating an additional factor into the model: time. The case of CRISPR demonstrates how scientific innovations can blindside regulators with issues which were previously invisible or non-existent. This mirrors Hancher and Moran's discussion of crisis as a force which induces change in the structure of regulatory space.[59] At the leading edge of technological development, actors are not only competing over known regulatory territory; they must also undertake an occupation of the newly revealed space. Significant understanding of the regulatory space for emerging gene editing technology will be lost if we ignore temporal dynamics.

Here, regulatory space will be deployed as an analytical aid in defining the particularities of the regulatory issue of interest. It will also serve to better understand and contrast formal legal and scientific governance actors and their respective role in this space.

B. Particularizing the regulatory space

The regulatory space identified here encompasses the regulation of emerging gene editing technology in humans. This regulation is targeted primarily at scientists, as they possess the knowledge and capabilities to use

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57 Colin Scott, "Analysing Regulatory Space: Fragmented Resources and Institutional Design" [Summer 2001] Public L 283.

58 Susan MC Gibbons, "Mapping the Regulatory Space" in Jane Kaye et al, eds, *Governing Biobanks: Understanding the Interplay Between Law and Practice* (Portland: Hart Publishing, 2012) 51 at 83, 89.

59 *Supra* note 49 at 160.

and improve existing techniques, as well as to develop new techniques. It is also targeted at clinicians who may potentially practice human gene editing in a clinical setting. While CRISPR is the focus of this paper, the term gene editing technology encompasses superior techniques that will likely emerge in the coming years. It also reflects the international conversation on this issue, which has so far been dominated by the wider question of gene editing technologies.[60]

There are three major particularities about the regulation of gene editing technology. First, as a scientific practice, it is largely a deterritorialized issue. Science has long been a field where national boundaries mean little. As Jarvie points out, the authority of science is not bounded by national jurisdiction; scientists are by and large working towards the same purportedly universal truth no matter their country of origin.[61] Scientists routinely collaborate transnationally[62] and scientific practices and knowledge are disseminated through journals that circulate around the world. For the purposes of regulating science then, national boundaries are of reduced importance.

When looking specifically at gene editing technology, the risks and benefits involved cannot be limited to a specific national entity; rather, they will be diffused globally. Modifications made in one country would clearly spread around the world in an era where transnational movement is rapid and inexpensive, making patchworks of national legislation ineffective.[63] Uneven bans on reproductive technologies in the past have resulted in the phenomenon of "reproductive tourism," where individuals travel abroad to undergo therapies that are banned in their own country.[64] Furthermore, the

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60 See e.g. Olson, *supra* note 7.

61 Ian Jarvie, "Science in a Democratic Republic" (2001) 68:4 Philosophy Science 545 at 560, 563.

62 See Diane Stone, *Knowledge Actors and Transnational Governance: The Private-Public Policy Nexus in the Global Agora* (Basingstoke, UK: Palgrave Macmillan, 2013) at 43–45.

63 See Noëlle Lenoir, "Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level" (1998) 30 Colum HRLR 537 at 541.

64 Debora Spar, "Reproductive Tourism and the Regulatory Map" (2005) 352:6 N Engl J Med 531 at 533.

human genome is widely seen as the common heritage of humanity; everyone has a stake in its stewardship regardless of nationality.[65] Regulation in specific territorialized subsections of the regulatory space are therefore likely to be ineffective at protecting this shared heritage.

Second, this regulatory space is fraught with uncertainty and a paucity of information. Our understanding of genetics and genomics has evolved rapidly in the sixty years since DNA was identified as the molecule carrying genetic information between generations. While the discovery of CRISPR has opened up a new avenue for scientific advancement, it also brings a new shadow of uncertainty and risk.[66] Regulating complex risk requires that a great deal of information be gathered and examined through an expert lens.[67] For example, the regulation of the risks associated with climate change involved a global process to evaluate and scrutinize evidence through the International Panel on Climate Change (IPCC).[68] In such settings, control over information – one of Scott's four key resources – is of prime importance, since those who can claim to better understand the risk can make more authoritative pronouncements about the direction regulation should take.[69] Additionally, without sufficient information and expertise, it becomes impossible to tell whether scientists are actually complying with imposed regulations.

Third, the regulatory space for emerging gene editing technologies is inherently dynamic. As described above, game-changing scientific discoveries like CRISPR arise without warning and alter the regulatory landscape, forcing actors to react. Actors who possess speed and flexibility in adapting to changes in the regulatory space may therefore be best suited to regulating at the leading edge of technological development.

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65 See *Universal Declaration on the Human Genome and Human Rights*, UNESCO General Conference, 11 November 1997, art 1 (endorsed by GA Res 152, UNGAOR, 53rd Sess, UN Doc A/53/625/Add 2 (1998)) [*UDHGHR*].

66 See Olson, *supra* note 7 at 6.

67 See Jacqueline Peel, *Science and Risk Regulation in International Law* (New York: Cambridge University Press, 2010) at 3–4.

68 See *ibid* at 321.

69 *Supra* note 57 at 285.

C. The place of law

Having particularized the regulatory space, I now consider the actors who may populate it. It is particularly useful to consider what role formal legal actors will play in the regulation of emerging gene editing technologies before moving on to consider the role of the ISHGE as an informal governance actor. For our purposes, formal legal actors include the three branches of the state: the executive, legislators, and judiciary, as well as their formally delegated agents.

Actors who wield the formal legal authority of states hold several obvious advantages, both practical and normative, within regulatory space. In the practical sense, modern states are usually highly organized entities that are capable of enforcing rules by means of physical force within their defined territory. In the normative sense, the exercise of this force is legitimized by the concept of sovereignty and the historical dominance of states, which has entrenched them as the "presumed locus of all regulatory power and activity."[70] These unique qualities make it possible for legal actors to wield considerable regulatory influence, exemplified by the fact that they alone hold the first in Scott's list of key resources: formal legal authority.[71]

It is important not to fall into the trap of equating this influence with unlimited power to exclude other regulatory actors. Informal actors can still wield greater influence where formal legal actors are unable or unwilling to regulate over a particular issue due to the nature of the regulatory space.[72] For example, formal legal actors may lack awareness of the issue to be regulated or may not prioritize it. The law may not be sufficiently precise to completely cover the field, so regulation from informal actors may fill in the neglected space. Alternatively, the gaps in overly detailed regulation can be revealed when technologies change and outgrow the precisely targeted language. In other cases, covert non-compliance with formal legal rules by the targets of the regulation may allow informal actors to exclude states from regulatory space.[73] I argue that the nature of the regulatory space

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70 Gibbons, *supra* note 58 at 56.

71 *Supra* note 57 at 6.

72 See Gibbons, *supra* note 58 at 80, 83, 90.

73 See Martin Herberg, "Bringing Professions Back In: A Fresh Look at the Dynamics of Institution-Building in (World) Society" in Christian Joerges & Josef

under consideration here is one in which formal legal actors are particularly maladapted.

First, formal legal actors are generally ineffective at tackling transnational problems. Since legal authority flows from states with defined territorial boundaries, this authority is inherently tied to specific geographic space. The ability of states to exercise jurisdiction beyond their borders has been the topic of considerable discussion, but it seems clear that even the most powerful states cannot make legitimate claims to legislate activity that occurs on the sovereign territory of another, in all but the narrowest of circumstances involving human rights violations.[74] States could be considered to informally influence the practice of science outside their borders by attaching conditions to funding of extraterritorial research but, in reality, this form of control is only available to the wealthiest states, like the United States. Furthermore, the failure of states and state-based international organizations to comprehensively address transnational issues, whether they be economic or environmental, is well documented.[75] As discussed above, the challenges posed by gene editing technology are inherently transnational. A state's ability to regulate only within a defined territory therefore weakens its ability to cover the regulatory space.

Second, states possess inadequate information and expertise about emerging scientific issues. As explored above, control over information is a key regulatory resource, especially in the context of the high risk and uncertainty that accompanies gene editing. While states may generally have the wealth and capacity to gather information, legal decision makers rarely have the kind of technical expertise to foresee and address regulatory dilemmas, relying instead on independent bodies of experts.[76] Legal actors often rely on the opinions of experts in making their decisions but the process of translating scientific discourse for a policy audience is riddled with difficulties.

Falke, eds, *Karl Polanyi, Globalization and the Potential of Law in Transnational Markets* (Oxford: Hart Publishing, 2011) 107 at 115.

74 See e.g. *R v Hape*, 2007 SCC 26 at paras 66–69, [2007] 2 SCR 292; Anthony J Colangelo, "A Unified Approach to Extraterritoriality" (2011) 97:5 Va L Rev 1019 at 1025.

75 See e.g. Olaf Dilling, "Enclosed Solutions for Common Problems?: Uncertainty, Precaution and Collective Learning in Environmental Law" in Joerges & Falke, *supra* note 73, 131 at 152; Brouder, *supra* note 9 at 2.

76 See Peel, *supra* note 67 at 51.

While organizations like the IPCC demonstrate the ability of intergovernmental institutions to amass and interpret large quantities of information, the translation challenges make this a costly and time-consuming process.[77] States, with finite resources, must prioritize the issues of which they wish to be informed. Staying abreast of the kind of "blue sky" research from which CRISPR emerged is unlikely to be a priority.

Finally, formal legal institutions struggle to adapt quickly to changing regulatory landscapes. Lawmaking is a process which takes significant time. For public administrative bodies, rule making is prolonged by procedural requirements, bureaucratic elements, and political influence.[78] Legal pronouncements from courts only occur once the right case is litigated, which can take years. In both cases, political actors must be sufficiently informed in order to take decisive regulatory action but, as considered above, the necessary information gathering, interpretation, and translation processes require significant time. The result is significant incongruence between the law and the state of science. Incongruence can take the form of loopholes in permissive regulation that renders it ineffective against new technology or the unintentional application of overly prophylactic restrictions on emerging technologies.[79] In both cases, the law is maladapted to the technological landscape.

The notion that law lags behind technological and scientific development has been much discussed. Ogburn argued that the cultural institutions of law and science develop at uneven paces, such that the former will always lag behind the latter.[80] This has been attributed not only to the practical

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77 See Peel, *supra* note 67 at 335–36. The IPCC is an intergovernmental organization endorsed by the United Nations General Assembly to produce reports on climate change. The IPCC Panel is made up of government and organizational appointees, usually with expertise relevant to its mandate, who summarize peer-reviewed scientific literature carried out outside the IPCC.

78 See Cornelius M Kerwin & Scott R Furlong, "Time and Rulemaking: An Empirical Test of Theory" (1992) 2:2 J Public Administration Research & Theory 113 at 116.

79 See generally Peter J Rugg-Gunn et al, "The Challenge of Regulating Rapidly Changing Science: Stem Cell Legislation in Canada" (2009) 4:4 Cell Stem Cell 285 at 287–88; Gary E Marchant & Douglas J Sylvester, "Transnational Models for Regulation of Nanotechnology" (2006) 34:4 J Law Med Ethics 714 at 715.

80 See Sheila Jasanoff, "Making Order: Law and Science in Action" in Edward J Hackett et al, eds, *The Handbook of Science and Technology Studies*, 3rd

constraints mentioned above but also to the fact that law is culturally geared towards looking back to judicial precedents and enacted rules, while science is designed to overwrite its previous conclusions when challenged by new information in a continuous cycle of innovation and discovery.[81]

Though the notion that law generally lags behind scientific developments is widely accepted in legal literature, emerging work challenges the simplicity of this proposition. Sheila Jasanoff points out that, through the concept of co-production, law does not simply react to scientific developments in a linear pathway, but rather the two institutions work together to structure our understanding of the social and natural worlds.[82] In addition, the concept of technological "deviancy" suggests that the newness of a technology results not from science but from the legal practice of targeting technologies which violate existing law as the subject of new regulation.[83] Under this conception, "new" technologies do not exist outside of current law, but rather are defined by it from the beginning.[84] It is therefore important not to oversimplify the phenomenon of law lag.

Additionally, states may adopt regulatory strategies that do not necessarily need to be adapted to each new technological innovation. For example, instead of focusing on regulations that target specific practices and technologies that represent the state of the art at the time of drafting, states can craft risk-based legal regimes that are adaptive and forward-looking. While it is impossible to predict the future, an approach that takes the focus off specific technologies may leave less of a legal vacuum as science progresses.

That said, and as explored in more depth below, CRISPR and gene editing are clear examples of areas where existing legal regulation has yet to adapt to the features of the scientific landscape. Regulation, where it exists, was created to regulate technology as it stood decades ago and formal

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ed (Cambridge: Massachusetts Institute of Technology Press, 2008) 761 at 768 [Jasanoff, "Making Order"], citing William F Ogburn, "Cultural Lag as Theory" (1957) 41 Sociol Social Res 167 at 167.

81 See Jasanoff, "Making Order", *supra* note 80 at 768.

82 *Ibid* at 772, 775.

83 See Francis Lord, "The Legal Interpretation of Technology" (2016) [unpublished] at 30.

84 See *ibid* at 34.

legal actors have yet to react to the emerging issues around gene editing.[85] Through the lens of technological deviancy, we might say that while formal legal actors have largely ignored the discovery of CRISPR – in other words, have not identified it as deviant – the ISHGE network, by starting a conversation around gene editing technology, is performing the legal practice of identifying novel technology requiring updated regulation. Therefore, even if it is true that identifying the novelty of a technology is a legal exercise, here it has been carried out by the scientific community rather than formal legal actors.

With a technology that raises significant health risks like CRISPR, it seems inevitable that formal legal regulation will eventually be applied.[86] However, as explored above, there are several reasons to expect that formal legal actors will be relatively weak within the regulatory space surrounding emerging gene editing technology. Confined within national borders, informationally disadvantaged, and facing delays in responding to emerging technology, formal legal actors may struggle to shape the practice of emerging gene editing technology through regulation. Without the ability to quickly, precisely, and comprehensively fill the newly opened space, gaps will inevitably emerge, allowing for informal regulation to exert disproportionate influence.

D. The state of the law

Examining the current state of legal regulation of gene editing technology illustrates the theoretical weaknesses laid out above. A recent survey of gene editing regulations carried out by the Centre of Genomics and Policy at McGill University describes a patchwork of national regulations which vary in form from outright bans, to permissive guidelines, to nothing at all.[87] Even where gene editing is covered by broad bans on genetic and reproductive technology, such as those adopted in Germany and Canada,

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85 See R Isasi, E Kleiderman & BM Knoppers, "Editing Policy to Fit the Genome?: Framing Genome Editing Policy Requires Setting Thresholds of Acceptability" (2016) 351:6271 Science 337.

86 See Nicholas Wade, "Scientists Seek Moratorium on Edits to Human Genome That Could Be Inherited", *New York Times* (3 December 2015), online: <https://www.nytimes.com/2015/12/04/science/crispr-cas9-human-genome-editing-moratorium.html>.

87 Isasi, Kleiderman & Knoppers, *supra* note 85.

there is little practical effect because the vagueness of the language and the references to obsolete technologies leave gaping loopholes.[88] This ambiguity is aggravated by enduring confusion about the meaning of basic terms critical to human gene editing, such as "human embryo" or "reproductive cells."[89] In addition, the enforcement of state regulations with criminal sanctions, where they exist, is made difficult by an unclear requirement of intentionality.[90] Meanwhile, in countries like China, Japan, and India, governments only have non-binding guidelines which forbid certain practices in this area.[91] Indeed, it was China where the genomes of human embryos were first modified, despite non-binding guidelines discouraging the practice.

It is important to note that this regulation, where it exists, results from historical waves of political concern over older technologies: stem cell research and human cloning.[92] The fact that the current regulatory landscape reflects these older technologies exemplifies the lag effect described earlier in Sub-Part C, especially considering these waves of legal regulation followed several years after the development of the targeted technology. Consequently, formal legal regulation of emerging gene editing technology is incongruent with the challenges being faced today. The combined effect of this incongruence, the inherent ambiguity and unenforceability of these regulations, and the diversity of national approaches to what is an inherently transnational issue results in its diminished importance to the practices and behaviour of scientists.

III. The International Summit on Human Gene Editing as a Regulatory Actor

Part III builds on the regulatory space framework developed in Part II by characterizing the ISHGE as an actor within this space. Drawing on literature that examines the social, legal, and political power of scientific

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88 See *ibid* at 337.

89 *Ibid* at 339.

90 See *ibid* at 337.

91 See Motoko Araki & Tetsuya Ishii, "International Regulatory Landscape and Integration of Corrective Genome Editing into In Vitro Fertilization" (2014) 12:108 Reprod Biol Endocrinol 1 at 8.

92 See Ledford, *supra* note 4 at 310.

bodies, as well as the sociology of professions, I will evaluate which regulatory resources the ISHGE has at its disposal. I will then examine how well adapted the ISHGE is to the specific regulatory challenge of emerging gene editing technology. I argue that the ISHGE is particularly well adapted to this deterritorialized, highly technical, and dynamic regulatory environment and consequently has the potential to wield significant power over the practice of gene editing.

It is important to clarify the composition of the actor itself. The name of the ISHGE is used here for simplicity, although the Summit was an event rather than an institution. The true actor here is the network, composed of the scientific academies that organized the Summit and mediate the ongoing deliberations. As mentioned in Part I, the policy documents generated by this network are authored by committees appointed by the constituent academies. The Organizing Committee wrote the policy conclusions at the close of the Summit[93] and a separate Expert Committee subsequently prepared more detailed guidelines.[94] Though these are two different groups, I will consider all policy activity undertaken within the collaboration framework set up by the academies to be attributable to a single actor, the ISHGE. Having clarified the composition of this actor, I will move on to consider the regulatory resources at its disposal.

A. Expertise and control of information

The ISHGE can claim a substantial amount of one regulatory resource: expertise and information relevant to the understanding of gene editing technologies. The academies count among their membership scientists who have expertise across a range of fields relevant to gene editing. This is the natural result of considering scientific expertise as a prerequisite to academy membership.[95] Moreover, the ISHGE committee members were chosen for their specific expertise relevant to gene editing technologies, which extends

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93 Olson, *supra* note 7 at 6–7.

94 *Supra* note 41.

95 See The National Academy of Sciences, "Membership Overview", online: <www.nasonline.org/membership> [National Academy, "Membership"]; The Royal Society, "Elections", online: <https://royalsociety.org/fellows/elections> [Royal Society, "Elections"]; Academic Division of the Chinese Academy of Sciences, "Brief Introduction", online: <english.casad.cas.cn/au/bi>.

beyond scientists to include legal and bioethics experts.[96] In short, the ISHGE was able to quickly gather a large amount of information on this subject and evaluate it through an expert lens. Through their ongoing discussions and report preparations, the ISHGE continues to amass information and study this issue in unprecedented depth.

The regulation of science by scientific organizations like the ISHGE is essentially an exercise in self-regulation. Self-regulation can offer significant benefits in technical fields like gene editing due to the inherent expertise of the regulator and the ease of access to information on the subject of regulation. Herberg highlights that professions may operate in "[s]ituations of complexity, uncertainty, instability and uniqueness," and that, as a result, the members of these professions are well placed to reflect upon and solve the particular problems in their domain.[97] Gene editing is arguably exemplary of this kind of situation. Self-regulation generally means that the cost of standard formulation and interpretation is low compared to external regulatory schemes, as resources need not be spent gathering expertise and information that is already internal to the regulator. Further, when the regulator and the regulated share a common expertise, the standards can be more precisely formulated and more accurately interpreted by relying on common understanding and vocabulary.[98] For these reasons, expertise native to the profession – in this case, science – is often essential to its regulation, which is why Herberg suggests that professional regulation cannot simply be left to bureaucratic or market forces, but rather requires some degree of self-regulation.[99]

Inherent expertise and access to information also allows the ISHGE to benefit from reduced costs of measuring compliance and enforcing standards. The monitoring and enforcement of guidelines is less costly where there is significant understanding of the subject of the guidelines, since information is readily available and comprehensible to the regulator.[100] In this context, that means not just being aware of the various projects on gene edit-

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96 See National Academies, "Statement", *supra* note 39.

97 *Supra* note 73 at 119–20.

98 See Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Portland: Hart Publishing, 2005) at 30–31, citing Anthony Ogus, "Rethinking Self-Regulation" (1995) 15 Oxford J Leg Stud 97 at 97–98.

99 *Supra* note 73 at 121.

100 See Schepel, *supra* note 98 at 30, citing Ogus, *supra* note 98 at 97–98.

ing being conducted around the world, but also possessing the scientific literacy to identify when projects deviate from the expected standards. While covert non-compliance can be employed by professions to resist external regulation, non-compliance is more likely to be identified from within the scientific community itself.[101] As a result, the ISHGE as a scientific organization can be expected not only to draw on scientific expertise to create more precise and functional regulation, but also to more effectively monitor compliance with this regulation.

It is also important to consider the ability of the ISHGE and its constituent academies to control the flow of information. It is not insignificant that the Royal Society and the National Academy of Sciences publish some of the world's most prestigious scientific journals, nor that the ISHGE is currently leading the international effort to amass and analyze data on the topic of gene editing.[102] Controlling the dissemination of information is a key source of power for networks of knowledge actors like the ISHGE in that it allows the regulatory challenge to be presented in a way that can structure future discourse on the topic. Not only does the ISHGE have expertise in gene editing, it also plays an ongoing and important role in characterizing the technology and its associated challenges to legal audiences.

In summary, the ISHGE, as a scientific organization regulating scientific practice, benefits from inherent expertise and access to information – two regulatory resources that are of particular importance in this regulatory space. Guidance flowing from the unprecedented concentration of multidisciplinary expertise at the ISHGE will carry more weight, not only because of its perceived quality and accuracy, but also because of the ease with which this expert body can identify work that diverges from its guidelines. In addition, the ISHGE holds influence over information flow that is used by others to conceptualize the techniques and associated challenges of gene editing.

B. Authoritative communication and prestige

A second major source of regulatory power for the ISHGE is its ability to draw on elite status and reputation to communicate its policy preferences.

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101 See Herberg, *supra* note 73 at 115, 121.

102 The Royal Society publishes *Proceedings of the Royal Society A & B*, as well as *Philosophical Transactions of the Royal Society A*, while the National Academy of Sciences publishes *Proceedings of the National Academy of Sciences*.

As mentioned in Part II, Gibbons highlights the importance of status and reputation as a key regulatory resource in biomedical spaces where scientists are accustomed to making value judgements based on authoritativeness.[103] Scientists may be particularly receptive to appeals to prestige since success in science, via high-impact publications and awards, is dependent on acceptance by the established members of the broader scientific community. Therefore, the ability to communicate authoritatively is a significant regulatory resource within the gene editing regulatory space.

Though the ISHGE is a new partnership without a prestigious narrative of its own, it can draw prestige both from its constituent organizations and the composition of its committees. The constituent academies of the ISHGE are self-selecting organizations where membership is based on scientific excellence. Scientific organizations emphasize this excellence and their historical contributions to their field in order to build their authoritative voice on scientific issues.[104] Indeed, the Royal Society and the US National Academies are quick to emphasize their illustrious histories and their roles in shaping the scientific enterprise as it exists today. The Royal Society can claim to have started the phenomenon of scientific publishing and to have published works as important as Newton's laws of physics and Benjamin Franklin's famous kite experiment.[105] The National Academy of Sciences also uses history to emphasize its prestige, emphasizing the fact that President Lincoln signed the congressional charter that created the organization.[106] The Chinese Academy, as a state agency in a communist society, can make a strong claim to represent the scientific community in the People's Republic, even though its history may not be as long or illustrious as its counterparts. Combining their mandates over three of the largest and most prestigious scientific communities worldwide, these three bodies can credibly claim to represent the global scientific elite.

In addition, the individual members of the ISHGE's committees represent preeminent members of the scientific community. The Chair of the Organizing Committee, David Baltimore, is not only the President Emeritus of the California Institute of Technology, but is a Nobel laureate, along with

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103 *Supra* note 58 at 83, 89.

104 See *ibid* at 83; Stone, *supra* note 62 at 47.

105 See Royal Society, "History", *supra* note 37.

106 National Academies, "Who We Are", *supra* note 36.

fellow committee member Paul Berg.[107] Jennifer Doudna, one of the discoverers of the CRISPR technique and a likely pick for a future Nobel Prize,[108] has a seat, as do other highly accomplished scientists and bioethicists. On both institutional and individual levels, the ISHGE's normative pronouncements are delivered by voices which project significant prestige within the scientific community and may accordingly have a stronger impact on the behaviour of scientists.

C. Control over scientific culture

In addition to expertise and prestige, the ISHGE can draw on the role its constituent academies play in controlling scientific culture to affect regulatory outcomes. As professional organizations, the academies that make up the ISHGE are positioned as the guardians of independence from both the state and the market.[109] These organizations work continuously to define the professional community and defend it by fostering a shared identity among members of that profession. This is reflected in the academies' mandates to protect and promote scientific culture and values. Transnational scientific organizations like the ISHGE take this to another level. By bringing together scientists from around the world and engaging them in a conversation that involves not only data but values, the ISHGE process could be seen as part of a larger effort by national academies to foster a transnational scientific culture.

As a network of these guardians of scientific professionalism, the ISHGE may exercise significant control over scientific practice. Empirical research done on scientific organizations in the biobanking context demonstrates that the inculcation of professional culture has significant impacts on the attitudes and day-to-day practices of scientists.[110] Though, admittedly, the cultural impact of the ISHGE is unlikely to be as strong as a national academy, the ISHGE taps into the larger, growing phenomenon of international

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107 See National Academies, "Statement", *supra* note 39; LaBarbera, *supra* note 7 at 1123.

108 See Julie Steenhuysen, "Nobel Prize Predictions See Honors for Gene Editing Technology", *Reuters* (24 September 2015), online: <https://www.reuters.com/article/us-nobel-predictions-thomsonreuters-idUSKCN0RO0BB20150924>.

109 See Herberg, *supra* note 73 at 120.

110 See Gibbons, *supra* note 58 at 83.

scientific culture. It has created a space to embody and communicate the norms of this culture in the specific context of gene editing in order to affect scientific practice.

D. Transnational reach

Though not a resource per se, the transnational reach of the ISHGE has important implications for its effectiveness as a regulatory actor in this space. As discussed in Part II, the governance of gene editing technology, as with other scientific practices, requires a transnational approach in order to overcome coordination problems and to protect the genome as the common heritage of humanity.

Transnational networks of national academies like the ISHGE have the potential to play a critical role in the transnational organization of science. International networks of scientists create venues where national identity matters little, leading to the erosion of national identity in favour a transnational professional identity.[111] Face-to-face meetings like the Summit that began the policy process under consideration here may be particularly important for this development. The ISHGE not only taps into the existing transnational identity of science, but it has also helped to foster it in the context of gene editing by bringing together scientists from around the world. We can therefore expect its policy guidance to be effective across borders.

The transnational nature of the ISHGE can also be gleaned by looking at its constituent academies. As some of the oldest and best funded national academies worldwide, the Royal Society and the US National Academies already have significant global impacts in terms of the publication of scientific research and science policy initiatives on their own. The inclusion of China is an important signal of the truly transnational nature of the ISHGE, broadening its reach beyond the Global North. In addition, the inclusion of representatives from other countries on the committees exemplifies the ISHGE's attempt to speak for the scientific community beyond the national constituencies of its host academies. The importance of transnational inclusiveness in the ISHGE process was highlighted in the Organizing Committee's conclusions to the Summit,[112] echoing the *Universal Declaration on*

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[111] See Stone, *supra* note 62 at 49.

[112] Olson, *supra* note 7 at 7.

the Human Genome and Human Rights in its commitment to the idea of the human genome as the common heritage of all.[113] The ISHGE purports to speak with a truly transnational voice and is likely to be heard not just in the home countries of its constituent academies, but worldwide.

E. Dynamism

It is also worth briefly assessing the ability of the ISHGE to react dynamically to changes in the regulatory landscape. As noted previously, in regulatory space characterized by emerging technologies, the ability to respond and adapt to scientific developments is of significant importance. The constituent academies of the ISHGE have the organizational capacity to quickly develop flexible networks that are focused on a particular regulatory issue. The decision to engage in an ongoing monitoring and expert study process shows how the academies continue to adapt the ISHGE process to the policy needs of the gene editing issue. In addition, the kind of guiding principles penned by the Organizing Committee do not require the same formalism as the adoption of formal legal instruments. This precise monitoring of developments in gene editing, paired with the relatively informal adoption procedures for its guidelines, provides the ISHGE and related networks with the ability to adapt to dynamic policy issues like gene editing.

To conclude, the ISHGE has several key resources at its disposal within the regulatory space for emerging gene editing technologies. It has the advantage of unparalleled expertise and control over information, significant prestige, and the ability to embody global scientific culture (at least within this narrow regulatory space). Recalling the particularities of the regulation of emerging gene editing technology, the ISHGE appears particularly well adapted to this environment. Specifically, it has the transnational reach required to address the problem and the ability to authoritatively pronounce on its technical aspects. Since its members were already well versed in the underlying mechanics of gene editing, and because of its informal nature, the ISHGE process has been dynamic, on track to produce detailed guidelines less than two years after the first human embryo experiments brought attention to the issue. Consequently, the ISHGE is positioned as a key actor in the regulation of emerging gene technology.

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[113] *Supra* note 65, art 1.

F. Mechanisms of action

It is worth briefly examining the mechanisms and pathways through which the ISHGE can leverage its resources to affect regulatory outcomes. These mechanisms can be classified into two broad categories. First, the ISHGE can mobilize these resources to influence scientific practice directly at the level of individual scientists, research institutions, and review boards. Second, the same resources could indirectly affect regulatory outcomes by influencing the development of formal legal regulation. I argue that both pathways are important to understanding the ISHGE's regulatory role.

Direct mechanisms of action have been alluded to earlier in Part III. The most visible pathway towards regulating scientific practice involves issuing best practices and other explicit policy guidance. The ISHGE did this at the close of the Summit[114] and with its release of the report by the Expert Committee.[115] These guidance documents explicitly provide scientists with indications about what is and is not acceptable to the ISHGE committees and, by extrapolation, to the international scientific community.

Less visible are the impacts the ISHGE process has had on scientific culture around CRISPR technology. The inculcation of a professional culture around normative frameworks is a key regulatory resource, especially in the biomedical context.[116] Beyond mere norm generation, regulatory actors regulate behaviour by exerting control over, and integrating regulated persons into, cultures. Beyond the consensus text, the Summit brought together many thinkers who engaged in a broad and complex conversation about CRISPR's acceptable uses and dangers. This is likely to affect the practice of science by having exposed scientists to alternative narratives and concerns and taking the first steps towards consensus building among the scientific community. Therefore, while the cultural impacts on the practice of science are more difficult to track and measure, it is important to recognize that the direct impacts of the Summit go beyond its consensus text.

As mentioned in Part II, it is widely expected that states will eventually adapt formal regulation to reflect new gene editing techniques – a development that is in fact encouraged by the Organizing Committee's consensus

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114 Olson, *supra* note 7 at 6–7.

115 *Supra* note 41.

116 See Gibbons, *supra* note 58 at 83.

document.[117] However, the increased regulation via formal legal processes in the regulatory space will not necessarily render the normative action of the ISHGE moot. Not only would the ISHGE process in this scenario generate interim policy guidance, but it could also influence the ultimate form of formal regulation. Indeed, the World Medical Association's *Declaration of Helsinki* provides a striking example of the extent to which states are willing to incorporate non-binding expert declarations in their legislation.[118]

This pathway can be conceptualized through a framework from political science known as "discourse coalitions."[119] Under this approach, actors organize themselves into coalitions to achieve certain policy goals by first shaping the public understanding and discourse around the issue and later influencing government responses.[120] This control of the public discourse constrains perceptions of other actors in a phenomenon known as "discourse structuration."[121] As the discourse becomes more deeply entrenched, it moves towards being accepted as truth by regulatory institutions in a process called "discourse institutionalization," though this is not inevitable and involves contestation between alternate discourses.[122] Institutionalized discourses shape public decision making until they are replaced or overwritten by new conceptualizations, continuing the cycle.

As an early and authoritative voice in the conversation on the regulation of gene editing technology, the ISHGE has the opportunity to structure how this problem is perceived. This position gives the ISHGE the potential to affect the form and content of future regulation at national and international levels. Indeed, the separation highlighted in the consensus statement

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117 Olson, *supra* note 7 at 6–7.

118 See Delon Human & Sev S Fluss, "The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspectives" (2001) [unpublished] at 2, online: Semantics Scholar <https://pdfs.semanticscholar.org/acde/7253a068d3eb2c738f3a90fc0d4eec1db243.pdf>.

119 Stone, *supra* note 62 at 50, citing Maarten A Hajer, "Discourse Coalitions and the Institutionalization of Practice: The Case of Acid Rain in Great Britain" in Frank Ficher & John Forester, eds, *The Argumentative Turn in Policy Analysis and Planning* (London: Duke University Press, 1993) 43 at 45.

120 See *ibid* at 47–48.

121 Stone, *supra* note 62 at 50.

122 *Ibid*.

between basic research and clinical approaches[123] represents a new conceptualization of the problem. Much of the discussion in the lead-up to the Summit concerned the appropriateness of germ line modification compared to somatic cell modification.[124] Under the Summit conclusions, however, both somatic and germ line modification are deemed acceptable in the basic research context; only the clinical applications of germ line modification are discouraged.[125] Under this framework, the study on human embryos that provoked backlash would actually be acceptable, since it would be classified as basic research, despite the fact that the germ line is being modified. Something as simple as the structure of the meeting's conclusions may insulate basic science from over-zealous restriction and could cement this outcome if the structure is replicated in formal legal regulation.

G. Lessons from the United Nations Declaration on Human Cloning

The *United Nations Declaration on Human Cloning* provides an interesting historical example of the influence of normative declarations from transnational scientific actors on formal legal outcomes.[126] When France and Germany went to the United Nations General Assembly looking for a simple declaration banning the practice of reproductive human cloning, the initiative was relatively uncontroversial.[127] However, the conversation was unexpectedly steered by a coalition including the United States and the Holy See towards a wider ban of all human cloning, including stem cell research.[128] The scientific community was caught off guard and scrambled to counter-mobilize. Another network of scientific academies, the InterAcademy Panel on International Issues (IAPII), called for a ban on reproductive cloning while opposing a wider ban.[129] While the declarations of the IAPII held significant weight in watering down the wording such that

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123 See Olson, *supra* note 7 at 6–7.

124 See e.g. Lanphier et al, *supra* note 3; Wade, *supra* note 86.

125 Olson, *supra* note 7 at 6–7.

126 GA Res 280, UNGAOR, 59th Sess, UN Doc A/59/280 (2005).

127 See Mahnoush H Arsanjani, "Negotiating the UN Declaration on Human Cloning" (2006) 100:1 Am J Intl L 164 at 166.

128 See *ibid* at 172.

129 See *ibid* at 174.

nothing was effectively banned, the resulting non-binding document was not at all clear[130] and accomplished very little for the regulation of stem cell research.[131]

This example not only shows that networks of scientific academies can shape formal legal instruments at the international level, it also demonstrates room for improvement. This process taught the scientific community that taking a passive approach to the regulation of emerging technology could have negative consequences for science and for effective public policy. By the time scientific organizations got involved in the human cloning debate, the conversation had been framed in moral and religious terms, rather than in ways that were more favourable to the scientific agenda.[132] With gene editing, by contrast, the ISHGE was quick to start the policy conversation in a form and arena that was better adapted to its policy priorities. As a result, we can expect that future formal legal regulation will conform more closely with the preferences of scientists.

The ISHGE is an important actor within the regulatory space of emerging gene editing technology. Drawing on scientific expertise and information about the emerging technology, the prestige of its constituent institutions and committee members, its role in shaping scientific culture, and possessing both a transnational reach and a dynamic, flexible structure, the ISHGE is well placed to affect regulatory outcomes in this area. Outcomes can be effected both through direct impacts on the scientific community, such as explicit guidelines and implicit cultural development, as well as indirectly by shaping the policy discourse in the lead-up to eventual formal regulation. The extent to which the ISHGE utilizes this power and the actual impact this will have on the scientific practice of gene editing remain to be seen.

IV. Assessing the Legitimacy of Transnational Scientific Governance

Having characterized the ISHGE's role in the regulatory landscape of gene editing technology and the ways in which it impacts regulatory outcomes, I now turn to examine the legitimacy of the exercise of this power.

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130 See *ibid* at 177.

131 See Channah Jarell, "No Worldwide Consensus: The United Nations Declaration on Human Cloning", Note, (2006) 35:1 Ga J Intl & Comp L 205 at 208.

132 See Arsanjani, *supra* note 127 at 174, 173.

Assessing the legitimacy of non-state actors is critical to understanding transnational governance.[133] As generally democratic states are increasingly forced to share the regulatory space with a multitude of non-state actors, observers have expressed concerns about technocracy and a loss of democratic accountability more generally.[134] Yet our conceptual tools for evaluating legitimacy were developed in the context of states and may not be suitable to the evaluation of non-state actors.[135] In this Part, I consider what it means to be a legitimate actor in transnational regulatory space, before evaluating the major challenges to the ISHGE's legitimacy by virtue of its status as a private, scientific body. I argue that despite inherent challenges, scientific governance bodies like the ISHGE retain the potential to claim legitimate authority over the regulation of emerging gene editing technology.

A. Legitimate authority outside the state

The concept of legitimacy has been the focus of numerous works across a variety of legal and non-legal disciplines. Central to many of these definitions is the notion that legitimacy is the property that turns the exercise of mere power into the exercise of authority.[136] While power can motivate individuals to accept laws or rules because of coercion or cost-benefit calculations, legitimate authority motivates individuals to accept those rules simply because they see the espoused norm as binding.[137] Legitimacy is often used as a prescriptive concept to evaluate the appropriateness of the use of power, but Weber argued that it can also be employed as a descriptive concept to explain the social fact that subjects accept a given governance

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133 See Brouder, *supra* note 9 at 6.

134 See e.g. Ngaire Woods, "The Challenge of Good Governance for the IMF and the World Bank Themselves" (2000) 28:5 World Development 823; Robert O Keohane, "Global Governance and Democratic Accountability" in David Held & Mathias Koenig-Archibugi, eds, *Taming Globalization: Frontiers of Governance* (Cambridge: Polity Press, 2003) at 125.

135 See Jens Steffeck, "The Legitimation of International Governance: A Discourse Approach" (2003) 9:2 European J Intl Relations 249 at 251.

136 See Brouder, *supra* note 9 at 28; A Claire Cutler, Virginia Haufler & Tony Porter, eds, *Private Authority and International Affairs* (Albany: State University of New York Press, 1999) at 5.

137 See Steffeck, *supra* note 135 at 254–55.

scheme.[138] Here, I examine various sources of legitimacy to assess why and in what contexts the public would accept regulation by private scientific bodies as binding.

Discussion of legitimacy is particularly important when examining informal governance actors like the ISHGE network. In contrast to states, most informal actors cannot mobilize the coercive force necessary to motivate individuals to follow their rules and guidelines through domination.[139] Instead, informal actors are expected to rely more on the persuasiveness of their norms in affecting individual behaviour, something that is likely affected by their perceived legitimacy. Therefore, while the legitimacy of a state is a normative element of its governance, the legitimacy of many informal actors like the ISHGE is a necessary precondition to playing an active role within the regulatory space.

The concept of legitimacy has received renewed attention in the 21st century in the context of globalization and the rising influence of non-state actors.[140] Yet, as Steffeck indicates, merely applying notions of state legitimacy to the non-state level is problematic.[141] For Steffeck, the emerging literature on legitimacy has focused too much on democratic participation and ignores other sources of legitimacy which exist in the absence of democratic institutions.[142] While an in-depth literature review on this topic is outside the scope of this paper, I will briefly outline three proposed sources of legitimacy before specifically examining the legitimacy of the ISHGE.

First, democratic participation theories of legitimacy are based around the idea that involving the governed in the acts of governance will make those acts more acceptable to them.[143] This version of legitimacy is based

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138 See *ibid* at 253, citing Max Weber, *Economy and Society* (Berkeley: University of California Press, 1978) at 31.

139 See Steffeck, *supra* note 135 at 259.

140 See Peel, *supra* note 67 at 13.

141 *Supra* note 135 at 251.

142 *Ibid* at 256–57.

143 See e.g. Christopher Lord & David Beetham, "Legitimizing the EU: Is There a 'Post-Parliamentary Basis' for Its Legitimation?" (2001) 39:3 J Common Market Studies 443; John S Dryzek, *Deliberative Global Politics: Discourse and Democracy in a Divided World* (Cambridge: Polity Press, 2006) at 62 [Dryzek, *Deliberative Global Politics*].

in the Lockean concept of the consent of the governed.[144] According to this theory, legitimate governance flows from institutions which were set up by a social contract between individuals and therefore involves the governed in the decision-making process.

This theory forms the basis for the declaration of a "democracy deficit" in transnational governance. The perceived growth in the impact of non-state actors is seen by some as a shift in power from generally democratic states to entities that are not directly accountable to the public.[145] This has spurred calls for the opening up of governance bodies to a more diverse group of civil society actors, with the aim of creating an environment of deliberative democracy.[146] Greater input from outside actors is seen by some authors as an important way to restore the legitimacy of transnational institutions.[147] However, Steffeck points out that considering only the democratic aspects of legitimacy at the international level fails to explain the existence of non-democratic international institutions, like the United Nations, whose rule making is nonetheless considered legitimate.[148]

Another source of legitimacy is the result achieved by a governance structure, rather than the processes that went into making those rules as considered above. This distinction was drawn by Scharpf using the concepts of input and output legitimacy.[149] Whereas input legitimacy is concerned with public participation as discussed above, output legitimacy asks whether the policy outcomes for the public are favourable. In the specific case of regulation, Majone has argued that the public's perception of the quality of regulation, along with transparency and accountability mechanisms, fosters legitimacy in these settings.[150] Specifically, rather than require that

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144 See Steffeck, *supra* note 135 at 256.

145 See Peel, *supra* note 67 at 42.

146 See e.g. Jan Aart Scholte, "Civil Society and Democracy in Global Governance" (2002) 8:3 Global Governance 281.

147 See e.g. *ibid* at 281; Peel, *supra* note 67 at 357–58.

148 *Supra* note 135 at 257.

149 Fritz W Scharpf, *Governing in Europe* (Oxford: Oxford University Press, 1999) at 2.

150 Giandomenico Majone, "The Regulatory State and Its Legitimacy Problems" (1999) 22:1 Western European Politics 1 at 22–23.

regulatory bodies become politicized and deliberative to gain legitimacy, Majone's argument is that legitimacy can be earned when it is apparent to the public that those bodies are the most appropriate venues for the regulatory task at issue.[151]

Conceptions of output legitimacy, while useful in expanding the concept of legitimacy beyond the democratic institutions of the state, are not without criticism. For instance, measuring the impacts of rules and understanding how this contributes to their legitimacy remains unclear in practice.[152] Whereas democratic participation is fairly easy to define, at least quantitatively, the quality of output is value-based and difficult to measure empirically. Different measures of desirable output may rise as others fall, making it difficult to gain a holistic assessment of a given actor's legitimacy. Further, reducing the quality of regulation to a simple cost-benefit calculation does not appear to capture true legitimacy, recalling that legitimate authority is contrasted with incentive structures as an alternate motivation for rule acceptance.[153]

Finally, a third approach proposed by Steffeck sees legitimacy outside the nation-state as the product of communicated rationality, or discourse. According to this argument, legitimacy at the international level has its basis in public agreement on the normative reasoning that will underlie governance.[154] Legitimacy can therefore only be won if this reasoning enters the public discourse, where the rationality can be scrutinized and challenged. In this public forum, a consensus can be built where the regulator and the public achieve normative congruency as to the reasons for the acceptability of a given rule.[155] In this framework, it is not the direct public contribution to the decision making that is important, nor even that the outcome be favourable, but rather that the rationale for the decision is normatively accepted.

Discourse theory shares many parallels to the idea of "throughput legitimacy." Rather than measuring public participation or outcome, this approach measures the "accountability, transparency and efficacy" of the

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151 *Ibid* at 22.

152 See Steffeck, *supra* note 135 at 257.

153 See *ibid*.

154 See *ibid* at 263–64.

155 See *ibid* at 264.

decision-making process itself.[156] These features contribute positively to the ability of an institution to communicate the rationale for decisions to the public. Therefore, both discourse theory and throughput legitimacy focus on the process of decision making, which is a source of legitimacy where it is shown to be rational and efficient.

Importantly, the notion of discourse goes further than mere transparency. Legitimacy in a discourse framework requires meaningful engagement between the rule-making party and the public in order to generate the required normative agreement. This agreement extends beyond the reasons behind the actual regulatory decisions to include agreement on the scope and guiding principles of the regulatory regime itself.[157] Legitimacy is therefore a function of a justificatory discourse which results in rational agreement on these points by the public.

According to this analysis, legitimacy may find its source from the inputs, outputs, and throughputs of governance, as well as how the throughput is communicated and received in public discourse. Ultimately, claiming legitimate transnational governance depends on the public perception of the normative acceptability of the governance structure and its conclusions as a result of the combination of these factors. I will now consider how this applies to the ISHGE's legitimacy as a regulator of gene editing technology.

B. Challenges to the legitimacy of private actors

The ISHGE faces an inherent challenge to its legitimacy as a private body. Unlike democratic public institutions, private institutions cannot claim a mandate from the public. The ISHGE was convened by private scientific bodies rather than elected governments and the committee members chosen to investigate more detailed guidelines were experts, not elected officials.[158] Under an approach solely focused on input legitimacy, the ISHGE's governance would be irreparably illegitimate and a sign of the "legitimacy deficit."

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156 Vivien A Schmidt, "Democracy and Legitimacy in the European Union" in Erik Jones, Anand Menon & Stephen Weatherill, eds, *The Oxford Handbook of the European Union* (Oxford: Oxford University Press, 2012) 661 at 661.

157 See Steffeck, *supra* note 135 at 267.

158 See Olson, *supra* note 7 at 1; LaBarbera, *supra* note 7.

However, in the absence of a world government, it is overly simplistic to suggest that private actors are illegitimate while states and state-based institutions are legitimate. At the transnational level, states also have a "private" character in the sense that they do not represent the international public but rather a specific national interest.[159] Moreover, the public knows relatively less about their state's policies at the international level than at the domestic level[160] and these issues are rarely determinative in elections.[161] The public can be said to participate less in setting policy priorities for states within transnational regulatory spaces.

Additionally, it can be argued that the ISHGE and its constituent bodies are not purely private actors. As its constituent organizations are largely funded by public money,[162] it may be more accountable to the elected political bodies that make decisions regarding this funding and therefore take on a quasi-public character.

Nevertheless, it is impossible to ignore the impact that a lack of democratic accountability can have on an institution's legitimacy in the eyes of the public. Recent anti-European Union discourse provides a stark example of the lack of trust the public can harbour for transnational governance actors, compared to their nationally elected governments.[163] Regardless of outcome or process, lack of democratic accountability is a powerful image that can have a significant impact on public acceptance of governance processes and consequently their legitimacy.

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159 See Brouder, *supra* note 9 at 11.

160 See *ibid*.

161 See e.g. Lawrence R Jacobs & Benjamin I Page, "Who Influences US Foreign Policy?" (2005) 99:1 Am Poli Sci Rev 107 at 121.

162 See The Royal Society, "Trustee's Report and Financial Statements" (2015) at 81, online: <https://royalsociety.org/~/media/Royal_Society_Content/about-us/reporting/2013-11-20-Trustees-Report.pdf?la=en-GB>; National Academy of Sciences, "Report of the Treasurer of the National Academy of Sciences for the Year Ended December 31, 2015" (2016) at 51, online: <https://www.nap.edu/23558>; Chinese Academy of Sciences, "2013 Annual Report" (2013) at 72, online: <english.cas.cn/about_us/reports>.

163 See e.g. Klaus Armingeon & Besir Ceka, "The Loss of Trust in the European Union during the Great Recession since 2007: The Role of Heuristics from the National Political System" (2013) 15:1 European Union Politics 82.

C. Challenges to the legitimacy of scientific actors

The interaction of science and policy has attracted a great deal of attention as authors try to come to grips with the high uncertainty and regulatory challenges in the biomedical field and beyond.[164] While scientific information has been increasingly called upon to create policy in these areas, there is disagreement about how to mediate the boundary between law and science. Scientific institutions carry with them distinct normative values and processes that complicate their interaction with both political actors and the public.[165] Consequently, we would expect that the scientific nature of the ISHGE would affect its claim to legitimate authority.

First, the input legitimacy of scientific bodies is negatively affected by the fact that participation in meaningful scientific discourse is limited to scientists and does not extend to the general public. Like other professions, membership in scientific institutions is restricted to a self-selecting elite[166] and, in reality, participation in scientific debate and discourse is limited to those who have earned an advanced degree in their field. Members of the constituent academies of the ISHGE must be elected by those who are already members upon recognition of their scientific accomplishments.[167] This requirement of scientific expertise and self-selection impedes the ISHGE from claiming input legitimacy given the severe limitation this places on public participation.

Exclusivity of membership also impacts legitimacy from a discourse perspective. This exclusivity can have a negative impact on the communication and reception of rationales for governance decisions.[168] Whereas

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164 See Peel, *supra* note 67 at 10.

165 See Jaye Ellis, "Logics of Science, Politics, and Law in International Environmental Protection: The Role of Boundary Organisations" (2015) [unpublished] at 1, online: SSRN <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2661750>.

166 See Gibbons, *supra* note 58 at 83.

167 See Royal Society, "Elections", *supra* note 95; National Academy, "Membership", *supra* note 95; Academic Divisions of the Chinese Academies of Science, "Statutes for Membership of the Chinese Academy of Science", online: <english.casad.cas.cn/au/re>.

168 See Steffeck, *supra* note 135 at 265.

argumentation within fully inclusive institutions will be formulated, necessarily, in a way that is comprehensible to the entire polity, argumentation within exclusive institutions will be geared towards an exclusive audience and may therefore not resonate as strongly with the wider public. Steffeck points to exclusivity as the reason that rules created at the United Nations General Assembly are seen as more legitimate than those created by the G8.[169] By analogy, organizations whose membership is limited to the scientific community may communicate rationales which are not congruent with the normative frames of the wider public.

That analogy is not perfect, however, as unique features of science as a discipline seem to have a positive impact on discourse legitimacy. Science claims to espouse universal truths and speaks a language of rationality that, according to discourse theory, should earn it legitimacy. The replacement of divine claims to legitimacy with rationality in the modern era has secured the place of science within contemporary political discourse – a process that has been extensively characterized within Science and Technology Studies (STS).[170] The patina of objectivity carried by scientific organizations may, as with expertise in general, create the perception that regulatory outputs are "right" and therefore legitimate based on notions of output legitimacy. Similarly, the public may be more willing to accept outcomes that are justified by scientific rationale or espoused by scientific organizations as legitimate.

However, there exist significant limitations to the ability of science to leverage its claims to objectivity in the policy context. Scientific actors face an inherent danger of politicization at the boundary between science and policy.[171] The power of scientific actors is derived from their claims to produce credible, objective knowledge,[172] which is threatened where they are seen to make judgments based on values rather than observation and logic. This risk is greater in cases of scientific uncertainty, where revealing these professional disagreements to the public within the context of policy arguments erodes the notion that science espouses objective truth.

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169 *Ibid*.

170 See *ibid* at 262; Alan Irwin, "STS Perspectives on Scientific Governance" in Hackett et al, *supra* note 80, 583 at 583; Jasanoff, "Making Order", *supra* note 80 at 762.

171 See Ellis, *supra* note 165 at 1.

172 See *ibid* at 3.

Unfortunately, it is in these areas of uncertainty – for example, risk regulation – that science is increasingly called upon as a policy tool.[173] There has therefore been a call for the development of "boundary organizations" to mediate between the science and policy realms, in order to protect the integrity of the normative orders.[174]

Recasting this dilemma within a discourse theory framework, the legitimacy of scientific organizations is under threat where the communicated rationale of their regulatory decisions incorporates subjective values and beliefs rather than the objective facts expected by the public. In conditions of uncertainty, scientific organizations face the challenge of maintaining legitimacy without being able to appeal to purely objective truth. Even where phenomena are well understood, regulatory decisions ultimately involve a judgment about acceptable levels of risk, which is subjective.[175] When this subjectivity is revealed in public discourse it opens up science to claims of corruption and illegitimacy.

In addition, an important challenge to the legitimacy of scientific organizations in the regulation of science is the appearance of a vested interest in a deregulated research landscape. Scientists may be perceived to have two sets of interrelated interests in deregulation: (1) material interests flowing from research on or the commercialization of new technologies and (2) a general interest in the advancement of scientific knowledge. While material interests will generally only be held by individual scientists with proprietary interests in the new technology or its spinoffs, the legitimacy of scientific organizations is compromised to the extent that they rely heavily on input from these experts, at tension with their institutional role in espousing expert opinions. Furthermore, even scientists without a material interest in a particular technology may be ideologically predisposed to deregulation given that their goals as scientists is to advance the state of knowledge. The proximity of scientists to the technology being regulated is an important regulatory resource, but may also generate the appearance of self-interest that could undermine legitimacy.

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173 See Peel, *supra* note 67 at 4.

174 Ellis, *supra* note 165 at 2; Maria Carmen Lemos & Christine Kirchhoff, "Boundary Organizations" in Jean-Frédéric Morin & Amandine Orsini, eds, *Essential Concepts of Global Environmental Governance* (New York: Routledge, 2015) 16 at 17.

175 See Peel, *supra* note 67 at 106–07.

The literature on legitimacy outside the nation-state provides for the possibility that the regulatory activities of the ISHGE can be legitimate even without a democratic mandate. However, as a network of private, scientific organizations, the ISHGE faces several challenges to its legitimacy. First, as a private actor with exclusive membership, it cannot, without major restructuring, rely on democratic participation as a source of legitimacy. Second, the exclusivity of its membership and of membership in the wider scientific community impairs its ability to frame its policy discourse in a way that will be recognized as legitimate by the public. Finally, while the perceived objectivity of science endows these organizations with legitimacy when making ontological claims, this legitimacy is endangered where it appears that these actors are making decisions based on subjective assessments of risk, subjective preferences, or self-interest. It is therefore clear that there are significant inherent challenges to the ISHGE's legitimacy and, consequently, that the sustainability of the regulatory processes begun by the ISHGE regarding gene editing is at risk. In the next Part, I consider the steps taken by the ISHGE to address these challenges and what can be done to increase the legitimacy of this scientific governance process in the future.

V. Legitimizing Scientific Governance

In this final Part, I assess various methods through which the ISHGE and related organizations could legitimize their regulatory role. First, I examine the possibility of increasing public participation in the decision-making process. While this strategy holds potential for strengthening both input and output legitimacy, I argue that its application in the case of the ISHGE would undermine the regulatory resources that allow it to influence policy outcomes in the first place. Second, I consider good governance principles, in particular, transparency, as an alternative legitimation strategy. While transparency is undoubtedly part of the solution, it carries certain dangers in the context of the scientific organizations that could be addressed by improving communication and discourse around the distinct policy role of these organizations.

A. Public participation and democratization

One of the most frequently cited ways to increase the legitimacy of transnational governance structures is to encourage broader participation from a wider array of stakeholder groups in decision-making processes. This plays off the notion that legitimacy increases where the public is able

to contribute to the development of the regulation that will affect them.[176] Several authors have proposed that opening up governance in this way can transform otherwise private structures into sites for deliberation of a transnational public.[177] In doing so, transnational governance could in theory become a way to engage and foster a global governance community, rather that removing governance from the public sphere.

The rationale for greater public participation is not, however, limited to discussion of input legitimacy. Widening participation may allow the public to feel more connected to the decision-making process while also leading to better policy outcomes,[178] thereby linking to notions of output legitimacy. Dryzek suggests that increased participation would occur by integrating different stakeholder perspectives, refocusing on the public interest, and incorporating feedback or accountability.[179] In a post-modern world where there is increasing doubt about our ability to uncover objective truths, unquestioningly following the guidance of experts has become unfeasible in practice.[180] Reforming processes of negotiation and including democratic validation mechanisms have been proposed as a way to achieve the goals of greater public participation.

The regulation of science and technology has not escaped such calls for wider participation. For example, Peel, in her discussion of risk regulation, argues that we can no longer overestimate the universal validity of science compared to non-scientific approaches.[181] In STS, the traditional narrative that the public is deficient in scientific knowledge is being replaced by the notion of co-production, which highlights the role that non-scientists play in the collaborative process of scientific knowledge creation.[182] While co-production is more descriptive than prescriptive, it has been the basis for the

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176 See Steffeck, *supra* note 135 at 256.

177 See e.g. Peel, *supra* note 67 at 371.

178 See John Dryzek, "Global Deliberative Democracy" in Morin & Orsini, *supra* note 174, 76 at 76.

179 *Ibid* at 76–77.

180 See Schepel, *supra* note 98 at 26; Jasanoff, "Making Order", *supra* note 80 at 775.

181 *Supra* note 67 at 8.

182 See Irwin, *supra* note 170 at 589.

call for hybrid forums where the public can interact with scientific experts to foster this process.[183]

While the ISHGE demonstrates certain features of public participation and is demonstrative of an evolving attitude in the scientific community towards public involvement, public participation was not a controlling feature of the process. Explicit effort was made to recruit non-scientific experts and stakeholders to participate and share their points of view at the Summit; however, it was ultimately the Organizing Committee of mostly scientific experts that drafted and summarized these perspectives in the consensus statements. While that committee called on the work following the Summit to be inclusive of "a wide range of perspectives,"[184] both expert and non-expert, all committee members who authored the report have an advanced degree of some kind, the vast majority being PhDs, MDs, or JDs.[185] Therefore, while the wider public was to be consulted in theory, the control of the process was still very much in the hands of experts.

Despite the potential of public participation for the legitimation of governance, there are important limits to the desirability of its application, especially in the context of transnational scientific actors like the ISHGE. One concern is that opening up regulatory processes to the wider public could undermine the very scientific credibility that is the source of its power as a regulatory actor. As explored in Part III, the regulatory force of the ISHGE flows in large part from its claims to expertise and its cultivated elite status. This power is undermined where non-experts are involved in decision making and have control over policy outcomes. Increasing legitimacy in this way would be for naught if it were to result in the erosion of the actor's regulatory power.

In addition, broader public participation in decision making could undermine the ISHGE's ability to embody and protect scientific culture. Losing its position as a defender of the scientific profession could have negative consequences for the ability of ISHGE guidelines to shape the day-to-day

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183 See *ibid* at 593.

184 Olson, *supra* note 7 at 7.

185 See The National Academies of Science, Medicine and Engineering, "Committee Members", online: <www.nationalacademies.org/gene-editing/consensus-study/committee/index.htm>.

behavior of scientists.[186] By inviting other stakeholders to have a determinative role in transnational scientific organizations, the scientific community would lose its ability to use these organizations to express their unique, though not universally true, perspective on policy that affects their community. Accordingly, while the broader public engagement that occurred at the Summit is undoubtedly valuable, pushing for greater public involvement at the decision-making stage risks undermining the role of scientific networks in this regulatory space.

B. Good governance and transparency

An alternate approach to legitimizing transnational regulation focuses not on the actors who contribute to regulatory decisions, but rather on the process of making regulatory decisions. Recalling the discourse and throughput sources of legitimacy considered in the previous Part, legitimacy can be gained by increasing the integrity and transparency of the process behind a decision.

Insight into ensuring that reasoning is communicated and is acceptable to the public can be gained by examining the good governance principles from the regulation literature, namely consistency, transparency, accountability, targeting, and proportionality.[187] Consistency is necessary to demonstrate to the public that there is a relatively stable rationality underlying regulatory decisions. Transparency of the decision-making process is necessary for the rationale to be verifiable, and accountability implies that this rationale can be challenged and additional justification can be requested. Targeting and proportionality ensure that the impacts of the decision affect the specific phenomenon being regulated and minimize other effects. Governance systems that claim conformity to these principles are more likely to be able to rationalize their regulatory decisions in ways that will be accepted by the public and can therefore claim legitimacy according to discourse and throughput conceptions.

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186 See Gibbons, *supra* note 58 at 83.

187 See e.g. UK, Better Regulation Task Force, *Principles of Good Regulation* (London: Her Majesty's Stationery Office, 2003), online: <webarchive.nationalarchives.gov.uk/20091111121217/http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf>.

Transparency is of particular interest in discussions of legitimacy, since it is necessary in order for the public to make a genuine assessment of the rationales and process behind regulatory decisions. Transparency has held a privileged place in the literature on "new" governance approaches that offer an alternative to democratization.[188] In theory, opening up regulatory processes to scrutiny creates an alternative mechanism of public input without compromising expert control over decision making and therefore protects a key source of power as described above.

The values of transparency and accountability are also gaining normative weight in the scientific community itself. The growth of the Open Science movement has advanced the idea that science should be more broadly comprehensible and collaborative.[189] Though the focus of Open Science is usually on knowledge generation rather than policy making, its rise demonstrates that the pull towards transparency and accountability exists within the scientific community. These values are reflected in growing demand for transparency in some of the world's most venerable expert bodies, such as the World Medical Association in its stewardship of the *Declaration of Helsinki* principles on human experimentation.[190]

The ISHGE process demonstrates a conscious effort to increase the transparency of its decision making. The Summit was broadcast online to thousands and presentation slides and video from the conference remain openly available online.[191] The conclusions of the Organizing Committee were accompanied by a summary of the Summit proceedings that presented diverging viewpoints on the usefulness and risks of gene editing.[192] The work of the Expert Committee was not accessible while they were prepar-

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188 See Irwin, *supra* note 170 at 596.

189 See Benedikt Fecher & Sascha Friesike, "Open Science: One Term, Five Schools of Thought" in Sönke Bartling & Sascha Friesike, eds, *Opening Science: The Evolving Guide on How the Internet Is Changing Research, Collaboration and Scholarly Publishing* (Heidelberg: SpringerOpen, 2014) 17 at 19–25.

190 See Michael DE Goodyear, Karmela Krleza-Jeric & Trudo Lemmens, "The Declaration of Helsinki: Mosaic Tablet, Dynamic Document, or Dinosaur?" (2007) 335 BMJ 624 at 625.

191 See Olson, *supra* note 7 at 1; National Academies, "Summit", *supra* note 34.

192 Olson, *supra* note 7.

ing their findings, though their meetings and the speakers and stakeholder groups in attendance were openly publicized.[193]

The ISHGE's exercise in openness can be contrasted with events like the secret genome synthesis meeting that occurred around the same time at Harvard University.[194] This group met behind closed doors, with the hundreds of attendees pledged to secrecy about the proposed project which involved the chemical synthesis of a human genome. The public backlash once the meeting was inevitably outed was significant and demonstrates that the level of transparency witnessed at the Summit is not yet the norm. The scientific community must resist historical impulses to organize in the shadows and embrace emerging norms of transparency and public accountability if they are to be seen as legitimate regulatory actors.

It is worth noting, however, that increased transparency could have negative consequences for the credibility of governance processes if it lays bare the weakness of governance structures. When mistakes and inconsistencies become apparent to the public, the credibility of the governance process as a whole suffers, whether or not the outcome of the process is actually affected.[195] Some insight into the aforementioned phenomenon can be gleaned from the controversy, dubbed "Climategate," where emails between scientists working within the IPCC process were leaked.[196] The leak led to

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193 See Lauren Scrudato, "Debate on Gene Editing Continues at Expert Committee Meeting", *Laboratory Equipment* (14 July 2016), online: <www.laboratoryequipment.com/news/2016/07/debate-gene-editing-continues-expert-committee-meeting>.

194 Interestingly, the meeting was much more controversial in foreign media than it was in the United States. Compare Andrew Pollack, "Scientists Talk Privately about Creating a Synthetic Human Genome", *New York Times* (13 May 2016), online: <https://www.nytimes.com/2016/05/14/science/synthetic-human-genome.html>; Pete Shanks, "Genome Games: A Secret Meet and a Controversy", *Deccan Chronicle* (22 May 2016), online: <www.deccanchronicle.com/technology/in-other-news/220516/genome-games-a-secret-meet-and-a-controversy.html>.

195 See e.g. Reiner Grundmann, "The Legacy of Climategate: Revitalizing or Undermining Climate Science and Policy?" (2012) 3 WIREs Climate Change 281 at 284 [Grundmann, "Legacy"]; Sheila Jasanoff, "Testing Time for Climate Science" (2010) 328 Science 695 at 696.

196 Reiner Grundmann, "'Climategate' and the Scientific Ethos" (2011) 38:1 Sci Technol Human Values 67 at 68–72.

widespread criticism and emboldened climate-denier groups, who used the emails to undermine the broadly accepted conclusion of scientific consensus regarding anthropogenic climate change.[197] Though this was the result of a leak, the same dangers could be imagined if processes are intentionally made transparent.

Conversely, it is perhaps even more dangerous for scientists and scientific organizations to attempt to pass off difficult judgment calls as objective truth in the hopes of maintaining credibility. In an increasingly interconnected world, it is inconceivable that scientific decision-making processes could be entirely hidden from public scrutiny, as the Climategate scandal helps to illustrate. Part of what made the leak so damaging was the sense of betrayal felt by the public at having been sold a story about the IPCC's objective rigor, and the objective rigor of science in general, when science cannot meet these expectations in a "post-normal" world, where "facts are uncertain, values in dispute, stakes high, and decisions urgent."[198] In short, while increased transparency in scientific decision-making processes carries the danger of undermined credibility, so too do futile attempts to seal away these processes from public scrutiny. Transparency, then, seems at best a partial solution to the legitimation of transnational scientific governance.

C. Embracing a policy role for scientific organizations

A critical consideration in the legitimation of the regulatory functions of scientific organizations is open communication, not just of the rationale behind policy choices but also regarding the organizations' policy-making role. If it is ineffective to simply open up scientific decision making and unsustainable to completely insulate it from this scrutiny, the only option is to more carefully mediate how the rationales for scientific decisions are communicated to the public. As demonstrated in the preceding Parts of this paper, scientific organizations have a key role to play in the regulation of emerging gene editing technologies. Scientific organizations should embrace this regulatory role, but they must explicitly communicate *why* they are doing so.

Specifically, scientific organizations need to communicate two distinct sets of additional rationale. First, it is important to clarify the distinct nature

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197 See Grundmann, "Legacy", *supra* note 195 at 283.

198 *Ibid* at 286.

of their policy role. While scientists are accustomed to communicating purportedly neutral observations of the natural world,[199] in regulatory contexts they must openly communicate that their role is a subjective assessment of the desired policy outcomes from the perspective of the scientific community. In other words, when the scientific community voices its perspective on a policy issue, it must communicate that this is a *perspective* rather than a scientific truth. By separating their two roles in this way, scientific organizations may better insulate themselves from the accusation that they are passing off value-laden policy preferences as scientifically determined fact.

Second, these organizations must effectively communicate to the public the reasons for which the scientific perspective should be privileged within the particular regulatory space. This relates to Majone's conclusion that the legitimacy of non-state governance actors depends on their ability to foster public belief in their appropriateness for the regulatory tasks they undertake.[200] In this way, scientific organizations can maintain their authoritative position in the regulatory space despite having revealed their role as subjective regulatory actors. For instance, a persuasive case can be made, for all the reasons outlined in previous Parts, that the regulatory conclusions of scientific organizations should be taken seriously within the realm of gene editing, but this may be less true in contexts where scientific expertise is judged by the public to be less relevant.

The legitimacy of scientific organizations would be enhanced through the effective communication of these points to the public. As explored above, a key source of legitimation is discourse that builds normative consensus between policy makers and the public. This consensus can only be achieved if the role of the policy maker is also subject to the same rational assent.[201] By carving out an explicit policy role for science and justifying this role to the public, scientific actors can emerge from the black box and find their voice as legitimate regulatory actors. Of critical importance to this exercise is the ability of these organizations to effectively communicate with the public but, unfortunately, research shows that this has been a challenge.[202]

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199 See Jasanoff, "Making Order", *supra* note 80 at 762.

200 *Supra* note 150 at 22.

201 See Steffeck, *supra* note 135 at 267.

202 See Alexander Gerber, "Science Caught Flat-Footed: How Academia Struggles with Open Science Communication" in Bartling & Friesike, *supra* note 189, 73 at 78.

The Open Science movement has awakened scientists to the need to revolutionize the way it communicates its role with the public. While data sharing and the absence of patent protection often take centre stage within the paradigm, the goal of the movement to strengthen science's public interface are equally important.[203] Open Science is about giving the public the tools to evaluate the conclusions of scientific work and about better communicating the details of the scientific process.[204] It has sparked conversation about increasing public accessibility and comprehensibility in science.[205] This extends to its policy role, where the scientific community must openly communicate to the public how it arrived at its policy conclusions, including non-objective factors, and in so doing provide the tools to engage in meaningful discourse.

Beyond public participation, good governance, and transparency, an alternative route to legitimation is the active and frank communication by scientific organizations of their policy role within the public discourse. In order to achieve this legitimation, the scientific community must improve its communication with the public. As the Open Science movement and the ISHGE itself demonstrate, there is renewed focus on improving this communication. This bodes well for the future role of transnational scientific organizations as legitimate regulatory actors.

Conclusion

The case of the ISHGE and emerging gene editing technology provides fertile ground for examining the role of transnational scientific organizations as regulatory actors. As presented here, the regulatory space for this technology is particularly ill-suited to formal legal regulation because of its transnational, highly technical, and dynamic character. I have argued that the ISHGE, in contrast, has the potential to be an important regulatory actor in the case of gene editing. Recognizing the role that scientific organizations play is critical to understanding the regulation of these emerging technologies.

The potential importance of scientific organizations in transnational governance is a phenomenon that deserves deeper engagement and study. In

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203 See Fecher & Friesike, *supra* note 189 at 44.

204 See *ibid* at 25.

205 See *ibid* at 19.

particular, while the focus here has been on contrasting the ISHGE with formal legal actors, a complete understanding of this regulatory space requires a more comprehensive cataloguing of regulatory actors and their dynamics and interactions. In addition, while I have often spoken of the ISHGE or the scientific community as a cohesive regulatory actor, further insight could be gained from examining internal regulatory competition between different scientific actors. There is more to be done in bringing together transnational governance and sociology of science literature to understand biomedical regulation.

I have argued the ISHGE guiding principles and the Expert Committee's report may not only shape the behavior of scientists directly but may indirectly impact future formal legal regulation in this area through the phenomenon of discourse structuration. I have highlighted historical lessons from the *United Nations Declaration on Human Cloning*, which may have empowered the scientific community to strengthen this indirect pathway. However, only time will reveal the actual impacts of the ISHGE process on both scientific behavior and formal regulation and these impacts will provide important evidence for refining the theoretical assessment laid out here.

I have also argued that, like other informal regulatory actors, the ISHGE must inevitably confront challenges to its legitimacy, especially given its private, non-democratic nature. Building a conceptualization of legitimacy outside the state is an ongoing exercise and one to which the consideration of scientific actors brings unique insights that are inherent to the science-policy interface.

In order to confront these challenges, I have outlined and evaluated several potential strategies the ISHGE and similar actors could adopt. In this context, increasing public participation and transparency in order to increase legitimacy are unideal and incomplete solutions, respectively. I have argued that focusing on improving the public communication of the role and rationale behind scientific organizations as regulatory actors is an important element of legitimation that deserves additional attention. In particular, there is difficult work to be done in carving out an explicit policy role for scientific organizations and communicating the parameters of this role to the public in a way that enhances legitimacy, while preserving regulatory power. The effort to develop and improve communication across the science-public interface connects to the goals and principles of the Open Science movement, a link that deserves further exploration. Ultimately, while the degree to which the ISHGE and other scientific organizations will be successful in optimizing and sustaining their regulatory role remains to be seen, their work holds significant promise for the transnational regulation of science.