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The Once and Future Role of Policy Advice for Health Regulation by Experts and Advisory Committees

Eric M. Meslin

There is nothing a government hates more than to be well informed, for it makes the process of arriving at decisions much more complicated and difficult.

—John Maynard Keynes

22.1 INTRODUCTION

In many countries, principally those with an established research infrastructure and a national commitment to science and technology policy, there is a loose ecosystem of advisory committees, experts, lobbyists and interested groups that are variously used to provide governments with expert advice and input on matters of policy. The government creates some of these structures for this purpose; others are formed unilaterally but at 'arm's length' from government. Some respond to requests for input from government, others volunteer it without being asked, hoping to convince government of the value and relevance of the knowledge offered. Some, as we shall see below, are more public in their work, others are more private. Common to all is that unlike the formal legislative and regulatory apparatuses of government common to civil society, this loose collection of experts and committees functions in the liminal spaces where regulation, guidelines and policies are developed, informed and debated. This helps explain why science advice to governments is more of an 'art' than a science.[1]

This chapter focuses on how governments make use of expertise to inform health regulation, where the expertise comes from sources connected to, but somewhat on the periphery of, the formal processes of policy development through legislation or judicial review. Two examples are drawn upon from direct experience (and are therefore somewhat subjective): (1) the use of expert panels supported by scholarly academies that are organised to provide input to government and (2) advisory committees established by government with a focus on the former US National Bioethics Advisory Commission. Both types play particular roles in the ecosystem of a country's policy advice regime but have different features. There is a both a rich scholarly literature[2] and a

[1] P. D. Gluckman, 'Policy: The Art of Science Advice to Government', (2014) *Nature*, 507(7491), 163–165.

[2] A. Fischer et al., 'Expert Involvement in Policy Development: A Systematic Review of Current Practice', (2014) *Science and Public Policy*, 41(3), 332–343; H. Douglas, *Science, Policy and the Value-Free Ideal* (University of Pittsburgh Press, 2009); S. Jasanoff, *Science and Public Reason* (New York: Routledge, 2012); R. Pielke, *The Honest Broker: Making Sense of Science in Policy and Politics* (Cambridge University Press, 2007).

grey literature on other structures and examples.[3] The main emphasis is that expert advice in its many iterations forms part of the regulatory apparatus that governments do make use of in developing regulation and other policy. However, these are often underappreciated and therefore difficult to assess with respect to impact.

22.2 THE ROLE OF EVIDENCE AND EVIDENCE GATHERING TO INFORM POLICY

In his first inauguration on 20 January 2009, President Barack Obama announced, 'We will restore science to its rightful place and wield technology's wonders to raise healthcare's quality and lower its costs'.[4] It was a statement as much about his predecessor George W. Bush's lack of support for science and evidence in decision-making, as it was about the future of the Republic. Obama's announcement was, one might say, a liminal proposition: he was looking back on almost a decade's worth of policy decisions, including restricting stem cell science, delaying the appointment of the FDA commissioner and the White science advisor, and outright ignoring science advice when making decisions about women's health led some critics to refer to Bush as 'science's worst-ever enemy'.[5] With that in the rear-view mirror, it was easy for Obama to look to a future of promise and hope. Indeed, on 21 June 2016, the White House released '100 examples of Obama's Leadership in Science, Technology, and Innovation', the first of which was that Obama 'elevated the quality and rigor of the science, technology, and innovation advice in the White House'.[6]

A similar anti-science assertion was made about Canada's prime minister, Stephen Harper, who was admonished for 'muzzling scientists' and reducing research funding during his decade in office.[7] In a manner reminiscent of Obama, and shortly after he was elected in 2015, Canadian Prime Minister Justin Trudeau asserted, 'We are a government that believes in science – and a government that believes that good scientific knowledge should inform decision-making'. Trudeau took a number of actions, including appointing a Minister of Science, prioritising the appointment of a Chief Science Advisor, and filled his first federal budget[8] with sixteen references to 'evidence', 'evidence-based decision-making', and textual support such as: the government 'understands the central role of science in a thriving, clean economy and in providing evidence for sound policy decisions'.[9] Subsequent federal budgets have made similar references to the value of evidence to inform decisions.

The USA and Canada examples were hardly unique. Indeed, it became *de rigour* for governments to embrace the value of using evidence in policy development, often referring to

[3] *Future directions for scientific advice in Whitehall*, R. Doubleday and J. Wilsdon (eds) (Cambridge: Centre for Science and Policy, 2013).

[4] The White House, 'Inaugural Address by President Barack Hussein Obama,' (*The White House President Barack Obama)*, www.obamawhitehouse.archives.gov/realitycheck/the_press_office/President_Barack_Obamas_Inaugural_Address.

[5] A. McCook, 'Sizing up Bush on Science', *The Scientist* (30 September 2006).

[6] The White House Office of the Press Secretary, 'IMPACT REPORT: 100 Examples of President Obama's Leadership in Science, Technology, and Innovation', (The White House President Barack Obama, 21 June 2016) www.obamawhitehouse.archives.gov/the-press-office/2016/06/21/impact-report-100-examples-president-obamas-leadership-science.

[7] S. Zhang, 'Looking Back at Canada's Political Fight Over Science', *The Atlantic* (26 January 2017).

[8] Canada. Budget 2016. Growing the Middle Class. Ottawa (Government of Canada) 2016.

[9] Ibid.

'evidence-based' or more accurately 'evidence-informed' policy as a goal. The UK,[10] Australia[11] and New Zealand[12] are three of the most visible, and who have been emphasising the value of evidence to inform policy for decades, though the support waxes and wanes depending on who is in power. Moreover, the call to use evidence is hardly new, particularly in medicine and healthcare.[13] The justification is that data provide an objective foundation on which to develop policy, avoiding perceptions of bias, ideology or subjectivity. This approach is satisfying at many levels, though there has always been, and more recently an apparent increase, in public scepticism about the role of experts and expertise.[14]

The assertion of the value of facts alone may also unwittingly camouflage two other values of equal import: first, the value of recognising the epistemic foundation for beliefs about facts. As my colleague Alessandro Blasimme and I argue elsewhere, science has become especially challenging for policy-making, precisely because liberal democracies lack a coherent way to accommodate pluralistic views about scientific innovation.[15] This is consistent with the view that using evidence is very different in practice than in theory. As Ian Boyd, Chief Scientific Advisor, UK Department of Environment, Food and Rural Affairs once suggested:

> People don't even think *about data in* the same way: When I think of data I think of binary or hexadecimal numbers. This betrays something of my background, but it was a surprise to me when in Defra, the UK Department of State with responsibility for food and the environment, we started to talk about data and I found that other people saw data very differently. Everybody had different preconceptions about data. Some seemed to be very confused. It had become trendy to talk about data, but few people appeared to think about data.[16]

The second type of camouflage concerns the role that ethical values play, since it should be unremarkable to claim that the test of good public policy is the degree to which it is supported by good evidence, good ethics and good epistemology. Therefore, while asking for evidence may seem sensible and pragmatic, what may be delivered depends on many factors. For instance, governments might think they want *evidence* given its popularity in public discourse and as found in a typical hierarchy of evidence (systematic reviews, randomised clinical trials, etc.), when what they may *need* is something quite different. In some instances specific answers to specific questions,[17] but equally, other types of assistance including problem framing, support for a position they are intending to adopt – or oppose – or being aware of best practices by other jurisdictions. They may also ask for advice because of the perception that seeking input from elsewhere shows a degree of transparency, or provides assurance to constituents that a fair process is being undertaken to consider relevant information before a law is passed or a

[10] UK House of Commons Science and Technology Committee, 'Scientific Advice and Evidence in Emergencies: Third Report of Session 2010–11', (House of Commons, 2011). An example of a review of the use of science in government.

[11] G. Banks, 'Evidence-Based Policy Making: What Is It? How Do We Get It?', *ANU Public Lecture Series*, 4 February 2006, (Productivity Commission, Canberra).

[12] P. D. Gluckman, 'The Role of Evidence in Policy Formation and Implementation: A Report by the Prime Minister's Chief Science Advisor', (Office of the Prime Minister's Science Advisory Committee, September 2013).

[13] M. J. M. Gray, *Evidence-Based Health Care* (London: Churchill Livingstone, 1996).

[14] N. Harrison and K. Luckett, 'Experts, Knowledge and Criticality in the Age of "Alternative Facts": Re-Examining the Contribution of Higher Education', (2019) *Teaching in Higher Education*, 24(3), 259–271.

[15] E. M. Meslin and A. Blasimme, 'Towards a Theory of Science Policy for Genetics', (2013) *European Journal of Human Genetics*, 21 (Suppl 2), 360.

[16] I. Boyd, 'The Stuff and Nonsense of Open Data in Government', (2017) *Scientific Data*, 4, 170131.

[17] M. Petticrew and H. Roberts, 'Evidence, Hierarchies, and Typologies: Horses for Courses', (2003) *Journal of Epidemiol Community Health*, 57(7), 527–529.

regulation implemented (or rescinded). This accounts for the range of instruments that governments may use, reflecting an epistemic hierarchy ranging from anecdotes, cases and stories to more organised collections of data and information, to something approaching comprehensive knowledge. I turn now to two examples of the use of experts to advise government.

22.3 LEARNED AND ACADEMIC SOCIETIES AS EXPERTS FOR GOVERNMENT

Collections of scholars and academic experts have a long and distinguished history. Among the oldest of these academic societies in Europe are the *Compangie du Gai Sçavoir*, founded in 1323 by seven wealthy patrons in Toulouse whose purpose was to promote the poetry of the Occitan language; the *Academia Platonica* – also known as the Neoplatonic Florentine Academy – in 1462–1522; and the Barber Surgeons of Edinburgh established in 1505. In their early years, these organisations functioned as private discussion groups for their own edification and enjoyment. Yet as my colleague Summer Johnson and I describe elsewhere,[18] it was not until the seventeenth century when academies of science and medicine were sought by governments for assistance in establishing public policy. Three of the most prominent were Britain's Royal Society, established by Royal Charter in 1662; Germany's Leopoldina established in 1652; and France's Royal Academy of Sciences, the latter beautifully depicted in Henri Testelin's painting of Jean-Baptiste Colbert presenting the Royal Academy to King Louis XIV at Versailles in 1667 (see Figure 22.1).

In the intervening years, and particularly in the nineteenth and twentieth centuries, learned societies emerged across the disciplinary spectrum. The American Council of Learned Societies, founded in 1919, lists seventy-five national or international 'member societies' in the humanities and related social sciences.[19] The UK learned societies Wikipedia page lists more than 230 organisations,[20] Canada's Federation for the Humanities and Social Sciences lists more than 160 universities, colleges, and scholarly associations[21] and France counts at least thirty-six separate organisations. As organisations that honour excellence by recognising their country's distinguished intellectuals and practitioners – usually with the title 'Fellow' – academies constitute a significant brain trust for any government to draw on. Increasingly, they are called upon to contribute scholarship, testify before legislatures, and offer their expert input. It is becoming common in the health research environment to seek out this type of expertise.[22]

In addition to the individual activities of academies in their respective countries, there are other arrangements of these groups.[23] The first are collections of academies that are regional or global in scope, including: the InterAcademy Partnership, the Network of African Science Academies, Association of Academies and Societies of Sciences in Asia, InterAmerican Network of Academies of Sciences, the European Federation of Academies of Sciences and

[18] E. M. Meslin and S. Johnson, 'National Bioethics Commissions and Research Ethics' in. E. J. Emanuel et al. (eds), *The Oxford Textbook of Clinical Research Ethics* (New York: Oxford University Press, 2008), pp. 187–197.

[19] 'Member Societies', (American Council of Learned Societies), www.acls.org/Member-Societies/Society-Profiles.aspx.

[20] 'Category: Learned Societies of the United Kingdom', (Wikipedia), www.en.wikipedia.org/wiki/Category:Learned_societies_of_the_United_Kingdom.

[21] Federation for the Humanities and Social Sciences, 'The Federation Membership: Our Community', (Federation for Humanities and Social Sciences), www.ideas-idees.ca/sites/default/files/sites/default/uploads/membership/membership_lists_2019_web_eng.pdf.

[22] A. S. Haynes et al., 'Identifying Trustworthy Experts: How Do Policymakers Find and Assess Public Health Researchers Worth Consulting or Collaborating With?', (2012) *PLoS ONE*, 7(3), e32665.

[23] E. M. Meslin and C. Stachulak, 'Organizations of National Academies – A Comparison', (2017) [unpublished internal review undertaken at the Council of Canadian Academies, available upon request].

FIGURE 22.1. Colbert presenting the Royal Academy to King Louis XIV at Versailles in 1667 – Henri Testelin.
Reprinted with permission from the Réunion des Musées Nationaux Grand Palais

Humanities, European Academies Science Advisory Council, Council of Academies of Applied Sciences, Technology and Engineering and the Federation of European Academies of Medicine.

The second is the unique subgrouping of national academies organised within a country to provide specific expert input to governments. Only seven countries have such organisations of organisations: Australia, Belgium, Canada, Finland, Germany, Switzerland and the USA. I offer some observations about the American and Canadian versions.

The US National Academies of Sciences, Engineering, and Medicine (NASEM) is perhaps the most well-known and longest serving, with the National Academy of Sciences established in 1863, the National Academy of Engineering established in 1964 and the National Academy of Medicine – formerly Institute of Medicine – established in 1970. NASEM receives approximately US $200M annually from US Government contracts and US $100M from private or non-federal contracts,[24] undertaking about 200 different assessments, reports and projects at any given time. Numerous NASEM reports have been used to support health research regulation including early studies on primate research[25] and human subjects research regulations.[26]

Modelled after NASEM, the Government of Canada responded to a proposal developed by Canada's three main academies – the Royal Society of Canada, the Canadian Academy of Engineering, and the Canadian Academy of Health Sciences – to fund the creation of the Council of Canadian Academies (CCA) in 2005 with a mission to undertake independent

[24] The National Academies of Sciences, Engineering, Medicine, 'Report of the Treasurer of the National Academy of Sciences for the Year Ended December 31, 2015', (The National Academies of Sciences, Engineering, Medicine, 2016), 6.

[25] National Research Council (US) Committee on Well-Being of Nonhuman Primates, *The Psychological Well-Being of Nonhuman Primates* (Washington, DC: The National Academies Press, 1998).

[26] National Research Council, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (Washington, DC: The National Academies Press, 2014).

assessments of evidence to provide government decision-makers, researchers and stakeholders with high-quality information required to develop informed and innovative public policy (https://cca-reports.ca/). Each of the three Canadian academies had well deserved reputations as a result their distinguished fellowship and missions. By early 2020, the CCA had completed more than fifty assessments on diverse topics in health, environment, science and technology, energy and public safety ranging. Like the US National Academies, the CCA's assessments fill an evidence gap to support policy decision-making, including topics where regulation and legislation is ripe for review or update. The CCA's 2019 reports on *Medical Assistance in Dying* and *When Antibiotics Fail* provide concrete examples of the gap-filling expertise governments welcome in health policy. Its 2020 release of *Somatic Gene and Engineered Cell Therapies* report will inform several regulatory needs: health research, innovation and disruptive technology. Importantly, the CCA expert panels take no normative positions on the subjects they assess. Rather, the CCA undertakes assessments that answer different descriptive questions, including: *What is the state of knowledge of . . .? What is the socio-economic impact of . . .? What are Canada's strengths in . . .? What are the best practices that exist for . . .?*

The work is less about practical advice-giving to government, and more about *evaluating available evidence*. It is challenging to assess the impact of this type of work, especially on specific issues arising in health research regulation. Rarely does an evidence-focused document lead directly to a new regulation or to revision or reform of an existing one, yet there is impact. Canada's Ministry of Innovation, Science and Economic Development undertook a comprehensive evaluation and audit of the CCA in 2018, using the NASEM, the UK Royal Society, the Australian Academy of Learned Societies and Germany's Leopoldina as international comparators, and found that the CCA 'addresses a need for independent, objective, and transparent scientific knowledge to support evidence-based decision-making' and that 'the demand for CCA assessments will continue to grow given the federal government's priority for credible scientific knowledge to support evidence-based decision-making'.[27] The evaluation lists several assessments by name that have supported federal and provincial government, industry and stakeholders. Positive though these might be, such metrics can be misleading since assessment work – and evidence generally – cannot always be tracked directly to a policy outcome, which the CCA evaluators noted: 'that there is a challenge in measuring this type of impact given that the CCA does not formulate recommendations or policy advice that could be tracked and attributed directly to its assessments'.[28] This same claim can be applied to another use of experts to inform government policy development: government-based advisory committees.

22.4 THE ROLE OF BIOETHICS ADVISORY COMMITTEES

As early as the eighteenth century, specialised committees were established to report on particular topics for governments. One such panel chaired by Benjamin Franklin was convened to investigate claims made by Anton Mesmer about the healing power of animal magnetism.[29]

[27] Innovation, Science and Economic Development (ISED), 'Evaluation of the Council of Canadian Academies', (Innovation, Science and Economic Development Canada, 16 March 2018).

[28] Ibid.

[29] B. Franklin, *Animal Magnetism: Report of Dr Franklin and Other Commissioners, Charged by the King of France with the Examination of the Animal Magnetism as Practised at Paris* (London: J. Johnson, 1785).

(The claims were rejected.)[30] Today, thousands of committees, working groups, royal commissions and advisory structures have been established by governments, non-governmental organisations, philanthropic bodies and industry. Until recently, in the USA alone, there were more than 1000 federal advisory committees authorised through the Federal Advisory Committee Act – until President Trump signed an Executive Order, on 14 June 2019, requiring at least one-third of them be terminated.

Unlike the CCA, these advisory bodies are intended to *advise*, that is, to make recommendations. One sub-category of these groups is the bioethics advisory bodies that have become a regular contributor to domestic and international debate about bioethics issues, and health research in particular. The WHO maintains a database of these groups, which currently number more than 110 around the world. Among the more influential are the standing committees such as the Nuffield Council on Bioethics and France's National Consultative Committee on Ethics, while others are ad hoc groups such as WHO's Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. I was fortunate to have a front row seat working for President Bill Clinton's National Bioethics Advisory Commission (NBAC) in the USA, an ad hoc advisory committee functioning between 1996 and 2001 with a focus on health research and genomics. NBAC was one in a series of such USA commissions, each of which played a key role in informing health research regulation.[31] As luck, and the advances of science, would have it, NBAC found itself occupying some of the most intriguing liminal spaces in health science regulation in a generation. Two are highlighted here.

Following the announcement of the birth of the cloned sheep Dolly, NBAC was asked by President Clinton on 24 February 1997 to 'undertake a thorough review of the legal and ethical issues associated with the use of this technology, and report back to be me within 90 days with recommendations on possible federal actions to prevent its abuse'.[32] One hundred and three days later, on 7 June 1998, NBAC delivered its report concluding, 'at this time it is morally unacceptable for anyone in the public or private sector, whether in research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning'.[33] NBAC made six recommendations for public action, many of which Clinton accepted, including maintaining the moratorium on the use of federal funds for attempts to create a child. Perhaps the most significant impact of this work was the international conversation that began in earnest in other countries, especially the UK, Canada and Australia, and in international organisations including UNESCO, CIOMS, the World Medical Assembly and the International Convention on Harmonisation. Dolly's birth moved the debate about reproductive cloning from one about a possible future technology to one in which it was now plausible to conceive of the possibility that a variety of public and professional actors would seek ways to make use of this technology.

Less than a year later, NBAC would take up a second controversial topic: embryonic stem cell research, following from the joint scientific announcements in November 1998 that human

[30] K. McConkey and C. Perry, 'Franklin and Mesmerism Revisited', (2002) *International Journal of Clinical and Experiment Hypnosis*, 50(4), 320–331.

[31] H. T. Shapiro and E. M. Meslin, 'Relating to History: The Influence of the National Commission and Its Belmont Report on the National Bioethics Advisory Commission' in J. F. Childress et al. (eds), *Belmont Revisited: Ethical Principles for Research with Human Subjects*. (Washington, DC: Georgetown University Press, 2005), pp. 55–76.

[32] National Bioethics Advisory Commission, 'Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission,' (*National Bioethics Advisory Commission*, Rockville, MD, 1997).

[33] Ibid.

embryonic stem cells and germ cells had been cultured and derived for the first time. As with Dolly, Clinton came to NBAC to request advice, calling on the commission to 'consider the implications of such research at your meeting next week, and to report back to me as soon as possible'.[34] Yet unlike the cloning report, the Clinton White House had a different reaction to NBAC's work on stem cell science – rejecting the commission's recommendations before they were formally submitted, the context for which I have described elsewhere.[35]

NBAC's experience is not unique in the world. Bioethics-by-commission is an area of scholarly study joining the emerging literature on the use of expert commissions to advise government. Some of this literature reminds us of the risks of relying on experts only, without appealing to the public.[36] Two examples from health research are illustrative: the influential role of patient advocates in the early debates around HIV prevention and treatment trials[37] and a similar story in breast cancer research.[38] In both cases, research regulations were amended to account for patient perspectives, and helped launch a patient engagement movement in health research that thrives today.

22.5 THE FUTURE OF ADVISING ON HEALTH RESEARCH REGULATION IN A LIMINAL WORLD

It is simplistic to conceive of regulations – or policy generally – as linear: that their trajectory is arrow-straight beginning with evidence and concluding with a shiny new regulation. Policy issues emerge for governments in often-unpredictable ways, requiring different types of responses. One reason is that science and society move in unpredictable ways, often responding to a recent study or an emergent problem.[39] For example, gene therapy research was proceeding slowly but cautiously in the 1990s until the death of Jesse Gelsinger set back research for decades.[40] But another reason, alluded to above, relates the democratisation of science and its place in the public sphere with seemingly opposing consequences. Public confidence and trust in science seem to be on the rise,[41] and yet public and social media are filled with anti-science, unfounded hyped-filled assertions about medicine and health.[42]

In the midst of these developments, a new expert is also emerging: the federal science advisor. These experts are 'of' government, and therefore play a different role and are exposed to different challenges. Only five years have passed since Dr Anne Glover was removed as Chief Science

[34] National Bioethics Advisory Commission, 'Ethical Issues in Human Stem Cell Research'. (*National Bioethics Advisory Commission*, Rockville, MD, 1999).

[35] E. M. Meslin and H. T. Shapiro, 'Bioethics Inside the Beltway: Some Initial Reflections on NBAC', (2002) *Kennedy Institute of Ethics Journal*, 12(1), 95–102.

[36] See for example, M. Leinhos, 'The US National Bioethics Advisory Commission as a Boundary Organization', (2005) *Science and Public Policy*, 32(6), 423–433.

[37] M. Manganiello and M. Anderson, 'Back to Basics – HIV/AIDS Advocacy as a Model for Catalyzing Change', www.meaction.net/wp-content/uploads/2015/05/Back2Basics_HIV_AIDSAdvocacy.pdf.

[38] J. Perlmutter et al., 'Cancer Research Advocacy: Past, Present, and Future', (2013) *Cancer Research*, 73(15), 4611–4615.

[39] E. M. Meslin, 'When Policy Analysis Is Carried Out in Public: Some Lessons for Bioethics from NBAC's Experience' in James Humber and Robert Almeder (eds), *The Nature and Prospect of Bioethics: Interdisciplinary Perspectives* (Totowa, NJ : Humana Press, 2003), pp. 87–111.

[40] L. Walters, 'Gene Therapy: Overview' in T. Murray and M. J. Mehlman (eds), *Encyclopedia of Ethical, Legal and Policy Issues in Biotechnology* (New York: Wiley, 2000), pp. 336–342.

[41] See for example: Council of Canadian Academies, 'Science Culture: Where Canada Stands. Expert Panel on Canada's Science Culture', (Council of Canadian Academies, 2014); C. Funk et al., 'Trust and Mistrust in Americans' Views of Scientific Experts', (Pew Research Center, 2 August 2019).

[42] T. A. Caulfield, *Is Gwyneth Paltrow Wrong about Everything?* (Toronto, Canada: Penguin Random House, 2016).

Advisor to the European Union in October 2014.[43] Predictably – and reassuringly – the reaction from the scientific community opposing the decision was swift.[44]

Appointing and dismissing chief scientists and science advisors is itself a political act for governments and one can read both too much and too little into these decisions. It took months for George W. Bush to appoint his science advisor, and even longer for Donald Trump to appoint his. On the other hand, Justin Trudeau made appointing his Chief Science Advisor a key commitment of his Minister of Science's first mandate.[45] New administrations have the right to appoint or dismiss any un-elected position. While the worst thing one can say about appointing a science advisor, or advisory commission, is that these are optically useful moves but unlikely to improve the quality of (health) regulations, the more ominous spin about decisions to remove, not appoint – or worse – to staff them with anti-science personalities, is that they cast an odious shadow on all policy advice that emerges from their office. Examples seem to abound in the USA in the Trump era, including unqualified 'industry-captured' scientists nominated to the Environmental Protection Agency's Science Advisory Board,[46] or the muzzling of a government scientist's report on climate change by the White House.[47] A more relevant health research example has been the ping-pong policy on foetal tissue and embryo research in the USA, which has been vacillating between permissive and restrictive depending on the political philosophy of the White House and the majority party in the US Congress.[48]

Health research regulation is fraught with ethical, social and cultural challenges, particularly where the object of regulation involves fundamental matters of human health, against a backdrop of medical experimentation. Not surprisingly, legislation often takes time to craft wisely, and the regulations that follow may take even longer. A proposed revision to the main health research regulations in the USA, called the Common Rule, was first developed in 1981, revised in 1991, again in 2017, but not fully implemented until 2019 – despite substantive input from advisory commissions and expert panels, professional societies and the general public.

As the examples suggest, health research regulation is not undertaken by a single policy instrument, a single mechanism of reform or informed by single discipline or set of inputs. Health research regulation by its nature involves evidence, but also values, technical expertise, and stakeholder contributions. These are the liminal spaces in which developing, crafting and implementing these regulations exist. Fifteen years ago, President Clinton's science advisor Neal Lane recognised what was needed:

> The successful application of new knowledge and breakthrough technologies . . . will require an entirely new interdisciplinary approach to policy-making that operates in an agile problem-solving environment works effectively at the interface of science, technology business and policy, is rooted in improved understanding of people, organizations, cultures, and nations, engages the

[43] D. Butler, 'European Commission Scraps Chief Scientific Adviser Post,' (*Nature News*, 13 November 2014).
[44] Science Media Center, 'Expert Reaction to News About Abolition of Post of CSA to European Commission,' (*Science Media Center*, 13 November 2014).
[45] B. Owens, 'Canada Names New Chief Science Adviser', *Science* (26 September 2017).
[46] M. Halpern M. 'The EPA Science Advisory Board Is Being Compromised. Here's Why That Matters', (Union of Concerned Scientists, 30 October 2017).
[47] M. Bryant, 'White House "Undercutting Evidence" of Climate Crisis, Says Analyst Who Resigned', *The Guardian*, (30 July 2019).
[48] D. Wertz, 'Embryo and Stem Cell Research in the United States: History and Politics', (2002) *Gene Therapy*, 9 (11), 674–678.

nation's top social scientists, including policy experts, to work in collaboration with scientists and engineers from many fields.[49]

Lane's foresight was prescient. Health research is brimming with inter- and multidisciplinary approaches, which has led to commensurate commitment to interdisciplinary governance emphasising scientific integrity.[50] It is also evident in the encouraging commitment of young people to the future of the planet, reflected in their active engagement in climate issues,[51] and efforts in citizen science,[52] and science diplomacy.[53] The future of health research regulation will be in good hands if society is open to advice from the expertise of experts and non-experts alike.

[49] N. Lane, 'Alarm Bells Should Help Us Refocus', (2006) *Science*, 312(5782), 1847.

[50] A. Kretser et al., 'Scientific Integrity Principles and Best Practices: Recommendations from a Scientific Integrity Consortium', (2019) *Science and Engineering Ethics*, 25(2), 327–355.

[51] S. Dickson-Hoyle et al., 'Towards Meaningful Youth Participation in Science-Policy Processes: A Case Study of the Youth in Landscapes Initiative', (2018) *Elementa Science of Anthropocene*, 6(1).

[52] A. Irwin, 'Citizen Science Comes of Age', (2018) *Nature*, 562, 480–482.

[53] D. Copeland, 'Science and Diplomacy after Canada's Lost Decade: Counting the Costs, Looking Beyond', (Canadian Global Affairs Institute, 2015).