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MORATORIA IN SCIENTIFIC RESEARCH: A REVIEW

VALERIE BONHAM*

“Whatever you do, don’t recommend a moratorium.”

So urged a very senior scientist as I worked with President Obama’s Bioethics Commission in 2010 on its first project: examining synthetic biology following the creation of a self-replicating bacterial cell with a wholly-synthesized genome.¹ Spoken from many decades of experience in the “science wars” of national debate surrounding controversial research activities, these remarks came across with inescapable urgency. A moratorium, that is, a suspension of federal funding, or some other legal prohibition or censure, even if temporary, would slow research progress. Further, even if temporary, it could affect public perception and support for scientific exploration for years, even decades. The modern scientific landscape since the 1970s has seen multiple moratoria, usually based on ethical concerns about controversial scientific endeavors. But, the appeal of a moratorium is understandable, particularly when ethical concerns cannot otherwise be resolved or sufficiently managed.

In June 2019 President Trump announced a moratorium on federal funding for research involving fetal tissue derived from elective abortions.² For many,

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1. Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, BIOETHICS.GOV, <https://bioethicsarchive.georgetown.edu/pcsbi/synthetic-biology-report.html> (last updated Jan. 17, 2017).

2. Amy Goldstein, *New Restriction on Fetal Tissue Research ‘Was the President’s Decision’*, WASH. POST (Jun. 5, 2019, 3:03PM), https://www.washingtonpost.com/health/trump-administration-imposes-new-restrictions-on-fetal-tissue-research/2019/06/05/b13433c0-8709-11e9-a491-25df61c78dc4_story.html.

this felt like Groundhog Day. Research with fetal tissue has been a political football in the United States for decades.³ While politicians were divided over this action and the scientific community was generally opposed, proponents saw it as a triumph for bioethics, as they understand it. To its supporters, banning this research was *ethically* warranted and justified, even mandatory. To at least some of its opponents, the ban was a crass attempt to curry favor with fickle or ill-informed voting blocs.⁴ Undoubtedly, it will slow some types of research advances or developments. President Biden may overturn the Trump policy (as of this writing that has not happened) easily enough through direction to the Secretary of Health and Human Services (“HHS”). Indeed, the Secretary could reverse the policy without Presidential direction. But reversing it, no matter how easy it is a technical matter, will surely carry public attention and stir debate.

Law is often a blunt instrument for bioethical issues (and other issues) at the intersection of science and society. Moratoria are quite blunt. They are also headline-grabbing, seemingly an “active” response to complex issues, and a tool to enable those who propose them to say that they are doing something. Unfortunately, they can be hard to un-do, even when they arise from discretionary policy rather than law or regulation. To facilitate discussion and illuminate how moratoria have been used in modern times, this article compiles a brief history of scientific moratoria with bioethics implications over the past 45 years, going back to the watershed Asilomar conference that followed from a voluntary moratorium on gene research in the early 1970s.⁵ The Appendix includes a table summarizing selected moratoria.⁶ The article discusses legislative and executive policy moratoria on the national level, and voluntary moratoria on the international level. Absent from the discussion are moratoria based on state or local statutes, regulation, and policy. Thus, the discussion is not a complete inventory. Instead, the article aims to be a resource and highlight some interesting and informative examples. The selection seeks to highlight experience and spark discussion about when moratoria do and do not make sense, and hopefully uncover the reasons behind these conclusions. For future policymakers, ethics committees, legislators, and regulators, it will be useful to consider this history carefully before enacting moratoria.

3. Debra Goldschmidt & Susan Scutti, *Trump Administration Limits Research Using Fetal Tissue*, CNN HEALTH, <https://www.cnn.com/2019/06/05/health/hhs-fetal-tissue-research-bn> (last updated Jun. 5, 2019, 4:26PM).

4. See, e.g., The Times Editorial Board, Editorial, *Trump’s Fetal Tissue Bane Will Hurt Many More Babies Than it ‘Saves,’* L.A. TIMES (Jun. 7, 2019, 3:05AM), <https://www.latimes.com/opinion/editorials/la-ed-fetal-tissue-ban-trump-20190607-story.html> (arguing the moratorium will stall research in several areas).

5. Adam Briggie, *Asilomar Conference*, ENCYCLOPEDIA.COM, <https://www.encyclopedia.com/science-and-technology/biology-and-genetics/cell-biology/asilomar-conference> (last updated Aug 13, 2018).

6. See *infra* Appendix: Selected Moratoria.

I. MORATORIA, GENERALLY

What exactly qualifies as a moratorium and how does it differ from a ban? The Merriam-Webster Dictionary defines a moratorium as either a “suspension of activity,” “legally authorized period of delay in the performance of a legal obligation or the payment of a debt,” or “waiting period set by an authority.”⁷ In each instance, a moratorium is demarcated by its impermanent nature.⁸ A moratorium, by its nature, should not last forever. On the other hand, a ban is defined as a “legal or formal prohibition.”⁹ Inherent in its definition, a ban has permanence baked into it. However, the use of moratoria and bans in science has not neatly complied with the distinct nature of the definitions of moratoria, as temporary prohibitions, and bans, as permanent ones. For example, as described in greater detail in this paper, a 1988 moratorium on transplantation research with human fetal tissue from induced abortions was supposed to end when a panel issued a report within the same year.¹⁰ After its report, the moratorium was extended indefinitely and was not repealed until 1993; this moratorium lasted five years.¹¹ In contrast, in 2019, HHS banned the purchase and use of human fetal tissue by National Institutes of Health (“NIH”) scientists.¹² This executive policy ban is susceptible to change by the Biden Administration. If so, the “ban” would have lasted for no more than a three-year period – notably shorter than the five-year moratorium of the late 1980s. Even more distinct, the Dickey-Wicker ban must receive regular renewal because it was a rider to a larger piece of legislation.¹³ Such regular renewal is hardly reflective of the permanent nature of a ban. Therefore, while some may thread the needle on the difference between a moratorium and ban, we use the two interchangeably for the purposes of this article, consistent with our observations on the practical applications of both terms.

7. *Moratorium*, MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/moratorium> (last visited Apr. 6, 2021).

8. Reetika Wadhwa & Nishtha Das, *Moratorium: Meaning and Relief Measures Introduced by RBI Amid Covid-19*, LEXOLOGY.COM (Apr. 17, 2020), <https://www.lexology.com/library/detail.aspx?g=7aa5bda5-e108-4a0f-99a2-0f8cefeb70df>.

9. *Ban*, MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/ban> (last visited Apr. 6, 2021).

10. See James F. Childress, *Deliberations of the Human Fetal Tissue Transplantation Research Panel*, in *BIOMEDICAL POLITICS* 215, 216, 218 (Kathi E. Hanna ed., 1991), for greater detail on the 1988 research.

11. Helen M. Maroney, *Bioethical Catch-22: The Moratorium on Federal Funding of Fetal Tissue Transplantation Research and the NIH Revitalization Amendments*, 9 *J. CONTEMP. HEALTH L. & POL’Y* 485, 487 (1993).

12. *Human Fetal Tissue Research: Frequently Asked Questions*, CONG. RSCH. SERV. <https://fas.org/sgp/crs/misc/R44129.pdf> (last updated Aug. 8, 2019).

13. Nidhi Subbaraman, *Research on Embryo-like Structures Struggles to Win US Government Funding*, *NATURE* (Jan. 17, 2020), <https://www.nature.com/articles/d41586-020-00127-z>.

Experts can debate the taxonomy, but we see three main types of moratoria: (1) those imposed legislatively, e.g., the Dickey-Wicker amendment, be they through appropriations or other legislation; (2) those created by government policy, e.g., stem cells, the White House's recent fetal tissue ban, and the NIH's chimera policy; and (3) those arising voluntarily from the scientific community, e.g., from Asilomar and more recently on germline-editing through CRISPR-Cas9.¹⁴

The origin and authority of a moratorium matter. They affect enforceability, penalties, reach, and impact. Legislative moratoria can only be removed by additional legislation or failure to approve statutory amendments or riders.¹⁵ Executive policy moratoria may be lifted by revision to federal rules after a public comment period or repeal of a memorandum, as applicable.¹⁶ Voluntary moratoria are overcome after community consensus has been reached on its dissolution, often after the adoption of community standards on conduct.¹⁷

II. LEGISLATIVE MORATORIA

Of the three types of moratoria discussed in this paper, legislative moratoria are the most powerful but also the most intractable. Legislative moratoria are established through the passage of legislation through Congress.¹⁸ These types of moratoria carry the full weight of the legislative branch, and, where Congress requires, executive policy must comply with its prohibitions.¹⁹

This power, however, comes with a trade-off: legislative moratoria cannot be instituted as quickly as other types of moratoria in response to an ethics emergency due to the nature of the deliberative process involved in legislating.²⁰ To succeed in passage, advocates of a moratorium must convince hundreds if not thousands of members of Congress, staff persons, lobbyists, and constituents to spend capital to realize their goal. Once passed, repeal of the legislative moratoria can be just as difficult – marshalling all the resources of individuals and organizations advocating for their interests for or against the moratorium.

Perhaps the most famous legislative moratorium in research is the Dickey-Wicker Amendment.

14. See Russell A. Spivak et al., *Moratoria and Innovation in the Reproductive Science: of Prext, Permanence, Transparency, and Time Limits*, 14 J. HEALTH & BIOMEDICAL L. 5, 6 (2018) (describing four types of moratoria, drawing a distinction between statutory moratoria that arise in appropriations law and require annual renewal and statutory moratoria that are permanent until repealed).

15. *Id.*

16. *Id.*

17. *Id.* at 26.

18. See *id.* at 6.

19. *Id.* at 10–11.

20. *Id.* at 26.

a. Dickey-Wicker Amendment

In 1994, the NIH Human Embryo Research Panel, which was assembled to evaluate when human embryo research should be federally funded, published their report.²¹ In it, the panel recommended that the creation of embryos for research purposes should be permitted under certain circumstances.²² While President Clinton accepted some of the panel's recommendation, he rejected this one.

In response,²³ in 1995 Congress passed an appropriations bill rider as an amendment to a bill, often referred to as the Dickey-Wicker Amendment after its congressional sponsors.²⁴ The amendment, which has been renewed regularly since original introduction, prohibits HHS from using federal funds for:

(1) [T]he creation of a human embryo or embryos for research purposes; or

(2) [R]esearch in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero . . .”²⁵

Human embryo was defined to include “any organism . . . that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”²⁶

Dickey-Wicker is a statutory limit from which there is no flexibility.²⁷ Consequently, the law is incorporated as a term and condition of award in the NIH *Grants Policy Statement*, which defines the terms and conditions under which NIH determines who receives federal funding research grants; all funding

21. See HAROLD VARMUS, *THE ART AND POLITICS OF SCIENCE* 197–98 (2009).

22. *Id.* at 199.

23. Marlene Cimons & Jonathan Peterson, *Clinton Bans U.S. Funds for Human Cloning Research: Science: He Urges Private Sector to Refrain From Such Experiments, Warns of New Ethical Burdens. The Federal Agency that Provide Money Doesn't Support Any Projects*, L.A. TIMES (Mar. 5, 1997), <https://www.latimes.com/archives/la-xpm-1997-03-05-mn-35032-story.html>. Note that, in 1994, President Clinton banned the use of federal funds to support the creation of human embryos solely for research purposes; this is an example of an executive policy ban that we will not delve into in the course of this article.

24. The Balanced Budget Downpayment Act, Pub. L. No. 104–99, § 128, 110 Stat. 26, 34 (1996).

25. Omnibus Appropriations Act of 2009, Pub. L. No. 111–8, § 509, 123 Stat. 524, 534 (1996).

26. Katrien Devolder, *What's In A Name? Embryos, Entities, and ANTitles In The Stem Cell Debate*, 32 J. MED. ETHICS 43, 45 (2006).

27. Omnibus Appropriations Act of 2009, Pub. L. No. 111–8, § 509, 123 Stat. 524, 534 (1996).

recipients must comply.²⁸ This means that there are individuals at NIH who spend a lot of time and effort navigating how to apply the law to ensure that neither intramural nor extramural funds are expended on any research that would violate the Dickey-Wicker prohibition.²⁹

Violations of the prohibition materialize in a number of ways: (1) NIH could intentionally or unintentionally allocate federal funds to research used in the creation of a human embryo, or (2) an NIH grant recipient could mislead NIH on the goal or process of its study to receive funds and apply those funds.³⁰

However, statutory requirements come with heavy penalties and are enforceable in concrete ways that voluntary moratoria are not. Anyone who does violate the law faces a loss of funding and possible restrictions on future research activities, and, at least theoretically, could face more severe penalties if the action were deemed an intentional effort to violate the law or the terms and conditions of funding, including the imposition of civil monetary penalties.³¹

This Amendment has been in place for well over twenty years with essentially zero legislative or public debate since its inception.³² The absence of debate related to its renewal indicates the broad consensus held in Congress to maintain, or at least not repeal, the Dewey-Wicker prohibition.³³ It illustrates also how difficult reversing legislative moratoria can be.

III. EXECUTIVE POLICY MORATORIA

Executive branch and agency moratoria are more flexible in comparison to legislative moratoria. Rather than seeking the approval of a majority of Congress – potentially hundreds of people – an executive policy moratorium may be overturned with the change of administrations in the White House or with the change of individuals within an agency. Additionally, they may be more susceptible to outside influence through the notice and public comment process.

However, executive policy moratoria tend to have limited scope. Where legislative moratoria may be expansive, limited only by the Congress' constitutional limitations and its own imagination, all executive policy must be founded in authorizations provided by legislation and limits on the powers of any

28. The Witherspoon Council, *Stem Cell Research Funding: Policy and Law*, NEW ATLANTIS, (2012), <https://www.thenewatlantis.com/publications/appendix-d-stem-cell-research-funding-policy-and-law>.

29. David G. Zacharias et al., *Impedance of Novel Therapeutics Technologies: The Case of Stem Cells*, 5 CLINICAL & TRANSLATIONAL SCI. 422, 423–24 (2012) (discussing the political and legal battle between the NIH and the Dickey-Wicker Amendment).

30. 42 U.S.C.A. § 289g.

31. Omnibus Appropriations Act of 2009, Pub. L. No. 111–8, § 509, 123 Stat. 524, 534 (2009).

32. Kirsten R.W. Matthews & Daniel Morali, *National Human Embryo and Embryoid Research Policies: A Survey of 22 Top Research-Intensive Countries*, 15 REGENERATIVE MED. 1905, 1908 (2020).

33. *See id.* at 1909 (stating that there has been no change either legislatively or judicially since the Amendment was passed).

given agency. For example, NIH moratoria often appear in the form of a ban on funding because NIH has the authority to draft grant funding guidelines.³⁴

a. Chimeras Research

Over the past two decades, an increasing number of researchers have been interested in experiments involving human and animal genetic mixing where human stem cells were being placed into non-human animal embryos.³⁵ The increased demand in growing human tissue in organs of animals alarmed NIH. In 2009, NIH published its Guidelines on Human Stem Cell Research,³⁶ pursuant to an executive order by President Obama.³⁷ The guidelines established a policy and procedure in which NIH would fund human stem cell research in an ethically responsible and scientifically worthy way.³⁸ However, the guidelines also prohibited the use of NIH funds for introducing human stem cells into early-stage embryos of non-human primates.³⁹

As researchers discovered new stem cell research opportunities, NIH became concerned about some scientists growing human tissue and organs in animals by introducing human stem cells into early stage non-human vertebrate embryos.⁴⁰ Consequently, in 2015 the NIH announced, effective as of the date of the announcement, that it would not fund “any new or competing grant applications or contract proposals for research in which human pluripotent cells are introduced into non-human vertebrate animal pre-gastrulation stage embryos.”⁴¹ The agency explained at the time the moratorium was implemented that the agency could “undertake a deliberative process to evaluate the state of the science in this area, the ethical issues that should be considered, and the relevant animal welfare concerns associated with these types of studies.”⁴²

34. See, e.g., NAT'L INST. OF PUB. HEALTH, NOT-OD-15-158: NIH RESEARCH INVOLVING INTRODUCTION OF HUMAN PLURIPOTENT CELLS INTO NON-HUMAN VERTEBRATE ANIMAL PRE-GASTRULATION EMBRYOS (2015); and NAT'L INST. OF PUB. HEALTH, NOT-OD-17-071: NOTICE ANNOUNCING THE REMOVAL OF THE FUNDING PAUSE FOR GAIN-OF-FUNCTION RESEARCH PROJECTS (2017).

35. Nicholas Wade, *New Prospects for Growing Human Replacement Organs in Animals*, N.Y. TIMES (Jan. 26, 2017), <https://www.nytimes.com/2017/01/26/science/chimera-stemcells-organs.html>.

36. National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 128 (Jul. 7, 2009).

37. Exec. Order No. 13505, 3 C.F.R. § 13505 (2009).

38. NAT'L INST. OF PUB. HEALTH, NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR HUMAN STEM CELL RESEARCH (2009).

39. *Id.*

40. Rob Stein, *Should Human Stem Cells Be Used To Make Partly Human Chimeras?*, NPR (Nov. 6, 2015, 3:39 AM), <https://www.npr.org/sections/health-shots/2015/11/06/454693391/should-human-stem-cells-be-used-to-make-partly-human-chimeras>.

41. NAT'L INST. OF HEALTH, NOT-OD-15-158, NIH RESEARCH INVOLVING INTRODUCTION OF HUMAN PLURIPOTENT CELLS INTO NON-HUMAN VERTEBRATE ANIMAL PRE-GASTRULATION EMBRYOS (2015).

42. *Id.*

As part of its policy-making process, the agency held an experts' workshop in 2015 to discuss the research and animal welfare issues.⁴³ The workshop identified a clear interest in producing animal models with human tissues or organics for several opportunities, including organ transplantation.⁴⁴ It also convened an internal "steering committee" to develop recommendations for NIH leadership and "monitor trends in this general field of research and the use of new technologies."⁴⁵

A year after announcing the chimera moratorium, the NIH requested comment on its thinking, expressly citing the potential benefits of the research.⁴⁶ Thereafter, it signaled its intent to lift the ban, with certain conditions.⁴⁷ But, that did not happen and the moratorium remains in place.⁴⁸ Notably, while NIH intends to end the moratorium on chimera research, it has requested comments on its proposal to expand the 2009 Guidelines prohibition against stem cell use in non-human primate embryos.⁴⁹

Unlike some past actions, the chimera moratorium arose in the modern era of notice and comment policymaking, with social media and technology-enabled advocacy available to influence or drive policymaker's actions.⁵⁰ Moreover, similar to stem cell research and anything that touches on the politics of human conception in the United States, this issue garnered interest from passionate constituencies interested in animal welfare and rights as well as those interested more generally in research and scientific advancement.⁵¹

Since then, it is not clear when, or how, the moratorium may be lifted, nor is it clear by what criteria NIH will make this choice. Because the ban is agency-imposed and discretionary, it can be lifted with little fanfare or process. But, the failure to lift it tells us something about the risks that can attach to a moratorium.

43. Carrie D. Wolinetz, *Next Steps on Research Using Animal Embryos Containing Human Cells*, NAT'L INST. OF HEALTH: OFF. OF SCI. POL'Y (Aug. 4, 2016), <https://osp.od.nih.gov/2016/08/04/next-steps-on-research-using-animal-embryos-containing-human-cells/>.

44. *Id.*

45. NAT'L INST. OF HEALTH, NOT-OD-16-128, REQUEST FOR PUBLIC COMMENT ON THE PROPOSED CHANGES TO THE NIH GUIDELINES FOR HUMAN STEM CELL RESEARCH (2016).

46. *Id.*

47. Jocelyn Kaiser, *NIH Plans to Fund Human-Animal Chimera Research*, SCIENCE MAG, Aug. 12, 2016, at 643.

48. Omnibus Appropriations Act of 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524 (2009).

49. Request for Public Comment on the Proposed Changes to the NIH Guidelines for Human Stem Cell Research and the Proposed Scope of an NIH Steering Committee's Consideration of Certain Human-Animal Chimera Research, 81 Fed. Reg. 51921 (Aug. 5, 2016). The Guidelines currently prohibit the use of stem cell research with blastocyst stage nonhuman primate embryos. *Id.* The proposal would include pre-blastocyst stage embryos. *Id.*

50. Douglas Yeung, *Social Media as a Catalyst for Policy Action and Social Change for Health and Well-Being: Viewpoint*, 20 J. MED. INTERNET RSCH. 1, 2 (2018).

51. Carolyn Plunkett Neuhaus, *Get the Public Involved in Chimera Research at NIH*, BIOETHICS.NET (Aug. 15, 2016, 10:48), <http://www.bioethics.net/2016/08/get-the-public-involved-in-chimera-research-at-nih/>.

Having announced the need to prohibit funding in this area of science, pending further deliberation, the agency is faced now with the challenge of back-peddling. The rules, procedures, and rationale attached the termination of the chimera moratorium will be widely scrutinized and will need to meet the serious concerns raised to justify its imposition in the first place. It is not that it cannot be done. In fact, the experience with recombinant DNA as described below, among other examples, shows that the agency can and does evolve its thinking over limits on research activities in light of changing circumstances and mores.⁵²

b. Chimpanzees in Research

The interest in animal welfare was not restricted to the chimera research moratorium. At that time, animal welfare issues were at the forefront of the agency's thinking.⁵³ In 2011, NIH announced new requirements on the use of research involving chimpanzees requiring that these protocols satisfy certain ethical criteria, namely:

1. That the knowledge gained must be necessary to advance the public's health;
2. There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects; and
3. The animals used in the proposed research must be maintained either in ethologically appropriate physical and social environments (i.e., as would occur in their natural environment) or in natural habitats.⁵⁴

Following that, in 2013 NIH announced a reduction in its use of NIH-owned or supported chimpanzees in NIH-funded research.⁵⁵ Dr. Collins, then Director of NIH stated, "I am confident that greatly reducing [chimpanzee] use in biomedical

52. *See, e.g.*, 84 Fed. Reg. 17858 (Apr. 26, 2019) (demonstrating that the NIH Guidelines occupy a unique space in the administrative framework, whereby regulations are not promulgated through notice and comment rulemaking in the conventional sense of informal rulemaking); *see also* NAT'L INST. OF HEALTH, NIH GUIDELINES (April 2019), https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

53. NAT'L INST. OF HEALTH, STATEMENT BY NIH DIRECTOR DR. FRANCIS COLLINS ON THE INSTITUTE OF MEDICINE REPORT ADDRESSING THE SCIENTIFIC NEED FOR THE USE OF CHIMPANZEES IN RESEARCH (2011).

54. *Id.*

55. NAT'L INST. OF HEALTH, NIH TO REDUCE SIGNIFICANTLY THE USE OF CHIMPANZEES IN RESEARCH (2013).

research is scientifically sound and the right thing to do” in accepting an NIH-commissioned study’s recommendations.⁵⁶

Shortly after announcing the chimera ban and consistent with its 2013 announcement on chimpanzee use in NIH research, the agency also announced an unprecedented decision to ban the use of the remaining NIH-owned and supported chimpanzees for research.⁵⁷ This ban was more significant than the 2013 limits on NIH-owned chimpanzees as well as the 2009 Guidelines, which merely banned use of stem cells in non-human primate embryos. In making this announcement, the NIH Director explained: “It is clear that we’ve reached a tipping point” in the need for, and social acceptability of, using chimpanzees in research.⁵⁸

As such, the ban on chimpanzees in research is a valuable story of policy change and use of a moratorium to advance an ethical goal, albeit within the somewhat limited realm of NIH-funded research.

c. Human Fetal Tissue Research

Human fetal tissue is used in scientific research in a range of ways such as vaccine development, stem cell research and transplantation, and chimeras. Historically, its use has been controversial because human fetal tissue is often collected from a still-born fetus or as a result of an abortion procedure.⁵⁹ The history of human fetal tissue research moratoria, restrictions, and prohibitions is a clear example of how scientific processes can be curtailed and limited by the influence of partisan social issues such as abortion.

Between 1974 and 1975, federal funds were prohibited from being used on research involving living fetuses while the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research studied the issue.⁶⁰ In 1975, the moratorium was lifted as the Commission released its report, concluding that such research was acceptable, and provided proper safety protocols and oversight.⁶¹ Shortly thereafter, the federal government published regulations adopting the recommendations of the Commission.⁶²

56. *Id.*

57. NAT’L INST. OF HEALTH, NIH WILL NO LONGER SUPPORT BIOMEDICAL RESEARCH ON CHIMPANZEES (2015).

58. *Id.*

59. Heather D. Boonstra, *Fetal Tissue Research: A Weapon and a Casualty in the War Against Abortion*, 19 GUTTMATCHER POL’Y REV. 9, 11 (2016).

60. ERIN D. WILLIAMS, CONG. RSCH. SERV., FEDERAL PROTECTION FOR HUMAN RESEARCH SUBJECTS 14 (2005).

61. NAT’L COMM’N FOR THE PROT. OF HUM. SUBJECTS OF BIOMEDICAL AND BEHAV. RSCH, RESEARCH. ON THE FETUS 63 (1975).

62. Fetuses, Pregnant Women, In Vitro Fertilization, 40 Fed. Reg. 33,526 (Aug. 8, 1975) (to be codified at 45 C.F.R. pt. 46).

However, the regulations led to an inadvertent moratorium in a limited circumstance: research on a fetus in utero.⁶³ The regulations required that research involving a fetus in utero must involve minimal risk.⁶⁴ Whether risk associated with any particular research was minimal or otherwise was not defined. A Congressionally mandated Ethics Advisory Board (“EAB”), formed to study the ethics of human embryo research, had authority to interpret and provide waivers for experiments that were risky.⁶⁵ From 1975 to 1980, the EAB did not issue a single waiver and was disbanded in 1980 for unrelated reasons, thereby depriving researchers who hoped to conduct research using a fetus in utero from an assessment or waiver related to the level of risk associated with a study. This created a de facto moratorium on such research that would last through interagency and political fights that would not be overcome until 1993.⁶⁶

At the same time, in 1988, HHS sent a memorandum to NIH imposing a moratorium on transplantation research with fetal tissue from induced abortions until the Human Fetal Tissue Transplantation Research Panel issued a report – which it did in December 1988.⁶⁷ The Panel reported a number of recommendations that were endorsed by the Advisory Committee to the Director of NIH, including a lift of the moratorium in place.⁶⁸ Despite the recommendation to lift the moratorium, HHS extended the moratorium indefinitely afterwards due to the politically partisan connection to the abortion debate in the 1980s in the Reagan and Bush administrations.⁶⁹

Congress expressly authorized the use of human fetal tissue to be used in research when it passed the National Institutes of Health Revitalization Act of 1993.⁷⁰ It defined “human fetal tissue” as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.⁷¹ The statute permits fetal tissue research regardless of whether the tissue is obtained from a spontaneous or induced abortion or because of a stillbirth so long as certain conditions are met.⁷²

63. 45 C.F.R. § 46.204 (1975).

64. *Id.* § 46.116(d)(1) (stating that the IRB can approve a procedure if “the research involves no more than minimal risk to the subjects.”).

65. *Id.* § 46.207; Fetuses, Pregnant Women, In Vitro Fertilization, 40 Fed. Reg. 33,526, 33,529 (Aug. 8, 1975) (to be codified at 45 C.F.R. pt. 46).

66. Meredith Wadman, *Senate Panel Seeks Middle Ground on Human Fetal Tissue Research and Abortion*, SCI. MAG. (Sept. 8, 2017 1:45 PM), <https://www.sciencemag.org/news/2017/09/senate-panel-seeks-middle-ground-human-fetal-tissue-research-and-abortion>.

67. Childress, *supra* note 10.

68. HUM. FETAL TISSUE TRANSPLANTATION RSCH. PANEL, REPORT OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH 6 (1988).

69. Maroney, *supra* note 11, at 485–86.

70. National Institutes of Health Revalorization Act of 1993, Pub. L. No. 103–43, § 111–14, 107 Stat 122, 129–33 (codified as amended at 42 U.S.C. § 289g-1).

71. *Id.*

72. 42 U.S.C. § 289g-1 (1944).

Congressional approval of the use of human fetal tissue in research, however, did not end concerns on the practice. In December 2018 HHS ordered Food and Drug Administration (“FDA”) and NIH researchers to stop purchasing fetal tissue.⁷³ The prohibition was part of a broader move under President Trump’s administration to prohibit or minimize the use of human fetal tissue.⁷⁴ In 2018, HHS also refused to renew on an annual basis a research contract with the University of California San Francisco that involved use of human fetal tissue; it elected to renew it for 90-day periods at a time.⁷⁵ HHS also canceled another contract between the FDA and a third party for the human of human fetal tissue from elective abortions.⁷⁶ The cancelations were followed by a nine-month review of all of HHS’ research involving human fetal tissue from elective abortions.⁷⁷ In June 2019, HHS announced that it would not extent the UCSF contract.⁷⁸ At the same time HHS also announced that intramural research using human fetal tissue would not be funded and extramural research would be subject to a lengthy, time-consuming additional review process by an ethics board.⁷⁹

Some have viewed the additional ethics board review as a deliberate attempt to restrict, delay, or deny the use of human fetal tissue in research. If effective, the additional burden on already complicated NIH grant application and review processes may result in a de facto moratorium of NIH funding on all human fetal tissue research. The policy may have short- to medium-term impact on research that utilizes human fetal tissue as applicants consider whether the additional delay in time and resources is worthwhile and alternative routes are available to avoid the use of human fetal tissue. However, the long-term impact may be limited because of the nature of executive policy moratoria. Under the Biden Administration, the policy may be overturned, and NIH may contract with organizations that conduct research using human fetal tissue and may alleviate the process burdens associated with grant funding of research that uses the same.

73. Denise Grady, *Fetal Tissue Research is Curtailed by Trump Administration*, N.Y. TIMES (Dec. 12, 2018, 11:59), <https://www.nytimes.com/2018/12/12/health/fetal-tissue-research-trump.html>.

74. *Id.*

75. *Id.*

76. *Id.*

77. Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue, 86 Fed. Reg. 2615, 2615 (Jan. 13, 2021) (to be codified at 45 C.F.R. pts. 46, 75).

78. DEP’T OF HEALTH & HUM. SERV., STATEMENT FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (2019), <https://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html>.

79. *Id.*

d. Human Cloning Research

In 1997, a Scottish scientist announced the successful creation of a baby sheep cloned using genetic materials from an adult sheep named Dolly.⁸⁰ That same year, researchers in Oregon successfully cloned two monkeys.⁸¹ These stories caught the attention of major media outlets and were reported on across the nation and the globe. Fear and controversy surged. Subsequently, President Clinton issued a ban on the use of federal funds for human cloning research.⁸² As already noted, however, Congress had previously prohibited the funding for human embryo research, indirectly prohibiting human cloning.⁸³ Additionally, in 1994 the President had banned the use of federal funds to support the creation of human embryos solely for research purposes.⁸⁴ Thus, the President's 1997 executive policy was intended to close any loopholes in the law.⁸⁵ In justifying the ban, the President stated: "Science often moves faster than our ability to understand its implications That is why we have a responsibility to move with caution and care."⁸⁶

The President's ban on human cloning research provides a prime example of a prohibition driven, at least in part, by the need to address and alleviate the public's concerns related to the rapid development of controversial scientific technology and its longer-term ramifications. In commenting on the President's ban, then NIH Director, Harold Varmus, stated that the policy was an attempt to provide reassurance to the public that federal funds were not used for human cloning.⁸⁷ Additionally, Director Varmus hoped it would "calm people's fears about those nightmarish possibilities that are extremely unlikely, and get them to focus on the real dilemmas."⁸⁸

The Clinton cloning policy continues and, at least as of this writing, faces few objections. Perhaps this is because the collective public opposition to human cloning, including from within the scientific community, is widely shared across the political spectrum.⁸⁹

80. Cimons & Peterson, *supra* note 23.

81. *Id.*

82. *Id.*; Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 1 PUB PAPERS 233 (Mar. 4, 1997).

83. Cimons & Peterson, *supra* note 23

84. *Id.*

85. *Id.*

86. Presidential Remarks Announcing the Prohibition on Federal Funding for Cloning of Human Beings and an Exchange with Reporters, 33 WEEKLY COMP. PRES. DOC. 21 (Mar. 4, 1997).

87. Cimons & Peterson, *supra* note 80.

88. *Id.*

89. See David Masci, *20 Years After Dolly the Sheep's Debut, Americans Remain Skeptical of Cloning*, PEW RSCH. (Feb. 22, 2017), <https://www.pewresearch.org/fact-tank/2017/02/22/20-years-after-dolly-the-sheeps-debut-americans-remain-skeptical-of-cloning/> (describing public opinion about cloning between 1997-2017).

IV. VOLUNTARY MORATORIA

Unlike legislative or executive policy moratoria, a voluntary moratorium that the scientific community imposes upon itself does not pose the risk of losing government funding or other threats arising from the power of the state. The penalty in such cases arises from community censure. This could include the loss of publication opportunities, for example where a journal decides not to publish a researcher's paper because the research violates a community standard, or the threat to employment in the event that a community moratorium is adopted as a matter of policy within an institution such as a research university or medical center.⁹⁰ Furthermore, depending on the scale of the violation and the degree of consensus within the community calling for the moratorium, an individual could face long-term threats to career advancement, and other more subtle actions that enable censure from the professional community of scientists to carry weight beyond, and materially different from, a legislative mandate.

a. Asilomar and Its Sequelae

The Asilomar story is a widely known example of the community of scientists coming together to self-censure and limit research until a consensus surfaces around how to proceed with an uncertain field of scientific inquiry.⁹¹ Prior to 1975, molecular biologists conducted research on the relatively new discovery of DNA, as revealed to the world in 1953.⁹² In the more than twenty years after its discovery researchers were entering a whole new world of possibilities with the development around recombinant DNA.⁹³ Recombinant DNA was DNA molecules formed artificially in a lab by combing genetic material from different organisms to form a DNA sequence that would not have otherwise been found.⁹⁴

Worried about potential for harm in the experiments they were performing, researchers in the very early years of recombinant DNA research asked the National Academy of Sciences for guidance.⁹⁵ Additionally, public anxiousness about the ramifications of the research was on the rise as the media began to tell

90. See Charlene Kalebic, *The Constitutional Question of Cloning Humans: Duplication or Procreation? An Examination of the Constitutional Right to Procreate*, 8 S. CAL. INTERDISC. L.J. 229, 248, 278 (1998) (describing the benefits and limitations of voluntary moratoriums).

91. Paul Berg, *Asilomar 1975: DNA Modification Secured*, 455 NATURE 290, 290 (2008).

92. 1953: *DNA Double Helix*, NAT'L HUM. GENOME RSCH. INST. (Apr. 23, 2013), <https://www.genome.gov/25520255/online-education-kit-1953-dna-double-helix>.

93. See Berg, *supra* note 91 (describing the concerns and possibilities surrounding recombinant DNA in the 1970s).

94. Leslie Pray, *Recombinant DNA Technology and Transgenic Animals*, 1 NATURE EDUC. 51, 51 (2008).

95. *Recombinant DNA Technologies and Researchers' Responsibilities, 1973–1980*, U.S. NAT'L LIBR. OF MED., <https://profiles.nlm.nih.gov/spotlight/cd/feature/dna> (last visited Apr. 7, 2021).

sensational stories.⁹⁶ The resulting Committee on Recombinant DNA Molecules in 1974 recommended that all recombinant DNA experiments cease.⁹⁷ The Committee stated it was “most important, that until the potential hazards of such recombinant DNA molecules have been better evaluated or until adequate methods are developed for preventing their spread, scientists throughout the world [should] join with the members of this committee in voluntarily deferring” these experiments.⁹⁸ The Committee also recommended that an international conference could be held to create guidelines for moving forward.⁹⁹ This recommendation, as well as two others, was adopted by the National Academy of Sciences and the now-famous Asilomar conference followed in 1975.¹⁰⁰

Concerns about researcher and environmental safety, containment, and other related issues drove the effort, which was sensitive also to how the press and negative public perception could threaten the nascent field.¹⁰¹ A consensus, of sorts, arose around a set of guidelines to govern this type of research; and the first iteration of the NIH-sponsored, independent advisory committee to the Director of the NIH, the Recombinant DNA Advisory Committee (“RAC”), met the same day that meeting closed.¹⁰² It passed the Asilomar group’s statement as a provisional set of standards to govern federally funded research in this field.¹⁰³ The agreements reached at the Asilomar conference were not substantively relaxed until the end of 1978.¹⁰⁴

Perhaps one of the most immediate results of the moratorium and Asilomar conference was the allaying of fears in the public perception. The moratorium may well have helped calm nerves related to science-gone-wrong nightmare scenarios depicted in the media at the time. The Asilomar conference specifically included a significant number of media personnel in attendance under an agreement of non-publication until after the conference was over.¹⁰⁵ Immediate media coverage of the Asilomar conference recommendations was

96. See Berg, *supra* note 91.

97. Paul Berg et al., *Potential Biohazards of Recombinant DNA Molecules*, 71 PROC. NATL. ACAD. SCI. 2593, 2593-94 (1974).

98. *Id.*

99. *Id.*

100. See Berg, *supra* note 91.

101. Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. NATL. ACAD. SCI. 1981, 1981-84 (1975).

102. Nelson A. Wivel, *Historical Perspectives Pertaining to the NIH Recombinant DNA Advisory Committee*, 25 HUM. GENE THERAPY 19, 19 (2014).

103. See Donald S. Frederickson, *Asilomar and Recombinant DNA: The End of the Beginning*, in BIOMEDICAL POLITICS 258-98 (Kathi E. Hanna ed., 1991) (providing a terrific summary of the Asilomar group’s meeting and its aftermath).

104. *Id.* at 283.

105. *Id.* at 274.

positive.¹⁰⁶ In combination, this moratorium and deliberative conference may have helped pave the way for public and scientific acceptance of research for which there was significant safety, ethics, or other concern.

The moratorium on recombinant DNA research and the principles debated during the Asilomar conference have had long-standing impact. Elements were found in the original NIH guidelines that govern the use of recombinant DNA technology introduced in the 1990s.¹⁰⁷ The *NIH Guidelines* included prohibitions on certain types of research (e.g., cloning) and evolved over time as knowledge expanded around risks and benefits.¹⁰⁸ Additionally, over time the RAC introduced a formal review system for studies involving insertion of new genes into humans; RAC approval was required before the FDA would consider any gene therapy proposal.¹⁰⁹ Thus, what was a limitation driven purely by community consensus became a more refined, and narrowed limitation through an executive branch policy.¹¹⁰

The RAC continued to function for decades after its creation, but in 2019 NIH finalized its revised Guidelines.¹¹¹ In it, it eliminated human gene transfer protocol approval by the RAC and modified the committee's scope and focus to better align with the changing landscape of research, namely, that recombinant DNA research was no longer an emerging technology that required such strict oversight.¹¹² The story of the Asilomar conference, its recommendations, and the RAC's work decades later is a testament to the positive impact a voluntary moratorium can have to focus attention and resources toward a common goal to address ethical and safety questions that arise with emerging technology.

106. JOHN LEAR, RECOMBINANT DNA: THE UNTOLD STORY 115–18 (Crown Publishing, 1st ed., 1978).

107. Frederickson, *supra* note 103, at 283–84.

108. See Bernard Talbot, *Development of the National Institutes of Health Guidelines for Recombinant DNA Research*, 98 PUB. HEALTH REP. 361, 363–66 (1983) (discussing the history of NIH Guidelines on Recombinant DNA research into the early 1980s).

109. INST. MED., OVERSIGHT AND REVIEW OF CLINICAL GENE TRANSFER PROTOCOLS: ASSESSING THE ROLE OF THE RECOMBINANT DNA ADVISORY COMMITTEE 47 (Rebecca N. Lenzi et al. eds., 2014).

110. NAT'L INST. OF HEALTH, Vol. 5, No. 20, 1–26, GUIDE FOR GRANTS AND CONTRACTS DNA RECOMBINANT RESEARCH (1976); see also Meredith Wadman, *U.S. Biologists Adopt Cloning Moratorium*, 389 NATURE 319, 319 (1997) (providing another example of community consensus rising to limit research in the voluntary moratorium on cloning that research societies adopted following recommendations from the National Bioethics Advisory Committee in 1997).

111. NAT'L INST. OF HEALTH, NOTICE OF THE PUBLICATION OF REVISED NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (2019).

112. *Id.*

b. Germline Gene Editing

Heritable germline editing is the process by which a person's genes are edited in such a way that the change may be inherited by offspring.¹¹³ In March 2019, the NIH Director joined other 17 senior leaders from the biomedical and public advocacy communities across the globe in a commentary in *Nature* calling for a "moratorium on all clinical uses of . . . heritable genome editing" in humans to make genetically modified children.¹¹⁴ The authors of this proposed moratorium included Paul Berg of Asilomar fame (who was one of the primary drivers of that effort).¹¹⁵

The call for a moratorium was driven by several concerns:

- The announcement that CRISPR-Cas9 had been used by a scientist in the People's Republic of China to induce heritable changes in two human babies.
- Other scientists were aware of the effort in China and did not "take adequate measures to stop it."
- The authors cited and increased interest in genetically modifying humans.
- Apparent confusion or mixed signals sent by different agencies in the U.S. government related to human genetic editing.
- An absence of a proper mechanism to stimulate international dialogue on appropriate clinical germline editing.¹¹⁶

The NIH Director's action in joining his colleagues in *Nature* is different from the NIH activities discussed above because the NIH Director did not follow the

113. See Josephine Johnston, *The U.S. Must Do Some Heavy Lifting to Prepare for Heritable Genome Editing*, STAT NEWS (Sep. 4, 2020), <https://www.statnews.com/2020/09/04/heritable-genome-editing-will-require-heavy-lifting-us-policy/> (discussing heritable genome editing and how it challenges U.S. health and technology policy).

114. Eric Lander et al., *Adopt a Moratorium on Heritable Genome Editing*, 567 NATURE 165, 165 (2019).

115. See Frederickson, *supra* note 103, at 265–83 (discussing the Asilomar Conference and Paul Berg's influence).

116. Jocelyn Kaiser & Dennis Normille, *Embryo Engineering Study Splits Scientific Community*, SCI. MAG., May 2015 at 486.

paper with any specific executive policy limit on NIH research funding.¹¹⁷ Such a policy is not needed, of course, because there is already a legislative moratorium in place in the U.S. to prohibit this type of research.¹¹⁸ In December 2015, Congress barred the FDA from considering clinical trials “in which a human embryo is intentionally created or modified to include a heritable genetic modification.”¹¹⁹ This includes mitochondrial DNA transfer, used to address some inherited diseases, for which there is concern and controversy from those wishing to see cures.¹²⁰ The ban is broader than any NIH funding limitation, including the Dickey-Wicker Amendment.

A few other things are worth examining in the *Nature* piece. First, the authors emphasize that they are seeking a global consensus of when germline editing in humans will be permitted and a framework for the same.¹²¹ They state:

By “global moratorium”, we do not mean a permanent ban. Rather, we call for the establishment of an international framework in which nations, while retaining the right to make their own decisions, voluntarily commit to not approve any use of clinical germline editing unless certain conditions are met.¹²²

As such, a moratorium is proposed as a way to create some breathing space, room for the international community to seek consensus over when and how so fundamental a process as human germline editing should be allowed. Interestingly, like many moratoria before this, the authors lead with a focus on science.¹²³ They discuss first “technical considerations,” then “scientific considerations,” followed by “medical considerations,” for a total of about 22 paragraphs, and then they add three paragraphs on “societal, ethical and moral considerations.”¹²⁴ This is not to suggest the authors do not recognize the serious ethical concerns at issue. Paragraph one of the three-paragraph “ELSI” subpart states:

Irrespective of all of the above, clinical germline editing should not proceed for any application without broad societal consensus on the appropriateness of altering a fundamental aspect of humanity for a

117. NAT’L INST. OF HEALTH, *supra* note 111.

118. Emily Mullin, *Patient Advocates and Scientists Launch Push to Lift Ban on “Three-Parent IVF”*, STAT NEWS (Apr. 16, 2019), <https://www.statnews.com/2019/04/16/mitochondrial-replacement-three-parent-ivf-ban/>.

119. *Id.*

120. *Id.*

121. Lander et al., *supra* note 114.

122. *Id.*

123. *Id.* at 166.

124. *Id.*

particular purpose. Unless a wide range of voices are equitably engaged from the outset, efforts will lack legitimacy and might backfire.¹²⁵

But the rest of this section includes a distinctly consequentialist bent:

The societal impacts of clinical germline editing could be considerable. Individuals with genetic differences or disabilities can experience stigmatization and discrimination. Parents could be put under powerful peer and marketing pressure to enhance their children. Children with edited DNA could be affected psychologically in detrimental ways. Many religious groups and others are likely to find the idea of redesigning the fundamental biology of humans morally troubling. Unequal access to the technology could increase inequality. Genetic enhancement could even divide humans into subspecies.

Moreover, the introduction of genetic modifications into future generations could have permanent and possibly harmful effects on the species. These mutations cannot be removed from the gene pool unless all carriers agree to forgo having children, or to use genetic procedures to ensure that they do not transmit the mutation to their children.¹²⁶

As illustrated by this example, ethics can and may need to be the driving force behind a moratorium, but oftentimes questions about safety, technical feasibility, and physical risks rise to the fore and become a dispositive way to side-step more complex and, sometimes, seemingly intractable problems.

c. Rejected Moratorium on Xenotransplants

Not all calls for moratoria are successful. In 1998, Professor Fritz Bach at Harvard Medical School and others called for a moratorium on clinical xenotransplant trials pending public debate on the risks.¹²⁷ Xenotransplantation is the transplant of organs from one species to another.¹²⁸ Research in this area dates back to the 17th century but in modern times, xenotransplantation attempts were underway starting in the mid-1960s.¹²⁹ Over decades, researchers

125. *Id.* at 167.

126. *Id.*

127. Interview with Fritz Bach, Professor, Harvard Med. Sch. (transcript available at <https://www.pbs.org/wgbh/pages/frontline/shows/organfarm/interviews/bach.html>).

128. *Xenotransplantation*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccines-blood-biologics/xenotransplantation> (last visited May 1, 2021).

129. *History of Xenotransplantation Experiments*, PBS FRONTLINE, <https://www.pbs.org/wgbh/pages/frontline/shows/organfarm/etc/cron.html> (last visited Apr. 8, 2021).

attempted to use organs of animals as replacements for missing or failing human organs.¹³⁰ For example, in 1963 Dr. Keith Reemtsma transplanted 13 chimpanzee kidneys into 13 humans; most died shortly afterwards but one patient lived for another nine months with medical assistance.¹³¹ In 1995, Dr. Suzanne Ilstaad transplanted bone marrow from a baboon into a patient living with AIDS.¹³² Baboon stem cells are resistant to AIDS; researchers hoped the transplantation would help the patient's bone marrow produce AIDS-fighting immune cells.¹³³ The attempt was not successful.¹³⁴

Professor Bach's call for a moratorium by the FDA however fell on deaf ears. FDA did not institute a moratorium, perhaps because a year earlier, in 1997, the FDA reacted to a researcher's alarming discovery; Professor Robin Weiss discovered a virus embedded in every pig cell, referred to as "PERV," could infect human cells.¹³⁵ Pig organs and cells had long been used in xenotransplantation experiments, so Dr. Weiss' discovery was distressing. In response, the FDA did place a moratorium on all clinical trials until researchers could prove they had developed procedures to detect low levels of PERV virus infection.¹³⁶ The FDA was satisfied by January 1998 and lifted the moratorium.¹³⁷

However, Professor Bach still believed there should be a moratorium. He stated:

[W]e should have a moratorium to allow the public discussion, to allow the public to be informed – as many people as possible – and to have segments of that public participate in what is known as public engagement, public deliberation, to help guide us in how to play. And as soon as they've helped us and we can define the conditions of how to proceed, then we should drop the moratorium, and, if we're ready to do it, move ahead with xenotransplantation.¹³⁸

Professor Bach was particularly frustrated with the FDA's existing review process. He argued that existing FDA open hearings were inadequate to address public concerns and hear public input:

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.*

138. Interview, *supra* note 127.

[A] person would have to know the hearing is taking place, pay their way to Bethesda, Maryland, and then try to get time to speak. I went down there. I think I'm a rather prominent individual in xenotransplantation, and I was told that I couldn't speak from the podium, that I should speak from the floor, and keep it very brief. That's very difficult; it's not a way to get public participation. There's been a lot of coverage in the news, but it hasn't been in a way to catch the public's attention. If you ask the vast majority of people, they still say, "What are you talking about?"¹³⁹

Professor Bach's unsuccessful drive to have a moratorium to address public concerns regarding xenotransplantation is informative in several respects. First, executive policy moratoria are difficult to institute by non-executive branch actors. Professor Bach was calling for an executive policy moratorium by the FDA although he held no particular influence or formal position at the agency. Second, voluntary moratoria may be successfully instituted when advocated by the right persons. When the Director of the NIH and researchers from countries around the globe called for a voluntary moratorium on heritable human gene editing, the call was effective due to the prominence of the authors combined with the nature of the moratorium – it was voluntary.¹⁴⁰ Third, moratoria may be more likely to be instituted where government or community action has not already begun. The FDA had set a moratorium that was lifted the same year Professor Bach called for a new one. Meanwhile, the FDA had already undertaken a review and public feedback process, one in which reasonable minds can differ when analyzing the extent the moratorium was sufficient or appropriate for the issue.

V. CONCLUSION

In 2010, the Presidential Commission for the Study of Bioethical Issues did not recommend a moratorium for any applications of the emerging technology of synthetic biology.¹⁴¹ The Commission members did offer an ethical framework for assessing emerging technologies that included recommendations about safety and feasibility and they emphasized transparency, public engagement, and accountability.¹⁴² This framework provided an effective

139. *Id.*

140. Lander, *supra* note 114; Wadman, *supra* note 110.

141. PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES V (2010) (finding no reason to endorse additional federal regulations or a moratorium on synthetic biology, and instead recommending an ongoing review of possible developments, risks, opportunities and oversight grounded in ethical principles of public beneficence, responsible stewardship, intellectual freedom and responsibility, democratic deliberation, and justice and fairness).

142. *Id.* at 4, 6, 9, 10.

method to manage public concerns and political; concerns.¹⁴³ Further, the lack of moratorium helped assure the continuation of scientific research into the emerging technology.

Calls for moratoria in biomedical research are not all that common, but they recur with some regularity. Moratoria can range from voluntary, community-based action to mandatory, executive policy or legislatively-based requirements. The examples discussed here illustrate a range of approaches. What do they suggest about why moratoria are established in the first place?

Almost all moratoria are inspired by a public fear or a need to preempt public fear of new techniques or emerging technologies. Given this motivation, it is important to recognize that the parameters, timing, and source of a moratorium can have profound impact on the public's perception of the technique or technology, and further, impact the ease with which the moratorium may be unwound. An approach that is policy-based, rather than legislative, is more flexible and essentially beholden to fewer constituents. Thus, it may be easier to change or refine over time as ethical concerns abate or wane. However, as the examples described here reflect, even these efforts may be difficult to unwind as circumstances change.

Further, moratoria can, and almost always are, to some degree, motivated by politics and the desire to respond to public concerns that may be fractured and inconsistent. In many instances, partisan political and social positions can drive government actors to adopt moratoria that change with the coming and going of presidential administrations and congressional sessions. But often, once adopted as a legislative mandate, moratoria may remain in place even after the scientific community and emerging technology may have matured. This is because removing them is often more difficult than avoiding them in the first instance.

143. Amy Gutmann, *The Ethics of Synthetic Biology: Guiding Principles for Emerging Technologies*, 41 HASTINGS CTR. REP. 17, 22 (2011); see also PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 141, at 152–53.

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MORATORIA IN SCIENTIFIC RESEARCH

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Appendix – Selected MoratoriaThe below chart provides a selection of moratoria on scientific research activities. These moratoria may be based on statutory requirements, executive policy, or community consensus. The chart is not intended to be a complete list of all moratoria.

Throughout this chart the following acronyms are used:

- EOP: Executive Office of the President
- HHS: Department of Health and Human Services
- IVF: In Vitro Fertilization
- NIH: National Institutes of Health

Year	Subject	Origin & Structure	Scope	Timeline	Type	Penalty
1973	Stem Cell Research ¹⁴⁴	HHS (Regulatory)	Prohibited NIH from funding research using live human embryos.	1973 – 1975	Mandatory	Loss of Funds
1974	Stem Cell Research ¹⁴⁵	Congress (Statutory)	Moratorium on federally funded clinical research on embryos and embryonic tissue, including research on IVF, infertility, and prenatal diagnosis, until national guidelines could be established.	1974- Present	Mandatory	Loss of Funds
1974	Fetal Tissue ¹⁴⁶	Congress (Statutory)	Prohibited research on a fetus from an elective abortion until the National Commission for Protection of Human Subjects in Biomedical and Behavioral Research completed its report to Congress in 1975.	1974 – 1975 ¹⁴⁷	Mandatory	Loss of Funds

144. Christopher R. Cogle et al., *An Overview of Stem Cell Research and Regulatory Issues*, 78 MAYO CLINIC PROC. 993, 999 (2003); THE PRESIDENT’S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH (2004), https://bioethicsarchive.georgetown.edu/pcbe/stemcells/chapter2_mon_research.html#edn1 (last visited May 18, 2021).

145. National Research Act, Pub. L. No. 93-348, § 213, 88 Stat. 342 (passed by the 93rd Congress as H.R. 7724, July 12, 1974).

146. *Id.* § 202(3)(b).

147. In effect, this moratorium continued until 1993.

Year	Subject	Origin & Structure	Scope	Timeline	Type	Penalty
1975	Recombinant DNA Experimentation ¹⁴⁸	Community (Consensus)	A moratorium on certain recombinant DNA experiments.	1975	Voluntary	Community Censure
1985	Fetal Tissue ¹⁴⁹	Congress (Statutory)	A moratorium on issuing waivers for fetal research; only research involving minimal risk or for therapeutic purposes.	1985 – 1988	Mandatory	Loss of Funds
1988	Fetal Tissue ¹⁵⁰	HHS (Regulatory)	A moratorium on transplantation research with fetal tissue from induced abortions until the Human Fetal Tissue Transplantation Research Panel issued its report – which it did in December 1988. HHS extended the moratorium afterwards.	1988 – 1993	Mandatory	Loss of Funds
1996	Dickey Wicker Amendment ¹⁵¹	Congress (Statutory)	Prohibits HHS using appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero.	1996 – Present	Mandatory	Loss of Funds; Other

148. See Berg, *supra* note 91, at 291.

149. Health Research Extension Act, Pub. L. No. 99-158, § 498, 99 Stat. 820 (1985).

150. *Setting the Stage: Fetal Research, Fetal Tissue Research, and Historical Timeline of Regulation and Legislation*, in INST. OF MED. CONFERENCE COMM. ON FETAL RESEARCH AND APPLICATIONS, (Nat'l Acad. Press 1994) (ebook); Federal Funding of Fetal Tissue Transplantation Research, 58 Fed. Reg. 7457 (Feb. 5, 1993) (memorandum from President Clinton to the Secretary of Health and Human Services lifting the moratorium on federal funding of fetal tissue research).

151. Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

Year	Subject	Origin & Structure	Scope	Timeline	Type	Penalty
2001	Stem Cell Research ¹⁵²	EOP (Executive Policy)	Ban on federal funding for research using ES cell lines (embryos) derived after August 9, 2001.	2001 – 2009	Mandatory	Loss of Funds
2005	Human Cloning ¹⁵³	United Nations (Consensus)	Bans human cloning as incompatible with human dignity and the protection of human life.	2005– Present	Voluntary	None
2012	Avial Influenze ¹⁵⁴	Community of Scientists (Consensus)	A moratorium on any research involving highly pathogenic avian influenza H5N1 viruses leading to the generation of viruses that are more transmissible in mammals.	1/20/2012 – 2/1/2013	Voluntary	None
2015	Human-Animal Chimera ¹⁵⁵	NIH (Regulatory)	Prohibition on human-animal chimeras and inheritable genome editing in human embryos research funding.	9/2015 – Present	Mandatory	Loss of Funds
2015	Heritable Human Gene Editing ¹⁵⁶	Congress (Statutory)	A federal ban that prohibited the use of federal funds for research involving genetically modifying human embryos, which includes MRT.	9/2015 – Present	Mandatory	Loss of Funds

152. President George W. Bush, Address on Stem Cell Research at the Bush Ranch (Aug. 9, 2001) (transcript available at <https://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>); NAT'L INST. OF HEALTH, NOTOD-02-005, NOTICE OF CRITERIA FOR FEDERAL FUNDING OF RESEARCH ON EXISTING HUMAN EMBRYONIC STEM CELLS AND ESTABLISHMENT OF NIH HUMAN EMBRYONIC STEM CELL REGISTRY (2001).

153. *General Assembly Approves Declaration Banning All Forms of Cloning*, U.N. NEWS (Mar. 8, 2005), <https://news.un.org/en/story/2005/03/131092-general-assembly-approves-declaration-banning-all-forms-cloning>.

154. Ron A.M. Fouchier et al., *Pause on Avian Flu Transmission Studies*, 481 NATURE 443, 443 (2012).

155. NAT'L INST. OF HEALTH, NOT-OD-15-158, NIH RESEARCH INVOLVING INTRODUCTION OF HUMAN PLURIPOTENT CELLS INTO NON-HUMAN VERTEBRATE ANIMAL PRE-GASTRULATION EMBRYOS (2015).

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Year	Subject	Origin & Structure	Scope	Timeline	Type	Penalty
2015	Chimpanzees for Biomedical Research ¹⁵⁷	NIH (Executive Policy)	Prohibits use of chimpanzees in NIH funded research.	2015 – Present	Mandatory	Loss of Funds
2019	Heritable Human Gene Editing ¹⁵⁸	NIH Director and scientists in seven countries	A moratorium on all clinical uses of human germline editing (changing heritable DNA in sperm, eggs or embryos) to make genetically modified children.	2019	Voluntary	Community Censure
2019	Fetal Tissue Research ¹⁵⁹	EOP, HHS (Executive Policy)	Fetal tissue research ban on scientists at NIH and on funding of new and renewed extramural research grants.	June 5, 2019 – Present.	Mandatory	Loss of Funds

157. Francis S. Collins, *NIH Will No Longer Support Biomedical Research on Chimpanzees*, NAT'L INST. OF HEALTH (Nov. 17, 2015), <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-will-no-longer-support-biomedical-research-chimpanzees#:~:text=On%20June%2016%2C%202015%2C%20the,it%20could%20harm%20the%20animal.>

158. Eric Lander et al., *supra* note 114; Carrie D. Wolinetz & Francis S. Collins, *NIH Pro Germline Editing Moratorium*, 567 NATURE 175, 175 (2019) (endorsing the international moratorium proposed by Eric Lander and other scientists within the international community).

159. Meredith Wadman, *Trump Administration Restricts Fetal Tissue Research*, SCIENCE (Jun. 5, 2019), <https://www.sciencemag.org/news/2019/06/trump-administration-restricts-fetal-tissue-research>; NAT'L INST. OF HEALTH, NOT-OD-21-111, UPDATE ON CHANGES TO NIH REQUIREMENTS REGARDING PROPOSED HUMAN FETAL TISSUE RESEARCH (2021).