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**GERM-LINE GENE EDITING AND CONGRESSIONAL REACTION IN CONTEXT: LEARNING FROM ALMOST 50 YEARS OF CONGRESSIONAL REACTIONS TO BIOMEDICAL BREAKTHROUGHS**

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*About the Article*

*On December 18, 2015, President Obama signed into law a policy rider forestalling the therapeutic modification of the human germ line. The rider, motivated by the science's potential unethical ends, is only the most recent instance in which the legislature cut short the ongoing national conversation on the acceptability of a developing science. This essay offers historical perspective on what bills were proposed and passed surrounding four other then-developing scientific breakthroughs—Recombinant DNA, in vitro fertilization, Cloning, Stem Cells—to better analyze how Congress is, and should, regulate this exciting and promising science.*

# GERM-LINE GENE EDITING AND CONGRESSIONAL REACTION IN CONTEXT: LEARNING FROM ALMOST 50 YEARS OF CONGRESSIONAL REACTIONS TO BIOMEDICAL BREAKTHROUGHS

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## I. INTRODUCTION

On December 18, 2015, President Obama signed into law a policy rider forestalling the therapeutic modification of the human germ line by prohibiting the Food and Drug Administration (FDA) from considering such applications.[1] Triggered by the unprecedented discovery of novel genome-editing tools and their application to the human embryo,[2] this congressional reaction cut short the ongoing national conversation on the very acceptability of such interventions. These conversations included, most significantly, the National Academies-sponsored *International Summit on Human Gene Editing* and the Consensus Study of the National Academy of Medicine on the *Scientific, Medical, and Ethical Considerations of Human Gene Editing*.[3] The rider was then renewed the following year.[4] Perhaps more significantly, the statute in question also undermines current efforts of the FDA to adjudicate germ line-modifying technologies to prevent mitochondrial DNA diseases.[5] Thus far, what little analysis there has been of this rider it has focused on the present. In this essay we seek to provide the long view. The rider is but the latest example of Federal legislative and regulatory

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[1] Consolidated Appropriations Act of 2016, Pub. L. No. 114-92, § 749, 129 Stat. 2242, 2283 (2015).

[2] *See, e.g.*, Martin Jinek et al., *A Programmable Dual RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCI. 816, 816–21 (2012); Puping Liang et al., *CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes*, 6 PROTEIN CELL 363, 363 (2015).

[3] *See* Press Release, The National Academies of Sciences, Engineering, and Medicine, On Human Gene Editing: International Summit Statement (Dec. 3, 2015), http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12032015a; *Human Gene Editing: Scientific, Medical and Ethical Considerations*, NAT'L ACADS. SCI., ENGINEERING & MED., https://www8.nationalacademies.org/cp/projectview.aspx?key=49750 (last accessed Aug. 8, 2016).

[4] Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, § 736 (2016).

[5] Meeting Notice, 78 Fed. Reg. 79,699, 79,699–700 (Dec. 31, 2013) (U.S. Food & Drug Admin., February 25-26, 2014: Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting).

reaction to biomedical breakthroughs. By discussing the history of federal reaction to four other such breakthroughs (Recombinant DNA, IVF, Cloning, Stem Cells), a tale that lasts almost 50 years, we can better situate and understand the current debate and congressional action and better predict where we may go next. We exhaustively reviewed congressional reactions—Bills proposed, passed, or important public statements by members of Congress—and summarize that history in this essay.

II. RECOMBINANT DNA (01/01/1969 – 12/31/1978)

While our story begins with Recombinant DNA, the national scientific landscape of the middle of the 20th century can be contextualized by calls for transparency. That only came in the form of the National Research Act of 1974,[6] which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[7] The Act would not cover the genetic sciences of recombinant DNA, so when scientific pursuit thereof began in earnest, there were, unsurprisingly, calls for its governmental oversight.[8]

The first successful production of recombinant DNA appeared in publications in 1972 and 1973 by multiple scientists across the United States.[9] In light of its potential applications, there were immediate calls for its governance and oversight.[10] The initial attempts to regulate recombinant DNA research did not take place at the federal level; rather, states and municipalities began debating whether they wanted to permit such research to continue in their borders. Maryland and New York passed statewide legislation governing research institutions in its borders, while California, Illinois, Massachusetts, New Jersey, and Wisconsin debated similar measures.[11] Berkeley, CA, Emeryville, CA, Amherst, MA, Cambridge, MA, Waltham, MA, and Princeton, NJ were the four municipalities to pass regulations that oversaw recombinant DNA activities via already existing or newly created local health boards or public officials.[12] Ann Arbor, MI discussed but did not enact such laws.[13]

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[6] National Research Act, Pub. L. No. 93-348, 88 Stat. 342, 42 U.S.C. § 289 (1974).

[7] *Id.* §§ 201–215, 289.

[8] *See infra* note 14.

[9] David A. Jackson, Robert H. Symons & Paul Berg, *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and the Galactose Operon of Escherichia Coli*, 69 PROC. NAT'L ACAD. SCI. U.S. AM. 2904, 2904–09 (1972); Janet E. Mertz & Ronald W. Davis, *Cleavage of DNA by R 1 restriction endonuclease generates cohesive ends*, 69 PROC. NAT'L ACAD. SCI. U.S. AM. 3370, 3370–74 (1972); Peter E. Lobban & A.D. Kaiser, *Enzymatic end-to end joining of DNA molecules*, 78 J. MOLECULAR BIOLOGY 453, 453–71 (1973); Stanley N. Cohen, Annie C. Y. Chang, Herbert W. Boyer & Robert B. Helling, *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. U.S. AM. 3240, 3240–44 (1973).

[10] Sheldon Krimsky & David Ozonoff, *Recombinant DNA Research: The Scope and Limits of Regulation*, 69 AM. J. PUB. HEALTH 1252, 1252 (1979).

[11] *Id.* at 1255. *See also* SUSAN WRIGHT, MOLECULAR POLITICS 222 (1994).

[12] Krimsky & Ozonoff, *supra* note 10, at 1255; WRIGHT, *supra* note 11, at 510.

[13] John E. Barkstrom, *Recombinant DNA and the Regulation of Biotechnology: Reflections on the Asilomar Conference, Ten Years Later*, 19 AKRON L. REV. 1, 82 (1985) (citing

Though national legislation was not passed immediately, this in no way indicated a lack of national interest. Rather, national action needed consensus from the scientific community. For that reason, biologists, lawyers, physicians, government officials, and journalists [14] met at the Asilomar Conference on Recombinant DNA in February 1975 to draw up research guidelines. Believing that "[conference participants] were making public policy, and [that] they were making it in private,"[15] Senator Ted Kennedy (D-MA) offered Congress' only legislative reaction in late 1975. The bill,[16] cosponsored by two Republicans, Richard Schewiker (R – PA) and Jacob Javits (R – NY), sought to form a commission to study scientific breakthroughs, including recombinant DNA advances.[17] While it failed to pass the Senate in 1975, it was not dead just yet. The NIH Director's Advisory Committee met in February 1976, in which "representatives of various public interest groups, representatives of various factions within the scientific community, and other interested parties" discussed the recently drafted NIH guidelines.[18] After this meeting, Senator Kennedy's bill passed the Senate in May 1976 but died in the House.[19]

The uptick in Congressional attention to recombinant DNA towards the end of the 1970s was likely precipitated by the issuance of the NIH guidelines regarding such research in June of 1976.[20] While meant as a compromise, the guidelines did have not the calming effect intended. Rather, it brought to light that this technology was no longer theoretical frontier science, but had gained practical usage necessary to support government intervention and regulation. In the wake of the guideline's issuance, a number of legislators found them insufficient and sought to modify them statutorily. Moreover, as the Hastings Center argued at the time, an abbreviated timeline between preliminary discussions and promulgated guidelines—4 months—did not permit sufficient public input, even if the actual substance of the guidelines were satisfactory.[21] Subsequent dissatisfaction may therefore have been caused as much by procedural as substantive discontent.

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CAMBRIDGE, MASS., REV. ORD. ch. 1i, art. 1I, § 11-7 (1977); PRINCETON, N.J., REV. ORD. ch. 26A, §§ 1-13 (1978); AMHERST, MASS., BYLAWS Art. III, § 10 (1978); WALTHAM, MASS., REV. ORD. ch 22, §§ 22-1, 22-2 (1981); BERKELEY CAL., ORD. 500-N.S. (1977); EMERYVILLE, CAL., RESOLUTION 77-39 (1977). *See also* Krimsky & Ozonoff, *supra* note 10, at 1256).

[14] These individuals included "journalists and government officials." Paul Berg, *Meetings That Changed the World: Asilomar 1975: DNA Modification Secured*, 455 NATURE 290, 290 (2008). *See also The Paul Berg Papers: Recombinant DNA Technologies and Researchers' Responsibilities, 1973-1980*, NAT'L LIB. MED., NAT'L INSTS. HEALTH, https://profiles.nlm.nih.gov/CD/Views/Exhibit/narrative/dna.html (discussing the presence of an unknown number of journalists and two lawyers in attendance). Berg was the organizer of the conference with, obviously, intimate knowledge of its participants.

[15] Barbara J. Culliton, *Kennedy: Pushing for More Public Input in Research*, 188 SCI. 1187, 1188 (1975) (quoting Sen. Kennedy).

[16] S. 2515, 94th Cong. (1975).

[17] *Id.*

[18] Daniel Callahan, *Recombinant DNA: Science and the Public*, 7 HASTINGS CEN. REP. 20, 20–21 (1977).

[19] *See President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research Act (1976; 94th Congress S. 2515)*, GOVTRACK.US, https://www.govtrack.us/congress/bills/94/s2515 (last accessed June 10, 2017).

[20] Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902 (July 7, 1976).

[21] *See* Callahan, *supra* note 18, at 21.

From the time the guidelines passed through the end of 1976 through 1978, only 14 unique bills were proposed in either House (3 were repeatedly considered with nominal changes).[22] Each was proposed by a Democratic lawmaker, and all but one enjoyed significant Democratic co-sponsorship (the lone exception only had one co-sponsor, a Republican).[23]

Some of bills called for commissions to study scientific issues—neither limited to nor prioritizing recombinant DNA over other issues to be studied.[24] The proposed commissions varied in small but important ways, including size and appointment.[25] Other bills called for a regulatory framework to oversee recombinant DNA research projects via licensure and or grant programs under the NIH's direction.[26] These proposed schemes included penalties for violations, ranging in criminality, financial fines, and required scienter, or underlying mental state.[27] Interestingly, multiple bills whose primary purpose was a regulatory framework included provisions to create similar commissions.[28]

Both Houses held hearings on a few of the bills proposed, and both the House and Senate held general hearings in 1977 to inquire about the overall status of Recombinant DNA research, the House in March, April, May, and September,[29] the Senate in November.[30] Ultimately, though,

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[22] *See* Table 1.

[23] *Id.* (noting H.R. 4849).

[24] *See* H.R. 4232, 114th Cong. (2015); S. 945. 114th Cong. (2015).

[25] *Compare, e.g.*, H.R. 4232, 114th Cong. (2015) (proposing a temporary one-year commission to study recombinant DNA) *with* S. 945, 114th Cong. (2015) (proposing a 27-month commission to study recombinant DNA), *and* H.R. 7897, 95th Cong. (1977) (proposing a 2-year commission), *and* S. 1217, 114th Cong. (2015) (establishing the Recombinant DNA Safety Regulation Commission), *and* H.R. 10453, 93rd Cong. (1973) (establishing a commission for the study of recombinant DNA activities composed of 17 people total, appointed by the Secretary of Health, Education and Welfare).

[26] *See* S. 945, 114th Cong. (2015); H.R. 4759, 108th Cong. (2003); H.R. 4849, 112th Cong. (2011); H.R. 5020, 113th Cong. (2013); H.R. 6158, 114th Cong. (2015); H.R. 7418 96th Cong. (1979); H.R. 7897, 95th Cong. (1977);

[27] *See, e.g.*, S. 621, 114th Cong. (2015) (imposing a fine of up to $10,000 and one year's imprisonment); H.R. 3191 111th Cong. (2009) (strict liability and criminal penalties); H.R. 4759, 108th Cong. (2003) (imposing a $1,000 fine); H.R. 6158, 114th Cong. (2016) (imposing a $5,000 fine for violation and potential imprisonment depending on willfulness); H.R. 7418, 89th Cong. (1967) (imposing a $50,000 fine for violation and potential imprisonment depending on willfulness).

[28] *See* S. 945, 114th Cong. (2015); H.R. 4849, 112th Cong. (2011).

[29] *See generally Science Policy Implications of DNA Recombinant Molecular Research: Hearing Before the Subcomm. on Science, Research & Technology of the H. Comm. on Science, Space and Technology*, 95th Cong. (1977).

[30] *See generally Regulation of Recombinant DNA Research: Hearings Before the Subcomm. on Science, Technology and Space of the S. Comm. on Commerce, Science and Transportation*, 95th Cong. (1977).

none of the above measures regarding recombinant DNA were signed into law in the immediate aftermath of the NIH's rules change.[31]

It can be said that the legislative response to the evolution and progression of recombinant DNA was relatively modest—even muted—in light of a hugely impactful scientific breakthrough. The obvious question is why? It may have been in part because the ethical concerns were not especially significant, or that those in a position to affect change simply did not understand the scientific implications. A different explanation is that the science's significant promise was already apparent to the scientific community. For example, by 1978, scientists had discovered how to use recombinant DNA-based science to isolate and produce human insulin, replacing more expensive animal sourcing.[32] Thus, despite the ethical concerns made known by several prominent legislators, the lack of demand for regulation—potentially aided by the tangible advantages of this technology—may have outweighed the ethical considerations. Whatever the cause, it is fair to say that the ethical concerns of recombinant DNA never gained sufficient critical mass to persuade a majority of Congresspersons.

III. IVF (01/01/1978 – 12/31/1982)

In 1969, Robert Edwards, Patrick Steptoe and their research team published a report that they fertilized human ova, the first steps towards in vitro fertilization.[33] After that initial study was published, Edwards published an article on the ethical implications of his research to assuage those who found the science morally questionable.[34] After publishing these two articles, however, there was little hoopla regarding the science of IVF, arguably because it appeared as if little work was being done in the field across the scientific community otherwise. The lack of work, though, was due in part to the United Kingdom's Medical Research Council "declin[ing] on ethical grounds" to use public funding for IVF research in 1971.[35] It is arguable that these ethical suspicions continued far into the history of IVF; indeed, some have speculated that this is what delayed the awarding Edwards the Nobel Prize until 2010—only Edwards would receive it, as Steptoe had passed and the award cannot be given posthumously.[36]

The two scientists resurfaced with extraordinary advances in the field 8 years later. In 1976, Edwards and Steptoe published an article saying they had successfully impregnated a woman

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[31] *See* Table 1.

[32] Press Release, Genentech, First Successful Laboratory Production of Human Insulin Announced (Sept. 6, 1978), http://www.gene.com/media/press-releases/4160/1978-09-06/first-successful-laboratory-production-o.

[33] Robert G. Edwards, Barry D. Bavister & Patrick C. Steptoe, *Did fertilization occur?*, 221 NATURE 981, 981–82 (1969).

[34] *See generally* Robert G. Edwards & David. J. Sharpe, *Social Values and Research in Human Embryology*, 231 NATURE 87 (1969).

[35] Martin H. Johnson et al., *Why the Medical Research Council Refused Robert Edwards and Patrick Steptoe Support for Research on Human Conception in 1971*, 25 HUM. REPROD. 2157, 2167 (2010).

[36] *See, e.g.*, *id.*; Nicholas Wade, *Pioneer of In Vitro Fertilization Wins Nobel Prize*, N.Y. TIMES, Oct. 4, 2010, http://www.nytimes.com/2010/10/05/health/research/05nobel.html?pagewanted=all&_r=0 ("The Swedish committee is believed to avoid controversial people and issues. The ethical objections to in vitro fertilization may have been one reason for the long delay. Scientists speculated that Dr. Edwards's political views — he has been a committed socialist — may have been another.").

using in vitro fertilization, though it was an ectopic pregnancy.[37] Two years later, on July 25, 1978, Louise Brown, the first IVF child, was born in Oldham, UK.[38] IVF eventually crossed the pond to the United States in 1981, given Ms. Brown's conception in 1977, we review Congressional reaction spanning the 95th, 96th, and 97th Congresses, or 1977–1982.

In general most of the Congressional reaction to IVF's breakthrough was not focused on IVF, but instead represented Congressional reaction to the *Roe v. Wade*[39] decision of 1973. Throughout these three sessions of Congress, 32 bills were proposed that mentioned in vitro fertilization or any synonymous concept (such as "test tube baby").[40] Of those 32 bills, 30 directly spoke to the question of what defines personhood in response to *Roe*.[41] 20 of the House's 26 bills in question proposed a Constitutional amendment guaranteeing the right to life as it relates to the unborn.[42] Another proposed making 1982 the "Year of the Unborn," while others aimed to identify life at conception without a constitutional amendment. The Senate did not fare any better: All 6 of its bills that related to IVF called for the recognition of life from conception, 2 of which proposed a constitutional amendment.[43]

Only 2 House bills discussed IVF without a mention of *Roe* or abortion: one 1978 bill proposed a commission to study ethical problems in biomedical and behavioral research, including but not limited to IVF,[44] and one 1981 concurring resolution "President to take certain actions in support of family planning both in the United States and abroad," which simply mentioned IVF as a possibility for families struggling to have children.[45] Both bills were put forward by Democratic sponsors—Rep. Paul Rogers and Rep. Sam Gejdenson, respectively—and yielded primarily, though not exclusively, Democratic co-sponsors.[46] Neither passed.[47] Admittedly, this was more attention given to IVF than had been given by the Senate—none at all.

The sparse legislative attention paid to IVF did not track the large scholarly attention paid to it. Calls for congressional intervention over IVF came from influential bioethicists, including Leon

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[37] Robert G. Edwards & Patrick C. Steptoe, *Reimplantation of a Human Embryo with Subsequent Tubal Pregnancy*, 307 LANCET 880, 880–82 (1976).

[38] Martin Hutchinson, *'I helped deliver Louise'*, BBC (1:13 p.m. EST, Jul. 24, 2003), http://news.bbc.co.uk/2/hi/health/3077913.stm.

[39] 410 U.S. 113 (1973).

[40] *See* Table 2.

[41] *See id.*

[42] *See id.*

[43] *See id.*

[44] H.R. 13662, 95th Cong. (1978).

[45] H. Con. Res 206, 97th Cong. (1981).

[46] H.R. 13662, 95th Cong. (1978); H. Con. Res 206, 97th Cong. (1981).

[47] *See* Table 2.

Kass,[48] Paul Ramsey,[49] Father Richard McCormick.[50] But given the scholarly cries, we must ask *why* there was so little congressional interest, and what, if any, implications could personhood bills have had on IVF should they have been enacted?

The answer lies somewhere in the history of IVF oversight. In the 1970s, human in vitro fertilization research required the approval of the Ethics Advisory Board (EAB), created in 1978 to sit under the Department of Health, Education and Welfare (now the Department of Health and Human Services).[51] In 1979, the EAB published guidelines requiring IVF research be conducted only after securing the Board's approval.[52] Moreover, approval required that informed consent for the gamete's use be given, that the research was "not reasonably attainable by other means," and that embryos not be maintained outside the body longer than fourteen days after fertilization.[53]

Ironically, however, due to miscommunications regarding whether the EAB would be reconstituted under to the newly formed President's Commission on Biomedical and Behavioral Research (PCBBR), the funds to be allocated for the EAB were transferred to the PCBBR "with the understanding that the role of ethics advising would also be transferred."[54] Congress, though, in an era of "constrained federal budgets [and] aggressive deregulation," did not follow through.[55] Despite unsuccessful attempts to reconstitute the then-defunct EAB in the 1980s, the Board remained dormant while the guidelines requiring its approval remained on the books. Thus, no further IVF research could be performed: the Board's approval was required but was impossible to obtain. This odd turn of events created a *de facto* moratorium on federally funded embryo research. Those who felt IVF embryo research was unethical were satisfied; they had no need to propose legislation making such research statutorily prohibited.

Bills aimed at *Roe v. Wade*, if passed, however, would have impacted IVF research. These bills, which sought to define life as beginning at conception, would have categorized fertilized ova used in IVF research as lives.[56] IVF research almost always involves freezing or manipulating

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[48] *See generally* Leon R. Kass, *Babies by Means of in Vitro Fertilization: Unethical Experiments on the Unborn?*, 285 NEW ENG. J. MED. 1174, 1174–79 (1971).

[49] *See generally* Paul Ramsey, *Shall We Reproduce I: The Medical Ethics of In Vitro Fertilization*, 220 J. AM. MED. ASS'N 1346 (1972); Paul Ramsey, *Shall We Reproduce II: Rejoinders and Future Forecast*, 220 J. AM. MED. ASS'N 1480 (1972).

[50] *See generally* Richard A. McCormick, *Fetal Research, Morality, & Public Policy*, 5 HASTINGS CEN. REP. 26, 26–31 (1975).

[51] *See Former Bioethics Commissions*, THE PRESIDENT'S COUNCIL ON BIOETHICS, https://bioethicsarchive.georgetown.edu/pcbe/reports/past_commissions/.

[52] *See generally* ETHICS ADVISORY BOARD, U.S. DEP'T HEALTH, EDUCATION & WELFARE, REPORT AND CONCLUSIONS: SUPPORT OF RESEARCH INVOLVING HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER (1979).

[53] *Id.* at 106, 107.

[54] J. BENJAMIN HURLBUT, EXPERIMENTS IN DEMOCRACY: HUMAN EMBRYO RESEARCH AND THE POLITICS OF BIOETHICS 77 (2017).

[55] *Id.* at 109.

[56] *See* Jonathan F. Will, Eli Y. Adashi & I. Glenn Cohen, *When Potential Does Not Matter: What Developments in Cellular Biology Tell Us About the Concept of Legal Personhood*, 13 AM. J. BIOETHICS 38, 38–40 (2013). As well, many of these bills do not offer detailed descriptions of "conception" or "fertilization." *See, e.g.*, H.R. 392, 97th Congr. (1981) (not offering any definition beyond "the moment of fertilization"); S. 2148, 97th Congr. (1981) (offering no definition of what constitutes "conception").

these embryos; scientists performing the experiments would be manipulating humans under such a definition.[57] Therefore, such personhood legislation would have its intended effect by curtailing abortion, but it may also have led to unintended secondary effects of barring IVF-related research or IVF itself. The degree to which these secondary effects materialized would have depended on the degree to which the enforcing agency or agencies read the laws to be strictly related to abortion as opposed to covering any fertilized ova. Additionally, had such personhood legislation passed, it might have proved politically divisive, splitting those who were against abortion into pro- and anti-IVF camps. We arguably saw a similar dynamic in the last several years in so-called "personhood" initiative, such as the one in Mississippi.[58]

There are two lessons to be learned from a study of in vitro fertilization and Congress' reaction thereof, one relating to Congress generally, and one relating to Congress' reaction to science. The former is Congress' bandwidth. Congress is a bureaucracy; in the face of what many Members considered a monumental problem, i.e. *Roe v. Wade*, there is reason to think that any other legislative priorities like IVF would have been relegated to spend political capital on abortion. The latter lesson, however, is how the ethical concern at the heart of IVF's critics may never have materialized. The ethical concerns focused on experimenting on—and therefore infringing upon the rights of—the unborn.[59] Those lobbing said critiques often grouped them with anti-abortion sentiments, but such a strategy ultimately did not gain a foothold. Instead, overextending what would be barred likely split support for such measures. But, interestingly, instead of infringing upon the rights of unborn children, which many feared, IVF has proven itself a promoter of childbirth that helped families with difficulties getting pregnant have children.

Though outside the temporal scope of the inquiry, it is worth briefly discussing the fate of the funding restrictions mentioned above. The Clinton administration eventually made substantial progress in supporting IVF research. While initially vetoed by the first Bush Administration,[60] President Clinton used his executive authority to open up research[61] and signed Rep. Waxman's

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[57] *See, e.g.*, Veerle Goossens et al., *Diagnostic efficiency, embryonic development and clinical outcome after the biopsy of one or two blastomeres for preimplantation genetic diagnosis*, 23 HUM. REPROD. 481, 481 (2008); Judy E. Stern et al., *Is cryopreservation of embryos a legitimate surrogate marker of embryo quality in studies of assisted reproductive technology conducted using national databases?*, 97 FERTILITY & STERILITY 890, 891 (2012).

[58] *See generally* I. Glenn Cohen, *Religion and Reproductive Technology*, *in* LAW, RELIGION, AND HEALTH IN THE UNITED STATES (Holly Fernandez Lynch, I. Glenn Cohen & Elizabeth Sepper eds., 2017 Forthcoming), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2798667.

[59] *See supra* notes 47–49 and accompanying text.

[60] President Bush vetoed the Act "because it would lift the current moratorium on the use of Federal funds for fetal tissue transplantation research where the tissue is obtained from induced abortions." George H. W. Bush, *Message to the House of Representatives Returning Without Approval the National Institutes of Health Revitalization Amendments of 1992*, *in* PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES, GEORGE BUSH 1992-1993 (1992).

[61] Memorandum from William J. Clinton to the Secretary of Health and Human Services, Federal Funding of Fetal Tissue Transplantation Research, 58 Fed. Reg. 7,457 (Jan. 22, 1993) (to be codified at 42 U.S.C. § 289g).

NIH Revitalization Act,[62] which nullified the Board Approval requirement.[63] In 1992, the Fertility Clinic Success Rate and Certification Act required all assisted reproduction facilities to report pregnancy success rates and embryo usage as well as required state inspectors and authorized federal inspectors to monitor facilities and manage the accreditation process thereof.[64] The bill was framed as a consumer protection measure, citing patterns of fraud and or poor treatment of those seeking reproductive assistance, though without an intelligible, discrete impetus. The most important development of the Clinton era, however, was 1995's inclusion of the Dickey-Wicker Amendment—which prohibits spending federal funds on "research 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"[65]—sealed the fate on federal funding for the generation of new stem cell lines, though funding for continued research on previously developed cell lines remains viable.

IV. CLONING (01/01/1994 – 12/31/1998)

The history of the science of cloning can be traced back to Hans Spemann's theorization of a "fantastic experiment" to replace an egg cell's nucleus with that of another cell and grow an embryo with the old nucleus in 1938.[66]

Cloning experimentation began in earnest in 1952, when Robert Briggs and Thomas King, having successfully transferred frogs' early-stage embryonic nuclei to enucleated frogs, demonstrated that nuclei of differentiated cells could nonetheless develop normally.[67] Six years later, Sir John Gurdon produced mature frogs by transferring tadpole's intestinal cells into enucleated frog eggs, showing that developed cells can be used in a regenerative manner.[68]

Gurdon and others continued cloning work into the next decades, Congress began to take notice. In 1971, Dr. James Watson—the father of modern genetics—was called to testify before the Congressional Panel on Science and Technology.[69] The Panel was charged with holding hearings "intended primarily to encourage the exchange of ideas and information between the

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[62] H.R. 4, 103rd Cong. (1994).

[63] Two years later, an advisory board, the NIH's Embryo Research Panel, voted to move ahead with the research, but public pressure compelled the president to override their decision. *See Policy Timeline*, CHILD. HOSP. BOS., http://stemcell.childrenshospital.org/about-stem-cells/stem-cell-research-ethics-and-policy/policy-timeline/ (last accessed May 2, 2016).

[64] Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, §§ 2–3, 106 Stat. 3146 (1992).

[65] Megan Kearl, *Dickey-Wicker Amendment, 1996*, THE EMBRYO PROJECT ENCYCLOPEDIA (Aug. 27, 2010), https://embryo.asu.edu/pages/dickey-wicker-amendment-1996. The original amendment was included in Balanced Budget Downpayment Act, I of 1996, Pub. L. No 104-99, § 128, 110 Stat. 26, 34 (1996).

[66] *Hans Spemann, 1869 – 1941*, EMBRYO PROJ., https://embryo.asu.edu/pages/hans-spemann-1869-1941 (last accessed May 3, 2016).

[67] *See generally* Robert Briggs & Thomas J. King, *Transplantation of Living Nuclei from Blastula Cells into Enucleated Frogs' Eggs*, 38 PROC. NAT'L ACAD. SC. 455 (1952).

[68] *See* John B. Gurdon, Tom R. Elsdale & Michael Fischberg, *Sexually Mature Individuals of Xenopus-Laevis from the Transplantation of Single Somatic Nuclei*, 182 NATURE 64, 64–65 (1958).

[69] *See Panel on Science and Technology, Twelfth Meeting, Proceedings before the H. Comm. on Science and Astronautics*, 92nd Cong. 1 (1971).

world scientific community and the Congress."[70] Though this particular hearing did not necessarily have a discrete impetus, Watson testified specifically regarding human cloning. Recognizing the march of scientific progress, the famed scientist argued that "[cloning] is a decision not for the scientists at all . . . It is a decision for the general public – do you want this or not? . . . [If] we do not think about it now, the possibility of our having free choice will one day suddenly be gone."[71] After his testimony, he would publish a seminal article in *The Atlantic* titled *Moving Toward the Clonal Man*[72] arguing the same point. Interestingly, Watson himself never explicitly stated a preference, though the article's tone suggests a preference for oversight and mitigation instead of unadulterated progress. But, to that point, no bills directly related to cloning had been proposed.

The final decades of the 20th century saw further developments in cloning. In 1981, scientists successfully cloned a mouse, albeit using an embryonic—not an adult—nucleus.[73] In 1994, scientists embarked on their first attempts to clone a sheep, though the cloned nucleus created an embryo that only grew to approximately 16 cells.[74] The following year, scientists were able to clone a sheep, but the nucleus taken was from a cell culture, not another living animal.[75] Science was knocking on the door to true adult cell cloning.

In light of this progress—combined with the recent lifting of the moratorium on public funding for such scientific research (the enactment of the NIH Revitalization Act)—Congress took notice. In its next appropriations bill after the 1995 cloning attempt, Congress banned the use of public funds for any such action relating to human cloning in Fiscal Year 1996.[76] This provision, known now as the Dickey-Wicker Amendment, prohibits spending federal funds for "the creation of a human embryo or embryos for research purposes; or research 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,"[77] defining embryos to include organisms derived by—amongst other things—cloning.

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[70] *Id.* (opening statement).

[71] *Id.* at 344 (statement of Dr. James Watson).

[72] James D. Watson, *Moving Toward the Clonal Man: Is this what we want?*, ATLANTIC, May 1971, at 58, http://www.theatlantic.com/magazine/archive/1971/05/moving-toward-the-clonal-man/305435/.

[73] *See* Walter Sullivan, *First Cloning of Mammals Produces 3 Mice*, N.Y. TIMES, June 6, 2017,http://www.nytimes.com/1981/01/04/us/first-cloning-of-mammals-produces-3-mice.html?pagewanted=all (last accessed Apr. 24, 2017).

[74] *See* Stanley L. Jaki, *Cloning and Arguing*, 65 LINACRE Q. 5, 6 (1998).

[75] *See* Keith H. Campbell et al., *Sheep Cloned by Nuclear Transfer from a Cultured Cell Line*, 380 NATURE 64, 64–66 (1996).

[76] The original amendment was included in Balanced Budget Downpayment Act. *See supra* note 65.

[77] H.R. 2880, 104th Cong. § 509(a) (1996).

But on July 5, 1996, the world was introduced to its first mammalian clone from an adult cell: Dolly the Sheep.[78] The British scientists who created Dolly, led by Sir Ian Wilmut, told the world of her existence in February of 1997.[79] The following month, Congress held hearings to solicit testimony from scientists in academia—including Dr. Wilmut himself and Dr. Harold Varmus, the NIH Director—and the private sector regarding the state of cloning science and the viability of human application.[80] The scientists also noted the ethical questions involved, attempting to assuage ethical concerns by citing myriad reasons that even if it could be, such technology would not be applied to humans.[81] Particularly, the scientists referenced the lack of need scientifically because of naturally existing identical twins, the promotion diversity generally, and the Dickey Wicker Amendment's funding ban.[82] Congress also called bioethicists, including Profs. Alta Charo, George Annas, and Karen Rothenberg, to present their views on the science.[83] The bioethicists discussed the ethics of sciences underpinning cloning—embryo research generally—and the particular ethics of cloning, Congress' history with respect to cloning, state and local laws on cloning, and the state of public funding bans.[84]

Despite the scientists' view that there would be no demand for it, Congress ensured that provisions against it were enacted via appropriations bills. Nine appropriations bills introduced in the House or Senate in the 104th and 105th Congresses—the session during which Dolly was born and its proceeding session—indirectly prohibited cloning via the Dickey-Wicker Amendment.[85] The four omnibus appropriations bills signed for Fiscal Years 1995, 1996, 1997, and 1998, respectively included the Amendment, and it remains in appropriations bills today.

In addition to the appropriations bills passed, narrower bills were proposed in both the House and the Senate that target cloning directly. Thirteen bills sought to "prohibit the expenditure of Federal funds to conduct or support research on the cloning of humans,"[86] while seven sought its outright prohibition.[87] Among the latter, two criminalize cloning, four proposed civil

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[78] *See, e.g.*, Gina Kolata, *Scientists Reports First Cloning Ever of Adult Mammal*, N.Y. TIMES (Feb. 23 1997), http://www.nytimes.com/1997/02/23/us/scientist-reports-first-cloning-ever-of-adult-mammal.html.

[79] *See generally* Ian Wilmut et al., *Viable offspring derived from fetal and adult mammalian cells*, 385 NATURE 810, 810–13 (1997).

[80] *See generally Scientific Discoveries in Cloning*: *Hearing Before the Subcomm. on Public Health and Safety of the S. Committee on Labor and Human Resources*, 105th Cong. (1997).

[81] *See generally id.*

[82] *See generally id.*

[83] *See generally id.*

[84] *See generally id.*

[85] *See* Table 3 (citing H.R. 2880, 104th Cong. (1996); H.R. 3755, 104th Cong. (1996); S.J.Res. 63, 104th Cong. (1996); H.R. 4278, 104th Cong. (1996); S. 1061. 105th Cong. (1997); H.R. 2264, 105th Cong. (1997); H.R. 2160, 105th Cong. (1997); H.R. 4272, 105th Cong. (1998); S. 2440, 105th Cong. (1998)).

[86] *See id.* (citing H.R. 2880, 104th Cong. (1996); H.R. 3755, 104th Cong. (1996); H.R. 4278, 104th Cong. (1996); H.R. 2264, 105th Cong. (1997); H.R. 2160, 105th Cong. (1997); H.R. 3133, 105th Cong. (1998); H.R. 4274, 105th Cong. (1998); S.J. Res. 63, 104th Cong. (1996); S. 368, 105th Cong. (1998); S. 1061, 105th Cong. (1997); S. 922, 105th Cong. (1998); S. 1602, 105th Cong. (1998); S. 2440, 105th Cong. (1998)).

[87] *See id.* (citing H.R. 922, 105th Cong. (1997); H.R. 923, 105th Cong. (1997); S. 1574, 105th Cong. (1998); S. 1599, 105th Cong. (1998); S. 1601, 105th Cong. (1998); S. 1602, 105th Cong. (1998); S. 1611, 105th Cong. (1998)).

damages, and two proposed both.[88] Many of these bills garnered substantial support—more so federal funding prohibitions than outright bans—including cross-aisle co-sponsors. Only one proposed bill did not seek to prohibit cloning; it instead proposed appointing a bioethical commission to "promote a national dialogue on bioethics," including the issue of cloning.[89] None of these measures passed, but that is not to say that cloning may be performed across the United States; as many as 17 states and Puerto Rico have enacted statewide bars on the practice, with two more putting state funding restrictions in place.[90]

Interestingly, many of the proposed federal bills referencing cloning did not differentiate between reproductive cloning—growing a human replica—and therapeutic cloning—farming the clone's stem cells without letting it live. Few bills, on the other hand, do so implicitly, foregoing scientific terminology. Rather, those bills define cloning as either creating a human being, implying reproductive cloning, or simply copying genetic material, which may be textually ambiguous.

Today, at least 45 countries have explicitly outlawed cloning[91]; the United States is not among them.[92] But this is not for a lack of trying. Even beyond the time period analyzed, attempts to ban cloning outright have persisted unsuccessfully; bills have been introduced in one or both

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[88] *See id.* (citing H.R 923, 105th Cong. (1997); S. 1574, 105th Cong. (1998); S. 1599, 105th Cong. (1998); S.1601, 105th Cong. (1998); S.1602, 105th Cong. (1998); S.1611, 105th Cong. (1998)).

[89] S. 1595, 105th Cong. (1998).

[90] *See* ARIZ. REV. STAT. ANN. § 35-196.04 (2005); ARK. CODE ANN. § 20-16-1002 (West 2003); CAL. HEALTH & SAFETY CODE § 24185 (West 2003); 410 ILL. COMP. STAT. ANN. 110/40 (West 2008); IND. CODE ANN. § 35-46-5-2 (West 2014); IOWA CODE ANN. § 707C.4 (West 2008); LA. REV. STAT. ANN. § 40:1300 (2015) (restricting the use of state funds for cloning, though not barring the practice outright); MD. CODE ANN. ECON. DEV. § 10-440 (West 2008); MASS. GEN. LAWS ANN. ch. 111L, § 8 (West 2005); MICH. COMP. LAWS ANN. § 750.430a (West 1998); MO. ANN. STAT. § 1.217 (West 1998) (restricting the use of state funds for cloning, though not barring the practice outright); MONT. CODE ANN. § 50-11-102 (West 2009); N.J. STAT. ANN. § 2C:11A-1 (West 2004); N.Y. PUB. HEALTH LAW § 265-a (McKinney 2007); N.D. CENT. CODE ANN. § 12.1-39-02 (West 2003); OKLA. STAT. ANN. tit. 63, § 1-727 (West 2009); 23 R.I. GEN. LAWS ANN. § 23-16.4-2 (West 2013); S.D. CODIFIED LAWS § 34-14-2 (2004); VA. CODE ANN. § 32.1-162.22 (West 2001); P.R. LAWS ANN. tit. 33, § 4744 (2004).

[91] *See Human Cloning Policies*, CENT. FOR GENETICS & SOCIETY, http://www.geneticsandsociety.org/article.php?id=325 (last accessed Aug. 15, 2016); Haley Cohen, *How Champion-Pony Clones Have Transformed the Game of Polo*, VANITY FAIR, Aug. 2015, http://www.vanityfair.com/news/2015/07/polo-horse-cloning-adolfo-cambiaso (claiming about 70 countries have outlawed cloning).

[92] *See Embryonic and Fetal Research Laws*, NAT'L CONF. STATE LEGISLATURES, http://www.ncsl.org/research/health/embryonic-and-fetal-research-laws.aspx (last accessed Apr. 24, 2017).

houses of Congress in 1999,[93] 2001,[94] 2003,[95] 2005,[96] 2007,[97] 2009,[98] 2012,[99] 2013,[100] and 2015.[101] The 2001 and 2003 bills passed the House, but the Senate did not act on it or its Senate-originated companion.[102] Why is this? No one can say for certain, but four reasons are most likely: an inability to decide on therapeutic versus reproductive cloning (which stymied U.N. efforts to ban cloning[103]), a lack of demand to clone, general anti-regulation sentiments, or the genuine position that cloning should not be outlawed.

Whatever the reason, the most important lesson to be learned from Congress' reaction—or lack thereof—to Dolly's creation is how Congress' decision not to preemptively legislate played out. Ethical concerns relating to cloning never materialized. Over 30 countries—many of which are first-world countries—ban cloning altogether,[104] including for both reproductive and therapeutic means, so even if such a demand for cloning existed, cloning would be even more likely housed in the United States.

Had you asked the American public at the time if, in the wake of Dolly, if they would prefer a blanket ban on cloning, they may well have said yes, claiming it was necessary to prevent human cloning, its questionable end. However, such hysteria went unrealized; market forces created a *de facto* ban on human reproductive cloning. The larger takeaway is therefore that at the moment a technology or science emerges and people clamor about its implications, we may not always be in the best position to evaluate how helpful legislative regulations—or prohibitions—would be; the free market, imbued with morality, may yet do the heavy lifting. What's more, as was the case with the countries who have only banned reproductive and not therapeutic cloning,[105] it may be better for science to ban the undesirable end—in this case cloning—instead of banning the underlying science altogether.

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93 H.R. 2326, 106th Cong. (1999).

94 S. 790, 107th Cong. (2001).

95 H.R. 2505, 107th Cong. (2001); H.R. 534, 108th Cong. (2003); H.R. 234, 108th Cong. (2003); S.245, 108th Cong. (2003).

96 H.R. 1357, 109th Cong. (2005); S. 658, 109th Cong. (2005).

97 H.R. 2560, 110th Cong. (2007); H.R. 2564, 110th Cong. (2007); S. 1036, 110th Cong. (2007).

98 H.R. 110, 111th Cong. (2009); H.R. 1050, 111th Cong. (2009).

99 H.R. 6623, 112th Cong. (2012).

100 H.R. 2164, 113th Cong. (2013).

101 H.R. 3498, 114th Cong. (2015).

102 S. 790, 107th Cong. (2001); S.245, 108th Cong. (2003).

103 *See* Joel Roberts, *U.N. Gives Up Global Cloning Ban*, CBSNEWS (Feb. 18, 2005, 10:34 PM), http://www.cbsnews.com/news/un-gives-up-global-cloning-ban/.

104 *See Cloning: Frequently Asked Questions*, NAT'L PUB. RADIO, http://www.npr.org/news/specials/cloning/faq_blanknav.html#country (last accessed Apr. 24, 2017).

105 *See id.*

V. STEM CELLS (06/01/1998 – 08/30/2015)

The term "stem cell" first appeared in scientific literature when Ernst Haeckel coined the term in 1868 to describe the fertilized egg that becomes an organism.[106] Fast-forward over a century and Leroy Stevens realized that some cells in cancer were pluripotent, or differentiable.[107] As we entered the last quarter of the 20th century, research forged onward. In 1981, scientists in England and the United States were able to isolate pluripotent stem cells[108]; because the practice was not banned outright, James Thomson and his lab were the first derive human embryonic stem cells from human blastocysts seventeen years later.[109]

Legislative attention paid to stem cell development has changed over the last two decades. In the period soon after Thomson's discovery, only one bill and one resolution relating to stem cells were proposed through the duration of the Clinton Administration;[110] comparatively, seventy-five were proposed under President Bush's eight years (averaging greater than nine per year) and forty-six under President Obama through the summer of 2015 (approximately 7 per year on average).[111] From 1998-2015, bills have ranged in subject matter: nine have offered tax credits for research, 29 are appropriations-specific provisions, four call for amending NIH guidelines, and thirteen aim to prevent cloning's use of such genetic material.[112] Interestingly, there have been bills proposing both expanding and restricting stem cell research—43 and 12, respectively.[113] Analysis of different Administrations' and Congresses' handling of the issue sheds light on both partisan biases.

Stem cell research under the Clinton Administration is highlighted in its promulgation of "guidelines that allow federal funding of embryonic stem-cell research."[114] And from 1998 to 2000, Congress only put forward one bill relating directly to the scope of stem cell research: Arlen Specter, a Republican (at the time) sponsored a bill to expand such research, though the bill never made it out of the Senate.[115] Beyond this sole effort, however, the Dickey-Wicker Amendment, discussed above, remained a part of appropriations bills throughout and beyond the Clinton era.

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[106] *See* Miguel Ramalho-Santos & Holger Willenbring, *On the Origin of the Term "Stem Cell"*, 1 CELL: STEM CELL 35, 35–38 (2007).

[107] Leroy C. Stevens, *Studies on Transplantable Testicular Teratomas of Strain 129 Mice*, 20 J. NAT'L CANCER INST. 1257, 1257–70 (1958).

[108] Martin John Evans & Matthew H. Kaufman, *Establishment in culture of pluripotent cells from mouse embryos*, 292 NATURE 154, 154–56 (1981).

[109] James A. Thomson et al., *Embryonic stem cell lines derived from human blastocysts*, 282 SCI. 1145, 1145–57 (1998).

[110] *See* 106 S. 2015, 106th Cong. (2000); 106 H. Res. 414, 106th Cong. (2000).

[111] *See* Table IV.

[112] *See id.*

[113] *See id.*

[114] John Ydstie & Joe Palca, *Embryonic Stem Cells Made Without Embyros*, NAT'L PUB. RADIO (Nov. 21, 2007, 6:00 AM), http://www.npr.org/templates/story/story.php?storyId=16493814.

[115] 106 S. 2015, 106th Cong. (2000).

The Bush Administration, though, moved to overturn the Clinton Administration's support for stem cell research. President Bush made his position official by adopting a policy in August of 2001 to ban the creation of new stem cell lines,[116] albeit permitting researchers to work with already-created cell lines. Bush formalized this position in Executive Order No. 13435, *Expanding Approved Stem Cell Lines in Ethically Responsible Ways*, in 2007. In response to President Bush's position, many bills were put forward seeking to directly expand stem cell research; the House and Senate twice passed such bills, but the President publically vetoed both measures and neither garnered sufficient votes to override that veto.[117]

President Obama's administration took a different tack. Shortly after being elected, he revoked the Bush Administration's position[118] to expand the number of stem cell lines. Democrats were unable to pass legislation to further expand stem cell research in President Obama's first two years, despite controlling both the House and Senate.

Both houses have since switched to Republican leadership, which, as expected, has produced more bills seeking to restrict stem cell research and undermine the President's Executive Order. Those measures have also not been passed. Analysis of the party-affiliations of bills' sponsoring and co-sponsorship Members and Senators offer some interesting results. Overall, 40% of proposed bills were Republican-backed, while 26% were neutrally sponsored and 34% were Democrat-backed.[119] To be sure, these numbers are partially skewed because of congressional leadership during the time period in question: Republicans controlled the House 80% of the time, as compared to 60% Democratic control of the Senate, tilting appropriations bills—and therefore overall bill count—Republican (as appropriations bills are typically not co-sponsored and only retain sponsorship of the committee member proposing them).[120] It is fair to say that stem cell concerns run in both major parties.

But more telling conclusions stem from considering the bills' intent based on their partisan sponsorship. Unsurprisingly, bills favoring research expansion via new lines of stem cells were primarily Democratic or Neutral sponsorship (15 and 15, respectively), as compared to seven that are primarily Republican-sponsored.[121] Conversely, Democrats primarily sponsored zero bills seeking to restrict research in any way, while nine such bills were Republican sponsored and three neutrally so.[122] Finally, eight of nine bills proposing tax credits for stem cell research were Republican-favored.[123]

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[116] *See President George W. Bush's address on stem cell research*, CNN (Aug. 9, 2001), http://edition.cnn.com/2001/ALLPOLITICS/08/09/bush.transcript/ (transcribing President Bush's speech outlining his policy decision). *See also* Julian Borger, *Bush compromise allows stem cell research in US*, GUARDIAN, Aug. 10, 2001, at 10, https://www.theguardian.com/world/2001/aug/10/medicalscience.usa.

[117] *See* Table IV (noting 109 H.R. 810 & 110 H.R. 3043).

[118] *See* Exec. Order No. 13,505, 3 C.F.R § 586 (2009).

[119] Defining Democrat-backed as having greater than 66% of sponsors be Democratic Members, Republican-backed as having greater than 66% of sponsors be Republican Members, and neutrally-backed as having in between 66% Republican-sponsored and 66% Democratically-sponsored.

[120] *See* Table IV.

[121] *See id.*

[122] *See id.*

[123] *See id.*

Finally, as for actual success, only 22 stem cell-related bills passed.[124] Of those 22: 15 were appropriations-specific (in the form of the Dickey-Wicker Amendment); two were simply resolutions; one related to Social Security (restricting S.S. funding), and four expanded research either by amending NIH guidelines or creating—then expanding—a stem cell blood bank (two of which were vetoed).[125]

Two major lessons can be distilled from the attempts at law making in this era. The first lesson stems from the distinct difference in the current debate over stem cell research as compared to the previous scientific breakthroughs mentioned above: here, Congress took action while the science and its potential applications are inconclusive. Recombinant DNA was a proven science that had myriad applications. While in its infancy, however, the science was not heavily regulated so as to manipulate where and how scientists can pursue further research on the topic. The same can be said for in vitro fertilization and cloning (at least reproductive cloning). For stem cells—and to the extent it overlaps with therapeutic cloning—where and how the technology's promise may ultimately be realized remains unknown. And yet it has been and remains heavily restricted due to the Dickey-Wicker Amendment. Undoubtedly, interfering before the science is complete has significantly hamstrung the realization of stem cell's promise. Rather, it may behoove Congress to permit the research to bear out its full potential and only then, once that information is available, make a more informed judgment.

The second lesson to be learned is the important role of appropriations in science. Despite having been unable to bar all stem cell research—or open up all such research—legislatively, policymakers can achieve their aims using the power of the purse. The United States government is one of, if not the biggest, source of funding for science research in the world. Manipulating funding based on policy preferences can significantly hinder science's progress, as such experimentation requires an immense amount of funding to conduct. The corollary to this is the deference the Executive must pay to Congress in these matters because of that power. Unless the President is willing to veto an entire appropriations bill over a scientific provision, a rare occurrence, Congresspersons will wield considerable power due to funding.

## VI. CONCLUSION

The legislative debates and subsequent actions surrounding the four scientific breakthroughs can offer some guidance both as to how the debate over gene editing technology is likely to proceed, but also how it ought to proceed. Just as there was a rush to regulate stem cells before the technology's full potential was realized, a similar story is unfolding as to CRISPR; this means that gene editing's future in the United States will likely most closely follow stem cell's treatment. Legislators will likely continue to debate expansion—or further restriction—of the permissible research under the regulatory schema as scientific discoveries within and beyond the United States demonstrates the technology's potential. The parallel between the new gene editing appropriations rider and the Dickey-Wicker amendment, though, should worry those who favor more robust funding and inquiry into gene editing. While these appropriations riders require yearly renewal, in the case of Dickey-Wicker they have proven very "sticky" and suggest the ban on funding for gene editing research may be here to stay.

The history of the regulation of cloning and IVF present alternate potential paths forward, one plausibly and one implausible. In the case of IVF despite widespread public and scholarly debate at the time, we saw shockingly little Congressional or other attempts to regulate the practice. This may be a unique result of historical contingency (the overshadowing of the technology by

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[124] *See id.*

[125] *See id.*

interest in *Roe v. Wade*) as well as successful attempts to portray the technology as an ordinary extension of the practice of medicine rather than a troubling new technology. Given the already-existing level of congressional interest and the fears associated with gene editing, we think an IVF-like story for gene editing is unlikely. Cloning represents a more plausible possible future state of play. Despite widespread ethical and regulatory concern over human reproductive cloning, proposed prohibitions were hotly debated and never became law. Far from the predictions of many commentators at the time, the combination of market forces and professional regulation appears to have been sufficient to prohibit feared abuses. It is possible that a similar result could occur with gene editing if no federal prohibition were put in place.

Whether such a future is desirable or not as is another matter entirely. The answer depends on how one answers several questions: how serious a risk is posed by gene editing as compared to these other technologies? How good will professional self-regulation and market forces be in restraining abuses? How much expertise does Congress possess in evaluating the science, its benefits, and its risks, as opposed relying on the expertise of those in the field to self-regulate?

## VII. APPENDIX

*Table 1: Bills Relating to Recombinant DNA*

| Bill | No. Dem. Sponsors | No. Dem. Co-Sponsors | No. Rep. Sponsors | No. Rep. Co-Sponsors | Enacted? |
|---|---|---|---|---|---|
| H.R. Res. 131, 95th Cong. (1977) | 1 | 0 | 0 | 0 | No |
| H.R. 3191, 95th Cong. (1977) | 1 | 0 | 0 | 0 | No |
| H.R. 3592, 95th Cong. (1977) | 1 | 19 | 0 | 4 | No |
| H.R. 3591, 95th Cong. (1977). | 1 | 19 | 0 | 4 | No |
| H.R. 4232, 95th Cong. (1977). | 1 | 0 | 0 | 0 | No |
| H.R. 4759, 95th Cong. (1977). | 1 | 7 | 0 | 2 | No |
| H.R. 4849, 95th Cong. (1977). | 1 | 0 | 0 | 1 | No |
| H.R. 5020, 95th Cong. (1977). | 1 | 8 | 0 | 1 | No |
| H.R. 6158, 95th Cong. (1977). | 1 | 0 | 0 | 0 | No |
| H.R. 7418, 95th Cong. (1977). | 1 | 0 | 0 | 0 | No |
| H.R. 7897, 95th Cong. (1977). | 1 | 8 | 0 | 3 | No |
| H.R. 10453, 95th Cong. (1978). | 1 | 0 | 0 | 0 | No |
| H.R. 11192, 95th Cong. (1978). | 1 | 1 | 0 | 0 | No |
| S. 621, 95th Cong. (1977). | 1 | 0 | 0 | 0 | No |
| S. 945, 95th Cong. (1977). | 1 | 0 | 0 | 0 | No |

| | | | | | |
|---|---|---|---|---|---|
| S. 1217, 95th Cong. (1977).[126] | 1 | 0 | 0 | 0 | No |

[126] This bill was introduced three times in the Senate.

*Table 2: Bills Relating to In Vitro Fertilization*

| Bill | *Roe* | Con. Amendment |
|---|---|---|
| H.R. 13662, 95th Cong. (1978). | | |
| H.J. Res 45, 96th Cong. (1979). | 1 | 1 |
| H.J. Res 56, 96th Cong. (1979). | 1 | 1 |
| S.J. Res 12, 96th Cong. (1979). | 1 | 1 |
| H.J. Res. 108, 96th Cong. (1979). | 1 | 1 |
| H.J. Res 142, 96th Cong. (1979). | 1 | 1 |
| H.J. Res. 211, 96th Cong. (1979). | 1 | 1 |
| H.J. Res. 250, 96th Cong. (1979). | 1 | 1 |
| H.J. Res 294, 96th Cong. (1979). | 1 | 1 |
| H.J. Res 300, 96th Cong. (1979). | 1 | 1 |
| H.J. Res 479, 96th Cong. (1980). | 1 | 1 |
| H.J. Res 576, 96th Cong. (1980). | 1 | 1 |
| H.J. Res 621, 96th Cong. (1980). | 1 | 1 |
| H.J. Res 626, 96th Cong. (1980). | 1 | 1 |
| H.J. Res 13, 97th Cong. (1981). | 1 | 1 |
| H.J. Res 32, 97th Cong. (1981). | 1 | 1 |
| H.J. Res 50, 97th Cong. (1981). | 1 | 1 |
| H.R. 392, 97th Cong. (1981). | 1 | 1 |
| S. 158, 97th Cong. (1981). | 1 | |
| H.R. 900, 97th Cong. (1981). | 1 | |
| H.J. Res 104, 97th Cong. (1981). | 1 | 1 |
| H.J. Res 106, 97th Cong. (1981). | 1 | 1 |
| S.J. Res 19, 97th Cong. (1981). | 1 | 1 |
| H.J. Res. 198, 97th Cong. (1981). | 1 | 1 |
| H.R. 3225, 97th Cong. (1981). | 1 | |
| H. Con. Res 206, 97th Cong. (1981) | | |
| S. 1741, 97th Cong. (1981). | 1 | |
| S.J. Res 137, 97th Cong. (1981). | 1 | 1 |

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|---|---|---|
| H.J. Res 380, 97th Cong. (1981). | 1 | 1 |
| S. 2148, 97th Cong. (1982). | 1 | |
| H.R. 5862, 97th Cong. (1982). | 1 | |
| H.J. Res 446, 97th Cong. (1982). | 1 | |

*Table 3: Bills Relating to Cloning*

| Bill | Appropriations Bill | Bar Fed. Funding | Prohibition | Criminalizing Cloning | Civil Penalty |
|---|---|---|---|---|---|
| H.R. 2880, 104th Cong. (1996) | Yes | 1 | | | |
| H.R. 3755, 104th Cong. (1997) | Yes | 1 | | | |
| H.R. 4278, 104th Cong. (1997) | Yes | 1 | | | |
| H.R. 923, 105th Cong. (1997) | | | 1 | | 1 |
| H.R. 922, 105th Cong. (1997) | | 1 | 1 | | |
| H.R. 2264, 105th Cong. (1997) | Yes | 1 | | | |
| H.R. 2160, 105th Cong. (1998) | Yes | 1 | | | |
| H.R. 3133, 105th Cong. (1998) | | 1 | | | |
| H.R. 4274, 105th Cong. (1998) | Yes | 1 | | | |
| S.J. Res. 63, 104th Cong. (1997) | Yes | 1 | | | |
| S. 368, 105th Cong. (1997) | | 1 | | | |
| S. 1061, 105th Cong. (1997) | Yes | 1 | | | |
| S. 1574, 105th Cong. (1998) | | | 1 | | 1 |
| S. 1595, 105th Cong. (1998) | | | | | |
| S. 1599, 105th Cong. (1998) | | | 1 | 1 | 1 |
| S. 1601, 105th Cong. (1998) | | | 1 | 1 | 1 |
| S. 1602, 105th Cong. (1998) | | 1 | 1 | | 1 |
| S. 1611, 105th Cong. (1998) | | | 1 | | 1 |
| S. 2440, 105th Cong. (1998) | Yes | 1 | | | |

*Table 4: Bills Relating to Stem Cells*

| Bill | Dem. Support | Neutral Support | Rep. Support | Passed | Approps. | Tax Credits | Restrict S.S. Research | Expand S.S. Research | Affecting / Instructing NIH | Cloning | Admin. / Public Awareness | Further Study | Other |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| S. 1626, 106th Cong. (1999) | | | 1 | 1 | | | | | | | | | 1 |
| S. 2015, 106th Cong. (2000) | | 1 | | | | | | 1 | | | | | |
| H. Res. 414, 106th Cong. (2000) | | 1 | | 1 | | | | | | | | | 1 |
| H. Con. Res. 17, 107th Cong. (2001) | | 1 | | | | | | | | | | | 1 |
| S. 723, 107th Cong. (2001) | 1 | | | | | | | 1 | | | | | |
| H.R. 1608, 107th Cong. (2001) | | | 1 | | | | | | | 1 | | | |
| H.R. 2059, 107th Cong. (2001) | 1 | | | | | | | 1 | | | | | |
| H.R. 2096, 107th Cong. (2001) | | | 1 | | | | | 1 | | | | | |
| H.R. 2747, 107th Cong. (2001) | | 1 | | | | | | | | | | 1 | |
| S. 1349, 107th Cong. (2001) | | | 1 | | | | | 1 | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| H.R. 2838, 107th Cong. (2001) | 1 | | | | | | | 1 | | | | | |
| H.R. 2863, 107th Cong. (2001) | 1 | | | | | | | | | | | 1 | |
| S. 1536, 107th Cong. (2002) | 1 | | | 1 | 1 | | | | | | | | |
| S. 1758, 107th Cong. (2001) | 1 | | | | | | | | | 1 | | | |
| S. 1893, 107th Cong. (2001) | 1 | | | | | | | | | 1 | | | |
| H.R. 4011, 107th Cong. (2002) | 1 | | | | | | | | | | | 1 | |
| S. 2439, 107th Cong. (2002) | 1 | | | | | | | | | 1 | | | |
| H. Res. 563, 107th Cong. (2002) | | 1 | | | | | | | | | | | 1 |
| S. Res. 347, 107th Cong. (2002) | | | 1 | | | | | | | | | | 1 |
| S. 303, 108th Cong. (2003) | 1 | | | | | | | | | 1 | | | |
| S. 1356, 108th Cong. (2004) | | | 1 | 1 | 1 | | | | | | | | |
| H.R. 2852, 108th Cong. (2003) | | | 1 | | | | | 1 | | | | | |

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| H.R. 2660, 108th Cong. (2004) | | | 1 | 1 | 1 | | | | | | | | |
| S. 1717, 108th Cong. (2003) | | | 1 | | | | | 1 | | | | | |
| H.R. 2673, 108th Cong. (2004) | | | 1 | 1 | 1 | | | | | | | | |
| H.R. 2660, 108th Cong. (2004) (Engrossed Amendment Senate) | | | 1 | 1 | 1 | | | | | | | | |
| H.R. 4818, 108th Cong. (2005) | | | 1 | 1 | 1 | | | | | | | | |
| H.R. 3960, 108th Cong. (2004) | 1 | | | | | | | 1 | | | | | |
| H.R. 4531, 108th Cong. (2004) | | | 1 | | 1 | | | 1 | | | | | |
| H.R. 4682, 108th Cong. (2004) | | 1 | | | 1 | | | 1 | | | | | |
| H.R. 4812, 108th Cong. (2004) | | | 1 | | | | | 1 | 1 | | | | |
| S. 2810, 108th Cong. (2005) | | | 1 | 1 | 1 | | | | | | | | |
| H.R. 162, 109th Cong. (2005) | 1 | | | | | | | 1 | | | | | |

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| H.R. 596, 109th Cong. (2005) | | 1 | | | | | | 1 | | | | | |
| H.R. 810, 109th Cong. (2005) | 1 | | | | | | | 1 | | | | 1 | |
| S. 471, 109th Cong. (2005) | | 1 | | | | | | 1 | | | | 1 | |
| S. 681, 109th Cong. (2005) | | 1 | | | | | | 1 | | | | | |
| H.R. 1650, 109th Cong. (2005) | | 1 | | | | 1 | | | | | | | |
| S. 876, 109th Cong. (2005) | | 1 | | | | | | | | 1 | | | |
| H.R. 1882, 109th Cong. (2005) | | 1 | | | | | | | | 1 | | | |
| H.R. 2520, 109th Cong. (2005) | | | 1 | 1 | | | | 1 | | | | | |
| H.R. 2541, 109th Cong. (2005) | | 1 | | | | | | 1 | | | | | |
| H.R. 2574, 109th Cong. (2005) | | | 1 | | | | 1 | | 1 | | | | |
| H.R. 810, 109th Cong. (2005) | 1 | | | 1 (Veto) | | | | 1 | | | | | |
| H. Con. Res. 166, 109th Cong. (2005) | 1 | | | | | | | | | | | | 1 |

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| S. 1317, 109th Cong. (2005) | | 1 | | | | | | 1 | | | | | |
| H.R. 3144, 109th Cong. (2005) | | | 1 | | | | 1 | | | | | | |
| H.R. 3010, 109th Cong. (2006) | | | 1 | | 1 | | | | | | | | |
| H.R. 3444, 109th Cong. (2005) | | | 1 | | | 1 | | | | | | | |
| S. 1557, 109th Cong. (2005) | | | 1 | | | | 1 | | | | | | |
| S. Res. 285, 109th Cong. (2005) | | 1 | | | | | | | | | | | 1 |
| S. 2754, 109th Cong. (2006) | | | 1 | | | | 1 | | | | | | |
| H.R. 5526, 109th Cong. (2006) | | | 1 | | | | 1 | | | | | | |
| H. Res. 924, 109th Cong. (2006) | | | 1 | | | | | | | | | | 1 |
| S. 51, 110th Cong. (2007) | | | 1 | | | | 1 | | | | | | |
| H.R. 3, 110th Cong. (2007) | 1 | | | | | | | 1 | | | | | |
| H.R. 457, 110th Cong. (2007) | | | 1 | | | 1 | | | | | | | |

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| S. 362, 110th Cong. (2007) | | | 1 | | | | | 1 | | | | | |
| S. 363, 110th Cong. (2007) | | | 1 | | | | 1 | | | | | | |
| S. 812, 110th Cong. (2007) | | 1 | | | | | | | | 1 | | | |
| S. 957, 110th Cong. (2007) | | | 1 | | | | | 1 | | | | | |
| S. 997, 110th Cong. (2007) | | 1 | | | | | | 1 | | | | | |
| S. 30, 110th Cong. (2007) | | | 1 | | | | 1 | | | | | | |
| S. 5, 110th Cong. (2007) | 1 | | | 1 (Veto) | | | | 1 | | | | | |
| H.R. 1892, 110th Cong. (2007) | 1 | | | | | | | 1 | | | | | |
| H.R. 2564, 110th Cong. (2007) | | | 1 | | | | | | | 1 | | | |
| H. Res. 464, 110th Cong. (2007) | 1 | | | | | | | | | | | | 1 |
| H.R. 2807, 110th Cong. (2007) | | 1 | | | | | 1 | | | | | | |
| S. 1710, 110th Cong. (2008) | 1 | | | | 1 | | | | | | | | |

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| H.R. 3043, 110th Cong. (2008) | 1 | | | 1 (Veto) | 1 | | | | | | | | |
| S. Res. 350, 110th Cong. (2007) | | | 1 | 1 | | | | | | | | | 1 |
| H.R. 2764, 110th Cong. (2008) | 1 | | | 1 | 1 | | | | | | | | |
| S. 2863, 110th Cong. (2008) | | | 1 | | | 1 | | | | | | | |
| S. 3230, 110th Cong. (20090) | | | 1 | | 1 | | | | | | | | |
| H.R. 6884, 110th Cong. (2008) | 1 | | | | | | | 1 | | | | | |
| H.R. 7141, 110th Cong. (2008) | | 1 | | | | | | 1 | 1 | | | | |
| S. 99, 111th Cong. (2009) | | | 1 | | | 1 | | | | | | | |
| H. R. 110, 111th Cong. (2009) | | | 1 | | | | | | | 1 | | | |
| H.R. 872, 111th Cong. (2009) | | 1 | | | | | | 1 | 1 | | | | |
| H.R. 873, 111th Cong. (2009) | | 1 | | | | | | 1 | | | | | |
| H.R. 1050, 111th Cong. (2009) | | 1 | | | | | | | | 1 | | | |

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| H.R. 1105, 111th Cong. (2009) | 1 | | | 1 | 1 | | | | | | | | |
| S. 487, 111th Cong. (2009) | 1 | | | | | | | 1 | | | | | |
| H.R. 1230, 111th Cong. (2010) | 1 | | | | | | | 1 | | | | | |
| H.R. 1654, 111th Cong. (2009) | | | 1 | | | 1 | | | | | | | |
| H.R. 2107, 111th Cong. (2009) | 1 | | | | | | | | | | 1 | | |
| H.R. 3293, 111th Cong. (2010) | | | 1 | | 1 | | | | | | | | |
| H.R. 4808, 111th Cong. (2009) | 1 | | | | | | | 1 | | | | | |
| S. 3686, 111th Cong. (2011) | 1 | | | | 1 | | | | | | | | |
| S. 3751, 111th Cong. (2010) | | 1 | | 1 | | | | 1 | | | | | |
| H.R. 6081, 111th Cong. (2010) | | 1 | | | | | | 1 | | | | | |
| H.R. 6083, 111th Cong. (2010) | | 1 | | | | | | 1 | | | | | |
| H.R. 3288, 111th Cong. (2010) | 1 | | | 1 | 1 | | | | | | | | |

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| S. 3766, 111th Cong. (2009) | 1 | | | | | | | 1 | | | | | |
| H.R. 3082, 111th Cong. (2011) | 1 | | | 1 | 1 | | | | | | | | |
| S. 88, 112th Cong. (2011) | | | 1 | | | 1 | | | | | | | |
| H.R. 640, 112th Cong. (2011) | 1 | | | | | | | 1 | | | | | |
| H.R. 2376, 112th Cong. (2011) | 1 | | | | | | | 1 | | | | | |
| H.R. 2951, 112th Cong. (2011) | | | 1 | | | | 1 | | | | | | |
| H.R. 2954, 112th Cong. (2011) | 1 | | | | | | | | | | | | 1 |
| S. 1599, 112th Cong. (2011) | | | 1 | | 1 | | | | | | | | |
| H.R. 3070, 112th Cong. (2012) | | | 1 | | 1 | | | | | | | | |
| H.R. 3671, 112th Cong. (2012) | | | 1 | | 1 | | | | | | | | |
| H.R. 2055, 112th Cong. (2012) | | | 1 | 1 | 1 | | | | | | | | |
| S. 2474, 112th Cong. (2012) | 1 | | | | | | | | | | | | 1 |

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| S. 3295, 112th Cong. (2013) | 1 | | | | 1 | | | | | | | | |
| H.R. 6623, 112th Cong. (2012) | 1 | | | | | | | | | 1 | | | |
| H.R. 6072, 112th Cong. (2012) | | 1 | | | | | | | | | | | 1 |
| S. 136, 113th Cong. (2011) | | | 1 | | | 1 | | | | | | | |
| H.R. 589, 113th Cong. (2013) | | 1 | | | | | | | | | | | 1 |
| H.R. 1740, 113th Cong. (2013) | | 1 | | | | | 1 | | | | | | |
| H.R. 2164, 113th Cong. (2012) | | | 1 | | | | | | | 1 | | | |
| H.R. 2433, 113th Cong. (2013) | | 1 | | | | | | 1 | | | | | |
| S. 1284, 113th Cong. (2014) | | | 1 | | 1 | | | | | | | | |
| H.R. 3547, 113th Cong. (2014)* | | 1 | | 1 | 1 | | | | | | | | |
| H.R. 5294, 113th Cong. (2014)* | 1 | | | | | | | | | | | | 1 |
| H.R. 5464, 113th Cong. (2015)* | 1 | | | | 1 | | | | | | | | |

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| H.R. 83, 113th Cong. (2015)* | 1 | | | 1 | 1 | | | | | | | | |
| S. 43, 114th Cong. (2015)* | | | 1 | | | 1 | | | | | | | |
| H.R. 2653, 114th Cong. (2015)* | | 1 | | | | | 1 | | | | | | |
| H.R. 2820, 114th Cong. (2015)* | | 1 | | | | | | 1 | | | | | |
| H.R. 3020, 114th Cong. (2016)* | | | 1 | | 1 | | | | | | | | |