

# Science as Speech

Natalie Ram\*

*ABSTRACT: In April 2015, researchers in China reported the successful genetic editing of human embryos using a new technology that promised to make gene editing easier and more effective than ever before. In the United States, the announcement drew immediate calls to regulate or prohibit outright any use of this technology to alter human embryos, even for purely research purposes. The fervent response to the Chinese announcement was, in one respect, unexceptional. Proposals to regulate or prohibit scientific research following a new breakthrough occur with substantial frequency. Innovations in cloning technology and embryonic stem cell research have prompted similar outcries, and even resulted in legislative action. Meanwhile, the U.S. government instituted a funding “pause” on certain infectious-disease research while it contemplated whether researchers should even be permitted to complete such work.*

*Regulations such as these often seek to prevent researchers from discovering information and, consequently, can limit discourse on important matters of public concern. This Article argues that such de facto censorship implicates the First Amendment, and that constitutional scrutiny is necessary whenever the government regulates scientific inquiry in an effort to suppress knowledge production. This Article establishes a framework for assessing whether and when legislatures cross the constitutional line by regulating scientific experimentation. Applying this framework in a variety of contexts, from gene editing and human cloning to infectious-disease research, this Article also identifies both constitutionally sound and constitutionally suspect purposes for which government actors have regulated scientific research.*

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\* Assistant Professor, University of Baltimore School of Law. Many thanks to Jack Balkin, John Bickers, Gregory Dolin, Edward Fallone, William Hubbard, David Jaros, Michael Mannheimer, Colin Starger, the Honorable Fred Smalkin, Matthew Tokson, and the participants of the Marquette University Junior Scholars Works-in-Progress conference and the Northern Kentucky University faculty workshop series for their helpful comments on this project.

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## I. INTRODUCTION

In April of 2015, researchers in China reported that they had successfully genetically edited human embryos.<sup>1</sup> Using the gene-editing tool known as CRISPR/Cas9,<sup>2</sup> the researchers modified the gene responsible for beta thalassemia, a heritable and potentially fatal blood disorder.<sup>3</sup> Although the researchers emphasized that they performed their work using non-viable embryos, which cannot result in a live birth,<sup>4</sup> controversy surrounded the announcement.

Even before this work was accepted for publication, rumors about it prompted prominent figures in the scientific community to urge caution, if not an outright halt, to such research. *Nature*, among the most prominent

1. Puping Liang et al., *CRISPR/Cas9-Mediated Gene Editing in Human Tripromuclear Zygotes*, 6 *PROTEIN & CELL* 363, 363 (2015); see also David Cyranoski & Sara Reardon, *Chinese Scientists Genetically Modify Human Embryos*, *NATURE* (Apr. 22, 2015), <http://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378>.

2. CRISPR stands for “clustered, regularly interspaced, short palindromic repeat” while Cas9 refers to “CRISPR-associated protein 9.” Jeffrey D. Sander & J. Keith Joung, *CRISPR-Cas Systems for Editing, Regulating and Targeting Genomes*, 32 *NATURE BIOTECHNOLOGY* 347, 347 (2014).

3. See generally Liang et al., *supra* note 1; Cyranoski & Reardon, *supra* note 1.

4. See Liang et al., *supra* note 1, at 364.

scientific journals, published a commentary entitled *Don't Edit the Human Germ Line*.<sup>5</sup> This commentary argued that, for both safety and ethical reasons, researchers should not utilize the CRISPR/Cas9 protocol to modify human embryos or gametes in ways that, if applied clinically, might give rise to heritable changes.<sup>6</sup> It also spoke approvingly of broader efforts to prohibit such techniques.<sup>7</sup> Similar calls for a moratorium on or prohibition of such research also emerged elsewhere in the scientific and bioethics communities.<sup>8</sup>

Others took a more sanguine approach. Two prominent researchers who played central roles in pioneering the CRISPR/Cas9 protocol have proposed that governments permit research, including on the human germline, to proceed.<sup>9</sup> These researchers nonetheless agreed that clinical use of germline editing should be kept at bay for the present time.<sup>10</sup> The regulatory body charged with licensing human-embryo research in the United Kingdom, meanwhile, recently approved just such an arrangement—permitting gene editing in embryos for research purposes, but not for clinical use.<sup>11</sup>

5. Edward Lanphier et al., *Don't Edit the Human Germ Line*, 519 NATURE 410 (2015).

6. *Id.* at 410; see also Gretchen Vogel, *Embryo Engineering Alarm: Researchers Call for Restraint in Genome Editing*, 347 SCIENCE 1301, 1301 (2015) (“Edward Lanphier, and four colleagues call for a moratorium on any experiments that involve editing genes in human embryos or cells that could give rise to sperm or eggs.”).

7. Lanphier et al., *supra* note 5, at 411; see also Tanya Lewis, *2 Leading Biologists Say We Should Allow Gene Editing on Human Embryos*, BUS. INSIDER (Nov. 30, 2015, 11:00 AM), <http://www.businessinsider.com/leading-biologists-say-we-should-allow-gene-editing-on-human-embryos-2015-11> (describing Lanphier’s commentary as “call[ing] for a ban on such research”); *Why Banning CRISPR Gene Editing Would Be Unnecessarily Cautious*, NEW SCIENTIST (Dec. 2, 2015), <https://www.newscientist.com/article/dn28594-why-banning-crispr-gene-editing-would-be-unnecessarily-cautious> (“Early this year, a few researchers . . . call[ed] for a temporary ban even on basic research.”).

8. See Jocelyn Kaiser & Dennis Normile, *Embryo Engineering Study Splits Scientific Community*, 348 SCIENCE 486, 486 (2015) (stating that, in the wake of the Liang et al. article reporting germline editing of non-viable human embryos, “[t]he Center for Genetics and Society in Berkeley, California, a watchdog group, called for a halt to such experiments. The Society for Developmental Biology in Bethesda, Maryland, called for a voluntary moratorium as well”); John Travis, *Germline Editing Dominates DNA Summit*, 350 SCIENCE 1299, 1300 (2015) (“Catholic theologian Hille Haker of Loyola University Chicago in Illinois . . . called for a ban on all human germline editing research.”); see also Hille Haker, Loyola Univ. Chi., Remarks at the International Summit on Human Gene Editing, Panel on Societal Implications of Emerging Technologies (Dec. 1, 2015) (calling for a moratorium on basic research on germline gene editing for two years to allow for development of “[r]egulations to exclude that basic research [that may be] used to pave the way for reproductive gene editing,” and arguing that both “[p]ublic [and] private research must be regulated by laws and/or effective forms of governance”).

9. David Baltimore et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, 348 SCIENCE 36, 37 (2015); Jennifer Doudna, *Embryo Editing Needs Scrutiny*, 528 NATURE S6, S6 (2015).

10. Baltimore et al., *supra* note 9, at 37; Doudna, *supra* note 9, at S6.

11. Press Release, Human Fertilisation & Embryology Auth., HFEA Approves Licence Application to Use Gene Editing in Research (Feb. 1, 2016), <http://www.hfea.gov.uk/10187.html>; see also Ewen Callaway, *UK Scientists Gain Licence to Edit Genes in Human Embryos*, NATURE (Feb. 4, 2016), <http://www.nature.com/news/uk-scientists-gain-licence-to-edit-genes-in>

The recent focus on gene editing is not without cause. CRISPR/Cas9 holds tremendous promise for efficient, effective, and relatively straightforward gene-editing capabilities far beyond previously existing technologies. CRISPR relies on the Cas9 enzyme that “uses a guide RNA molecule to home in on its target DNA, then edits the DNA to disrupt genes or insert desired sequences.”<sup>12</sup> In other words, in combination with a known and desired DNA target sequence, the CRISPR/Cas9 protocol can precisely excise, insert, or otherwise modify that sequence.<sup>13</sup> Previous methods for gene editing were cumbersome, inexact, expensive, or all three.<sup>14</sup> CRISPR/Cas9 might just change all that. And so the question of whether and where to draw lines between permissible and impermissible applications of this technology—as well as who should be drawing those lines—urgently demands an answer.

The fervent response to the Chinese announcement was, in one respect, unexceptional. Indeed, questions about the appropriate bounds of scientific research recur with relative frequency. In 1996, researchers produced a sheep, Dolly, using somatic cell nuclear transfer (“SCNT”), commonly known as “cloning.”<sup>15</sup> Ever since, the United States has struggled to identify an appropriate approach to human cloning and to codify that approach in law. Members of Congress have repeatedly introduced bills that would prohibit some or all human cloning.<sup>16</sup> In 2001 and 2003, the House of Representatives passed measures banning human cloning for both reproductive and research purposes, though the Senate did not take up either measure.<sup>17</sup> Meanwhile, at least six states have enacted laws prohibiting all human cloning, whether for reproductive or research purposes.<sup>18</sup> By contrast, other states, including

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human-embryos-1.19270 (describing and discussing the newly-issued license for embryo research, including use of CRISPR/Cas9 technique).

12. Heidi Ledford, *CRISPR, the Disruptor*, 522 NATURE 20, 21 (2015).

13. *See id.*

14. *See id.*

15. *See generally* K. H. S. Campbell et al., *Sheep Cloned by Nuclear Transfer from a Cultured Cell Line*, 380 NATURE 64 (1996).

16. *See, e.g.*, Human Cloning Prohibition Act of 2105 [sic], H.R. 3498, 114th Cong.; Human Cloning Prohibition Act of 2012, H.R. 2164, 113th Cong.; Human Cloning Prohibition Act of 2012, H.R. 6623, 112th Cong.; Human Cloning Prohibition Act of 2009, H.R. 110, 111th Cong.; Human Cloning Prohibition Act of 2007, H.R. 2564, 110th Cong.; Human Cloning Prohibition Act of 2005, H.R. 1357, 109th Cong.; Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong.; Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong.; Human Cloning Prohibition Act of 1998, S. 1599, 105th Cong.

17. Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (as passed by House, Feb. 27, 2003); Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. (as passed by House, July 31, 2001).

18. *See* Russell Korobkin, *Stem Cell Research and the Cloning Wars*, 18 STAN. L. & POL'Y REV. 161, 169 (2007) (“To date, at least six states—Arkansas, Indiana, Iowa, Michigan, North Dakota, and South Dakota—have enacted statutes that prohibit all human cloning, for therapeutic as well as reproductive purposes, within their borders.” (citations omitted)).

California and New Jersey, explicitly protect cloning for biomedical research.<sup>19</sup> California has gone further still, appropriating substantial funds to support cloning for biomedical research.<sup>20</sup>

The debate over human cloning again grabbed headlines when, in 2004, South Korean researcher Woo Suk Hwang claimed that he had created the first stem cell line derived from a human embryo created through SCNT.<sup>21</sup> Just over a year later, Hwang reported that he had followed this success with another: the creation of 11 patient-specific stem cell lines derived from SCNT embryos using the patient's somatic cells.<sup>22</sup> Following the announcement of Hwang's supposed research successes, some members of Congress renewed their calls for a complete ban on human cloning in the United States.<sup>23</sup> Hwang's reports, had they accurately reflected Hwang's research, would have put the hopes of stem cell research and personalized cell-based therapies within reach. The cell lines Hwang reported creating would have been the first successfully derived-from-human SCNT embryos, and those lines would have been created on a much more efficient scale than previously reported SCNT attempts. As it turned out, however, Hwang faked his research results and had accomplished nothing close to what he had claimed.<sup>24</sup> Along the way, Hwang had obtained (in some instances, unethically) and wasted more than 2,000 human eggs from 129 women.<sup>25</sup>

Moreover, matters of scientific regulation arise not only in the context of advanced embryo research; questions about the appropriate bounds of scientific experimentation and dissemination of its results also have arisen

19. See *id.* at 169, 169 n.54 (identifying supportive statutes in California, Massachusetts, New Jersey, Rhode Island, and Virginia).

20. See Wesley J. Smith, *Cloning for California?: A Money Grab for Human-Cloning Research*, NAT'L REV. (May 6, 2004, 8:30 AM), <http://www.nationalreview.com/article/210551/cloning-california-wesley-j-smith>; see also generally California Stem Cell Research and Cures Act, CAL. HEALTH & SAFETY CODE §§ 125290.10–125290.80 (West 2012); California Stem Cell Research and Cures Bond Act of 2004, CAL. HEALTH & SAFETY CODE §§ 125291.10–125291.85 (West 2012).

21. See generally Woo Suk Hwang et al., *Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst*, 303 SCIENCE 1669 (2004).

22. See generally Woo Suk Hwang et al., *Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts*, 308 SCIENCE 1777 (2005).

23. See *Call Renewed in U.S. for Ban on Human Cloning*, L.A. TIMES (Feb 13, 2004), <http://articles.latimes.com/2004/feb/13/nation/na-clonereact13>.

24. See generally David Cyranoski, *TV Tests Call into Question Cloner's Stem-Cell Success*, 438 NATURE 718 (2005); Maggie Fox, *U.S. Scientist Further Questions Korean Clone Study*, STAR ONLINE (Dec. 14, 2005, 12:00 AM), <http://www.thestar.com.my/news/world/2005/12/14/us-scientist-further-questions-korean-clone-study>. Subsequent research has made advances toward the results Hwang fabricated but, to this day, has not achieved all that Hwang's publications promised. See generally, e.g., Young Gie Chung et al., *Human Somatic Cell Nuclear Transfer Using Adult Cells*, 14 CELL STEM CELL 777 (2014); Masahito Tachibana et al., *Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer*, 153 CELL 1228 (2013).

25. See Nicholas Wade & Choe Sang-Hun, *Human Cloning Was All Faked, Koreans Report*, N.Y. TIMES (Jan. 10, 2006), <http://query.nytimes.com/gst/fullpage.html>.

with regard to infectious-disease research. In December of 2011, the National Science Advisory Board for Biosecurity (“NSABB”), a government advisory board, asked *Nature* and *Science* to censor certain “experimental details and mutation data” in articles describing research involving the A/H<sub>5</sub>N<sub>1</sub> influenza virus (“H<sub>5</sub>N<sub>1</sub>”), commonly known as “avian flu.”<sup>26</sup> Research teams in the United States and the Netherlands had created strains of the avian flu virus that were highly transmissible in ferrets, which contract the same flu viruses as humans.<sup>27</sup> The government’s request rested on concerns that the full publications “would enable replication of the experiments,”<sup>28</sup> creating a national security threat. After a 60-day moratorium and an international summit regarding the propriety of publication, the NSABB reversed its request and *Nature* and *Science* published articles describing the research in full.<sup>29</sup> The NSABB concluded, “[n]ew evidence has emerged that underscores the fact that understanding specific mutations may improve international surveillance and public health and safety.”<sup>30</sup>

The U.S. government and others have had similar concerns about other infectious-disease research. In 2005, the U.S. government expressed concern about, though it did not request censorship of, articles describing research that reconstructed the deadly 1918 influenza virus.<sup>31</sup> In 2014, it instituted a “pause” on certain federally funded virology studies.<sup>32</sup> Pursuant to this “pause,” the government halted “virology studies that involve tweaking influenza, MERS, and SARS viruses in ways that could make them more transmissible or pathogenic in mammals” and encouraged all researchers conducting such studies (regardless of their funding source) to suspend their

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26. Denise Grady & William J. Broad, *Seeing Terror Risk, U.S. Asks Journals to Cut Flu Study Facts*, N.Y. TIMES: HEALTH (Dec. 20, 2011), <http://www.nytimes.com/2011/12/21/health/fearing-terrorism-us-asks-journals-to-censor-articles-on-virus.html>.

27. *Id.* (“In the experiments, conducted in the United States and the Netherlands, scientists created a highly transmissible form of a deadly flu virus that does not normally spread from person to person. It was an ominous step, because easy transmission can lead the virus to spread all over the world. The work was done in ferrets, which are considered a good model for predicting what flu viruses will do in people.”); Donald G. McNeil, Jr., *Bird Flu Paper Is Published After Debate*, N.Y. TIMES (June 21, 2012), <http://www.nytimes.com/2012/06/22/health/h5n1-bird-flu-research-that-stoked-fears-is-published.html> (writing that the research conducted by scientists in the Netherlands “identified five mutations apparently necessary to make the bird flu virus spread easily among ferrets, which catch the same flus that humans do”).

28. Grady & Broad, *supra* note 26.

29. McNeil, *supra* note 27.

30. NAT’L SCI. ADVISORY BD. FOR BIOSECURITY, STATEMENT OF THE NSABB (2012), [http://osp.od.nih.gov/sites/default/files/resources/NSABB\\_Statement\\_March\\_2012\\_Meeting.pdf](http://osp.od.nih.gov/sites/default/files/resources/NSABB_Statement_March_2012_Meeting.pdf).

31. Peter Palese, *Don’t Censor Life-Saving Science*, 481 NATURE 115, 115 (2012).

32. See *Biosecurity: National Science Advisory Board for Biosecurity (NSABB)*, NAT’L INSTITUTES HEALTH, <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb> (last visited Jan. 15, 2017); Jocelyn Kaiser, *Moratorium on Risky Virology Studies Leaves Work at 14 Institutions in Limbo*, SCIENCE (Nov. 17, 2014, 3:30 PM), <http://www.sciencemag.org/news/2014/11/moratorium-risky-virology-studies-leaves-work-14-institutions-limbo>.

work.<sup>33</sup> James Clapper, U.S. Director of National Intelligence, recently identified “genome editing,” like CRISPR and the avian flu research, as a “weapon[] of mass destruction and proliferation.”<sup>34</sup>

Of course, the government’s request regarding the H<sub>5</sub>N<sub>1</sub> articles, and even the virology research “pause,” differ from outright research prohibitions. The H<sub>5</sub>N<sub>1</sub> request concerned the publication of material pertaining to already-completed experiments. There is no doubt that prior restraint of publication implicates serious First Amendment scrutiny.<sup>35</sup> Moreover, the government ultimately reversed its request and supported full publication.<sup>36</sup> As for the virology research “pause,” the government only stopped research it was directly funding, while requesting voluntary suspension of similar research with alternative funding sources.<sup>37</sup> But it is not difficult to imagine that the impulse to try and answer difficult national security questions before they arise with a compulsory prohibition, regardless of the funding source, would be attractive.

Scientific research undoubtedly serves socially desirable goals. It seeks to make sense of the natural world, to push the boundaries of human understanding, and to harness the very building blocks of life for the amelioration of human suffering. Yet, science can also tread on questions of ethics and human dignity, and it can raise legitimate and significant national security concerns. Against this backdrop of controversy, ethical consideration, and evolving patchworks of legislation is a serious question about whether and how government should be permitted to regulate the means or ends of scientific inquiry. This Article takes on that question, concluding that some regulations of scientific research run afoul of the Constitution’s Free Speech Clause.<sup>38</sup>

33. Kaiser, *supra* note 32. The federal government has imposed similar funding bans in other areas of public health research, including gun violence. See Michael Hiltzik, *The NRA Has Blocked Gun Violence Research for 20 Years. Let’s End Its Stranglehold on Science*, L.A. TIMES (June 14, 2016, 9:58 AM), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-gun-research-funding-20160614-snap-story.html> (describing how, for 20 years, the Centers for Disease Control and Prevention’s National Center for Injury Prevention and Control has been declined, refused, or prevented from receiving funding for gun violence research).

34. *Worldwide Threat Assessment of the US Intelligence Community: Hearing Before the S. Armed Services Committee*, 113th Cong. 6, 9 (2016), [https://www.dni.gov/files/documents/SASC\\_Unclassified\\_2016\\_ATA\\_SFR\\_FINAL.pdf](https://www.dni.gov/files/documents/SASC_Unclassified_2016_ATA_SFR_FINAL.pdf) (statement for the record of James R. Clapper, Director of National Intelligence); see also Antonio Regalado, *Top U.S. Intelligence Official Calls Gene Editing a WMD Threat*, MIT TECH. REV. (Feb. 9, 2016), <https://www.technologyreview.com/s/600774/top-us-intelligence-official-calls-gene-editing-a-wmd-threat>.

35. See, e.g., *N.Y. Times Co. v. United States*, 403 U.S. 713 (1971) (per curiam); *United States v. Progressive, Inc.*, 467 F. Supp. 990, 992 (W.D. Wis. 1979) (“[A]ny prior restraint on publication comes into court under a heavy presumption against its constitutional validity.”), *appeal dismissed*, 610 F.2d 819 (7th Cir. 1979)).

36. *Progressive, Inc.*, 467 F. Supp. 990.

37. Kaiser, *supra* note 32.

38. U.S. CONST. amend. I; see also *infra* Part III.

Efforts to regulate scientific research may seek to prevent people from discovering information and, consequently, can limit discourse on important matters of public concern. This Article argues that such de facto censorship should trigger First Amendment scrutiny. In so doing, this Article makes three contributions to the existing literature. First, after Part II lays out a foundation identifying what it means to regulate “science,” Part III argues that First Amendment scrutiny is necessary whenever the government regulates scientific inquiry in an effort to suppress knowledge production. This Part establishes that a primary First Amendment concern is the creation and dissemination of new ideas and information, building on and extending the work of other scholars who have linked the First Amendment to knowledge production and exchange.

Second, recognizing that not all government regulations that affect scientific research raise similar constitutional concerns, Part III establishes a framework for assessing whether and when legislatures cross the constitutional line by regulating such research. Part IV extends this inquiry by exploring, incorporating, or rejecting other theories for constitutionally protecting scientific research. This Part argues that these earlier approaches mischaracterize the essence of the relationship between science and the First Amendment: the role of science in producing ideas, information, and knowledge. Finally, Part V applies this new framework for First Amendment analysis of scientific-research restrictions to the contemporary scientific controversies, including gene editing of human embryos, human cloning, and infectious-disease research. In so doing, this Part identifies both constitutionally sound and constitutionally suspect purposes for which legislatures and other rule-making bodies have regulated scientific research.

## II. DEFINING “SCIENCE”

Before exploring the limits that the First Amendment places on government regulation of scientific inquiry, it is first necessary to define what counts as “science.” After all, it is both more difficult and less helpful to explicate a relationship between the Constitution and scientific research if “science” remains an opaque subject against which the First Amendment might be tested.

Unfortunately, defining “science,” “scientific inquiry,” and “scientific research” is not at all straightforward: “Throughout the history of science, philosophers and scientists have sought to describe a single systematic procedure that can be used to generate scientific knowledge, but they have never been completely successful.”<sup>39</sup> Indeed, philosophers of science have repeatedly struggled with “the intellectual and practical difficulties of identifying those characteristics of science that define it as a discrete social

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39. NAT’L ACAD. OF SCI. ET AL., ON BEING A SCIENTIST: RESPONSIBLE CONDUCT IN RESEARCH 3 (2d ed. 1995).

practice, distinguishing it from neighboring mansions, competing intellectual practices, or pretenders to its epistemological throne.”<sup>40</sup>

Beyond the difficulties inherent in demarcation generally, defining “science” is yet more difficult in light of the fact that the meaning of “science” has changed over time. The Constitution, for instance, invokes “Science” by name in its Progress Clause, empowering Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>41</sup> As other scholars have explored at length, however, the “Science” named here is quite distinct from what falls into the modern ken of “science” and “scientific research.”<sup>42</sup> On one account, “[t]he original understanding of the aim of the [Progress Clause] was that Congress must aim at the encouragement of systematic knowledge or learning of enduring value.”<sup>43</sup> “Science,” more specifically, “denote[d] any branch of organized or demonstrated knowledge.”<sup>44</sup> By contrast, our modern understanding of the scope of “science” tends to hew more narrowly. This means that a long history of consistent use cannot adequately guide the modern definitional inquiry.

Nonetheless, some rough lines may be drawn. What appears critical to the modern definition of “science” is “an emphasis on the systematic collection or generation of *empirical* data (i.e., information based on human observation of events or phenomena in the perceivable world); and . . . the utilization of unbiased and rigorous modes of testing, analysis, and evaluation to draw inferences and conclusions about those data.”<sup>45</sup> Similarly, the *Oxford English Dictionary* observes that modern use of the term “science” is “often treated as synonymous with ‘Natural and Physical Science’, and thus restricted to those branches of study that relate to the phenomena of the material universe and their laws, sometimes with implied exclusion of pure mathematics.”<sup>46</sup> These general definitions describe the general contours of the classical scientific method, although in terms broad enough to embrace not only lab science, but also observational sciences like astronomy,

40. CHARLES ALAN TAYLOR, *DEFINING SCIENCE: A RHETORIC OF DEMARCATION* 4 (1996); see also Robin Feldman, *Historic Perspectives on Law & Science*, 2009 STAN. TECH. L. REV. 1, 11–12 (describing “the difficulty of defining science at all”).

41. U.S. CONST. art. I, § 8, cl. 8.

42. See Lawrence B. Solum, *Congress’s Power to Promote the Progress of Science: Eldred v. Ashcroft*, 36 LOY. L.A. L. REV. 1, 47–53 (2002).

43. *Id.* at 53.

44. I. BERNARD COHEN, *SCIENCE AND THE FOUNDING FATHERS* 281 (1995).

45. Barry P. McDonald, *Government Regulation or Other “Abridgements” of Scientific Research: The Proper Scope of Judicial Review Under the First Amendment*, 54 EMORY L.J. 979, 988–89 (2005) (defining “science” as “adherence to a certain process or method of deriving knowledge”); see also NAT’L ACAD. OF SCI. ET AL., *supra* note 39, at 2 (“[Scientists] are able to make claims about the world that are subject to empirical tests.”).

46. 14 J.A. SIMPSON & E.S.C. WEINER, *THE OXFORD ENGLISH DICTIONARY* 649 (2d ed. 1989).

climatology, and perhaps observational social sciences. Adherence to these processes and methods of deriving information should describe “science” for purposes of First Amendment adjudication.

While the Constitution’s Progress Clause is of limited aid in defining “science” for the present purposes, the law that has grown out of that clause provides a useful foil for the modern definition in two ways. First, as with patents and copyrights, it is fundamental that scientific research “seek[s] to increase the store of human knowledge.”<sup>47</sup> “Science” is committed to the production of generalizable knowledge and to knowledge production that builds on the past work of others.<sup>48</sup> This requires something more than private experimentation for one’s own edification alone.<sup>49</sup> Second, looking to the limits of patent law may help identify key concepts that lie within the realm of “science,” precisely because they are unpatentable. Patent law has long distinguished between discovery and invention, holding that only the latter is patentable subject matter.<sup>50</sup> Patent law has excluded “[p]henomena of nature, though just discovered,” from the scope of patentable subject matter because “they are the basic tools of scientific and technological work. And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.”<sup>51</sup> The Supreme Court has recognized, in other words, that certain results from scientific inquiry cannot be patentable because they are too close to the core of “science” itself, such that a patent would impede, rather than encourage, “the Progress of Science and useful Arts.”<sup>52</sup> By contrast, the modern understanding of “science” need not make a similar distinction. If anything, those matters that are deemed “discoveries” beyond patentable subject matter represent the *sine qua non* of “science” more so than patentable inventions.<sup>53</sup>

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47. *Lasercomb Am., Inc. v. Reynolds*, 911 F.2d 970, 976 (4th Cir. 1990).

48. See generally Sheila Jasanoff, *Transparency in Public Science: Purposes, Reasons, Limits*, 69 L. & CONTEMP. PROBS. 21 (2006) (“In technologically advanced democracies, it is almost an article of faith that openness is essential both for the advancement of science and for its beneficial interaction with society.”); Letter from Sir Isaac Newton to Robert Hooke (Feb. 5, 1675), [http://digitallibrary.hsp.org/index.php/Detail/Object/Show/object\\_id/9285](http://digitallibrary.hsp.org/index.php/Detail/Object/Show/object_id/9285) (“If I have seen further, it is by standing on the shoulders of giants.”).

49. See McDonald, *supra* note 45, at 990 (describing the importance of dissemination to the meaning of “scientific knowledge”).

50. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293–94 (2012).

51. *Id.* at 1293 (citation omitted).

52. U.S. CONST. art. I, § 8, cl. 8.

53. By contrast, at least some of what the patent laws deem patentable lies beyond the scope of “science” itself. Business method patents, for instance, are commercially oriented, mathematically based programs. See generally *Bilski v. Kappos*, 561 U.S. 593 (2010). They are not necessarily the product of processes to uncover and create new knowledge.

### III. KNOWLEDGE PRODUCTION AND THE FIRST AMENDMENT

Constitutional protection for scientific experimentation may not, on its face, appear fitting. After all, First Amendment doctrine typically distinguishes between “expression,” which the Constitution protects against unnecessary government regulation, and “nonexpressive conduct,” which ordinarily falls beyond the scope of First Amendment protection.<sup>54</sup>

But such an approach is unduly narrow. Scientific experimentation, as one of the primary modes of producing new information and knowledge, reflects fundamental principles and values of First Amendment theory. Part III.A locates knowledge production at the heart of multiple strands of First Amendment theory, grounding the proposition that government regulations that suppress knowledge production may trigger First Amendment scrutiny. Part III.B identifies three primary modes of knowledge production, including scientific experimentation. Finally, Part III.C sets forth a framework for analyzing government regulations that affect scientific experimentation, clarifying that constitutional scrutiny is most appropriate where the purpose of such regulations is to prevent knowledge from coming into being.

#### A. IDEAS, KNOWLEDGE, AND THE FIRST AMENDMENT

Constitutional scholars have devoted extensive time and energy to identifying the values underlying the First Amendment’s Free Speech Clause. Under some theories, the ability of listeners to access information is of utmost importance,<sup>55</sup> while participation in meaning-making is most closely valued under others.<sup>56</sup> Across these theories, however, runs a common concern: preventing the State from skewing the range of knowledge available to consider, try on, or build upon. In turn, as set forth below, these theories evince a concern about government interference with knowledge production.

Such a concern is readily apparent in both the self-governance and truth-seeking theories of the First Amendment. Under the self-governance theory, Alexander Meiklejohn described the First Amendment as insurance “that no suggestion of policy shall be denied a hearing because it is on one side of the issue rather than another,” and not as “the guardian of unregulated talkativeness.”<sup>57</sup> Under the truth-seeking theory, all ideas outside of low-

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54. See, e.g., *Ashcroft v. Free Speech Coal.*, 535 U.S. 234, 253 (2002) (“[T]he Court’s First Amendment cases draw vital distinctions between words and deeds, between ideas and conduct.”).

55. See *infra* notes 58–59 and accompanying text.

56. See Jack M. Balkin, Commentary, *Digital Speech and Democratic Culture: A Theory of Freedom of Expression for the Information Society*, 79 N.Y.U. L. REV. 1, 33–35 (2004) (linking “meaning-making” to “democratic culture” and linking “democratic culture” in turn to the First Amendment); see also *infra* notes 60–67 and accompanying text.

57. ALEXANDER MEIKLEJOHN, *FREE SPEECH AND ITS RELATION TO SELF-GOVERNMENT* 25–26 (1948).

speech categories<sup>58</sup> are equally protected because “[a]n individual who seeks knowledge and truth must hear all sides of the question, consider all alternatives, test his judgment by exposing it to opposition, and make full use of different minds.”<sup>59</sup> The central concern of the pursuit-of-truth understanding of the First Amendment, as in the self-governance theory, is for the ideas expressed rather than a particular speaker’s ability to speak.

The principal instinct in both the truth-seeking and self-governance theories suggest that the First Amendment is concerned primarily with facilitating knowledge formation and exchange. Building from this foundation, the First Amendment must also be concerned with the production of ideas and information. James Madison recognized the connection between an informed public and one able to pursue the production of information, writing, “[a] popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy; or perhaps both.”<sup>60</sup> Just as the First Amendment constrains the State in closing down sectors of debate simply because the State does not like the ideas involved, the First Amendment must likewise constrain (to some degree) the State’s authority to suppress activities that generate ideas and knowledge in the first place. If this were not so, then the State would be free to shape and control the cacophony within the public sphere of free expression in impermissible ways by selectively suppressing the production of knowledge about certain subjects and ideas.

Concern for knowledge production is similarly at the core of other prominent First Amendment theories. Under Seana Valentine Shiffirin’s thinker-based approach, free speech theory “takes to be central the individual agent’s interest in the protection of the free development and operation of her mind.”<sup>61</sup> In articulating the scope of what triggers First Amendment scrutiny pursuant to the thinker-based approach, Shiffirin identifies

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58. See *Chaplinsky v. New Hampshire*, 315 U.S. 568, 572 (1942) (defining low-speech as speech that is “of such slight social value as a step to truth that any benefit that may be derived from [it] is clearly outweighed by the social interest in order and morality”). Low-speech categories are somewhat of an exception to the rule of content neutrality, as they permit content-based restrictions on speech. However, even in the context of low-speech categories, government is relatively constrained from imposing viewpoint-based restrictions on speech. See *R.A.V. v. City of St. Paul*, 505 U.S. 377, 383–84 (1992) (“What [cases identifying low speech-categories] mean is that these areas of speech can, consistently with the First Amendment, be regulated *because of their constitutionally proscribable content* (obscenity, defamation, etc.)—not that they are categories of speech entirely invisible to the Constitution, so that they may be made the vehicles for content discrimination unrelated to their distinctively proscribable content. Thus, the government may proscribe libel; but it may not make the further content discrimination of proscribing *only* libel critical of the government.” (alterations in original)).

59. THOMAS I. EMERSON, *THE SYSTEM OF FREEDOM OF EXPRESSION* 6–7 (1970).

60. 9 *THE WRITINGS OF JAMES MADISON* 103 (Gaillard Hunt ed., 1910).

61. Seana Valentine Shiffirin, *A Thinker-Based Approach to Freedom of Speech*, 27 *CONST. COMMENT.* 283, 287 (2011).

knowledge production. She explains that government regulation may run afoul for the thinker-based approach when, among other things, it “ban[s] or attempt[s] to ban the free development and operation of a person’s mind or those activities or materials necessary for its free development and operation.”<sup>62</sup> In other words, government regulation implicates the First Amendment where it interferes with activities that give rise to the free development and operation of the mind. Moreover, Shiffrin explains that speech is especially important and worthy of constitutional protection because it has the capacity to be “exploratory[,] to allow us in a non-committal way to try on an idea.”<sup>63</sup> This description of the importance of speech reflects the importance of knowledge production in two ways. First, that if there may be regulation of knowledge produced, there will be a skewed universe of ideas to “try on.” Second, that scientific experimentation, more specifically, may itself be described in much the same way Shiffrin describes speech—as “exploratory” and a way to test an idea.<sup>64</sup>

Similarly, those who link the First Amendment to democratic culture and the information society recognize the central role of knowledge production and access to knowledge. Jack Balkin argues that “[t]he purpose of freedom of speech . . . is to promote a democratic culture” that “allows ordinary people to participate freely in the spread of ideas and in the creation of meanings that, in turn, help constitute them as persons.”<sup>65</sup> Balkin explains that “[i]n a democratic culture people are free to appropriate elements of culture that lay to hand, criticize them, build upon them, and create something new that is added to the mix of culture and its resources.”<sup>66</sup> He emphasizes “each individual’s ability to participate in the production and distribution of culture.”<sup>67</sup> Indeed, much of Balkin’s theory of democratic culture focuses on “production” and “creation”—acts that cohere with a First Amendment drive toward knowledge production. Under this approach, Balkin criticizes state regulations that target “party A in order to control speaker B.”<sup>68</sup> Collateral

62. *Id.*; see also Jane Bambauer, *Is Data Speech?*, 66 STAN. L. REV. 57, 88 (2014) (relying on Shiffrin’s thinker-based approach in articulating a broad “right to create knowledge”). Bambauer describes Shiffrin’s thinker-based approach as “the backbone” of Bambauer’s own proposal for an uninhibited right to collect and mine data. Bambauer, *supra*, at 83 n.114.

63. Shiffrin, *supra* note 61, at 307.

64. See William J. McGuire, *A Perspectivist Approach to the Strategic Planning of Programmatic Scientific Research*, in PSYCHOLOGY OF SCIENCE: CONTRIBUTIONS TO METASCIENCE 214, 214 (Barry Gholson et al. eds., 1989) (“[O]ur conceptions of science emphasize (and perhaps overemphasize) its empirical hypothesis-testing because it is the defining feature that most distinguishes science from other approaches to knowledge.”); see also *supra* Part II (discussing the definition of “scientific experimentation”).

65. Balkin, *supra* note 56, at 3–4.

66. *Id.* at 5.

67. *Id.* at 3–4.

68. Jack M. Balkin, *Old-School/New-School Speech Regulation*, 127 HARV. L. REV. 2296, 2298 (2014).

ensorship of this kind similarly arises in the context of knowledge-production regulation more broadly, wherein the State restricts individuals engaged in knowledge production in order to prevent certain knowledge from becoming available for debate and discussion. In both instances, the State targets a non-traditional actor in order to suppress related First Amendment activity. Viewing the First Amendment as essential to a democratic culture once again necessitates First Amendment attention to government regulation of knowledge production itself.

Finally, characterizing the First Amendment as concerned with knowledge production also brings it into harmony, rather than tension, with the Progress Clause. The Supreme Court has observed, “[t]he [Progress] Clause and First Amendment were adopted close in time. This proximity indicates that, in the Framers’ view, copyright’s limited monopolies are compatible with free speech principles.”<sup>69</sup> As discussed above, the “Science” identified in the Progress Clause “was used to denote any branch of organized or demonstrated knowledge.”<sup>70</sup> Thus, the Framers of the Constitution intended the Progress Clause to promote knowledge production broadly. A First Amendment that is likewise protective of knowledge producing activities is most appropriate theoretically, historically, and doctrinally.

In sum, knowledge production generally embodies deep principles and values of First Amendment theory. Under a number of theories about the guiding principles of the Free Speech Clause, a concern for knowledge production is essential. The ability to speak or listen to all ideas or viewpoints—activities that the First Amendment strongly protects—is of little meaning if the State can simply prevent people from ever discovering certain kinds of knowledge.

#### B. SCIENCE AND THE MODES OF KNOWLEDGE PRODUCTION

Scientific experimentation is one of the primary means by which people develop new knowledge. There are three readily identifiable modes of producing knowledge, two of which already receive strong First Amendment protection: philosophy (knowledge production by dialectic) and art (knowledge production through expression). Science, or knowledge production through experimentation guided by empirical methodologies, deserves similar constitutional attention.

Philosophy and the liberal arts are notable knowledge-production engines because they rely on processes of dialectic, analysis, and reason to arrive at novel conclusions or conjectures. Philosophy is presently protected under the First Amendment on theories of protection for communicative acts as well as for “individual freedom of mind.”<sup>71</sup> As set forth above, the freedom

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69. *Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003).

70. COHEN, *supra* note 44, at 281.

71. *Wooley v. Maynard*, 430 U.S. 705, 714 (1977); *see also Baird v. State Bar of Ariz.*, 401

to think is indispensable to discovering new ideas and information, and the knowledge generated in dialectic exchange is a core First Amendment concern.<sup>72</sup> Accordingly, philosophy and the liberal arts merit First Amendment protection because they are primary modes of knowledge production. Indeed, courts frequently act in accord with the knowledge-production rationale in their holdings, if not in their explicit reasoning.<sup>73</sup>

Art, like philosophy, not only introduces and expresses new ideas, but it can also trigger, result from, or represent new ways of thinking about the world. Art can provoke intense discussion, make a statement, or challenge norms and the status quo.<sup>74</sup> Visual art is generally deemed protected expression under the First Amendment.<sup>75</sup> Because of its ability to communicate directly, courts recognize that art falls within the scope of “speech” that is the forefront of First Amendment protection.<sup>76</sup> Insofar as art

U.S. 1, 6 (1971) (“The First Amendment gives freedom of mind the same security as freedom of conscience.” (quoting *Thomas v. Collins*, 323 U.S. 516, 531 (1945))).

72. See Shiffrin, *supra* note 61, at 287. The truth-seeking and self-governance rationales of the First Amendment likewise place emphasis on the role of communication leading to idea formation and dissemination. See *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting) (“[W]hen men have realized that time has upset many fighting faiths, they may come to believe even more than they believe the very foundations of their own conduct that the ultimate good desired is better reached by free trade in ideas—that the best test of truth is the power of the thought to get itself accepted in the competition of the market, and that truth is the only ground upon which their wishes safely can be carried out.”); MEIKLEJOHN, *supra* note 57, at 26 (“When men govern themselves, it is they—and no one else—who must pass judgment upon unwisdom and unfairness and danger. . . . Just so far as, at any point, the citizens who are to decide an issue are denied acquaintance with information or opinion . . . [that] is relevant to that issue, just so far the result must be ill-considered . . .”).

73. See, e.g., *Riley v. Nat’l Fed’n of the Blind of N.C., Inc.*, 487 U.S. 781, 791 (1988) (“The very purpose of the First Amendment is to foreclose public authority from assuming a guardianship of the public mind through regulating the press, speech, and religion.” (quoting *Thomas*, 323 U.S. at 545 (Jackson, J., concurring))).

74. See, e.g., *Brooklyn Inst. of Arts & Scis. v. City of New York*, 64 F. Supp. 2d 184, 191, 205 (E.D.N.Y. 1999) (granting museum a preliminary injunction on a First Amendment claim following the mayor’s withholding of previously appropriated public funds in response to “disgusting” art, most prominently Chris Ofili’s Holy Virgin Mary painting including elephant dung); *id.* at 199 (explaining that the mayor and city government “are not insulated from a claim that they are violating the overwhelming body of First Amendment law establishing that government cannot suppress ideas indirectly any more than it can do so directly”); JOLI JENSEN, *IS ART GOOD FOR US?: BELIEFS ABOUT HIGH CULTURE IN AMERICAN LIFE* 144 (2002) (identifying an “art-as-medicine perspective” under which defenders of controversial art argue that such art is “valuable *because* it is patently offensive, valuable *because* it is designed to destabilize the status quo”).

75. See, e.g., *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos., Inc.* 515 U.S. 557, 569 (1995) (noting that Jackson Pollack’s artwork is “unquestionably shielded” under the First Amendment); *Bery v. City of New York*, 97 F.3d 689, 695 (2d Cir. 1996) (“Visual art is as wide ranging in its depiction of ideas, concepts and emotions as any book, treatise, pamphlet or other writing, and is similarly entitled to full First Amendment protection.”); Daniel Mach, Note, *The Bold and the Beautiful: Art, Public Spaces, and the First Amendment*, 72 N.Y.U. L. REV. 383, 386–92 (1997) (discussing the First Amendment status of art).

76. Direct communication of a “particularized message” is not, however, required for

produces knowledge, however, it should likewise trigger First Amendment scrutiny.

Finally, science represents one of the primary ways in which people produce knowledge. CRISPR/Cas9 and SCNT technology, among other scientific advances, introduced new knowledge about our genetic heritage and how it may be manipulated; they also raise profound questions about what it is to be human and a morally relevant member of the human community.<sup>77</sup> Similarly, research investigating what made the 1918 flu so virulent allayed some scientific and public health concerns about recurrence of that virus, while also raising fears that the results of such research might be misused to create new pathogens.<sup>78</sup>

To say that the knowledge produced through science can change the way in which we see the world and ourselves in it is an understatement. After all, Nicolaus Copernicus challenged centuries of settled “truth” by radically suggesting that the Sun, and not the Earth, was the center of the solar system.<sup>79</sup> Charles Darwin challenged humanity’s superiority to other animals by suggesting a close relationship between man and other apes.<sup>80</sup> Albert Einstein revolutionized physics and our understanding of the universe through his theory on relativity.<sup>81</sup> James Watson and Francis Crick cracked the riddle of DNA and put biology and biotechnology into common knowledge.<sup>82</sup>

That science may draw political fire is likewise apparent. The most recent U.S. presidential election cycle featured a candidate campaigning on the blunt statement, “I believe in science.”<sup>83</sup> Nor is such controversy a recent phenomenon. Galileo Galilei faced the Inquisition over his embrace of the Copernican solar system and his own research stemming from it.<sup>84</sup> Darwin’s work continues to reverberate in many spheres, leading to political strife and

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constitutional protection. *See Hurley*, 515 U.S. at 569 (“[A] narrow, succinctly articulable message is not a condition of constitutional protection, which if confined to expressions conveying a ‘particularized message,’ would never reach the unquestionably shielded painting of Jackson Pollock, music of Arnold Schönberg, or Jabberwocky verse of Lewis Carroll.” (citation omitted)).

77. *See supra* notes 1–30 and accompanying text.

78. *See infra* notes 276–79 and accompanying text.

79. *See generally* NICOLAUS COPERNICUS, COPERNICUS: ON THE REVOLUTIONS OF THE HEAVENLY SPHERES (A. M. Duncan trans., 1976).

80. *See generally* CHARLES DARWIN, THE ORIGIN OF SPECIES: A VARIORUM TEXT (Morse Peckham ed., 1959).

81. *See generally* EINSTEIN’S MIRACULOUS YEAR: FIVE PAPERS THAT CHANGED THE FACE OF PHYSICS (John Stachel ed., 1998).

82. *See generally* J.D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953).

83. *See* Evan Lehmann, *Hillary Clinton Declares, “I Believe in Science”*, SCI. AM. (July 29, 2016), <http://www.scientificamerican.com/article/hillary-clinton-declares-i-believe-in-science>.

84. *See generally* MAURICE A. FINOCCHIARO, THE GALILEO AFFAIR: A DOCUMENTARY HISTORY (1989).

political capital.<sup>85</sup> It was at Einstein's urging that President Theodore Roosevelt authorized the Manhattan Project, which created the atom bomb.<sup>86</sup> And Ian Wilmut's work on SCNT<sup>87</sup> triggered worldwide outcry because cloning, if applied to humans, threatened to undermine what it means to be human. Human reproductive cloning, after all, "forces us to rethink in the most basic way the meaning of individuality, personal identity, family, and reproductive liberty. These concepts are well-formed at their core, but they blur at the margins."<sup>88</sup>

If regulating scientific experimentation fell entirely outside the scope of the First Amendment, then much of the information that informs new understandings of the world, much less understandings of policy proposals in the United States, would be in jeopardy. Science tends to shake things up and to undermine long-held assumptions. In many cases, the knowledge produced through science can seem politically threatening to those in power. Germline gene editing, like human cloning, may destabilize traditional notions surrounding "individuality, personal identity, family, and reproductive liberty" by potentially putting tremendous power to shape future generations gene by gene in the control of reproducing (or cloning) individuals.<sup>89</sup> Beyond the biological sciences, research on gun violence might yield data supporting open-carry legislation as a means to save lives—or it might show that such legislation increases, rather than decreases, gun violence and gun deaths.<sup>90</sup>

The power to exclude unfavorable or disliked information from the public sphere of free expression by prohibiting experimentation aimed at its discovery would vest extraordinary power in the hands of government to shape the content of public discourse. This means that a First Amendment concerned with protecting the production of knowledge must protect in some measure science from undue regulation.

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85. See generally *Edwards v. Aguillard*, 482 U.S. 578 (1987) (challenging the constitutionality of a Louisiana act requiring creationism to be taught alongside the theory of evolution); *Epperson v. Arkansas*, 393 U.S. 97 (1968) (challenging the constitutionality of an Arkansas "anti-evolution" statute); *Kitzmiller v. Dover Area Sch. Dist.*, 400 F. Supp. 2d 707 (M.D. Pa. 2005) (challenging the school district's policy of teaching a theory of intelligent design as an alternative to Darwin's theory of evolution).

86. See Gene Dannen, *Einstein to Roosevelt, August 2, 1939*, <http://www.dannen.com/ae-fdr.html> (last modified July 26, 1998).

87. See generally I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810 (1997); see also generally Campbell et al., *supra* note 15.

88. John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371, 1372 (1998).

89. *Id.*

90. See Hiltzik, *supra* note 33 (identifying four topics on which research relating to gun violence would be helpful in crafting effective public policy).

## C. A FRAMEWORK FOR PROTECTION

That scientific experimentation is a matter of First Amendment concern is not to say that all regulations of scientific experimentation should trigger searching First Amendment scrutiny—or that all such regulations are unconstitutional. To the contrary, many statutes and regulations governing scientific research would likely pass constitutional muster.<sup>91</sup> Ultimately, however, knowledge produced through scientific experimentation is of fundamental First Amendment concern. Courts adjudicating these regulations should approach them within the context of First Amendment scrutiny.

Certain lodestars offer guidance in identifying a legal standard by which courts may evaluate government regulations affecting scientific experimentation. First, where the government regulates the content of indisputably expressive activity, such as scientific publication, the regulation is presumptively unconstitutional. As in other areas of speech doctrine, courts will uphold a regulation that aims directly at the content of protected speech elements only if the government shows that the regulation serves a compelling state interest and is the least restrictive means for achieving that interest.<sup>92</sup> This standard of review should—and already does—apply to content- and viewpoint-based restrictions on scientific publications and speeches,<sup>93</sup> as well as to restrictions on philosophy and art as means of knowledge production.

Second, the First Amendment is implicated whenever the government acts with a purpose to thwart knowledge production, regardless of where in

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91. See *infra* Part V for some examples.

92. *Widmar v. Vincent*, 454 U.S. 263, 269–70 (1981) (“In order to justify discriminatory exclusion from a public forum based on the religious content of a group’s intended speech, the University must therefore satisfy the standard of review appropriate to content-based exclusions. It must show that its regulation is necessary to serve a compelling state interest and that it is narrowly drawn to achieve that end.”); *First Nat’l Bank of Bos. v. Bellotti*, 435 U.S. 765, 786 (1978) (“Especially where, as here, a prohibition is directed at speech itself, and the speech is intimately related to the process of governing, ‘the State may prevail only upon showing a subordinating interest which is compelling,’ ‘and the burden is on the government to show the existence of such an interest.’ Even then, the State must employ means ‘closely drawn to avoid unnecessary abridgment . . . .’” (citations omitted)); see also *Police Dep’t of Chi. v. Mosley*, 408 U.S. 92, 95–96 (1972) (“[A]bove all else, the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content. . . . Any restriction on expressive activity because of its content would completely undercut the ‘profound national commitment to the principle that debate on public issues should be uninhibited, robust, and wide-open.’” (quoting *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 270 (1964))).

93. See *McDonald*, *supra* note 45, at 993 (“[I]f a law or government action were to target any expressive or communicative aspects of that process for regulation—such as a scientist’s receipt of information from a willing provider, the dissemination of her research results, or even the recording of her observations or the memorialization of her findings and conclusions—there is little question that such regulation would warrant some form of First Amendment scrutiny.”); John A. Robertson, *The Scientist’s Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1217 (1978) (“[S]cientific publications would ordinarily be protected by first amendment rights to publish.”).

the process of knowledge formation and exchange the government acts. In a recent article synthesizing the Supreme Court's First Amendment jurisprudence of non-expressive conduct, Wesley J. Campbell suggests that government regulation of such conduct triggers First Amendment scrutiny when "the government uses a rule that targets speech."<sup>94</sup> Jane Bambauer similarly argues that First Amendment analysis of data regulations should "ask[] what purpose a regulation seeks to serve and how the regulation operates in practice."<sup>95</sup> Consistent with these scholars, when the government regulates scientific experimentation for the purpose of preventing unwanted information from coming into being, First Amendment scrutiny is appropriate.

Purpose-driven analysis of government regulation has a considerable history as part of First Amendment doctrine,<sup>96</sup> particularly where conduct that is not inherently expressive is at issue. The Supreme Court has recognized that speech is a "process," and that the First Amendment may guard against efforts to suppress speech even when such efforts target non-speaking parts of that process.<sup>97</sup> The Court has even developed a test for determining when government regulation of First Amendment-related conduct runs afoul of that constitutional protection. In *United States v. O'Brien*, the Court considered whether a prohibition on draft-card burning could be validly applied to an individual who burned his draft card in protest.<sup>98</sup> Recognizing that the act of burning a draft card contains both "speech" and "nonspeech" elements, the Court explained that regulations governing such conduct are valid:

- [1] [I]f it is within the constitutional power of the Government;
- [2] if it furthers an important or substantial governmental interest;
- [3] if the governmental interest is unrelated to the suppression of free expression; and [4] if the incidental restriction on alleged First

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94. Wesley J. Campbell, *Speech-Facilitating Conduct*, 68 STAN. L. REV. 1, 6 (2016).

95. Bambauer, *supra* note 62, at 89. Shiffrin, on whom Bambauer relies, has argued that First Amendment scrutiny applies:

[W]hen a statute, regulation, court decision, or lawmaking activity (1) on its face exhibits a design to "ban or attempt to ban the free development and operation of a person's mind or those activities or materials necessary for its free development and operation"; (2) has the effect of interfering too greatly with the free development and operation of a person's mind; or (3) has a rationale which, even if not overtly designed to conflict with the free development of a person's mind, is nevertheless unacceptably inconsistent with that right.

*Id.* at 88 (quoting Shiffrin, *supra* note 61, at 287).

96. See generally Elena Kagan, *Private Speech, Public Purpose: The Role of Governmental Motive in First Amendment Doctrine*, 63 U. CHI. L. REV. 413 (1996).

97. See *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 336 (2010) ("Laws enacted to control or suppress speech may operate at different points in the speech process.").

98. *United States v. O'Brien*, 391 U.S. 367 (1968).

Amendment freedoms is no greater than is essential to the furtherance of that interest.<sup>99</sup>

Scientific experimentation, like the conduct at issue in *O'Brien*, combines both First-Amendment-relevant (knowledge production) and First-Amendment-irrelevant (the specific conduct of the scientific protocol) elements in the same act. Accordingly, constitutional review of regulations governing scientific experimentation should follow the same framework,<sup>100</sup> albeit modified to examine whether “the governmental interest is unrelated to the suppression of [production of knowledge].”<sup>101</sup> This less-demanding standard of review is also appropriate given the Court’s concerns that “[t]here are few restrictions on action which could not be clothed by ingenious argument in the garb of decreased data flow.”<sup>102</sup> Adopting the modified *O'Brien* standard of review for regulations of scientific methods means that regulations that aim at the “suppression of production of knowledge” are presumptively invalid, while regulations unrelated to such suppression—like those that aim to limit the harms or invasions of others’ rights occasioned by the conduct of science—are presumptively valid exercises of state power.<sup>103</sup>

This framework for evaluating government regulation of scientific experimentation tracks not only *O'Brien*, but also aligns with the ordinary standards of scrutiny applicable to speech *qua* speech. Where regulation seeks to prohibit knowledge creation, it smacks of content- or viewpoint-based regulation. That is, where the government aims to prevent people from discovering certain types of knowledge, it effectively takes the position that such knowledge (or knowledge leading to or about some topic) is bad or wrong. Were the production of knowledge inherently expressive,<sup>104</sup> it would be subject to searching First Amendment scrutiny. Conversely, “where regulation aim[s] at preventing harms unconnected with the subject of the inquiry,” such restrictions are presumptively valid as time, place, and manner regulations.<sup>105</sup> In other words, where the government directs its regulation at

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99. *Id.* at 376–77.

100. See Bambauer, *supra* note 62, at 89; Richard Delgado et al., *Can Science Be Inopportune? Constitutional Validity of Governmental Restrictions on Race-IQ Research*, 31 UCLAL. REV. 128, 166 (1983).

101. *O'Brien*, 391 U.S. at 377.

102. *Zemel v. Rusk*, 381 U.S. 1, 16–17 (1965).

103. Identifying the state’s purpose in enacting a restriction on scientific research, as in other contexts in which purpose is significant, is not straightforward. See generally Brooks Holland, *The Road Round Edmond: Steering Through Primary Purposes and Crime Control Agendas*, 111 PENN ST. L. REV. 293 (2006) (analyzing the determination of “primary purpose” for Fourth Amendment analysis in the context of multipurpose traffic checkpoints). This has not, however, prevented the Supreme Court from requiring such determination where constitutional rights are at issue.

104. It is not. See *infra* Part IV.A.

105. Delgado et al., *supra* note 100, at 165–66; see also *Kovacs v. Cooper*, 336 U.S. 77, 88–89 (1949) (upholding a municipal ordinance prohibiting the use of sound trucks on public streets); *Cox v. New Hampshire*, 312 U.S. 569, 570–71, 578 (1941) (affirming convictions of Jehovah’s Witnesses who violated a state statute prohibiting any “parade or procession” on any public street

the methods of conducting science—for instance, by requiring certain protections for human subjects participating in scientific research—this would likely be a valid exercise of its power. Courts will not, however, always uphold these regulations. For instance, courts have invalidated regulations to eliminate entirely a means of communication.<sup>106</sup> Were the government to enact a blanket prohibition of all science, courts would almost certainly invalidate this restriction on the grounds that it unreasonably curtails First Amendment activities.

#### IV. GRAPPLING WITH UNHELPFUL ANALOGIES

Existing scholarship advocating for First Amendment protection of scientific methodologies generally advocates one of two approaches.<sup>107</sup> One approach views scientific experimentation as scientific expression and the methodologies employed as expressive conduct, like *O'Brien's* draft-card burning as protest.<sup>108</sup> Under this approach, because the legal prohibition aims to suppress the message expressed by the methodology, the prohibition violates the principles of free expression embodied in the First Amendment.<sup>109</sup> Alternatively, commentators have argued that scientific experimentation is analogous to newsgathering and that newsgathering is, or ought to be, constitutionally protected speech activity.<sup>110</sup> Under this approach, scientific research is a “necessary precondition[.]” to scientific speech (e.g., publishing and disseminating results) and, therefore, is deserving of constitutional protection.<sup>111</sup>

This Part takes up these alternative views of the relationship between the First Amendment and science regulation. As set forth below, these accounts of the relationship between scientific experimentation and the First Amendment misperceive the expressive content of scientific processes and rely on faulty analogies to validate overly broad and categorical constitutional protections. Both fundamentally mischaracterize the essence of the relationship between science, the First Amendment, and government regulation.

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without first obtaining a permit).

106. See, e.g., *City of Ladue v. Gilleo*, 512 U.S. 43, 45–48 (1994) (invalidating a city ordinance prohibiting homeowners from displaying signs on their property).

107. Arguments have also been suggested for protection of scientific experimentation under the Due Process Clause of the Fifth and Fourteenth Amendments, building on a right to privacy. See Robertson, *supra* note 93, at 1212–14. Moreover, others have suggested that government regulations of scientific experimentation invoke the First Amendment's Establishment Clause. See Edward A. Fallon, *Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy*, 12 MARQ. ELDER'S ADVISOR 247, 289–92 (2011). This Article focuses only on the scope of First Amendment free speech protection.

108. See generally *United States v. O'Brien*, 391 U.S. 367 (1968).

109. See, e.g., *supra* note 45 and accompanying text.

110. See Robertson, *supra* note 93, at 1226–46.

111. *Id.* at 1217–18.

By contrast, the knowledge-production approach this Article advocates avoids these missteps. Scientific experimentation is relevant to the First Amendment because of its role in producing ideas, information, and knowledge. Government regulation triggers First Amendment concerns when it aims to suppress knowledge, not merely when it affects experimentation. The role of science as one of the primary modes of knowledge production is the most important factor in triggering First Amendment concern—not some inherently expressive feature of experimentation or a much broader principle protecting all preconditions to speech.

A. *SCIENTIFIC RESEARCH AS EXPRESSIVE CONDUCT*

One of the primary theories for First Amendment protection for scientific methodologies argues that such methodologies are expressive conduct—nonverbal conduct that is constitutionally protected expression. Under this theory, *O'Brien* established a baseline for regulating expressive conduct.<sup>112</sup> The Supreme Court concluded that even if *O'Brien's* actions—burning his draft card in protest—were expressive, Congress could legitimately proscribe them because the statute barring draft-card destruction served “an important or substantial government interest,” that was “unrelated to the suppression of free expression,” and “the incidental restriction” of *O'Brien's* First Amendment freedoms was “no greater than is essential to the furtherance of that interest.”<sup>113</sup>

Following *O'Brien*, the Supreme Court held that a number of statutes prohibiting flag desecration violated the First Amendment's free-speech guarantee. In *Spence v. Washington*, for instance, the Court held that the State's interest in prohibiting flag desecration was directly related to Spence's expression, and that the prohibition was therefore antithetical to the First Amendment's protection of expression.<sup>114</sup> In reaching this conclusion, the Court held that expressive conduct exists where there is “intent to convey a particularized message” and a “great” likelihood “that the message would be understood by those who viewed it.”<sup>115</sup> Because Spence's conduct met these requirements, his conviction entailed “prosecution for the expression of an idea through activity.”<sup>116</sup> In *Spence*, unlike in *O'Brien*, the statute was concerned with the protest message expressed by the flag desecration, not with the hazards of the physical conduct itself.

On the basis of these cases, some proponents of protected scientific experimentation draw an analogy between burning a draft card or desecrating a flag and employing scientific methodologies. Implementing scientific

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112. See generally *O'Brien*, 391 U.S. 367.

113. *Id.* at 377.

114. *Spence v. Washington*, 418 U.S. 405, 415 (1974).

115. *Id.* at 410–11.

116. *Id.* at 411.

methodologies, they argue, “inten[ds] to convey a particularized message” likely to “be understood by those who view[] it,” as required under *Spence*.<sup>117</sup>

But it is far from obvious that scientific experimentation survives such an analogy. With respect to the first prong of *Spence*’s formulation of expressive conduct, that such conduct must “inten[d] to convey a particularized message,”<sup>118</sup> it is not at all clear that merely implementing scientific methodologies conveys any message, much less a particularized one. Research methods are not themselves expressive. They seek information; they do not convey meaning. An experiment may or may not verify the scientist’s (protected) ideas about the world, but carrying out that experiment is not directly expressive.

The relationship between researcher and research materials speaks to *Spence*’s second requirement that there be a “great” likelihood “that the message would be understood by those who viewed it.”<sup>119</sup> A scientist does not engage in expression when she applies research methodologies to “materials within [her] lawful control.”<sup>120</sup> Under *Spence*, often, the only “viewer” of a scientist’s conduct in the act of implementing research methodologies is the research materials. Indeed, *Spence*’s second prong makes clear that expressive conduct requires at least two conscious communicators—one to convey and another to receive.<sup>121</sup> Where applying scientific methodologies is concerned, there is often only one conscious communicator.

Other courts have also recognized that expressive conduct requires two conscious communicators. In *Universal City Studios, Inc. v. Corley*, the Second Circuit held that computer object code is expressive and “speech” protected under the First Amendment.<sup>122</sup> Although object code instructs a computer to operate in certain way, it can also function as a message between programmers. Object code is a language that may be the medium for the expression of ideas between one programmer and another. Scientific experimentation, meanwhile, often involves only the researcher and her research materials (which are themselves often inanimate or incapable of consciousness). Subsequent sharing and analysis of experimental results may properly involve expressive activities, but the experimental conduct itself

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117. *Id.* at 410–11.

118. *Id.*

119. *Id.* at 411.

120. Robertson, *supra* note 93, at 1239.

121. This is not to say that all speech activities falling within the scope of First Amendment protection require both speaker and listener. Such a rule would exclude diaries from First Amendment protection, a result at odds with several prominent First Amendment theories. *See, e.g.,* Martin H. Redish, *Freedom of Thought as Freedom of Expression: Hate Crime Sentencing Enhancement and First Amendment Theory*, 11 CRIM. JUST. ETHICS 29, 30–31 (1992); Shiffrin, *supra* note 61, at 285. The scope of protected expressive conduct, however, may be more narrowly circumscribed than the scope of protected speech as such.

122. *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 445–49 (2d Cir. 2001).

generates information in only one direction. This type of conduct is not inherently expressive.

This conclusion is further compelled by the Supreme Court's discussion of expressive conduct in *Rumsfeld v. Forum for Academic and Institutional Rights* ("FAIR").<sup>123</sup> In *FAIR*, the Supreme Court declined to recognize law-school recruiting as expressive conduct. In so doing, the Court recognized that, although some conduct is protected under the First Amendment, this protection extends "only to conduct that is inherently expressive."<sup>124</sup> Moreover, the Court reiterated its rejection of the "view that 'conduct can be labeled 'speech' whenever the person engaging in the conduct intends thereby to express an idea.'"<sup>125</sup> In distinguishing the non-expressive conduct of law-school recruiting from the expressive conduct protected in *Spence* and related cases, the Court wrote, "law schools 'expressed' their disagreement with the military by treating military recruiters differently from other recruiters. But these actions were expressive only because the law schools accompanied their conduct with speech explaining it."<sup>126</sup> The Court continued, finding:

The expressive component of a law school's actions is not created by the conduct itself but by the speech that accompanies it. The fact that such explanatory speech is necessary is strong evidence that the conduct at issue here is not so inherently expressive that it warrants protection under *O'Brien*. If combining speech and conduct were enough to create expressive conduct, a regulated party could always transform conduct into "speech" simply by talking about it.<sup>127</sup>

*Spence's* message was clearly expressed simply through his defacing of an American flag—no talking required. Scientific methodologies, conversely, are not themselves typically a medium for expressing ideas. Like the Court's treatment of law-school recruiting, scientific experimentation requires speech (as well as analysis) in order to give it expression and dissemination. As such, scientific experimentation is a medium for generating knowledge that may subsequently be expressed—but it is not expression itself.

To be sure, scientific experimentation may sometimes involve groups of individuals. Researchers are not hermits, toiling away alone in laboratories and experimenting only with inanimate materials. To the contrary, research involving human subjects is commonplace.<sup>128</sup> Researchers also frequently

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123. *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 66–68 (2006).

124. *Id.* at 66.

125. *Id.* at 65–66 (quoting *United States v. O'Brien*, 391 U.S. 367, 376 (1968)).

126. *Id.* at 66.

127. *Id.*

128. See *Trends, Charts, and Maps*, CLINICALTRIALS.GOV, <https://clinicaltrials.gov/ct2/resources/trends> (last updated Dec. 19, 2016) (reporting that there were 232,733 registered clinical trials as of December 19, 2016, of which 84,965 were taking place solely in the United States); see also generally

work in teams to tackle complex research questions.<sup>129</sup> In these contexts, communication among collaborating researchers, and between researchers and study participants, might well trigger First Amendment protection as pure expression or expressive conduct.

But it would be a mistake to limit the scope of First Amendment attention for scientific research to such group settings. While research collaboration is increasing, it is not universal.<sup>130</sup> And while research involving human participants is common, it is not the only type conducted.<sup>131</sup> Yet knowledge produced by individual researchers working with non-human participants or research materials may still generate important knowledge. Moreover, generating this knowledge may still be targeted by the State. A constitutional distinction between collaborative and solo researchers, or between human-subjects and other research, would simply be arbitrary for purposes of the value of knowledge produced through such work. Accordingly, limiting the

CLINICALTRIALS.GOV, <https://clinicaltrials.gov> (last visited Jan. 15, 2017) (“ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.”).

129. See Jonathan Adams, *The Rise of Research Networks*, 490 NATURE 335, 335 (2012) (documenting the rise in research collaborations and observing “[a]n issue of *Nature* today has a similar number of Letters to one from 60 years ago, but at least four times more authors”).

130. See, e.g., *id.* at 336 (arguing that there is a need both for more collaboration and for preserving the role of “[t]he iconoclastic, the maverick and the marginal” in scientific research); Jennifer Lamberts, *Two Heads Are Better than One: The Importance of Collaboration in Research*, HUFFINGTON POST: BLOG, [http://www.huffingtonpost.com/dr-jennifer-lamberts/two-heads-are-better-than\\_1\\_b\\_3804769.html](http://www.huffingtonpost.com/dr-jennifer-lamberts/two-heads-are-better-than_1_b_3804769.html) (last updated Oct. 23, 2013) (identifying benefits flowing from research collaboration and then exploring the question of: “If scientific collaboration is so useful, why then do not all researchers do it?”).

131. Considerable research involves matters and subjects that are not human. See, e.g., Adrian Cho, *Gravitational Waves, Einstein’s Ripples in Spacetime, Spotted for First Time*, SCIENCE (Feb. 11, 2016, 10:30 AM), <http://www.sciencemag.org/news/2016/02/gravitational-waves-einstein-s-ripples-spacetime-spotted-first-time> (reporting research that detected gravitational waves for the first time); Madhusree Mukerjee, *Trends in Animal Research*, SCI. AM. 86, 86 (Feb. 1997) (“The U.S. uses between 18 and 22 million animals a year, but exact numbers are unknown for roughly 85 percent of these—rats, mice and birds.”). Not even all “human subjects research” involves fully formed, conscious human beings as study participants. See *Human Specimens, Cell Lines, or Data: Frequently Asked Questions*, NAT’L INSTITUTES HEALTH, <https://humansubjects.nih.gov/human-specimens-cell-lines-data> (last updated May 5, 2016) (explaining the circumstances under which research with “human specimens, cells, cell lines, or data” does and does not constitute “human subjects research”). Under proposed amendments to federal regulations governing human subjects research, secondary research using human biological samples would be classified as “human subjects research,” regardless of de-identification or anonymization. Press Release, U.S. Dep’t of Health & Human Servs., HHS Announces Proposal to Update Rules Governing Research on Study Participants (Sept. 2, 2015), <http://www.hhs.gov/about/news/2015/09/02/hhs-announces-proposal-to-update-rules-governing-research-on-study-participants.html>; see also Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933 (proposed Sept. 8, 2015) (summarizing major provisions of the proposed rule); *id.* at 54,047 (setting out proposed section 5F.102(e) and defining “human subject” to include “a living individual about whom an investigator (whether professional or student) conducting research . . . [o]btains, uses, studies, or analyzes biospecimens”).

scope of First Amendment scrutiny of scientific research to collaborative or human-based studies would be decidedly underinclusive.

Ultimately, while scientific hypotheses are likely expressive and protected under the First Amendment as articulable, communicable statements, scientific methodologies performed to test those hypotheses are not themselves expressive. If these methodologies are to be protected under the First Amendment, an alternative theory of the relationship between scientific experimentation and the First Amendment is required.

*B. SCIENTIFIC RESEARCH AS A NECESSARY PRECURSOR TO PROTECTED SPEECH*

One alternative idea is that the main value of science comes from scientific publication and dissemination, which are clearly protected by the First Amendment. Given this protection, several scholars argue that activities that are not themselves expressive—like applying scientific methodologies—may be accorded First Amendment protection because of their close relationship to protected-speech activities. In a nutshell, “[i]f writing, printing, and reproducing information are essential for publication, and, therefore, are protected, it must also follow that even earlier stages in the publication process are protected.”<sup>132</sup> In reaching this conclusion, these scholars rely on an analogy of the generation of scientific information to a presumed right to gather news inhering generally in the press.

This essential-preconditions approach based on a newsgathering right stands on firmer footing than its expressive-conduct counterpart. The Court has, at times, applied what appears to be heightened scrutiny to First Amendment claims by newsgathering entities. In *Branzburg v. Hayes*, the Court recognized that “without some protection for seeking out the news, freedom of the press could be eviscerated.”<sup>133</sup> Similarly, the Court in *Houchins v. KQED* recognized “an undoubted right to gather news ‘from any source by means within the law.’”<sup>134</sup>

There are, however, a variety of complications with the analogy to newsgathering and the essential-preconditions approach. Most importantly, although the Court has alluded to some protection for newsgathering, the scope and even the existence of such a right remain frustratingly unclear. The Supreme Court has consistently declined to enforce such protection. In *Zemel v. Rusk*, for instance, the Court upheld the denial of Zemel’s passport application for travel to Cuba, despite Zemel’s information-gathering purpose in seeking to travel.<sup>135</sup> Similarly, despite its solicitous language in *Branzburg*, the Court nonetheless denied journalists the ability to withhold the names of

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132. Robertson, *supra* note 93, at 1217.

133. *Branzburg v. Hayes*, 408 U.S. 665, 681 (1972).

134. *Houchins v. KQED, Inc.*, 438 U.S. 1, 11 (1978) (quoting *Branzburg*, 408 U.S. at 681–82).

135. *Zemel v. Rusk*, 381 U.S. 1, 16–17 (1965).

confidential sources from grand juries.<sup>136</sup> Even *Houchins* is of little aid in defining a newsgathering right on which a right to employ scientific methodologies might be based. *Houchins* denied the press (as opposed to the public) a special right of access to investigate prisons.<sup>137</sup> In the primary outlier case, *Richmond Newspapers v. Virginia*, the Court established a right of access for the press (and the public) to criminal trials, invalidating a Virginia statute authorizing the closing of courts.<sup>138</sup> However, the Court based this right on “tradition” and not on the press’ information-gathering power.<sup>139</sup> It is therefore a mistake to hinge a right to employ scientific methodologies on a right to gather news, because it is unclear whether and to what extent a right to gather news even exists.

The Court’s reluctance to embrace a newsgathering right is perhaps unsurprising, given the context on which the Court focuses in such cases: instances in which the entity from which the press seeks information has strong countervailing claims. The government’s interest in preventing the press from gathering as-yet-undisclosed government information has weighed strongly in the Supreme Court’s line of newsgathering cases.<sup>140</sup>

Furthermore, even if the Court were inclined to protect a right to newsgathering, it is not clear that such a right would also protect implementing scientific methodologies. As described above, the Court has continually declined to identify the scope and contours of a newsgathering right. In *Branzburg*, the Court provided some indication for this hesitancy, stating that “[t]he administration of a constitutional newsman’s privilege would present practical and conceptual difficulties of a high order.”<sup>141</sup> The Court explained that demarcating a right to newsgathering would be perilous

136. *Branzburg*, 408 U.S. at 679–82.

137. *Houchins*, 438 U.S. at 11.

138. *See generally* *Richmond Newspapers, Inc. v. Virginia*, 448 U.S. 555 (1980).

139. *See id.* at 583–84. The Court has continued to uphold general rights of access to court proceedings on the basis of *Richmond Newspapers*. *See generally* *Press-Enter. Co. v. Superior Court*, 464 U.S. 501 (1984) (invalidating a state court order closing voir dire examination of prospective jurors in a criminal trial); *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596 (1982) (invalidating a Massachusetts law requiring judges to exclude the press and general public from the courtroom during the testimony of a victim in trials for specified sexual offenses involving victims under the age of 18).

140. *See, e.g., Houchins*, 438 U.S. at 9 (“This Court has never intimated a First Amendment guarantee of a right of access to all sources of information within government control. Nor does the rationale of the decisions upon which respondents rely lead to the implication of such a right.”); *Branzburg*, 408 U.S. at 684 (“It has generally been held that the First Amendment does not guarantee the press a constitutional right of special access to information not available to the public generally. . . . Despite the fact that news gathering may be hampered, the press is regularly excluded from grand jury proceedings, our own conferences, the meetings of other official bodies gathered in executive session, and the meetings of private organizations.” (citations omitted)); *Zemel*, 381 U.S. at 17 (“[T]he prohibition of unauthorized entry into the White House diminishes the citizen’s opportunities to gather information he might find relevant to his opinion of the way the country is being run, but that does not make entry into the White House a First Amendment right.”).

141. *Branzburg*, 408 U.S. at 703–04.

because it would require courts either to engage in making unconstitutional distinctions between classes of protected speech (and their necessary precursors) or to accept a seemingly limitless right to engage in essential precursors to protected speech in all its forms.<sup>142</sup>

The Supreme Court has long recognized the lack of a limiting principle for a right to gather information, noting that “[t]here are few restrictions on action which could not be clothed by ingenious argument in the garb of decreased data flow.”<sup>143</sup> If all such restrictions were invalid, then many necessary criminal laws would suddenly become inoperative. The Supreme Court has identified entry into the White House,<sup>144</sup> stealing documents,<sup>145</sup> and private wiretapping<sup>146</sup> as activities that “could provide newsworthy information,” but for which “neither reporter nor source is immune from conviction for such conduct, whatever the impact on the flow of news.”<sup>147</sup> Moreover, even innocuous activities would be protected under the First Amendment on an essential-preconditions approach. For instance, baking a cake could be constitutionally protected if its purpose was to inform later writing and publication about that experience (and the proliferation of self-publication about food on blogs,<sup>148</sup> Instagram,<sup>149</sup> and Pinterest<sup>150</sup> suggest that such purpose is not unlikely).<sup>151</sup> Such a broad approach to protecting otherwise non-expressive conduct under the First Amendment is in tension, if not in conflict, with the purposes of the Free Speech Clause, which may include protection for all manner of communication, but cannot logically aim to encompass every act that may further communication.<sup>152</sup>

142. *Id.* at 705 (“The informative function asserted by representatives of the organized press in the present cases is also performed by lecturers, political pollsters, novelists, academic researchers, and dramatists.”).

143. *Zemel*, 381 U.S. at 16–17.

144. *Id.* at 17.

145. *Branzburg*, 408 U.S. at 691.

146. *Id.*

147. *Id.* *Bartnicki v. Vopper* held that anti-wiretap statutes may not apply to newsgatherers who come into possession of illegally taped conversations, so long as the newsman is not also the taping party. *Bartnicki v. Vopper*, 532 U.S. 514, 528–29, 535 (2001). This does not alter the force of the Court’s statement in *Branzburg*, however, which stands for the proposition that newsmen may not violate otherwise valid criminal laws in their efforts to secure news.

148. See SERIOUS EATS, <http://www.serious eats.com> (last visited Jan. 15, 2017).

149. See Veronica Lopez, *15 Food Instagram Accounts You Need to Follow Immediately*, COSMOPOLITAN (Aug. 5, 2015), <http://www.cosmopolitan.com/food-cocktails/news/a44229/foodstagram-feed-delicious>.

150. See *Food and Drink*, PINTEREST, [https://www.pinterest.com/categories/food\\_drink](https://www.pinterest.com/categories/food_drink) (last visited Jan. 15, 2017).

151. Some courts have recognized that recipes themselves trigger First Amendment scrutiny. See *Bernstein v. U.S. Dep’t of State*, 922 F. Supp. 1426, 1435 (N.D. Cal. 1996) (“Instructions, do-it-yourself manuals, recipes, even technical information about hydrogen bomb construction . . . are also speech.” (citation omitted)).

152. See *supra* notes 135–42 and accompanying text.

Acknowledging this limitation, some defenders of a right to newsgathering and a correlated right to employ scientific methodologies have attempted to carve out newsgathering and science as especially protected “[b]ecause scientific researchers, like the press, generate knowledge relevant to a wide range of public and private decisionmaking.”<sup>153</sup> This logic attempts to tease out certain kinds of speech as more worthy of protection than others, the essential precursors of the former receiving constitutional protection as well. Yet, such an approach would require courts to engage in substantive evaluations of the worthiness of different classes of protected speech. To be sure, the Supreme Court has undertaken such efforts at the margins of free speech doctrine, where it has identified categories of speech that merit no constitutional protection.<sup>154</sup> In the main, however, the Court has insisted that the First Amendment’s free speech protections apply without variance to all speech within its purview.<sup>155</sup>

Accordingly, an essential-preconditions approach that is grounded on a right to newsgathering, while facially appealing, is flawed. It relies on an uncertain doctrinal basis and sweeps too broadly.

The information-production approach set out in Part III, by contrast, need not trigger similar concerns. Unlike newsgathering, which often runs up against government interests in secrecy and information control, a great deal of scientific knowledge production does not seek to discover information from sources with independent national security or privacy claims.<sup>156</sup> The natural sciences, for example, produce information about the natural world, which itself has no First Amendment interests. Insofar as scientific research produces information about individual persons, informed consent serves the role of protecting individual interests in privacy and human dignity while not

153. Robertson, *supra* note 93, at 1226.

154. See *Chaplinsky v. New Hampshire*, 315 U.S. 568, 571–72 (1942) (“There are certain well-defined and narrowly limited classes of speech, the prevention and punishment of which have never been thought to raise any Constitutional problem. These include the lewd and obscene, the profane, the libelous, and the insulting or ‘fighting’ words—those which by their very utterance inflict injury or tend to incite an immediate breach of the peace.” (footnotes omitted)).

155. See, e.g., *Roth v. United States*, 354 U.S. 476, 484 (1957) (“All ideas having even the slightest redeeming social importance—unorthodox ideas, controversial ideas, even ideas hateful to the prevailing climate of opinion—have the full protection of the guaranties . . . .”); *Thornhill v. Alabama*, 310 U.S. 88, 102 (1940) (“Freedom of discussion, if it would fulfill its historic function in this nation, must embrace all issues about which information is needed or appropriate to enable the members of society to cope with the exigencies of their period.”); see also Robertson, *supra* note 93, at 1215 (“[T]he state can make no distinction based on the worth of ideas.”).

156. Where a researcher seeks to work with materials uniquely within the government’s control, such as military technology, the government’s right to control that technology would likely prevail, as it does in the newsgathering cases. But such a result is consistent with the knowledge-production approach, which recognizes that government constraints on how research is conducted (rather than on the knowledge the research seeks to uncover) are likely to be constitutional. See *infra* Part V.B.2 and V.C (discussing this distinction under the knowledge-production approach).

preventing discovery from moving forward.<sup>157</sup> Indeed, knowledge production is a qualitatively different act from newsgathering in part because it typically seeks the discovery of truth not already known, rather than broader access to information already possessed by some.<sup>158</sup> This difference is most evident in the newsgathering cases seeking access to information held by the government.<sup>159</sup>

Moreover, the expansive reach of an essential-preconditions approach need not infect the information-production approach. The focus on government suppression of knowledge production set out in Part III differs from the perspective offered by most advocates of the newsgathering analogy. The scope of activities that courts could characterize as essential preconditions to protected speech is nearly infinite.<sup>160</sup> The scope of activities encompassed by knowledge production, conversely, is more narrowly defined. This is especially so in light of the limitation of the knowledge-production approach identified here to government efforts to prevent people from acquiring new knowledge.<sup>161</sup> Insofar as hesitancy to extend protection to non-expressive conduct turns on the lack of a limiting principle, the knowledge-production approach offers firmer guidance.

## V. SCRUTINIZING SCIENCE REGULATION

The role of scientific experimentation as a primary driver of knowledge production makes government regulation of such experimentation a subject of First Amendment concern.<sup>162</sup> Where the State seeks to prevent people from discovering certain information, thereby shaping the content available for public consideration, it runs afoul of the First Amendment's commitment to free expression.<sup>163</sup> This Article has defined a framework for identifying when regulations that affect scientific experimentation are in fact regulations on knowledge production, and therefore presumptively unconstitutional.<sup>164</sup> This Part maps that framework to critical sites of controversy regarding the appropriateness of continued scientific experimentation. As identified at the outset, government regulation has been proposed or adopted regarding

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157. See Robertson, *supra* note 93, at 1256 (“Laws requiring informed, free, and competent consent from research subjects promote interests in individual autonomy and welfare, whatever the subject matter content of the research.”).

158. See *Scientific Discovery*, STAN. ENCYCLOPEDIA PHIL. (Mar. 6, 2014), <http://plato.stanford.edu/entries/scientific-discovery/#SciInqDis> (“Several natural and experimental philosophers, notably Bacon, Descartes, and Newton, expounded accounts of scientific methods for arriving at new knowledge. . . . [T]hose accounts of scientific method function as guides for acquiring new knowledge and at the same time as validations of the knowledge thus obtained.”).

159. See generally *Houchins v. KQED, Inc.*, 438 U.S. 1 (1978).

160. See *supra* notes 141–52 and accompanying text.

161. See *supra* notes 100–06 and accompanying text.

162. See *supra* Part III.A–B.

163. See *supra* Part III.C.

164. See *supra* Part III.C.

advances in gene editing using the CRISPR/Cas9 protocol (particularly as applied to human embryos), human cloning for biomedical research purposes, and infectious-disease research. Applying the modified *O'Brien* test, this Part suggests that, while some regulations of these scientific advances may be appropriate, others are unlikely to survive First Amendment scrutiny.

#### A. PROHIBITING GERMLINE GENE EDITING RESEARCH

The CRISPR/Cas9 protocol has the potential to transform how researchers and, eventually, clinicians undertake gene editing.<sup>165</sup> CRISPR/Cas9 offers tantalizing potential for more efficient, effective, and affordable gene editing.<sup>166</sup> Yet, along with great promise, CRISPR/Cas9 threatens to destabilize what it means to be human and to enable genetic engineering of future generations in ways that previously appeared impossible.

Already, the federal government has drawn a line against research deploying CRISPR/Cas9 on germ cells.<sup>167</sup> In a statement on behalf of the National Institutes of Health (“NIH”), Francis Collins explained that “NIH will not fund any use of gene-editing technologies in human embryos.”<sup>168</sup> By contrast, NIH is already funding and will continue to fund scientific research deploying CRISPR/Cas9 and related technologies on other cells, both human and non-human.<sup>169</sup> In justifying the differing treatment of germline and other uses of gene editing technology, Collins focused on “[t]he concept of altering the human germline in embryos for clinical purposes” and how such alteration “has been viewed almost universally as a line that should not be crossed.”<sup>170</sup> To date, the federal government has not acted to regulate or

165. *See supra* notes 12–14 and accompanying text.

166. *See supra* notes 12–14 and accompanying text.

167. *See* Francis S. Collins, *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, NAT’L INSTITUTES HEALTH (Apr. 28, 2015), <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos>.

168. *Id.*

169. *Id.* (“Genomic editing is already widely studied in a variety of organisms. For example, CRISPR/Cas9 has greatly shortened the time it takes to produce knockout mouse models of disease, enabling researchers to study more easily the underlying genetic causes of those diseases. This technology is also being used to develop the next generation of antimicrobials, which can specifically target harmful strains of bacteria and viruses. In the first clinical application of genomic editing, a related genome editing technique (using a zinc finger nuclease) was used to create HIV-1 resistance in human immune cells, bringing HIV viral load down to undetectable levels in at least one individual. All of these examples of research using genomic editing technologies can and are being funded by NIH.”).

170. *Id.* The NIH’s decision not to fund gene editing research that involves human germ cells likely escapes First Amendment scrutiny for reasons beyond the scope of this paper. For one thing, government decisions to fund some research projects but not others are likely to be deemed reasonable exercises of government speech, which courts have largely held are not subject to ordinary First Amendment scrutiny. *See, e.g.*, *Nat’l Endowment for the Arts v. Finley*, 524 U.S. 569, 585 (1998) (holding that the additions of “decency” and “respect” criteria to NEA’s grant-making criteria were not unconstitutional on their face, and explaining that “absolute

prohibit the use of the CRISPR/Cas9 technique or related technologies beyond restrictions on federal funding for the research.<sup>171</sup>

Some researchers, philosophers, and others, however, have advocated that the government draw the line between germline and other uses of gene editing technologies more broadly, including by federal statute.<sup>172</sup> In *Nature*, Edward Lanphier and colleagues called for a moratorium or outright government prohibition “on any experiments that involve editing genes in human embryos or cells that could give rise to sperm or eggs.”<sup>173</sup> Elsewhere, Lanphier questioned, “Are there ever any therapeutic uses that would demand . . . modification of the human germ line? We don’t think there are any . . . . Modifying the germ line is crossing the line that most countries on our planet have said is never appropriate to cross.”<sup>174</sup> In sum, for Lanphier, “[i]f germline editing is never going to be allowed, there is no reason to conduct research using human embryos or reproductive cells.”<sup>175</sup> Hille Haker, a philosopher participating in a recent international summit on gene-editing technology, similarly argued that both “[p]ublic [and] private research must be regulated by law and/or effective forms of governance . . . to exclude that basic research [that may be] used to pave the way for reproductive gene editing.”<sup>176</sup>

Yet, under the modified *O’Brien* rubric identified above, it is far from clear that such a prohibition would survive First Amendment scrutiny. To be sure, it would likely satisfy the first *O’Brien* inquiry—that a regulation be “within the constitutional power of the Government.”<sup>177</sup> Both state and federal governments have the constitutional power necessary to regulate or prohibit private use of CRISPR/Cas9 technology. States are governments of general jurisdiction, and their general authority to regulate the conduct of scientific research within their borders is broad.<sup>178</sup> Moreover, federal power

neutrality” is “inconceivable” where a funding agency “has limited resources, and . . . must deny the majority of the grant applications that it receives”); *Rust v. Sullivan*, 500 U.S. 173, 193–94 (1991) (upholding Title X of the Public Health Service Act, which prohibited federal funding of family planning programs “where abortion is a method of family planning”).

171. See Sara Reardon, *US Congress Moves to Block Human-Embryo Editing*, NATURE (June 29, 2015), <http://www.nature.com/news/us-congress-moves-to-block-human-embryo-editing-1.17858> (discussing proposed funding limitations to the FDA, but observing more broadly that “[p]rivately funded research on editing the human germline remains legal in the United States”).

172. See *supra* note 5–8 and accompanying text.

173. Vogel, *supra* note 6, at 1301 (discussing Lanphier’s comments).

174. Tina Hesman Saey, *Editing Human Germline Cells Sparks Ethics Debate*, SCI. NEWS (May 6, 2015), <https://www.sciencenews.org/article/editing-human-germline-cells-sparks-ethics-debate> (quoting Lanphier).

175. *Id.*

176. Haker, *supra* note 8.

177. *United States v. O’Brien*, 391 U.S. 367, 377 (1968).

178. See *Bond v. United States*, 134 S. Ct. 2077, 2086 (2014) (“The States have broad authority to enact legislation for the public good—what we have often called a ‘police power.’” (citing *United States v. Lopez*, 514 U.S. 549, 567 (1995))).

tied to the Commerce Clause almost certainly provides the jurisdictional hook required for federal legislation.<sup>179</sup> Modern science, particularly science involving human biological materials, is very often a venture that involves moving research materials, funds, or people across state lines. Where that is so, the Commerce Clause permits the federal government to exercise lawmaking authority.<sup>180</sup>

More importantly, however, a state or federal prohibition on all germline gene editing research along the lines Collins, Lanphier, and Haker have identified would inevitably fail as government action that aims to suppress the production of new knowledge.<sup>181</sup> Recall that under the knowledge-production approach proposed here, government regulations of scientific experimentation must “further[] an important or substantial governmental interest” that is “unrelated to the suppression of [production of knowledge].”<sup>182</sup> Each of these proponents has emphasized the same concern about germline gene editing research when explaining why such research should not be permitted: the use of the same technology for clinical purposes. Collins explained that “altering the human germline in embryos *for clinical purposes*” drives the distinction in federal funding policy between germline and other gene editing research.<sup>183</sup> Lanphier similarly emphasized the “therapeutic uses” (or lack thereof) to which germline gene editing might be put.<sup>184</sup> And Haker bluntly called for a prohibition “to exclude that basic research [that may be] used to pave the way for reproductive gene editing.”<sup>185</sup>

An interest in barring clinical uses of germline gene editing may well be “an important or substantial” one.<sup>186</sup> Insofar as that interest reflects concern about ensuring safe and ethical clinical use of germline gene editing, that interest is one in protecting the health and safety of persons, albeit ones not yet born.<sup>187</sup> Courts have long held that protecting the health and safety of

179. U.S. CONST. art. I, § 8, cl. 3.

180. See *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2586 (2012) (recognizing the “expansive scope” of Congress’s power under the Commerce Clause to regulate activity that, in the aggregate, substantially affects interstate commerce).

181. See *supra* Part III.C.

182. See *O'Brien*, 391 U.S. at 377; see also *supra* text accompanying notes 99–104 (describing the *O'Brien* test and its modification for knowledge production).

183. Collins, *supra* note 167 (emphasis added). Collins also noted that, above and beyond ethical concerns about such research, “there are multiple existing legislative and regulatory prohibitions against this kind of work.” *Id.* Most notably, “[t]he Dickey-Wicker amendment prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed.” *Id.*

184. Saey, *supra* note 174.

185. Haker, *supra* note 8.

186. See *O'Brien*, 391 U.S. at 377; see also *supra* Part III.C.

187. There is a firm basis for concluding that at least some of the proponents of a bar on clinical germline gene editing hold that view due to concerns about the health and safety of individuals ultimately born following the use of such technology. See Collins, *supra* note 167 (identifying among “the strong arguments against engaging” in clinical germline gene editing:

individuals is not simply an “important or substantial” government interest, but indeed is a compelling interest justifying curtailing even fundamental rights.<sup>188</sup> Moreover, the Supreme Court’s abortion jurisprudence leaves no doubt that the State has an “important and legitimate interest in protecting the potentiality of human life.”<sup>189</sup> When developing human life is located within the body of a human woman, the State’s interest in that life must be balanced against the woman’s right to her own dignity and autonomy.<sup>190</sup> But the thorny and difficult issues that arise in the context of pregnancy and abortion do not have the same force where the issue is the appropriateness of human germline gene editing, even for clinical purposes. In that context, scientists do their work before a pregnancy is ever established, and so the State’s interest in the health and safety of nascent human life may have more force.

It is less clear whether a broader state interest in preventing researchers from “playing God” would constitute an “important or substantial” state interest for prohibiting clinical germline gene editing. Such an interest is evident in declarations that germline gene editing is “a line that should not be crossed.”<sup>191</sup> Properly described, this interest is one in preserving a particular moral view—one that insists that reproductive technology and related research transgress a fundamental line between human beings and God or nature.<sup>192</sup> It is not clear, however, whether preserving public morals is an interest that carries weight in prohibiting all types of germline gene editing, not merely its clinical uses. The Supreme Court has cast doubt on the role that preserving public morals may play in justifying infringement of fundamental, constitutionally protected rights.<sup>193</sup> Whether this means that

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“the serious and unquantifiable safety issues, ethical issues presented by altering the germline in a way that affects the next generation without their consent, and a current lack of compelling medical applications justifying the use of CRISPR/Cas9 in embryos”).

188. See, e.g., *Hill v. Colorado*, 530 U.S. 703, 715 (2000) (concluding that the “traditional exercise of the States’ ‘police powers to protect the health and safety of their citizens’” was a legitimate interest that could justify a restriction on speech (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996))).

189. *Roe v. Wade*, 410 U.S. 113, 162 (1973); see also *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 875–76 (1992) (joint opinion) (reaffirming *Roe*’s explication of relevant State interests).

190. *Casey*, 505 U.S. at 851–52.

191. Collins, *supra* note 167; see also Sacy, *supra* note 174 (“Modifying the germ line is crossing the line that most countries on our planet have said is never appropriate to cross.” (quoting Laphier)).

192. See NAT’L BIOETHICS ADVISORY COMM’N, CLONING HUMAN BEINGS 44–45 (1997), <https://bioethicsarchive.georgetown.edu/nbac/pubs/cloning1/cloning.pdf> (describing the “moral stop sign” that the warning against “playing God” invokes).

193. See generally *Lawrence v. Texas*, 539 U.S. 558 (2003). *Lawrence* has not categorically eliminated “public morality” or “social values” as a constitutionally sound basis for all legislation. See Dov Fox, *Interest Creep*, 82 GEO. WASH. L. REV. 273, 309–12 (2014). On the application of *Lawrence* to matters of scientific research, see generally Steven Goldberg, Commentary, *Cloning Matters: How Lawrence v. Texas Protects Therapeutic Research*, 4 YALE J. HEALTH POL’Y, L., & ETHICS 305 (2004).

“public morality” is also too weak to qualify as an “important or substantial” government interest is decidedly less clear. In any event, we can assume *arguendo* that there remains an “important or substantial” government interest in preventing individuals from “playing God” by putting germline gene editing to clinical use, as the existence of such an interest does not alter the analysis that follows.

Despite the potential presence of one or more substantial government interests in prohibiting clinical germline gene editing, the government’s chosen means for effectuating its interest are impermissible if they prohibit non-clinical research involving human germline gene editing. A prohibition on non-clinical germline gene editing research only jeopardizes the health and safety of future-born persons, or public morality surrounding them, insofar as the knowledge that research generates makes the clinical application of germline gene editing easier to accomplish. The chosen means, in other words, are directly related to the suppression of knowledge production. The State could most effectively prevent health, safety, and other concerns about clinical germline gene editing by prohibiting the clinical use of such technology. Prohibiting non-clinical research involving germline gene editing, conversely, serves the State’s purpose only indirectly, through collateral censorship,<sup>194</sup> and it does so by interfering directly with the production of knowledge that the First Amendment protects. Pragmatically, the standard that the knowledge of one thing could lead to its misuse on another thing could be extended to *all* types of gene editing—whether using CRISPR/Cas9 or other gene editing technologies, or whether in human somatic cells, animals, bacteria, and anything else.<sup>195</sup> Connections between knowledge production and abuse may be extraordinarily creative and, if taken seriously, could limit science with an extraordinarily broad reach.

In this way, a statute or regulation barring germline gene editing research in order to make downstream clinical use of such technology less likely not only employs impermissible means, but also does so with an impermissibly loose “fit” between the means and the end sought.<sup>196</sup> The Supreme Court has long recognized that muzzling those engaged in First Amendment activities in order to prevent the unlawful acts of others rarely justifies regulation.<sup>197</sup> Most prominently, in *Brandenburg v. Ohio*, the Court declared that the First

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194. See Balkin, *supra* note 68, at 2298 (discussing the rise of collateral censorship and its problematic impact on First Amendment expression).

195. *But see* Collins, *supra* note 167 (discussing federal funding of research using CRISPR/Cas9 in mice and antimicrobials and of research using a related technology to accomplish gene editing in human immune cells).

196. See *United States v. O’Brien*, 391 U.S. 367, 377 (1968) (identifying as the fourth factor for First Amendment analysis whether “the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest”); see also *supra* Part III.C.

197. See generally, e.g., *Bartnicki v. Vopper*, 532 U.S. 514 (2001); *Brandenburg v. Ohio*, 395 U.S. 444 (1969).

Amendment protects even speech that advocates unlawful action, but that does not rise to the level of incitement.<sup>198</sup> Under *Brandenburg*, speech becomes proscribable only when it is “directed to inciting or producing imminent lawless action and is likely to incite or produce such action.”<sup>199</sup> Likewise, the Court’s decision in *Bartnicki v. Vopper* compels the conclusion that the State’s interest in preventing premature (or any) clinical use of human germline gene editing cannot be achieved through suppression of knowledge production about germline gene editing through non-clinical research. The Court held that a newsman could not be held liable under wiretap statutes for broadcasting an unlawfully recorded telephone call.<sup>200</sup> In reaching this conclusion, Justice Stevens, writing for the Court, stated:

The normal method of deterring unlawful conduct is to impose an appropriate punishment on the person who engages in it. . . . But it would be quite remarkable to hold that speech by a law-abiding possessor of information can be suppressed in order to deter conduct by a non-law-abiding third party.<sup>201</sup>

Although *Brandenburg* and *Bartnicki* applied strict-scrutiny review, their treatment of collateral censorship used to silence First Amendment activity because of unlawful acts associated with that activity is relevant to the analysis here. The same principle, that the government cannot suppress First Amendment-protected activity in order to prevent possible downstream effects, holds true under the information-production approach. Accordingly, the First Amendment ought not permit the State to suppress knowledge production through non-clinical research involving human germline gene editing in an effort to prevent the alleged harms of clinical use of such knowledge.

### B. PROHIBITING HUMAN CLONING FOR BIOMEDICAL RESEARCH

While state and federal government actors have so far stayed their hands from enacting outright prohibitions on research involving human germline gene editing, the same cannot be said of research involving human SCNT. In nearly half of Congress’s sessions since 1996 (when researchers announced Dolly), members have introduced legislation that would prohibit human cloning for both reproductive and research purposes.<sup>202</sup> Twice, the House of

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198. *Brandenburg*, 395 U.S. at 448–49.

199. *Id.* at 447.

200. *Bartnicki*, 532 U.S. at 518.

201. *Id.* at 529–30.

202. See, e.g., Human Cloning Prohibition Act of 2105 [sic], H.R. 3498, 114th Cong.; Human Cloning Prohibition Act of 2012, H.R. 2164, 113th Cong.; Human Cloning Prohibition Act of 2012, H.R. 6623, 112th Cong. (2012); Human Cloning Prohibition Act of 2009, H.R. 110, 111th Cong.; Human Cloning Prohibition Act of 2007, H.R. 2564, 110th Cong.; Human Cloning Prohibition Act of 2005, H.R. 1357, 109th Cong.; Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong.; Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong.; Human

Representatives passed such measures, though the Senate declined to follow suit.<sup>203</sup> At least six states, by contrast, have successfully enacted legislation prohibiting cloning for biomedical research.<sup>204</sup>

Advocates for prohibiting all human cloning have articulated at least two distinct rationales for their position. First, these advocates have argued that a law prohibiting only cloning for producing children will be ineffective to prevent such children from being born. According to Representative Tom Weldon, “If you allow research cloning to proliferate all over the country . . . [i]t will be very easy for an unscrupulous physician to implant one of those human embryos into a woman in the privacy of the doctor-patient relationship.”<sup>205</sup> The concern is that human cloning for producing children will be much easier to accomplish once researchers generate the technical know-how for it through cloning for biomedical research.

Second, though less frequently, those concerned about human cloning for biomedical research have drawn attention to the potential for exploitation or coercion of the women who will be the sources of the many human eggs required to facilitate SCNT research and therapies.<sup>206</sup> The great promise of cloning for biomedical research lies in personalized medicine. Researchers envision a multi-step process in which they use a patient’s somatic cell to generate a SCNT embryo, from which they can subsequently derive an embryonic stem cell line.<sup>207</sup> Such a process would produce an individualized and patient-matched stem cell line that could be used for disease research or to grow immunologically matched replacement tissues or organs.<sup>208</sup> This process also fundamentally depends on a steady stream of human eggs with which to conduct the research and derive therapies. After all, human cloning

Cloning Prohibition Act of 1998, S. 1599, 105th Cong.

203. H.R. 534 (as passed by House, Feb. 27, 2003); H.R. 2505 (as passed by House, July 31, 2001).

204. Korobkin, *supra* note 18 at 169.

205. 149 CONG. REC. H1309 (daily ed. Feb. 25, 2003) (statement of Rep. Weldon); *see also* 149 CONG. REC. H1428 (daily ed. Feb. 27, 2003) (statement of Rep. Smith) (rejecting an alternative provision that would prohibit human cloning to produce children, but not for biomedical research, because “it would make the hard part of human cloning completely legal and would make the relatively easy part, implantation, illegal”).

206. *See generally Human Cloning and Embryonic Stem Cell Research After Seoul: Examination Exploitation, Fraud, and Ethical Problems in the Research: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, & Human Res. of the H. Comm. on Gov’t Reform*, 109th Cong. (2006) [hereinafter *Human Cloning and Embryonic Stem Cell Research After Seoul*]. State initiatives are also beginning to pay attention to the potential harms to women that human cloning for biomedical research poses. *See Joint Oversight Hearing on the Implementation of Proposition 71, the Stem Cell Research and Cures Act: J. Hearing Before the Cal. S. Subcomm. on Stem Cell Research Oversight, the S. Health Comm., & the Assembly Health Comm.*, 2005 Leg. (Mar. 9, 2005) [hereinafter *Hearing on Proposition 71*] (statement of Francine Coeytaux, MPH, Pro-Choice Alliance for Responsible Research), [http://www.genetics-and-society.org/resources/items/20050309\\_senate\\_coeytaux.html](http://www.genetics-and-society.org/resources/items/20050309_senate_coeytaux.html).

207. *See* Robert P. Lanza et al., *Prospects for the Use of Nuclear Transfer in Human Transplantation*, 17 NATURE BIOTECHNOLOGY 1171, 1171 (1999).

208. *See id.*

by SCNT requires both a human somatic cell and a human egg into which the somatic cell can be transferred.

Even in an ideal world, the number of human eggs required to support these endeavors would be massive; in the real world, that number is even greater. In the ideal world, researchers could accomplish both the processes of SCNT embryo creation and subsequent stem cell derivation efficiently, requiring only a single human egg for each desired cell line. Even then, the numbers of eggs required would place an enormous burden on the egg-bearing population. To meet the demand for the custom therapeutics envisioned, millions of cell lines would likely be developed—one for every patient.<sup>209</sup> In the real world, the numbers of eggs required are even greater. To date, the efficiencies of both SCNT embryo creation and stem cell derivation are far from 100%.<sup>210</sup> Indeed, only a small number of research teams have reported successfully deriving stem cell lines from SCNT-created embryos at all, indicating that more and more basic research is required to develop this technology.<sup>211</sup> In sum, the number of human eggs that would be required to support basic and other scientific research on human cloning is staggering.<sup>212</sup>

Applying the modified *O'Brien* test called for under the information-production approach assists in separating constitutionally valid from constitutionally suspect motivations for regulating human cloning for biomedical research. As with regulations of gene-editing technology, both federal and state governments likely have sufficient constitutional authority to act in this domain.<sup>213</sup> Much of the remaining analysis of the primary rationales for prohibiting human cloning for biomedical research differs, however, depending on which rationale is at issue. The remainder of this Subpart addresses each rationale in turn, concluding that one (prohibiting human cloning for biomedical research because it makes human cloning to produce children easier to accomplish) is constitutionally suspect, while the other (prohibiting human cloning for biomedical research because it poses significant risks of exploitation to the woman whose eggs are required to support it) likely is not.

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209. *See id.*

210. *See* Chung et al., *supra* note 24, at 778 (reporting that, beginning with 77 human eggs from four donors, researchers successfully derived two chromosomally normal, diploid embryonic stem cell lines matched to adult somatic cell donors); Tachibana et al., *supra* note 24, at 1231, 1231 fig.3 (reporting efficiency gains in derivation of stem cell lines from SCNT-created embryos where 42 human eggs exposed to caffeine were ultimately transformed into four “ESC-like colonies”).

211. *See* Chung et al., *supra* note 24, at 777; Tachibana et al., *supra* note 24, at 1228.

212. *See* 149 CONG. REC. H1400 (daily ed. Feb. 27, 2003) (statement of Rep. Davis) (“Just to treat 16 million Parkinson’s patients, it is estimated that a minimum of 800 million human eggs would be needed from a minimum of 80 million women of childbearing age.”).

213. *See supra* notes 178–80 and accompanying text.

### 1. Preventing Research Developments that Can Be Used to Facilitate Human Cloning for Producing Children

The remaining analysis of government prohibitions of human cloning for biomedical research, where the goal of that prohibition is collaterally to reinforce a prohibition on human cloning to produce children, continues to mirror the analysis of government prohibitions of non-clinical human germline gene-editing research set forth above. Objections to human cloning for producing children reflect many of the same concerns that attach to clinical applications of human germline gene editing. Here, too, the principal objections include preventing science from “playing God”<sup>214</sup> and protecting society and potential children born through cloning from the harms thereof.<sup>215</sup> The former, as set forth above, reflects an interest in preserving public morality, and rests on somewhat shaky jurisprudential grounds at least insofar as it intrudes on otherwise constitutionally protected activity.<sup>216</sup> The latter, meanwhile, invokes health and safety concerns that likely constitute an “important or substantial” government interest, even as applied to in vitro embryos intended to develop into born persons.<sup>217</sup> Indeed, the potential negative health effects to individuals created through human cloning are worthy of attention.<sup>218</sup> The state of the art in SCNT is still developing, and so the use of SCNT for human reproduction would “pose the risk of . . . possibly severe developmental abnormalities in any resulting child.”<sup>219</sup> Such risks are not without basis: Dolly’s relatively early death raised questions about developmental and other differences between cloned individuals and those conceived through traditional sexual reproduction.<sup>220</sup>

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214. See, e.g., Elizabeth Price Foley, *The Constitutional Implications of Human Cloning*, 42 ARIZ. L. REV. 647, 719–21 (2000) (discussing the State’s interest in “[p]reserving the [s]anctity of [h]uman [l]ife”); Matthew B. Hsu, Note, *Banning Human Cloning: An Acceptable Limit on Scientific Inquiry or an Unconstitutional Restriction of Symbolic Speech?*, 87 GEO. L.J. 2399, 2416–21 (1999) (characterizing the primary interest served through banning human cloning as an “[i]nterest in [p]romoting [h]uman [d]ignity”); see also *id.* at 2417–18 (describing a ban on cloning as aimed at preventing science from “playing God”).

215. See, e.g., Foley, *supra* note 214, at 709–30 (discussing and rejecting state interests in preserving marriage and the family, “protecting personal autonomy and privacy” (i.e., cloned children are deprived a “right to ignorance”), “protecting the health and safety of human embryos,” and “preserving genetic diversity” (footnotes omitted)); Hsu, *supra* note 214, at 2421–29 (discussing and rejecting justifications for prohibiting human cloning, including preventing physical and psychological harms to children, prohibiting experimentation that is unethical because it interferes with natural conception, preventing negative social consequences arising from cloned children, and guarding against losses in genetic diversity).

216. See *supra* note 193 and accompanying text.

217. See *supra* notes 186–90 and accompanying text.

218. See NAT’L BIOETHICS ADVISORY COMM’N, *supra* note 192, at 64–65.

219. *Id.* at 64.

220. See Will Knight, *Dolly the Sheep Dies Young*, NEW SCIENTIST (Feb. 14, 2003), <https://www.newscientist.com/article/dn3393-dolly-the-sheep-dies-young>.

But like prohibiting germline gene editing research, prohibiting human cloning for biomedical research is an impermissible means for achieving these legitimate state interests. Here, too, such a prohibition serves its intended goals by preventing the production of scientific knowledge. As advocates of such a prohibition have made clear, they fear human cloning for biomedical research because it makes the subsequent reproductive use of such technology easier to accomplish.<sup>221</sup> Yet that is simply a way of saying that the State's interest in prohibiting human cloning for biomedical research is an interest in preventing people from acquiring the knowledge and know-how of human-cloning techniques. This interest is directly related to the suppression of knowledge production—precisely what the modified *O'Brien* test is supposed to guard against.<sup>222</sup> As in the case of germline gene editing, preventing harm by prohibiting discovery of knowledge that might facilitate that harm runs afoul of the knowledge-production approach to the First Amendment. Preventing the harms of human cloning for producing children could be most directly achieved by prohibiting human cloning for producing children, full stop. Prohibiting non-clinical research involving germline gene editing, conversely, advances the State's purpose only through indirect collateral censorship<sup>223</sup> that directly interferes with knowledge production that the First Amendment protects. Moreover, the collateral relationship between the means chosen and the ends sought indicate that those means are not closely tailored to the interest that regulation seeks to serve—another crucial flaw under the modified *O'Brien* test.<sup>224</sup> In sum, this type of targeted knowledge suppression cannot stand.

## 2. Preventing the Exploitation or Coercion of Women in Egg Extraction

The other primary rationale for prohibiting human cloning for biomedical research, preventing the exploitation or coercion of women in egg extraction, fares quite differently under the remainder of the modified *O'Brien* analysis.

Here again, the primary government interest at work is one in the health and safety of individuals. Unlike concerns about the health and safety of in vitro embryos, however, the population concerned under this rationale is

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221. See, e.g., 149 CONG. REC. H1428 (daily ed. Feb. 27, 2003) (statement of Rep. Smith) (rejecting an alternative provision that would prohibit human cloning to produce children, but not for biomedical research, because “it would make the hard part of human cloning completely legal and would make the relatively easy part, implantation, illegal”).

222. See *supra* text accompanying note 104.

223. See Balkin, *supra* note 68, at 2310–11 (discussing the rise of collateral censorship and its problematic impact on First Amendment expression).

224. See *United States v. O'Brien*, 391 U.S. 367, 377 (1968) (identifying as the fourth factor for First Amendment analysis whether “the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest”); see also *supra* Part III.C.

born human women. There is no question that this interest qualifies as “important or substantial.”<sup>225</sup>

There is also a firm basis in fact for concluding that embracing any form of human cloning—whether for research, therapy, or reproduction—would place unique health and safety burdens on women. Human cloning requires human eggs. As described above, given the current inefficiencies in both SCNT and stem cell derivation technologies, the number of human eggs that would be required to support basic and other scientific research on human cloning is staggering.<sup>226</sup> According to one estimate, “[j]ust to treat 16 million Parkinson’s patients, it is estimated that a minimum of 800 million human eggs would be needed from a minimum of 80 million women of childbearing age.”<sup>227</sup> Acquiring the necessary eggs to support human cloning research is made more difficult still by the fact that current demand for human eggs already outstrips the available supply.<sup>228</sup> In part, this is because egg donation is a time-consuming, painful, and potentially dangerous procedure. The process of multiple egg extraction requires the donor to take drugs for a month that may cause breast tenderness, backaches, headaches, insomnia, bloating, and increased vaginal discharge and place the donor at risk for severe ovarian hyperstimulation syndrome (“OHSS”), a rare but potentially fatal reaction to superovulatory drugs occurring in roughly 1% of cycles (milder forms of OHSS may be present in up to 20% of cycles). Superovulation has also been linked to increased risks of ovarian cancer, although current data is not dispositive. Following this period of superovulation, donors undergo laparoscopic surgery to retrieve the eggs, a procedure that may result in bleeding, pelvic infection, accidental bowel injury, superficial hemorrhage, and retained gas. Additional risks are introduced through the use of anesthesia and laparoscopy.<sup>229</sup>

To be sure, the National Academies of Science have issued voluntary guidelines recommending that eggs used in research only be obtained from unpaid donors and that consent to donation be fully informed and freely given.<sup>230</sup> But the massive demand for human eggs for use in research risks jeopardizing these voluntary limitations. The results of investigations into

225. See *supra* note 187 and accompanying text.

226. See *supra* notes 209–12 and accompanying text.

227. 149 CONG. REC. H1416 (daily ed. Feb. 27, 2003) (statement of Rep. Manzullo).

228. See generally Donna Dickenson, Commentary, *Commodification of Human Tissue: Implications for Feminist and Development Ethics*, 2 DEVELOPING WORLD BIOETHICS 55 (2002) (noting a general shortage of egg donors in northern hemisphere nations).

229. Lynette Reid et al., *Compensation for Gamete Donation: The Analogy with Jury Duty*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 35, 36 (2007) (footnotes omitted).

230. NAT’L RES. COUNCIL & INST. OF MED. OF THE NAT’L ACADS., GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 101–02 (2005). In other work, I have discussed how remunerating those providing human tissue, like eggs, that are essential for research need not inevitably lead to the exploitation of the poorest members of society. See generally Natalie Ram, Book Review, *Body Banking from the Bench to the Bedside*, 129 HARV. L. REV. 491 (2015).

Woo Suk Hwang's research are telling. The Korean National Board of Bioethics and Seoul National University found that Hwang had obtained more than 2,000 human eggs from 129 women.<sup>231</sup> Egg providers included at least one junior member of Hwang's research team, indicating a serious exploitation of the power imbalance between research leader and junior team member.<sup>232</sup> At a minimum, researchers or egg brokers are likely to turn to women in the developing world (where fewer human-subjects protections are present or enforced) to obtain needed eggs<sup>233</sup> or extract consent through other forms of direct and indirect coercion.<sup>234</sup> Truly informed consent may be put in jeopardy not only because of pressures to obtain eggs, but also because adequate safety data about the risks of egg donation remains relatively unknown.<sup>235</sup>

Accordingly, if the government permits human cloning for biomedical research to move forward, it will raise substantial concerns about the health and safety of women. Although promising research suggests that embryonic stem cells may be coaxed into becoming functional eggs, this research has not yet been demonstrated with human stem cells.<sup>236</sup> For the time being, human eggs required for research must be obtained from women. Congress and state

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231. Wade & Sang-Hun, *supra* note 25.

232. Ian Sample, *Stem Cell Pioneer Accused of Faking All His Research. Apart from the Cloned Dog*, *GUARDIAN* (Jan. 11, 2006, 5:36 AM), <https://www.theguardian.com/science/2006/jan/11/genetics.research>.

233. *Hearing on Proposition 71*, *supra* note 206 (statement of Francine Coeytaux) ("In SCNT the egg is stripped of the donor's genetic material so the focus will simply be to recruit young, healthy women. And if financial payments are made even in the guise of 'reimbursement,' in all likelihood the majority of women offering their eggs will be poor women."); *see also generally* Dickenson, *supra* note 228. The fact that many eggs obtained for use in biomedical research will likely be obtained from non-American women does not diminish the need to guard against unethical and unjust practices. American law frequently criminalizes behavior for which victims are non-citizens. For example, possession of child pornography is illegal in part because its very creation involves child abuse. Yet, possession is illegal regardless of whether the child depicted is American. *See* 18 U.S.C. § 2252 (2012). The harm perpetrated by the production of child pornography depends on the status of the victim as a child, not as a citizen. In turn, the harms perpetrated by exploitative and coercive egg extraction must depend on the status of the victim as a woman, not as a citizen.

234. *See, e.g.*, Ian Sample & Donald MacLeod, *Cloning Plan Poses New Ethical Dilemma*, *GUARDIAN* (July 26, 2005, 5:15 AM), <https://www.theguardian.com/science/2005/jul/26/businessofresearch.highereducation> (noting concerns about creating an undue moral inducement for egg donors); Wade & Sang-Hun, *supra* note 25 (noting that Hwang's research team fabricated evidence).

235. *See* 149 CONG. REC. H1416 (daily ed. Feb. 27, 2003) (statement of Rep. Manzullo); *Hearing on Proposition 71*, *supra* note 206 (statement of Francine Coeytaux).

236. *See generally* Charles A. Easley IV et al., *Gamete Derivation from Embryonic Stem Cells, Induced Pluripotent Stem Cells or Somatic Cell Nuclear Transfer-Derived Embryonic Stem Cells: State of the Art*, 27 *REPROD., FERTILITY, & DEV.* 89 (2014); *see also generally* Amander T. Clark et al., *Spontaneous Differentiation of Germ Cells from Human Embryonic Stem Cells In Vitro*, 13 *HUM. MOLECULAR GENETICS* 727, 727-28 (2004) (demonstrating that human embryonic stem cells can be differentiated into germ cells *in vitro*); Zubin Master, *Embryonic Stem-Cell Gametes: The New Frontier in Human Reproduction*, 21 *HUM. REPROD.* 857, 857-58 (2005) (canvassing the available research on deriving gametes from embryonic stem cells).

governments enacting legislation regulating or prohibiting human cloning for biomedical research in order to limit the exploitation or coercion of women egg providers are advancing an “important or substantial” state interest.

Turning to the relationship between the State’s interest and the means chosen (here, prohibiting human cloning for biomedical research), the modified *O’Brien* analysis indicates that such a prohibition is likely to survive constitutional scrutiny. A statute that aims to suppress conduct for its own sake, rather than for the knowledge it might generate, is not geared towards the suppression of knowledge production. Under this rubric, preventing harm to women arising from coercive and exploitative egg extraction raises few *O’Brien*-type concerns because it is unrelated to any information-producing quality of cloning techniques. Statutes advancing this interest would not intend to suppress conduct in order to suppress the information generated through such conduct or the dissemination of that information. Such statutes would simply seek to prevent harms sustained through the conduct of cloning research itself. Because concern about harm to women would arise “regardless of whether the discoverer alone performed these acts, or whether such know-how were publicly disseminated to enable more widespread application[] . . . treating restrictions on conduct designed to discover such information as ones that were effectively designed to suppress expression would appear to be improper.”<sup>237</sup>

Other First Amendment scholars likewise acknowledge that protecting human health and safety is an important state purpose unrelated to the suppression of expression or knowledge production. John Robertson, a key proponent of the essential-preconditions approach, observes, “the right to experiment . . . is a weaker right than the right to select the end of research. . . . [The scientist] may not cause direct, substantial harm to the cognizable interests of others.”<sup>238</sup> Given the risks associated with multiple-egg extraction, activities necessitating massive egg collection—like human cloning for biomedical research—directly implicate the “cognizable interests of others.” This means that preventing the exploitation and coercion of women is a substantial and legitimate state interest that survives scrutiny under the third prong of modified *O’Brien* scrutiny.

Having established that the interest in preventing (or at least limiting) the exploitation or coercion of women providing eggs for human cloning research is an interest unrelated to the suppression of knowledge production, a government regulation of scientific experimentation serving that interest is presumptively constitutional.<sup>239</sup> So long as there is some reasonable fit between the means chosen and the ends sought, such regulation will survive

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237. McDonald, *supra* note 45, at 1032.

238. Robertson, *supra* note 93, at 1206.

239. See *supra* Part III.C.

First Amendment scrutiny. To be sure, *O'Brien* stated that a government regulation of expressive conduct survives constitutional scrutiny only “if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.”<sup>240</sup> In interpreting that language, however, the Supreme Court has required something less than narrow tailoring.<sup>241</sup> The Court has explained “that the *O'Brien* test ‘in the last analysis is little, if any, different from the standard applied to time, place, or manner restrictions.’”<sup>242</sup> Thus, “an incidental burden on speech is no greater than is essential, and therefore is permissible under *O'Brien*, so long as the neutral regulation promotes a substantial government interest that would be achieved less effectively absent the regulation.”<sup>243</sup>

Here, although there is some doubt as to whether prohibiting human cloning for biomedical research is the best fit for the substantial interest identified, that fit is likely to be sufficient for present purposes. At a minimum, given the risk of harm to women through egg extraction on a massive scale, prohibiting cloning for biomedical research serves the interests of protecting women more effectively than allowing unregulated scientific experimentation in this area to proceed. Prohibiting human cloning for biomedical research would significantly diminish the demand for human eggs, and consequently the risks to women associated with obtaining those eggs.

To be sure, more narrowly tailored means may exist. For example, regulations requiring that human eggs used in cloning for biomedical research be obtained through free and informed consent (and perhaps from domestic donors)<sup>244</sup> would interfere with or prevent far less research than a prohibition on human cloning for biomedical research. But as the interest at issue here is unrelated to the suppression of knowledge production, this government regulation is presumptively constitutional and a “best fit” is not required.

Furthermore, there are good reasons to defer to Congress and state legislatures on their choice of a cloning prohibition. As Hwang’s research in South Korea demonstrated, coercive and unethical practices for obtaining human eggs are often difficult to detect—conclusive findings about egg extraction from at least one junior research member only came to light well after Hwang’s research had been published.<sup>245</sup> Considering the large number

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240. *United States v. O'Brien*, 391 U.S. 367, 377 (1968).

241. *See* *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 450 n.25 (2d Cir. 2001) (“*Turner Broadcasting* made clear that the narrow tailoring requirement [in *O'Brien*] is less demanding than the least restrictive means requirement of a content-specific regulation . . .”).

242. *Ward v. Rock Against Racism*, 491 U.S. 781, 798 (1989) (quoting *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 298 (1984)).

243. *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 67 (2006) (quoting *United States v. Albertini*, 472 U.S. 675, 689 (1985)).

244. This is similar to the approach endorsed by the National Academies of Science. *See* NAT’L RES. COUNCIL & INST. OF MED. OF THE NAT’L ACADS., *supra* note 230, at 101–02.

245. *See* *Sample*, *supra* note 232; *Wade & Sang-Hun*, *supra* note 25.

of human eggs that may be needed to facilitate research, conduct that would be harmful to women in order to obtain this precious material is likely to occur.<sup>246</sup>

Finally, in considering whether and how prohibiting human cloning for biomedical research might nonetheless limit scientific progress,<sup>247</sup> it is worth noting that many of the goals advanced in support of such cloning research may be achieved through related research on non-controversial or less controversial biological sources. For example, the primary goal supporting human cloning for biomedical research is to derive embryonic stem cell lines matched to a specific individual.<sup>248</sup> If such a cell line could be created and effectively differentiated to create replacement tissues, organs, and other biological materials, the health risks of immune rejection in transplantation would likely be greatly diminished. Yet, research in other avenues may also be able to overcome the immune rejection problem. In the first instance, it is possible that stem cells will not trigger the same immune reaction as other transplanted tissues, mooted the need for personalized cells.<sup>249</sup> Alternatively, research to reprogram adult cells to their de-differentiated state may advance sufficiently to replace the need for cell lines created with SCNT embryos. Such research is ongoing, and the cells created through such research are known as “induced pluripotent stem (iPS) cells.”<sup>250</sup> Indeed, when scientists announced the first (actually successful) stem cell lines created from SCNT embryos, one researcher commented, “the most surprising thing [about this paper] is that somebody is still doing human [SCNT] in the era of iPS cells.”<sup>251</sup> At present, none of these alternatives is a certainty,<sup>252</sup> but, then again, neither are SCNT-embryonic stem cell derived therapeutics. The availability of

246. See *supra* notes 224–34 and accompanying text.

247. Were government regulation of scientific experimentation to leave researchers without credible alternative avenues for research, such a regulation, even if not enacted to suppress knowledge production, might raise constitutional concerns. See *supra* note 109 and accompanying text; see also generally *City of Ladue v. Gilleo*, 512 U.S. 43 (1994) (invalidating a city ordinance prohibiting homeowners from displaying signs on their property).

248. See, e.g., *Human Cloning and Embryonic Stem Cell Research After Seoul*, *supra* note 206 (statement of Rep. Souder) (“[R]esearch cloning involves the deliberate creation of cloned human embryos for [the] sole purpose of destroying them to obtain their stem cells.”); 148 CONG. REC. S5580 (daily ed. June 14, 2002) (statement of Sen. Feinstein) (linking human cloning for biomedical research to stem cell research); Hsu, *supra* note 214, at 2403; Lanza et al., *supra* note 207, at 1171.

249. This idea is not necessarily far fetched. In bone marrow replacement, for instance, the body better tolerates antigen mismatches when cord blood stem cells, as opposed to bone marrow stem cells, are used. See Angela R. Smith & John E. Wagner, *Alternative Hematopoietic Stem Cell Sources for Transplantation: Place of Umbilical Cord Blood*, 147 BRIT. J. HAEMATOLOGY 246, 246–47 (2009).

250. David Cyranoski, *Human Stem Cells Created by Cloning*, 497 NATURE 295, 296 (2013).

251. *Id.*

252. Although researchers have successfully created iPS cells in the laboratory, they have been unable to do so reliably and efficiently. See Chung et al., *supra* note 24, at 777 (“SCNT and induced pluripotent stem cell (iPSC) reprogramming are both inefficient processes.”).

alternative research paths directed at a similar goal—the creation of immunocompatible human biological materials for transplant—supports constitutionality here. This is not a circumstance in which a prohibition otherwise unrelated to knowledge production nonetheless raises significant constitutional concerns by acting as a blanket prohibition of an entire field of research.<sup>253</sup>

A second goal of human cloning for biomedical research is to expand the number of stem cell lines available for research. However, several hundred thousand human embryos are currently in cryostorage in American in vitro fertilization (“IVF”) clinics.<sup>254</sup> The vast majority of these are awaiting future use by infertile persons to complete their families, although people have donated some embryos for use in research, including stem cell research.<sup>255</sup> Moreover, providing potential donors—couples pursuing IVF who have completed their families—with better and more information about the research use of existing human embryos may increase the number of embryos donated for this purpose.

Not all government regulations of scientific experimentation run afoul of the First Amendment’s commitment to knowledge production. Where, as here, the State seeks to advance an “important or substantial” government interest unrelated to the suppression of knowledge production, the regulation is presumptively constitutional. And where, as here, the relationship between the government’s articulated goal and the means chosen for effectuating that goal is significant, the Constitution will not bar that regulation.

### C. PROHIBITING INFECTIOUS-DISEASE RESEARCH

When the U.S. government institutes a “pause” on certain virology studies or requests that prominent scientific journals not publish the results of others, it inserts itself into the process of producing and disseminating knowledge.<sup>256</sup> The relationship between government intervention and knowledge production cannot be clearer than when the government justifies its actions by citing “significant concerns that the information . . . could be misused to

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253. See *supra* note 106 and accompanying text.

254. See David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1068 (2003) (calculating that there were nearly 400,000 cryopreserved human embryos in the United States in 2002). One branch of the U.S. Department of Health and Human Services estimates the number of cryopreserved embryos in the United States at more than 600,000. See *Embryo Adoption*, U.S. DEP’T OF HEALTH & HUM. SERVS., OFFICE OF POPULATION AFFAIRS, <http://www.hhs.gov/opa/about-opa-and-initiatives/embryo-adoption/> (last visited Jan. 15, 2017).

255. See Hoffman, *supra* note 254, at 1066 tbl.1. Hoffman estimated that roughly 11,000 human embryos (less than 3% of embryos in cryopreservation) had been donated for research purposes. *Id.*

256. See *supra* 26–37 and accompanying text.

endanger public health and national security.”<sup>257</sup> It is here that the modified *O’Brien* analysis guards against enticing, but flawed, efforts to regulate scientific experimentation. Moreover, that analysis can help refocus regulatory efforts in more productive and constitutionally sound ways.

To be sure, the government’s conduct with respect to infectious-disease research has, thus far, been limited to federal funding decisions and requests for voluntary action. Such conduct is likely constitutional for reasons unrelated to the knowledge-production analysis discussed here.<sup>258</sup> But should the government move from these more limited methods to broader, coercive prohibition, the modified *O’Brien* analysis would have a role to play in separating constitutionally valid rationales for regulating research from constitutionally invalid ones.

With respect to the first *O’Brien* requirement, both federal and state governments likely have sufficient constitutional authority to act in this domain, just as they do in regulating gene-editing technology and human cloning.<sup>259</sup> As in these other spheres, the government is likely to have acted pursuant to “an important or substantial” government interest, thus satisfying the second prong of *O’Brien*.<sup>260</sup> Where the government has acted to prevent researchers from completing or publishing infectious-disease research, it has done so in the name of “public health and national security.”<sup>261</sup> Each of these interests exceeds the “important and substantial” baseline. The Supreme Court has remarked, “[e]veryone agrees that the Government’s interest in combating terrorism is an urgent objective of the highest order.”<sup>262</sup> Similarly, the Court has observed that “[i]t is a traditional exercise of the States’ ‘police powers to protect the health and safety of their citizens,’” and concluded that this interest may be sufficiently weighty to justify a restriction on speech.<sup>263</sup>

Yet, prohibiting infectious-disease research, where it is driven by the specter of how the results of such research might be misused, founders on the third prong of the modified *O’Brien* analysis. The express purpose of such a prohibition—whether phrased as a “pause” or an outright ban—is to prevent

257. NAT’L SCI. ADVISORY BD. FOR BIOSECURITY, FINDINGS AND RECOMMENDATIONS 1 (2012), [http://osp.od.nih.gov/sites/default/files/resources/03302012\\_NSABB\\_Recommendations\\_1.pdf](http://osp.od.nih.gov/sites/default/files/resources/03302012_NSABB_Recommendations_1.pdf); see also Howard Markel, Opinion, *Don’t Censor Influenza Research*, N.Y. TIMES (Feb. 1, 2012), <http://www.nytimes.com/2012/02/02/opinion/censorship-hinders-influenza-research.html> (government feared “that terrorists might use the data to weaponize influenza”).

258. On the relationship between the First Amendment and federal funding decisions, see *supra* notes 167–70 and accompanying text.

259. See *supra* notes 177–80 and accompanying text. In addition, protecting public health has long been among the “conspicuous examples of the traditional application of the police power” that state and municipal governments wield. See *Berman v. Parker*, 348 U.S. 26, 32 (1954).

260. *United States v. O’Brien*, 391 U.S. 367, 377 (1968); see *supra* Part III.C.

261. NAT’L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 257.

262. *Holder v. Humanitarian Law Project*, 561 U.S. 1, 28 (2010).

263. *Hill v. Colorado*, 530 U.S. 703, 715 (2000) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996)).

people from discovering certain knowledge for fear of its misuse. That goal, in turn, is directly related to the suppression of knowledge production. This is precisely what the modified *O'Brien* test is designed to guard against.<sup>264</sup>

Prohibiting certain infectious-disease research is also unlikely to satisfy *O'Brien's* final requirement, that the “restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.”<sup>265</sup> In most instances, efforts to prohibit scientific publication have been rendered moot by similar research conducted outside the United States or by the scope of other publicly available information. Consider the H<sub>5</sub>N<sub>1</sub> research the U.S. government sought initially to censor: the publications at issue stemmed from research conducted in the United States and in the Netherlands.<sup>266</sup> Even had the government suppressed or prohibited research conducted within its borders, its efforts would have been undermined by comparable research taking place elsewhere. Alternatively, consider the U.S. government’s earlier efforts to prevent publication of information about the hydrogen bomb.<sup>267</sup> A district court initially granted the government’s request to enjoin publication of an article collating sensitive information about the bomb.<sup>268</sup> On appeal, the government ultimately abandoned its request for injunctive relief because the sensitive information it had sought to protect had already been quite widely publicly disclosed.<sup>269</sup> In other words, the “secret” the government sought to protect did not remain a secret for long.<sup>270</sup> As is frequently the case, efforts to suppress certain information can backfire, increasing efforts to uncover and expose that controversial data.<sup>271</sup>

Accordingly, it is unlikely that a government prohibition on infectious-disease research due to the possible misuse of its results could survive constitutional scrutiny under the modified *O'Brien* test. Two caveats to this conclusion are pertinent here. First, where the State is entitled to a restraint on publication of research results—a government interference subject to the

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264. See *supra* text accompanying note 104.

265. *O'Brien*, 391 U.S. at 377.

266. Grady & Broad, *supra* note 26.

267. See generally *United States v. Progressive, Inc.*, 467 F. Supp. 990 (W.D. Wis. 1979), *appeal dismissed*, 610 F.2d 819 (7th Cir. 1979).

268. See *id.* at 999–1000; Ian M. Dumain, *No Secret, No Defense: United States v. Progressive*, 26 CARDOZO L. REV. 1323, 1325–32 (2005) (describing the *Progressive* case, in which the government sought to bar publication of a magazine article detailing information about the hydrogen bomb).

269. Dumain, *supra* note 268, at 1331–32.

270. Dumain describes the information at issue in the *Progressive* case as, effectively, a collation of otherwise publicly available information. *Id.* at 1325 (describing *The Progressive's* article as “demonstrating that even sensitive information about hydrogen bomb design could be ferreted out by a magazine reporter operating entirely in the open, without recourse to secret government documents” (quoting Samuel H. Day, Jr., Book Review, *Breaking the Code of Silence*, 53 BULL. ATOMIC SCIENTISTS 57, 58 (May/June 1997))).

271. See, e.g., T.C., *What Is the Streisand Effect?*, ECONOMIST (Apr. 16, 2013, 12:50 AM), <http://www.economist.com/blogs/economist-explains/2013/04/economist-explains-what-streisand-effect>.

most searching First Amendment scrutiny<sup>272</sup>—it is equally entitled to restrain the underlying research itself. The *O'Brien* standard, after all, is a less demanding one than the strict standard to justify a prior restraint.<sup>273</sup> The Supreme Court has suggested that prior restraint might be appropriate where national security is at stake,<sup>274</sup> although it has also declined to permit such restraint even when national security could be negatively affected.<sup>275</sup> Second, if certain forms of knowledge were inherently destructive to the State, or only capable of being used for ill, then a prohibition on discovery might fare differently under the *O'Brien* test. At a minimum, prohibiting discovery might well be deemed the most direct way of preventing those ills—a restriction “no greater than is essential.”<sup>276</sup>

But in the main, knowledge about infectious diseases will rarely, if ever, be so one-sided.<sup>277</sup> As the NSABB acknowledged in a report following the “pause” of infectious-disease research funding, “[r]esearch involving pathogens is essential to global health and security. Such research provides insight into the fundamental nature of human-pathogen interactions, enables the assessment of the pandemic potential of emerging infectious agents, and informs public health and preparedness efforts, including the development

272. See *N.Y. Times Co. v. United States*, 403 U.S. 713, 714 (1971) (per curiam) (declining to permit prior restraint despite national security interest); *Near v. Minnesota ex rel. Olson*, 283 U.S. 697, 716 (1931) (discussing prior restraint in the interest of national security).

273. Compare *Near*, 283 U.S. at 716 (explaining that prior restraint is constitutionally permissible “only in exceptional cases”), and *N.Y. Times Co.*, 403 U.S. at 714 (“Any system of prior restraints of expression comes to this Court bearing a heavy presumption against its constitutional validity.” (quoting *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 70 (1963))), with *Holder v. Humanitarian Law Project*, 561 U.S. 1, 26–27 (2010) (describing *O'Brien* as a standard of “intermediate scrutiny”).

274. *Near*, 283 U.S. at 716 (“No one would question but that a government might prevent actual obstruction to its recruiting service or the publication of the sailing dates of transports or the number and location of troops.”).

275. See *Neb. Press Ass’n v. Stuart*, 427 U.S. 539, 591–92 (1976) (“In *New York Times Co. v. United States*, . . . we specifically addressed the scope of the ‘military security’ exception alluded to in *Near* and held that there could be no prior restraint on publication of the ‘Pentagon Papers’ despite the fact that a majority of the Court believed that release of the documents, which were classified ‘Top Secret-Sensitive’ and which were obtained surreptitiously, would be harmful to the Nation and might even be prosecuted after publication as a violation of various espionage statutes.”).

276. *United States v. O’Brien*, 391 U.S. 367, 377 (1968).

277. The National Science Advisory Board for Biosecurity, in a recent report setting forth findings and recommendations regarding the infectious-disease research it had “paused,” identified one candidate: “the insertion of a virulence gene from an unrelated organism into the genome of a virus that is transmissible through the respiratory route, which would be highly unlikely to occur through natural recombination.” NAT’L SCI. ADVISORY BD. FOR BIOSECURITY, RECOMMENDATIONS FOR THE EVALUATION AND OVERSIGHT OF PROPOSED GAIN-OF-FUNCTION RESEARCH 38 (2016), [http://osp.od.nih.gov/sites/default/files/NSABB\\_Final\\_Report\\_Recommendations\\_Evaluation\\_Oversight\\_Proposed\\_Gain\\_of\\_Function\\_Research.pdf](http://osp.od.nih.gov/sites/default/files/NSABB_Final_Report_Recommendations_Evaluation_Oversight_Proposed_Gain_of_Function_Research.pdf). According to the NSAAB, “[t]his study, and others that involve the transfer of virulence genes between disparate microbes would appear to lack public health benefit, since the novel, laboratory-generated pathogen is unlikely to arise naturally and would therefore entail potentially significant and unnecessary risks.” *Id.*

of medical countermeasures.”<sup>278</sup> More specifically, in withdrawing its request regarding the publication of research results on the H<sub>5</sub>N<sub>1</sub> virus, the NSABB explained, “understanding specific mutations may improve international surveillance and public health and safety.”<sup>279</sup> Researchers working in the field have similarly emphasized the importance of their research in supporting public health and national security. One of the researchers working to reconstruct the 1918 flu virus has explained that, although the “experiments may seem dangerously foolhardy, they are actually the exact opposite. They gave us the opportunity to make the world safer, allowing us to learn what makes the virus dangerous and how it can be disabled.”<sup>280</sup>

This does not mean, however, that the government is without tools to mitigate the risks of these types of research. The modified *O'Brien* approach takes issue with efforts to suppress knowledge from coming into being; it does not affect reasonable regulations that aim to make the conduct of research safe and secure. Enforcing guidelines for how research is conducted—the means researchers employ—need not be tethered to (and typically are untethered from) the knowledge the research seeks to produce. For example, a requirement that such research take place only in laboratories with certain biocontainment conditions would likely survive *O'Brien* scrutiny. This requirement is unrelated to any information-producing quality of the research at issue. It focuses on preventing exposure, illness, and pandemic arising from the research directly, rather than from the downstream application of the knowledge produced through the research.

Indeed, this is the direction in which the government has moved in regulating potentially troubling infectious-disease research. For instance, while the NSABB initially expressed unease about research reconstructing the 1918 flu virus, “within a week, the NSABB recommended that we continue to study the virus under biocontainment conditions, and publish the results so that other scientists could participate in the research.”<sup>281</sup> The NSABB, in other words, focused on how the research was conducted—under biocontainment conditions—rather than on what exactly the research would reveal. A similar focus on *how* researchers can safely conduct infectious-disease research, not simply *what* information such research might generate, permeates the NSABB’s final report following the federal government’s funding “pause” of such research.<sup>282</sup>

The modified *O'Brien* approach would also leave unaffected statutes applied to terrorist activity seeking to develop or unleash pandemic viruses in the general population. For one thing, such activity is unlikely to qualify as

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278. *Id.* at 1.

279. NAT’L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 30.

280. Palese, *supra* note 31, at 115.

281. *Id.*

282. See NAT’L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 277, at 2–3, 40–51.

“science,” as it seeks injury and mayhem, rather than controlled data.<sup>283</sup> For another, such activity would surely be without the informed consent of nearly all affected individuals. Informed consent, like biocontainment conditions, is a requirement going to how research is conducted, not what research question is at issue.<sup>284</sup> It is therefore similarly likely to fall outside the scope of serious *O’Brien* scrutiny.<sup>285</sup>

In sum, although the misuse of knowledge generated through infectious-disease research is of real concern, the constitutional bar for prohibiting such research based on such concerns is high. Conversely, regulating the means by which such research is accomplished is unlikely to face serious constitutional challenge. In this way, examining the role of knowledge production through the First Amendment lens channels regulation into means that can protect public health and national security without sacrificing the (likely beneficial) fruits of scientific research.

## VI. CONCLUSION

First Amendment theory must be concerned with the production of knowledge, though it need not be concerned with conduct-specific harms resulting from production processes. If the government regulates scientific experimentation in order to suppress the knowledge such experimentation might generate, then that government interest aims at impermissible ends and accordingly triggers significant constitutional scrutiny. Conversely, if the government regulates or restricts scientific experimentation for reasons unrelated to the results of such research—focusing instead on harms sustained in the conduct of research itself—then the statute does not aim at knowledge production at all, and the statute may survive constitutional scrutiny. Purpose matters. Legislatures must think carefully about the purposes for which they enact legislation regulating or restricting scientific inquiry, and they should take care to promote the progress of science while preventing harms sustained in its conduct.

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283. See *supra* text accompanying notes 39–40.

284. See Robertson, *supra* note 93, at 1256 (“Laws requiring informed, free, and competent consent from research subjects promote interests in individual autonomy and welfare, whatever the subject matter content of the research.”).

285. But see Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271, 297–99 (arguing that federal research requirements for informed consent pose a First Amendment problem).