THE NEW ATLANTIS

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Editor's Note: Investigating the moral and political meaning of new technologies has been central to the mission of this journal since its founding, and few new biotechnologies raise such vexing questions as human cloning. With the recent creation of the first cloned human embryos, the implications of human cloning deserve more attention than they have received from policymakers, the news media, academic bioethicists, and the public at large. And so we devote this entire issue of *The New Atlantis* to a report from the Witherspoon Council on Ethics and the Integrity of Science examining human cloning and making the case against it—whether for the purpose of producing children or for the purpose of biomedical research.

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The New Atlantis

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The New Atlantis *(1627) was the title Francis Bacon selected for his fable of a society living with the benefits and challenges of advanced science and technology. Bacon, a founder and champion of modern science, sought not only to highlight the potential of technology to improve human life, but also to foresee some of the social, moral, and political difficulties that confront a society shaped by the great scientific enterprise. His book offers no obvious answers; perhaps it seduces more than it warns. But the tale also hints at some of the dilemmas that arise with the ability to remake and reconfigure the natural world: governing science, so that it might flourish freely without destroying or dehumanizing us, and understanding the effect of technology on human life, human aspiration, and the human good. To a great extent, we live in the world Bacon imagined, and now we must find a way to live well with both its burdens and its blessings. This very challenge, which now confronts our own society most forcefully, is the focus of this journal.*

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Executive Summary

Human cloning has advanced considerably since it was last widely debated. This report—written to be understood by non-specialists, including policymakers and the general public—explains the history of cloning as well as recent developments. The report offers an ethical and policy analysis, articulating what makes cloning morally repugnant and calling for the practice to be definitively prohibited in the United States.

The Threat of Human Cloning begins by laying out the scientific and policy background of the cloning debates. When the world learned in 1997 of Dolly the sheep, the first clone produced from an adult mammal, a broad public discussion about the ethics of human cloning ensued, largely focused on the nature, meaning, and future of human procreation. However, following the successful derivation of human embryonic stem cells in 1998, the debate over human cloning largely shifted to the question of whether it is acceptable for scientists to create human embryos only to destroy them. The subsequent discovery of promising alternative techniques for generating stem cells without creating or destroying embryos seemed to show that scientific progress would obviate the demand for cloning. But cloning research continued, and American scientists announced in 2013 that they had for the first time successfully obtained stem cells from cloned human embryos.

Although the latest scientific work related to cloning has been focused on potential medical applications, much of that research is relevant to the creation of cloned children. Not only would cloning-to-produce-children be a dangerous experimental procedure, one that cannot be consented to by its subjects (the children created by it), it is also a profound distortion of the moral meaning of human procreation. Giving adults the opportunity to have what has been called the "ultimate 'single-parent child'" would contribute to the commodification of children, and would withhold from children the possibility of a relationship with both a genetic mother and father. Cloning-to-produce-children could also be used to attempt to control the physical and even psychological traits of children, extending the eugenic logic of those who would use reproductive biotechnology to have the perfect child. This form of genetic engineering would deny the children it produces an open future, burdening them with the expectation that they will be like the individuals from whom they were cloned.

And cloning could make possible still more dramatic forms of genetic engineering.

Cloning-for-biomedical-research is also profoundly unethical, as it turns human reproduction into a manufacturing process in the most literal sense: human embryos are created to serve as raw materials for the production of biomedical research supplies. This kind of cloning is today being performed at several scientific labs in the United States, despite the availability of alternative techniques that produce cells of nearly the same scientific and medical value but that require neither the creation nor destruction of human embryos. Cloning-for-biomedical-research also endangers the health and safety of the women called on to undergo dangerous hormone treatments to serve as egg donors. If research cloning is not stopped now, we face the prospect of the mass farming of human embryos and fetuses, and the transformation of the noble enterprise of biomedical research into a grotesque system of exploitation and death.

The Threat of Human Cloning concludes by calling for laws prohibiting both human cloning and the creation of embryos for research. Other policy options, such as supposed compromises that would prohibit "reproductive cloning" but permit "therapeutic cloning" by prohibiting not the act of creating a cloned embryo but the act of transferring a cloned embryo to a woman's uterus, would inherently mandate the wide-scale destruction of human embryos. The United States government can, and must, outlaw human cloning.

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Preface

Cloning Then and Now

In May 2013, American scientists announced a long-awaited development: that they had produced stem cells from cloned human embryos. Using a technique called nuclear transfer—the same technique employed by Scottish researchers over a decade earlier to create the cloned sheep Dolly—Shoukhrat Mitalipov and his team at Oregon Health & Science University removed the nuclei from human egg cells and inserted nuclei taken from skin cells; the resulting cloned embryos were then destroyed to produce stem cells. The researchers' paper, published online in the science journal *Cell*,[1] became one of the most talked-about items in the scientific community in 2013.[2] It was labeled "a holy grail" by University of Pennsylvania researcher John Gearhart.[3] "This is a huge scientific advance," said Harvard scientist Dr. George Daley, "but it's going to, I think, raise the specter of controversy again."[4]

Mitalipov also expected as much, noting in a press release that "nuclear transfer breakthroughs often lead to a public discussion about the ethics of human cloning."[5] A reporter for *Nature* opined that Mitalipov's announcement "is sure to rekindle" the debate about cloning.[6] Declared the author Wesley J. Smith on *National Review Online*: "The great cloning debate is about to begin."[7]

And yet no such debate has materialized. While news of the Oregon cloning breakthrough was widely reported, very few publications offered editorials or op-eds discussing its implications; radio, television, and Internet outlets produced nearly no in-depth analyses or panel discussions; and policymakers stayed almost entirely silent.[8]

Contrast this muted response to the public reaction following researcher Ian Wilmut's 1997 announcement that he and his colleagues had used nuclear transfer to create Dolly, the first cloned mammal. World leaders condemned the research. The U.S. Congress held a series of hearings on the ethics of cloning, a federal bioethics commission was charged with making "every effort to consult with ethicists, theologians, scientists, physicians, and other citizens" to address the ethical and legal implications of the Dolly breakthrough,[9] and President Bill Clinton signed an executive order forbidding the use of federal funds for cloning research.[10] The media coverage was intense, with hundreds of op-eds, radio discussions,

and television debates, not to mention a flood of books and academic articles.[11] A handful of biotech boosters made the case for cloning, like molecular biologist Lee Silver, who argued that cloning would allow genetic engineering to become a reality.[12] On the other side were arrayed critics, like Pope John Paul II, who in 2001 condemned cloning as "irresponsible" and "unworthy of man."[13] The United Nations General Assembly in 2005 adopted a declaration calling on its member nations to "prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."[14]

Today, these passionate and proactive debates regarding both the extraordinary hopes for and the deep moral anxieties about human cloning have all but disappeared from the public discourse—a failing this report is intended to help rectify. As human cloning has arrived on our doorstep, we need now more than ever to discuss the ethical problems it raises and to develop a plausible political and legal approach to address those problems.

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Part One

Scientific and Historical Background

We begin with a brief history of cloning, highlighting some of its technical aspects and showing how the science and technology of cloning have fit together in the wider history of biotechnology as well as in the imagination and the actions of scientists and the public. We draw particular attention to a conceptual shift that first emerged in the late 1990s, in which the conventional understanding of cloning as a new mode of reproduction came to be replaced by an understanding of cloning as a form of biomedical research. In an important sense, the distinction between "reproductive cloning" and "therapeutic cloning" is spurious: all cloning is "reproductive," and the act of "therapeutic cloning" represents a profound transformation in the meaning of human procreation.

What Is Cloning?

One point of contention in the debates over human cloning has been the definition of the word "cloning" itself, with many advocates of certain forms of cloning seeking to circumvent debate through terminological obfuscation.[1] Rather than using the word "cloning," advocates of cloning-for-biomedical-research have sometimes preferred to use specific technical terms like "nuclear transplantation to produce stem cells,"[2] or to speak not of human cloning but of "therapeutic cloning,"[3] "cloning stem cells,"[4] or "cell reprogramming."[5] Understanding what cloning really is means looking at cloning not in narrow technical terms, but from a broad, conceptual perspective.

The noun *clone* comes from the Greek word for twig or branch, and was originally used in something like its current biotechnological context in 1903 by American plant physiologist Herbert J. Webber for plants that are propagated by cuttings or grafts and that are therefore "not individuals in the ordinary sense, but are simply transplanted parts of the same individual, and in heredity and in all biological and physiological senses such plants are the same individual."[6] The noun *cloning*, the adjective *cloned*, and the verb *to clone* came on the scene around 1930, all originally limited to plant physiology.[7] In subsequent decades, however, these words

came to refer to the replication of various kinds of biological entities, particularly cells and biological molecules, especially DNA. In today's scientific literature, the noun *clone* generally refers to each individual molecule, cell, or organism propagated from the original ancestor or template.[8]

Because the terms "clone" and "cloning" are used in so many different ways, an etymological survey will not do much to clarify their meaning. Whatever the moral implications of cloning molecules of DNA, even human DNA, it is clear that they will be very different from the moral implications of cloning human beings.

What concerns us is of course not cloning in general, but *human cloning*, which we can briefly characterize as *the biotechnological replication of human organisms*. This is the sense in which we will use the term human cloning in this report. The idea of "replication" must admit of some vagueness—cloned animals are not simply copies, nor "simply transplanted parts of the same individual," but the similarity between a clone and its genetic progenitor is much greater than the similarity between children resulting from sexual reproduction and their parents.

One of the early precedents for asexual reproduction in animals was the American biologist Jacques Loeb's discovery in 1899 of artificial parthenogenesis, a technique that could be used to transform some species' egg cells into embryos without fertilization by sperm.[9] Although this technique could not be used to produce genetically identical embryos (and so could not be considered a kind of cloning), the announcement of asexual reproduction in animals inspired a wave of controversy and enthusiasm similar to that which greeted the cloning of Dolly a century later. Loeb, who was dedicated to a mechanistic and reductionistic understanding of biology, saw this discovery as a step toward reducing the phenomena of life to "physico-chemical explanation" and transforming biology into an engineering discipline that would enable scientists to manipulate life at the most fundamental level.[10] He believed he had made an important step toward "the chemical theory of life and may already see ahead of us the day when a scientist, experimenting with chemicals in a test tube, may see them unite and form a substance which shall live and move and reproduce itself."[11] Though scientists were divided on whether or when artificial parthenogenesis could be achieved in higher animals, including humans, there were evidently at least some women enthused by the prospect of Loeb's discovery "having finally freed the woman from the shameful bondage of needing a man to become a mother."[12]

Artificial parthenogenesis would never lead to the kind of mastery over human reproduction that many longed for or feared. But it has

become an important research tool for experimental embryology, and in recent years it has been defended by some prominent cloning scientists as a potentially valuable source of human embryonic stem cells.[13] Some bioethicists have argued that the products of parthenogenesis are not really embryos—on the grounds that mammal embryos created through this technique are not viable—and so it would be less morally problematic to use them to study human embryology.[14]

The history of artificial parthenogenesis presages important features of the history of cloning—in particular, the way a reproductive biotechnology went from inspiring vague ambitions for transforming the human family to becoming another tool in an incremental scientific research program.

Early Cloning Experiments

Unlike Jacques Loeb, whose experiments with artificial parthenogenesis were motivated by grand ambitions, the researchers whose experiments laid the groundwork for cloning were more concerned with solving specific puzzles in embryology and developmental biology. In the early twentieth century there was uncertainty and controversy in these fields over whether the differentiated cells in an adult animal's body all contained the same basic genetic information as the original single-celled embryo, or whether the differentiated kinds of cells of the body each only received the information necessary to carry out its own specialized functions.

The German embryologist Hans Spemann sought to address this question by investigating whether individual parts of a sixteen-celled salamander embryo could go on to grow into embryos on their own. Spemann found that an individual cell isolated from these embryos would develop as a normal individual embryo, rather than grow into one-sixteenth of an embryo. In his 1938 book *Embryonic Development and Induction*, Spemann proposed the cloning technique we now call somatic cell nuclear transfer—which he admitted "appears, at first sight, to be somewhat fantastical"—as an experiment that could help determine whether "even nuclei of differentiated cells can initiate normal development in the egg protoplasm."[15] The experiments Spemann proposed would in fact be carried out through the 1950s and 1960s, and while the history of science tends to be more incremental than a timeline of milestones and landmarks can represent, the most historically significant of these early cloning experiments is generally agreed to have been developmental biologist John Gurdon's 1962 work with frogs, for which he would receive the Nobel Prize five decades later.[16]

In his landmark experiment, Gurdon transferred the nuclei of intestinal cells taken from tadpoles into frog embryos that had had their nuclei removed; these cloned embryos went on to develop into tadpoles. Gurdon later showed that nuclear transfer using frog somatic cells could even produce mature adults.[17] Previous work by other scientists seemed to indicate that differentiated cells, like those taken from a tadpole rather than an embryo, would not be able to support the development of clones through nuclear transfer.[18] Though Gurdon's cloning experiment did not use nuclei from fully mature adults, the tadpole intestinal cells he used were thought to be as fully differentiated as any in an adult frog's body, and were certainly more differentiated than cells used in previous experiments. The experiment seemed to prove that whatever caused the differentiation of adult tissues, the process could be reversed by transferring the cell nucleus into an egg that had had its nucleus removed.

Eugenics and Other Early Ethical Debates

In the early 1960s when the technology of animal cloning was being pioneered, the term "cloning" was still not yet in wide currency, either among scientists or the public. (Neither Gurdon nor the other scientists performing nuclear transfer experiments used the term "cloning" in their papers at the time.) One of the earliest references to human cloning that actually used the term was by the biologist J. B. S. Haldane in a 1963 speech at a symposium on "Man and His Future."[19] Haldane used the term to refer to what is still perhaps the best known literary representation of human cloning, his friend Aldous Huxley's dystopian *Brave New World*.[20] As it happens, Huxley did not use the term "cloning" in that 1932 novel, and the reproductive technology he did describe is somewhat different from what we now think of as human cloning, both in technical respects and in terms of what it is said to accomplish.

In the novel's "Bokanovsky's process," a single embryo was transformed into a large batch of genetically identical embryos, yielding "standard men and women; in uniform batches."[21] In real life, modern techniques for embryo splitting can achieve a somewhat similar goal, and have been used in the production of genetically identical livestock. However, these techniques are not so different from the natural phenomenon that results in identical twins, and are not capable of producing more than four or perhaps eight genetically identical embryos.[22] Proposals to use these techniques to improve the efficiency of in vitro fertilization (IVF) were entertained in the mid-1990s, and continue to be considered by some IVF

practitioners,[23] but unlike contemporary techniques for cloning such as the one used to create Dolly, Huxley's fanciful Bokanovsky's process could not be used to replicate any particular individuals.

In his speech, Haldane criticizes the fictional society's policy of creating clones from a single fertilized embryo as being "of little social value."[24] Instead, Haldane advocates producing clones "from cells of persons of attested ability"—just what Gurdon's nuclear transfer technique, if it could be used in humans, would enable.[25]

Some scientists in the 1960s also thought that cloning offered a superior path to achieving eugenic aims widely embraced by geneticists in the early twentieth century. For example, the Nobel-laureate geneticist Joshua Lederberg would go on to advocate the use of cloning (which he also called "vegetative" reproduction) for human beings in an influential 1966 essay.[26] Lederberg argued that cloning, more than the emerging methods of genetic engineering, would answer "the technical specifications of the eugenicists in a way that Mendelian breeding does not."[27] Cloning, unlike sexual reproduction, would allow eugenicists to copy superior individuals directly "rather than suffer all the risks of recombinational disruption, including those of sex."[28] Furthermore, cloning would permit the "free exchange of organ transplants with no concern for graft rejection" and cloned people would, like identical twins, perhaps have an easier time communicating with one another, making teams of clones well suited to high-stress occupations.[29]

Paul Ramsey, ethicist and theologian, responded with a highly critical analysis of cloning, arguing that "to attempt to soar so high above an eminently human parenthood . . . is inevitably to fall far below—into a vast technological alienation of man. . . . setting sexual love and procreation radically asunder entails depersonalization in the extreme."[30] In 1971, James Watson (of Watson and Crick fame) attempted to stimulate a public debate about cloning, concluding that "if we do not think about it now, the possibility of our having a free choice will one day suddenly be gone."[31] In 1972, Dr. Leon R. Kass argued that the surrender of procreation "to the demands of the calculating will" would be "seriously dehumanizing no matter how 'optimum' the product."[32]

As is so often the case with advanced science and technology, the general public initially learned more about cloning from fiction than from scientists or journalists. Starting especially in the mid-1970s, cloning appeared as a central theme or plot device in many novels, movies, and television shows. Often the technical aspects of cloning were glossed over, but sometimes they were described with surprising detail and accuracy, as

in the case of the 1976 novel and 1978 film *The Boys from Brazil*.[33] The typically dark depictions of cloning in fiction have done a great deal to shape public opinion,[34] although it is possible that the decades of frightening stories have counterintuitively had the effect of making the public more accepting of, or even indifferent to, real-life developments.

One of the chief obstacles to applying Gurdon's cloning research to humans was the challenge of obtaining unfertilized human egg cells (oocytes). Gurdon had used frogs for his initial cloning research in part because of the easy availability of unfertilized frog eggs. But the development of in vitro fertilization in the 1970s, culminating in the birth of the world's first IVF baby in 1978 and the creation soon thereafter of the IVF industry, brought with it new techniques for extracting large numbers of human oocytes—making it easier to imagine how scientists could obtain enough eggs to apply cloning to humans.

Cloning and the Embryo Debates of the 1990s

Debates over embryo research in the early 1990s helped lay the political and moral groundwork for some of the controversy that would come later. In 1994, the National Institutes of Health (NIH) convened a panel to help develop guidelines for government funding of research conducted on human embryos. The Human Embryo Research Panel discussed several kinds of research, including "nuclear transplantation" and the possibility of producing embryonic stem cells.[35] However, the panel did not draw out the connections between these two areas of research that would soon become so important. In its final report, the panel's discussion of cloning was limited to techniques "for producing genetically identical copies, or clones of a single mammalian embryo"—in contrast to techniques for creating embryos that are genetically identical to adult mammals.[36] Several techniques for such "embryo twinning" were debated by scientists and ethicists in the early 1990s,[37] and even today there are some who believe that it could be a useful method for improving IVF outcomes.[38] Troubling as they are, these embryo-twinning techniques are not what most Americans have in mind when they think of human cloning. (The panel dismissed broader public concerns about cloning in a footnote, stating that "Popular notions of cloning derive from science fiction books and films that have more to do with cultural fantasies than with scientific experiments."[39] It is not clear to which "popular notions" this sentence refers.)

The Human Embryo Research Panel did examine nuclear transplantation, but here again, its analysis was limited to the transfer of nuclei from

embryos rather than from adults.[40] In hindsight, we can see that this was a significant lapse, as the first successful cloning of an adult mammal, Dolly, occurred less than two years after the panel's report was published. The panel did, however, anticipate other important developments. For example, it raised the possibility of using nuclear transplantation for the "correction" of certain kinds of defects in oocytes, by transplanting the nucleus of one embryo into the nucleus of an oocyte from which the genetic material has been removed.[41] A similar procedure, which would result in the creation of children with three genetic parents, was approved in the United Kingdom in early 2015, and, as of this writing, U.S. government agencies are considering whether and how to regulate these technologies.[42]

In its discussion of producing human embryonic stem cells—a possibility then still a few years away from becoming a reality—the panel's final report predicted that patient-specific pluripotent stem cells could be obtained by a variation on nuclear transplantation.[43] What the panel meant was not cloning, but rather the transfer of the nucleus of a patient's cell into an embryonic stem cell, in hopes that the stem cell would retain its pluripotency while becoming a genetic match for the patient. This line of investigation was pursued in the early days of embryonic stem cell research, and while the method achieved some preliminary success with animal stem cells,[44] it was never demonstrated to work with human stem cells.

The Human Embryo Research Panel recommended the use of federal funding for a wide range of research that involved the destruction of embryos, including research that would create embryos specifically for the purpose of experimentation that would destroy them. The panel's work met with immediate opposition, including thousands of letters from the public and criticism in the press.[45] President Bill Clinton rejected part of the panel's recommendations, saying, "I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research."[46]

Following the 1994 election that brought Republican majorities to the House and Senate, Congress in 1995 passed and President Clinton signed the Dickey-Wicker Amendment, a law prohibiting the use of federal funding for "the creation of a human embryo or embryos for research purposes" or for research "in which embryos are created or destroyed."[47]

Cloning After Dolly

In February 1997, a team of Scottish researchers led by Ian Wilmut announced it had created Dolly the sheep, the first live-born mammal

cloned from adult tissue.[48] This announcement implied that human cloning might be imminent, and so a political debate ensued, one that brought out many of the public's longstanding anxieties over biotechnology. Immediately after the Dolly news broke, President Clinton instructed the National Bioethics Advisory Commission (an entity his administration had created two years earlier) to "undertake a thorough review of the legal and ethical issues" associated with cloning and to report back "with recommendations on possible federal actions to prevent its abuse."[49] The next week, the president ordered in a memorandum that "no federal funds shall be allocated for cloning of human beings."[50] "Any discovery that touches upon human creation," he said, "is not simply a matter of scientific inquiry, it is a matter of morality and spirituality as well."[51] (Given the Dickey-Wicker Amendment's prohibition on federal funding for research involving the creation of human embryos, President Clinton's ban on funding was largely symbolic.)

President Clinton also called for a moratorium on any private-sector cloning efforts, urging

> the entire scientific and medical community, every foundation, every university, every industry that supports work in this area, to heed the federal government's example. I'm asking for a voluntary moratorium on the cloning of human beings until our Bioethics Advisory Commission and our entire nation have had a real chance to understand and debate the profound ethical implications of the latest advances.[52]

Legislation was soon introduced in the U.S. Congress addressing human cloning, including one bill that would make "it unlawful for any person to use a human somatic cell for the process of producing a human clone."[53] The House and Senate held hearings on the ethics of cloning and on whether and how human cloning could be prohibited, with committees seeking testimony from scientists, theologians, and ethicists.[54] While opposition to cloning was widespread, legislators were also concerned lest they unduly restrict medical research. For example, at one hearing, Representative Constance Morella (D.-Md.) advised, "We must be careful not to outlaw or restrict potentially positive scientific developments with overly prescriptive legislation aimed at aspects of cloning which we don't support or condone, such as human cloning."[55] Later, when calling upon Congress to pass a law banning cloning-to-create-children, President Clinton explained that "Banning human cloning reflects our humanity."[56]

The National Bioethics Advisory Commission issued its report three months later. The pages of that report offer the first prominent attempt

to draw bright moral distinctions between different ends to which cloning might be directed. On one hand, the commission concluded that "at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning."[57] The commission recommended that the federal moratorium and the voluntary private-sector moratorium be extended until Congress could pass a law prohibiting the creation of children through cloning.[58] (However, even this recommendation was tentative: the commission recommended that the law should sunset after "three to five years," so that the country could revisit the issue.[59]) On the other hand, the commission took great pains to emphasize the "many applications that nuclear transfer cloning might have for biotechnology" and "new medical approaches."[60] Because of these potential uses of cloning, the commission recommended that any legal "prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research."[61]

Just a year and a half after the Dolly news, the debate over cloning shifted with the announcement by James Thomson's team at the University of Wisconsin that it had succeeded at deriving lines of human embryonic stem cells.[62] Embryonic stem cells seemed to hold enormous promise for medical research, as scientists could use them to make any kind of tissue in the human body. However, creating human embryonic stem cells requires the destruction of human embryos. And using embryonic stem cells to provide patients with genetically matching cells, tissues, or organs for therapeutic purposes would require creating cloned embryos and then destroying them. This is how the cloning and stem cell debates converged.

Scientists and those who closely followed scientific research were aware of this potential application of human cloning before Thomson's discovery was announced in November 1998. Embryonic stem cell lines from mice were first established in 1981,[63] and the idea of using human embryos to acquire stem cells had been endorsed by the Human Embryo Research Panel in its 1994 report.[64] Scientists and biotech-industry advocates used the prospect of regenerative medicine to argue against federal laws or regulations prohibiting cloning research after the Dolly announcement.[65] And the National Bioethics Advisory Commission report even imagined a future in which everyone would have a cloned embryo created and destroyed in order to produce "an embryonic stem cell line for each individual human" to provide us tissue we might someday want for medical reasons.[66]

Despite the commission's recommendation, no federal law was passed prohibiting human cloning in the United States. The only noteworthy piece of federal legislation on cloning to become law in the aftermath of the Dolly announcement was an alteration to the Dickey-Wicker Amendment adding cloning to the list of practices for which federal funding cannot be used.[67] (Cloning law and policy are discussed at greater length in Part Four of this report.)

Cloning, Fraudulent and Real

In the late 1990s and throughout the administration of President George W. Bush, the issue of human cloning remained entangled with the debates over embryo-destructive experimentation and medicine. However, scientific developments continued apace.

The hype and controversy surrounding human cloning attracted several hucksters and hoaxers who made extravagant, unverified, and unlikely claims about having been the first to clone human embryos or even to bring cloned children to term.[68] But the most important fraud during this era came from a respected scientist, the South Korean researcher Hwang Woo Suk.[69] Hwang manipulated images and fabricated data, deceiving the scientific community into believing that he had cloned human embryos from which he subsequently acquired stem cells. While Hwang had created embryos and embryonic stem cell lines, later examinations of Hwang's stem cells showed that he had generated embryos not through cloning, but through parthenogenesis.[70] In addition to his scientific fraud, Hwang also violated a number of the ethical rules South Korea had enacted to protect egg donors: he pressured a number of his own technicians and lab members to donate their own eggs for the procedure, and he offered cash payments, in violation of South Korea's Bioethics and Safety Act.[71]

Other human cloning experiments had been conducted both before and after Hwang's fraudulent work, but they did not succeed at obtaining embryonic stem cells from cloned embryos. In 2001, scientists from the biotech firm Advanced Cell Technologies reported that they had created three cloned embryos from adult skin cells, though none of them developed past the six-cell stage.[72] In 2005, after Hwang's work was published but before it was revealed to have been fraudulent, another team of scientists announced that it had created a cloned human embryo that developed to the blastocyst stage—the stage at which the embryo can be transferred to the uterus of a woman or destroyed to generate stem cells. However, these scientists did not create an embryonic stem cell line from their

cloning experiment, and in fact the cells the embryos were cloned from were themselves embryonic stem cells.[73] Creating embryos using embryonic stem cells is not an impressive demonstration of the power of cloning techniques, and it is of little practical benefit if the goal is to generate *new* embryonic stem cell lines that genetically match a patient.

In 2008, scientists at the California-based Stemagen Corporation reported that they had cloned human blastocysts from adult cells (in fact, they used cells from one of the scientists), however the experiment did not result in the production of any stem cell lines.[74] More cloned human embryos were created by scientists in 2011, but, again, they were unable or did not attempt to create embryonic stem cells.[75] A team led by Dieter Egli at the New York Stem Cell Institute in 2011 succeeded in generating embryonic stem cells via somatic cell nuclear transfer,[76] but the scientists were only able to succeed by using egg cells that had *not* had their nuclei removed—resulting in embryos and stem cells that had three, rather than the normal two, sets of chromosomes, meaning that this nuclear transfer experiment could not be called "cloning," since the embryos would be far from genetically identical to any other individual, and would be of limited utility because of their genetic abnormality.

Scientists faced not only technical challenges while they were working on their human cloning research, they were also hampered by the difficulty of finding egg donors—especially in jurisdictions where paying women for their eggs was prohibited. Scientists' frustration with these ethical and legal limitations was palpable in their public advocacy on the issue and even in the pages of scientific journals.[77]

Alternatives to Cloning-for-Biomedical-Research

The most important development in the field of regenerative medicine in the first decade of the twenty-first century was the discovery that adult cells could be "reprogrammed" to have properties similar to embryonic stem cells. The resulting cells are called induced pluripotent stem cells (iPS cells).[78] Producing them does not require the creation or destruction of human embryos, nor the use of human eggs, meaning that iPS cells are far less morally problematic than embryonic stem cells. And because iPS cells would be genetically identical to whatever patient they were derived from, they offered precisely the advantage cloning was supposed to provide: patient-specific pluripotent stem cells.

It was widely thought that iPS cells could help resolve the embryo debates. However, embryo-destroying research, including cloning research,

has continued. Some scientists have offered a number of reasons for why cloning may be superior to the reprogramming methods used to generate iPS cells,[79] while others have simply argued that we should pursue all possible lines of research.[80] (For an overview of the scientific debate regarding iPS cells and stem cells produced through human cloning, see Part Three of this report.)

In this context, it is interesting to note that the 2012 Nobel Prize in Physiology and Medicine was awarded not only to Shinya Yamanaka, who was the first researcher to create iPS cells, but also to John Gurdon, for his 1962 cloning experiments with frogs. The work of both these researchers, though their experiments were separated in time by decades, demonstrated a similar basic scientific claim—that the biological development through which the cells of the embryo become the myriad specialized cells of the adult body is, in principle, reversible.

It is clear that the discovery of iPS cells has diverted scientific attention from cloning. For instance, Ian Wilmut, the scientist who cloned Dolly, announced in 2008 that he was moving away from cloning research toward iPS cell research, citing the practical, ethical, and political difficulties associated with obtaining human oocytes and creating human embryos, as well as the surprising technical simplicity of the methods involved in creating iPS cells.[81] But an important lesson can be drawn from the fact that cloning research did not stop after the breakthrough with iPS cells: it shows that technical innovation cannot by itself solve an ethical dilemma. Moral argumentation and political pressure are needed to turn the *less ethically problematic alternative* into the *alternative preferred by scientists.*

Background to the 2013 Cloning Breakthrough

Before we turn to the 2013 cloning breakthrough reported by Shoukhrat Mitalipov and his colleagues in Oregon, it is worth briefly surveying some of the work he and his team did in the years leading up to their landmark research.

Scientists at the Oregon National Primate Research Center, a research center affiliated with Oregon Health & Science University, have been working on cloning non-human primates since the late 1990s. In 1997, this lab was the first to use nuclear transfer technology to clone primates (although the clones were copies of embryos, not adult monkeys).[82] In the early 2000s, Mitalipov and his colleagues attempted to extend these embryo-cloning techniques to cloning adult primates, either to produce embryonic stem cells or to produce cloned rhesus monkey offspring that

could be used as model organisms for studying human disease—but these attempts did not succeed.[83]

Perhaps the most important milestone on the road to human cloning was reached in 2007, when Mitalipov and his team reported that they had produced embryonic stem cells from embryos cloned from rhesus monkeys.[84] One of the techniques they refined in their cloning experiments was the ability to remove the genetic material from oocytes without causing so much damage as to render them unable to support embryonic development.

Using the techniques they developed for manipulating primate oocytes to produce cloned embryos, Mitalipov and his team also experimented with a new reproductive technology called "spindle transfer" that would make it possible for mothers with heritable mitochondrial diseases to have genetically related children who do not have those diseases.[85] This new method creates embryos that have three genetic parents, but it bears some similarities to cloning, both in the techniques it employs, in the aims it could serve, and in the ethical problems it raises. In a technical sense, both cloning and spindle transfer require removing the genetic material from a human egg cell and replacing it with genetic material from another cell, so improvement in one of these techniques can contribute to improvement in the other. And both cloning and spindle transfer could enable parents to prevent the transmission of genetic disease to their children while at the same time controlling the genetic identity or genetic parentage of their children. One related method—developed not by Mitalipov's lab but by scientists in the United Kingdom—actually *is* a grotesque form of human cloning, wherein nuclear DNA is extracted from one embryo, killing it, before putting the DNA into another embryo that has also been killed by having its nuclear DNA extracted.[86] Like cloning, these reproductive technologies are radical forms of experimentation that put unknown and unknowable risks on unconsenting subjects—the children—who will not themselves benefit from these procedures.

Another cloning-related area that Mitalipov's team explored was the creation of primate "chimeras"—animals that are composed of tissues derived from more than one genetically distinct individual, whether of the same species or from different species. Biologists have artificially created mouse chimeras since the 1980s,[87] and the Oregon experiments with chimeras in 2012 were in part an attempt to apply those methods to a species more closely related to humans.[88] By combining six different embryos, the researchers produced chimeras that were found to have grown up to be composed of cells from at least three different embryos, with genetically

distinct cells in all of their tissues and organs.[89] They were apparently normal and healthy.[90] The three chimeras that were born were males, though at least one was found to have a small proportion of genetically female cells.[91] Such experiments could be used to test the pluripotency of primate embryonic stem cells by showing that they are capable of contributing to all of the body's tissues in the resulting chimeric animals.

While Mitalipov and his team were able to create monkey chimeras, they were unable to do so using stem cells, leading them to speculate that primate embryos lend themselves less readily to supporting the development of chimeras than do mouse embryos.[92] (An alternative interpretation would be that primate embryonic stem cells, presumably including human stem cells, are less than fully pluripotent—a finding suggested by other scientists comparing human stem cells to mouse stem cells.[93]) Mitalipov's research on chimera formation in primates has two chief implications for human cloning. First, it suggests that some of the animal-cloning techniques that scientists had believed might also work on humans might not work after all.[94] But at the same time, the ability to create primate chimeras could contribute to our understanding of how cloned embryos develop.[95]

The Oregon team has also made progress in producing cloned monkey offspring. In a 2010 paper, the researchers noted that they had used 67 cloned rhesus monkey embryos to attempt to produce viable cloned offspring; from these attempts, only one pregnancy developed to the fetal stage, and although the researchers were able to detect a heartbeat, the pregnancy "failed to go to term and was [spontaneously] aborted at day 81 of gestation" (about half the normal gestation period for that species).[96] As of this writing, this appears to be the closest that any scientist has come to bringing a cloned primate offspring to term.

Building on all of this primate embryo research—related to cloning, chimera formation, and transferring chromosomes between oocytes—Mitalipov and his team went on to perform their landmark 2013 human cloning experiments. As noted above, cloned human embryos had been produced earlier, but Mitalipov's work was the first to successfully use cloned human embryos to produce embryonic stem cells, which has long been a major goal of human cloning research.[97]

One important finding in Mitalipov's 2013 paper is that the procedure is more efficient than many people expected. Researchers' previous experience indicated that cloning would have a very low success rate, requiring perhaps hundreds of eggs to produce just one embryonic stem cell line.[98] But one of Mitalipov's procedures had a much higher success rate—a rate

of nearly one in five.[99] The researchers also found that cloning attempts were much more successful using eggs from some women rather than others.[100] And the authors noted that eggs collected via a less-intensive hormone treatment, one that resulted in the collection of fewer eggs per cycle, seemed to be more effective for cloning than those collected using more strenuous ovarian-stimulation treatments.[101] All these findings are relevant to the political debate about cloning, since they suggest that egg collection can be made more efficient and less dangerous—perhaps mitigating, though by no means eliminating, concerns about the large numbers of egg donors needed and the potential risks they face. However, it is also worth noting that all of these findings are very far from conclusive, and are based on the most tentative and preliminary of evidence.

As of this writing, only two other research teams have succeeded at human cloning since the 2013 breakthrough, both publishing reports of successful human cloning in 2014. While the somatic cells used in the Oregon cloning experiment in 2013 came from commercially available fetal and newborn cell lines, the teams behind the two 2014 papers both obtained somatic cells from older adults, including a 32-year-old woman affected by type-1 diabetes[102] and a 75-year-old man.[103] As with Mitalipov and his team, these scientists also found that eggs from some donors resulted in more efficient cloning than others.[104] Contrary to Mitalipov's results, however, the 2014 papers did not find any relationship between the efficiency of cloning and the number of eggs donated or the method of egg collection.[105] It would seem probable, as with IVF, that the quality of oocytes matters a great deal and that the eggs of different women vary in their usefulness for cloning—but predicting which women will make better egg donors or discovering better egg-collection methods would likely involve an extensive and morally dubious research project requiring harvesting and testing eggs from a very large number of women.

Conclusion: Cloning for Science and Reproduction

Scientists and the public have different understandings of what is important about human cloning. Most scientists seem to consider cloning a promising albeit difficult technique for studying genetics and developmental biology or for producing cells and tissues that can be used for research or for treating patients. Since the development of embryonic stem cells, with their alluring promise of personalized regenerative medicine, the biomedical applications of cloning have come to captivate the

imagination of much of the American public as well. However, moral concerns remain about obtaining stem cells through such a troubling technology. And scientists, regardless of their moral views, face a range of political and technical challenges when attempting to pursue cloning research. Meanwhile, the idea of using cloning to produce children, which most scientists profess to be uninterested in, continues to hold the public imagination—most often as a source of concern, indignation, and fear.

In Parts 2 and 3 of this report, we discuss the ethical issues raised by cloning and its applications, beginning with the use of cloning to create children.

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Part Two

The Case Against Cloning-to-Produce-Children

Why should we care about the possible use of human cloning to create children? It is not part of any respectable research agenda. Public opinion polls have shown consistent and overwhelming opposition to the idea of using cloning to create children.[1] Whenever the issue has been discussed by policymakers, opposition has been largely bipartisan. So why is it necessary to make a case against this practice?

One reason is that there are some advocates—both academics and activists—who have been arguing for the use of cloning to produce children, and while they are still in the minority, that may change. Their arguments in favor of a future of biotechnologically facilitated reproductive liberty may gain traction, especially if concerns about safety appear to diminish as research advances. Meanwhile, the deeper sources of Americans' opposition to the use of cloning to create children can be difficult to understand, articulate, and defend—in part because, over the last half century, sexuality and procreation have become increasingly detached in our culture.

In this section, we attempt to make the case against the use of cloning to create children. Of course, many arguments have already been made over human cloning—following the cloning of Dolly, the bioethicist Daniel Callahan claimed, not altogether implausibly, that "no arguments have been advanced this time that were not anticipated and discussed in the 1970s."[2] The best articulation of the deeper moral issues raised by human cloning can be found in *Human Cloning and Human Dignity*, a 2002 report of the President's Council on Bioethics.[3] Here, we will restate, expand upon, and update that report's arguments, defending them against the criticism they have received since 2002 and showing how the debate over cloning-to-produce-children is part of a broader conflict in our society between different understandings of the moral meaning of the family.

Health and Safety

Perhaps the most commonly cited, and the most clear and straightforward reason for opposing cloning-to-produce-children is a concern for the health and safety of those involved: the women donating their eggs

for cloning or carrying cloned children to term, and the children created through cloning. Though the pursuit of health can be taken too far, and the meaning of health can, in some cases, be ambiguous,[4] health as such is one of the clearest and least controversial of human goods.

The available scientific evidence indicates that many or most children created through cloning would suffer from medical problems as a result of the procedure used to create them. If cloning technology improves and scientific evidence comes to show that cloning may be performed with less risk to children, then safety may come to be a less important part of the debate over cloning. The contingency of ethical objections based on safety can be seen in the proposals sometimes put forward that any legislation prohibiting cloning be revisited after a few years.[5]

As we will argue in detail below, the first attempts at cloning-to-produce-children would be unavoidably unethical human experimentation. But it is also worth surveying the state of scientific evidence to see just what risks cloning will pose to children, and whether those risks have changed in recent years.

Health Problems in Cloned Animals

Cloning has been found to cause defects and health problems in animals at all stages of development, from the embryo to the mature adult.

The high death rates of cloned embryos and fetuses. In their 1997 paper, Ian Wilmut and his team described how they created 277 cloned sheep embryos; 90 percent of them failed to develop long enough to be implanted in a womb; Dolly was the only sheep to be born.[6] In 2001, Wilmut and other colleagues described the very high rates of "fetal retardation," cardiopulmonary defects, and "pregnancy failure" they were seeing in pregnancies involving cloned offspring.[7] In the years since, the situation has not changed much. As recently as 2010, about only 1 to 3 percent of cloned animal embryos transferred to females resulted in live births.[8]

There is no reason to think that cloned human embryos would fare any better. In the 2013 cloning experiments, roughly one in five cloned embryos reached the blastocyst stage,[9] while scientists from one of the teams that succeeded at human cloning in 2014 wrote that "a realistic expectation is that this protocol will result in about 10 percent of the oocytes developing to the blastocyst stage."[10] (By way of comparison, this puts the viability of cloned human embryos well below the survival rate of embryos produced through IVF, where roughly half of fertilized

embryos survive to the blastocyst stage.[11]) In their attempts to create cloned rhesus monkeys, Mitalipov and his team reported in 2010 that they had transferred 67 cloned embryos to ten females. Five pregnancies were established, with a single fetus reaching the stage at which a heartbeat could be detected before a miscarriage at eighty-one days of gestation (about half the normal gestation period for that species).[12]

Although the precise mechanisms that account for the impaired development in cloned embryos remain poorly understood, scientists do have some tentative explanations. For example, it seems that when the nuclei of adult cells are used for cloning, the newly created cells go on acting like adult cells, failing to become as embryo-like as they need to be—that is, they might continue to express genes involved in their "former lives" as, say, skin cells instead of the genes necessary for embryonic development.[13] Also, defects in the placenta have been found by scientists to account for many of the miscarriages of cloned animals,[14] including the Mitalipov team's monkey-clone pregnancy.[15] And medical problems continue to manifest during later stages of fetal development in cloned animals.[16]

In short, any project with any hope of succeeding at human cloning would result in a large number of pregnancies that miscarried, a larger number of implanted embryos that failed to result in pregnancies, and a still larger number of embryos that failed to develop to the point at which they could be implanted. This is a grim picture indeed.

Birth defects and long-term problems. Cloned animals that survive long enough to be born often suffer from health problems. A literature survey of developmental defects in cloned animals showed that while postnatal defects are relatively uncommon in mice and pigs (typically 10 percent or fewer clones display defects), they are wide-ranging in cattle (from 0 to 100 percent in selected studies, with a median of 44 percent displaying defects).[17] Common problems include kidney disorders, liver fibrosis, and heart defects.[18]

Cloned ruminants in particular often display symptoms of large offspring syndrome (LOS), which typically involves unusually large size and a variety of organ defects.[19] The symptoms of LOS are somewhat similar to Beckwith-Wiedemann syndrome (BWS) in humans. BWS entails a larger-than-usual growth pattern and a range of health risks and physical abnormalities. The fact that BWS has a significantly higher incidence among children who are produced using in vitro fertilization[20] suggests that at least some of the symptoms associated with LOS and BWS stem from embryonic manipulation rather than the cloning procedure itself.[21]

Another concern is the length of telomeres in cloned animals. Telomeres are nucleotide sequences that protect the ends of chromosomes from deterioration. Under normal conditions, the length of telomeres in an animal's cells gradually shortens through fetal development, continuing to shorten through adulthood and old age. Since somatic cell nuclear transfer involves the use of an adult cell nucleus, it has been thought that clones might have shorter telomeres than normal organisms and display accelerated aging (a concern that was first raised in the case of Dolly).[22] Analyses of cloned animals have differed in their findings on telomere length: some cloned animals display shorter than normal telomeres, some have telomeres of normal length, and some even have longer-than-normal telomeres.[23]

Supposed Benefits of Cloning-to-Produce-Children

Despite the risks described above, some advocates have argued that, if cloning could be made safe, it could offer a way to improve the health and well-being of children. This argument takes three general forms. First, cloning could allow individuals or couples who are affected by genetic disease to have children genetically related to (one of) them while reducing the risk that their children would inherit the disease. Second, cloning could allow prospective parents to protect their children from a broad array of diseases known to be associated with genetic risk factors. Third, the technique could be used to create "enhanced" children by cloning an individual considered excellent in some way.

Cloning to select against bad genes ("negative eugenics"). The most straightforward scenarios in which cloning could be used to prevent genetic disease involve what are called simple genetic diseases, or diseases that are caused by mutations in single genes and are passed on in accordance with the basic Mendelian rules of inheritance. For instance, if both members of a couple know, as a result of genetic testing or from their family history, that they each carry a single copy of the same recessive gene for Tay-Sachs disease, then there will be a one-in-four chance that any child the couple naturally conceives will inherit the recessive gene from both parents, and therefore have the disease. By instead cloning one or the other would-be parent, the couple can be guaranteed to have a child with only a single copy of the recessive disease-causing gene, thus ensuring that the child will not be affected by the disease.

However, scenarios like this one (and others involving simple genetic diseases) seem implausible, because there are other existing technologies

that doctors can recommend to achieve the same end—including sperm or egg donation and preimplantation genetic diagnosis (PGD). If a couple used a sperm or egg donor who is not a Tay-Sachs carrier (which can be ascertained through relatively simple genetic testing), the couple could be sure that their child would not be affected by the disease. Likewise, PGD could be used to select only those embryos that do not have two copies of the Tay-Sachs gene.

To be sure, neither of these methods is without its own moral problems—particularly PGD, which involves selectively discarding embryos that are deemed "defective." But the existence of these alternatives makes it less likely that cloning will be used to prevent serious genetic diseases.

Cloning to select for good genes ("positive eugenics"). In addition to preventing simple genetic diseases, cloning could also be used to reduce the risk of diseases caused by combinations of genetic risk factors. Many, perhaps even most, serious diseases—from heart disease and stroke to cancer—have some heritable, genetic component. Sexual reproduction will always result in unpredictable combinations of genes, including combinations that will dispose children to unpredictable varieties of diseases. Cloning could be used to avoid the uncertain genetic outcomes of sexual reproduction, and to give children the best, most healthful genes possible. For example, bioethicist Gregory E. Pence imagines a fictional scenario in which a couple might choose to clone the mother's healthy 90-year-old grandfather, on the assumption that "a human baby born with his genes now has a life-expectancy of 120 years."[24]

But choosing a genome that will tend to be free of disease is more difficult than simply finding a person who has lived a long and healthy life. The effect of most genes on health and well-being is not deterministic but probabilistic, and is subject to environmental influences. A perfectly healthy person, even a perfectly healthy 90-year-old, may nonetheless have genes that give him a relatively high probability of developing certain complex diseases under certain environmental conditions. It could be that the 90-year-old man's genes were uniquely suited for the place and time and ways in which he lived, but not for the conditions under which his clone will live, conditions that could be very different.

Furthermore, while improvements in technology may reduce the risks associated with cloning, using cells from exceptionally long-lived individuals to select for genes disposing to health and longevity may pose its own risks. Older individuals will have shorter telomeres and a higher chance of having accumulated mutations in their somatic cells, and will

likely have cells that will be more difficult to "reprogram" through cloning.[25] For cloning to seem like a reasonable way to ensure the health of one's child, one would need to be very sanguine about the many concrete risks of developmental defects and simultaneously very paranoid about vague genetic risk factors for diseases.

Cloning for "human enhancement." Much of the enthusiasm for and anxiety about human cloning over the years has been concerned with the use of cloning as a genetic enhancement technology. Scientists, and especially science-fiction writers, have imagined ways of using cloning to replicate "persons of attested ability" as a way to "raise the possibility of human achievement dramatically," in the words of J. B. S. Haldane.[26] As molecular biologist Robert L. Sinsheimer argued in 1972, "cloning would in principle permit the preservation and perpetuation of the finest genotypes that arise in our species."[27] Candidates for this distinction often include Mozart and Einstein, though the legacy of eugenics in the twentieth century has left many authors with an awareness that those who would use these technologies may be more interested in replicating men like Hitler.[28] (While in most cases, the idea of cloning a dictator like Hitler is invoked as a criticism of eugenic schemes, some writers have actually advocated the selective eugenic propagation of tyrants—for instance, the American geneticist Hermann J. Muller who, in a 1936 letter to Stalin advocating the eugenic use of artificial insemination, named Lenin as an example of a source of genetic material whose outstanding worth "virtually all would gladly recognize."[29])

Today, eugenics has a deservedly negative reputation, and the idea of using a biotechnology like cloning to replicate individuals of exceptional merit is *prima facie* ethically suspect. However, advocates of eugenic enhancement have never entirely disappeared, and their influence in bioethics is arguably not waning, but waxing. In recent years academic bioethicists like John Harris and Julian Savulescu have been attempting to rehabilitate the case for eugenic enhancements on utilitarian grounds.[30] For these new eugenicists, cloning-to-produce-children represents "power and opportunity over our destiny."[31]

This new eugenics needs to be confronted and refuted directly, since insisting on the self-evident evil of eugenics by pointing to historical atrocities committed in its name may become increasingly unpersuasive as memories of those atrocities dim with time, and as new technologies like cloning and genetic engineering make eugenic schemes all the more attractive. Furthermore, as the philosopher Hans Jonas noted in a

critique of cloning, the argument in favor of cloning excellent individuals, "though naïve, is not frivolous in that it enlists our reverence for greatness and pays tribute to it by wishing that more Mozarts, Einsteins, and Schweitzers might adorn the human race."[32]

In an important sense, cloning is not an enhancement, since it replicates, rather than improves on, an existing genome. However, as Jonas's remark about the human race indicates, the cloning of exceptional genotypes could be an enhancement at the population level. And from the point of view of parents who want children who can checkmate like Kasparov, belt like Aretha, dunk like Dr. J, or bend it like Beckham, cloning could represent a way to have offspring with the exceptional abilities of these individuals.

Arguably, cloning is a less powerful form of genetic engineering than other techniques that introduce precise modifications to the genome. After all, cloning only replicates an existing genome; it doesn't involve picking and choosing specific traits. This weakness may also, however, make cloning more appealing than other forms of genetic engineering, especially when we consider the genetic complexity of many desirable traits. For example, some parents might seek to enhance the intelligence of their children, and evidence from twin studies and other studies of heredity seems to indicate that substantial amounts of the variation in intelligence between individuals can be attributed to genetics.[33] But any given gene seems to have only a tiny effect on intelligence; one recent study looking at several genes associated with intelligence found that they each accounted for only about 0.3 points of IQ.[34] With such minor effects, it would be difficult to justify the risks and expense of intervening to modify particular genes to improve a trait like intelligence.

Cloning, on the other hand, would not require certain and specific knowledge about particular genes, it would only require identifying an exceptionally intelligent individual and replicating his or her genome. Of course the cloned individual's exceptional intelligence may be due to largely non-genetic factors, and so for a trait like intelligence there will never be certainty about whether the cloned offspring will match their genetic progenitor. But for people seeking to give their child the best chance at having exceptional intelligence, cloning may at least seem to offer more control and predictability than gene modification, and cloning is more consistent with our limited understanding of the science of genetics. Genetic modification involves daunting scientific and technical challenges; it offers the potential of only marginal improvements in complex traits, and it holds out the risk of unpredictable side effects and consequences.

Of course, it is possible that cloning could be used in conjunction with genetic modification, by allowing scientists to perform extensive genetic manipulations of somatic cells before transferring them to oocytes. In fact, genetic modification and cloning are already used together in agriculture and some biomedical research: for larger animals like pigs and cattle, cloning remains the main technique for producing genetically engineered offspring.[35] (The prospect of cloning being used in combination with other genetic engineering techniques is discussed in detail in Part Three.)

Using cloning as an enhancement technology requires picking some exceptional person to clone. This necessarily separates social and genetic parenthood: children would be brought into the world not by sexual pairing, or as an expression of marital love, or by parents seeking to continue and join their lineages, but by individuals concerned with using the most efficient technical methods to obtain a child with specific biological properties. Considerations about the kinds of properties the child will have would dominate the circumstances of a cloned child's "conception," even more than they already do when some prospective parents seek out the highest-quality egg or sperm donors, with all the troubling consequences such commodified reproduction has for both buyers and sellers of these genetic materials and the children that result. With cloning-to-produce-children for the sake of eugenic enhancement, parents (that is, the individuals who choose to commission the production of a cloned child) will need to be concerned not with their genetic relationship to their children, but only with the child's genetic and biological properties.

Normally, the idea of cloning as an enhancement is to create children with better properties in which the improvement resides in an individual and his or her traits, but some thinkers have proposed that cloning could be used to offer an enhancement of social relationships. This is the very reason given in the novel *Brave New World*: the fictional society's cloning-like technology "is one of the major instruments of social stability!…Standard men and women; in uniform batches," allowing for excellence and social order.[36] And as the geneticist Joshua Lederberg argued in 1966, some of the advantages of cloning could flow from the fact of the clones' being identical, independent of the particular genes they have. Genetically identical clones, like twins, might have an easier time communicating and cooperating, Lederberg wrote, on the assumption "that genetic identity confers neurological similarity, and that this eases communication" and cooperation.[37] Family relationships would even improve, by easing "the discourse between generations," as when "an older clonont would teach his infant copy."[38] Lederberg's imaginings will

rightly strike today's readers as naïve and unsettling. Such a fixation on maintaining sameness within the family would undermine the openness to new beginnings that the arrival of each generation represents.

Before we embark on asexual reproduction in order deliberately to select our offspring's genes, we would do well to remember that sexual reproduction has been the way of our ancestors for over a billion years, and has been essential for the flourishing of the diverse forms of multicellular life on earth. We, who have known the sequence of the human genome for a mere fifteen years—not even the span of a single human generation—and who still do not have so much as a precise idea of how many genes are contained in our DNA, should have some humility when contemplating such a radical departure.

Cloning as a Source of Genetically Matched Tissues

Sometimes, cloning-to-produce-children is discussed in another context—one that would not serve to benefit the created children, but rather to benefit older people with the same genome, by producing children to serve as sources of genetically identical cells, tissues, or even organs for transplantation.

The idea of creating clones to harvest their organs is a staple of dystopian science fiction; in many stories, cloned people are kept as disposable organ banks for morally depraved elites.[39] These fictional societies, in which the most basic notions of human rights are abandoned, can easily be dismissed as highly unrealistic. The National Bioethics Advisory Commission, in its 1997 report, wrote that "the notion of using human cloning to produce individuals for use solely as organ donors is repugnant, almost unimaginable, and morally unacceptable."[40] The commission went on to write that a "morally more acceptable and potentially feasible approach is to direct differentiation along a specific path to produce specific tissues (e.g., muscle or nerve) for therapeutic transplantation rather than to produce an entire individual."[41] However, since the product of human cloning is a human embryo, using cloning to produce tissues or organs directly rather than producing "an entire individual" ignores the fact that the product of human cloning already is "an entire individual," and manipulating its development to transform it into specific tissues would amount to killing it.

But there are more realistic, and less obviously unethical, applications of cloning to create genetically matched cells and tissues. Parents with a child affected by a disease like leukemia may wish to clone that child in order to provide the affected child with genetically matched cord blood or

bone marrow for transplantation. The first uses of bone marrow transplantation to treat chronic myeloid leukemia involved identical twins,[42] but doctors soon discovered that siblings, or even unrelated donors with identical human leukocyte antigens, could also provide bone marrow.[43] Today, parents with children affected by diseases like these may use IVF and PGD to have a child whose cord blood will be a match for their sick child, since one in four siblings will have compatible bone marrow and cord blood.[44] Such "savior siblings" are generally created so that they may provide hematopoietic stem cells (the stem cells found in bone marrow or cord blood) for transplantation, rather than organs like kidneys. However, scientists have found evidence that kidney transplantation is more effective between identical twins than between siblings, including siblings that have compatible human leukocyte antigens.[45] Human cloning could be used to produce children who will serve as savior siblings, providing not only cord blood, which can be collected with little risk to the child, but also perhaps organs like kidneys.[46]

Creating savior siblings through PGD and IVF is ethically problematic even when the child is subject only to the relatively safe procedure of cord blood collection. Cloning would take the instrumentalization of the newly created child even further, and may open the door toward more dangerous and exploitative forms of transplantation.

An Unjustifiable Experiment

The application of cloning to human beings will always be an ethically unacceptable form of human experimentation.

The first children to be cloned would be in no position to consent to being research subjects for the experimental use of a new technology. Whatever improvements might someday be made in the safety of animal cloning, the high variability between the health outcomes of cloned animals of different species means that the safety of cloning-to-produce-children will initially be unknowable.[47]

Similar arguments were made against IVF when it was under development in the 1970s. Medical ethics holds that "the move to human experimentation is made only when physicians secure the partnership of an informed, consenting volunteer," wrote Paul Ramsey in 1972.[48] The first IVF experiments could not be carried out ethically, he warned, since "the unmade child has not 'volunteered' to help the scientist."[49] To ensure that a technique for creating life is safe enough to be ethically justifiable would paradoxically require experiments made under conditions where

that knowledge is not available, and such experiments would themselves be unjustifiable: as Ramsey writes, "we cannot morally *get to know* how to perfect this technique."[50]

Though IVF has not been perfected—it remains associated with some elevated risks of birth defects and health problems[51]—it has apparently proven safe for the great majority of babies born through it, which is why the technique has come to be embraced by most doctors, prospective parents, and bioethicists. Some cloning advocates argue that cloning-to-produce-children might follow the same path as IVF, skipping from ethically unacceptable experimentation to a widely accepted practice. In 2001, IVF pioneer Robert Edwards compared criticism he had received in the 1970s to the criticism being leveled at human cloning, and argued that eventually cloning could come to be accepted as an infertility treatment just as IVF has been.[52] A 2006 article in the *Journal of Medical Ethics* noted that pro-cloning arguments are "highly analogous to rationalizations [that were] used to justify IVF treatment" and concluded that cloning should be permitted to proceed as IVF was.[53]

The fact that IVF has proven (relatively) safe in humans, at least for those embryos that develop into babies, is of course not evidence that the very different technology of cloning by somatic cell nuclear transfer will also prove safe in humans. And the fact that IVF has proven safe proves neither that the original IVF experiments were ethical (they were not) nor that the success of the IVF experiments provides ethical justification for proceeding with human cloning experiments (it does not). The notion that experiments can be ethically justified by their results would render medical ethics meaningless, since it implies that *any* experiment can turn out to be ethically justified if harm happens not to befall the subjects, or if the harm to some subjects is judged to be outweighed by the benefits to others. As Dr. Henry K. Beecher wrote in his seminal 1966 article on the ethics of clinical research, "an experiment is ethical or not in its inception; it does not become ethical *post hoc*—ends do not justify means."[54]

Some advocates of human cloning argue that because the cloned child does not exist until he is cloned, then the cloned child cannot claim to have been really harmed unless the harms that result from his being created are so grievous that he would be better off not existing.[55] This doctrine would leave us unable to make the most straightforward judgments about the responsibilities we owe to future generations unless we adopt the dark notion that a person can be so grievously injured that his or her life is not worth living. For example, imagine a morally odious experiment in which a scientist induces random mutations in human sperm and egg cells using

chemicals or radiation, and then uses those cells to create embryos. The scientist transfers the embryos to willing surrogates that carry the embryos to term. Such actions would clearly put the resulting children at an elevated risk of a wide range of genetic defects. Surely the scientist could be said to be responsible for the diseases and birth defects that would predictably result from having exposed the germ cells to radiation or other mutagens. And surely we would hold that these diseases and birth defects were bad for the children. Therefore we could conclude that the scientist has harmed them, and that for this reason (among others) the scientist should not have performed the experiment. Even if the scientist had been able to find gamete donors to give free and informed consent to exposing their genetic offspring to such risks, the proper response would not be to conclude that, having obtained the consent of the relevant parties, the scientist conducted the study ethically. Rather, we would condemn these callous gamete donors as complicit in a grave evil perpetrated on their children.

The above thought experiment is not meant as a suggestion that approving cloning-to-produce-children will put us on a slippery slope to such obviously unethical experiments. Rather, it is intended to illustrate the absurdity of believing that (as University of Texas law professor John A. Robertson put it) "the harmful effects of cloning cannot truly harm the clone, because there is no unharmed state, other than non-existence, that could be achieved as a point of comparison."[56] Such a lax standard denies us the most compelling and obvious reasons for condemning experiments that are clearly unethical.

Whether it is ethical to create children using experimental methods turns not only on the scientific evidence (because, among other reasons, the scientific evidence will necessarily be decisively incomplete at first) but also on the moral meaning of the relationship between prospective parents and their children. If parenthood is seen simply as a project chosen by individual adults—much like any of the other projects individuals happen to choose—then the interests of the as-yet-to-exist child and the responsibilities of the parents toward that child fall out of view. If, as argued below, we view parenthood in the context of the lived experience and traditional meaning of human procreation, we can see the obligations that parents have to those who are not yet born.

Deeper Moral Issues

The potential health and safety problems and the unavoidably experimental nature of cloning-to-produce-children are reasons enough to put

it beyond the pale. But there are other reasons that cloning is morally objectionable—deeper reasons hinted at by the indignation that the prospect of cloning elicits in many Americans. Surveys of Americans' positions on moral issues have consistently ranked cloning-to-produce-children as among the most universally condemned actions. (In a 2014 Gallup survey of 1,028 U.S. adults, marital infidelity was the only polled option to rank as less morally acceptable than cloning.[57])

The public's strong moral opposition to cloning can be unclear and difficult to express. Broadly speaking, commentators have tended to divide into two camps concerning the public's moral reaction against human cloning. Some have sought to articulate the moral insights about human procreation and the meaning of the family that concerns about cloning might intimate. Others have evaluated the public's objections to cloning in terms of moral doctrines of autonomy and individual choice, concluding that those objections are largely misplaced.

Our position is that the repugnance most people feel at the idea of human cloning is justified, if in need of articulation and clarification. The deeper moral objections to cloning also need to be defended against bioethicists and philosophers who have sought to debunk them. Americans who harbor a sense that cloning is morally wrong but cannot quite explain why should have a good conscience about their good consciences.

Repugnance and Its Discontents

In an influential 1997 essay, Dr. Leon R. Kass argued that, in crucial cases, a feeling of repugnance can be "the emotional expression of deep wisdom, beyond reason's power fully to articulate it."[58] Cloning, Kass argued, is one of those cases:

> We are repelled by the prospect of cloning human beings not because of the strangeness or novelty of the undertaking, but because we intuit and feel, immediately and without argument, the violation of things that we rightfully hold dear.[59]

While of course "revulsion is not an argument," Kass stated, we should take seriously our feelings about the wrongness of cloning, seeking to understand their origins and weigh their validity.[60]

Some critics dismiss the common revulsion at cloning as merely an emotional response that has no place in rational public debate. Kass's claim that repugnance may be "the emotional expression of deep wisdom"[61]

has been derided by some as "the yuck factor."[62] Its detractors note that disgust is an inadequate source of moral guidance, pointing out actions that are commonly thought to be disgusting but are nonetheless morally uncontroversial. For example, Martha Nussbaum mentions "open heart surgeries and colonoscopies" as examples of actions commonly thought to be disgusting but nonetheless morally acceptable.[63]

But in Kass's essay, which is generally mentioned by these critics as a prime example of faulty moral reasoning from disgust, the word "disgust" does not even appear. Kass instead uses the term "repugnance." This is not simply an issue of critics misreading a single essay, but rather reflects a distorted view of the *moral* character of the common reactions against cloning. "Repugnance" carries with it a sense of moral disapprobation, indignation, and even horror that are not at all implied in the far more morally neutral term "disgust." So when Martha Nussbaum and others note that there are many activities that are commonly thought to be disgusting but that are nonetheless morally acceptable, this has little bearing on whether a sense of *repugnance* should be taken seriously, because while colonoscopies may commonly be considered *disgusting*, no one finds them *repugnant*.

To be sure, the fact that most people find the idea of human cloning morally troubling and repugnant is not proof that cloning is wrong. There have been times when majorities have been wrong about what is morally repugnant: xenophobia and racism are often accompanied by a moralistic sense of repugnance, yet we rightly reject them both. The question is how moral philosophy should respond to powerful and widespread, yet poorly articulated, moral reactions. The philosopher Hilary Putnam offered a useful analysis of the role of strong moral reactions against cloning in a 1999 lecture, in which he argued that the strong and immediate moral condemnation of human cloning was justified, even though the grounds for this condemnation could not be "easily derived from already-codified moral doctrines."[64] Reflecting on the unease we feel about human cloning that cannot be articulated in terms of liberal individualism, Putnam argues that the family is an important "moral image," one that illustrates values like a willingness to accept and celebrate diversity, since "with one's children (and one's parents) we can only accept what God gives one to accept."[65] Rather than taking "already-codified moral doctrines" as the starting point and evaluating both cloning and the moral reactions against cloning in terms of these doctrines, Putnam took seriously the spontaneous moral horror at the idea of cloning, and by reflecting on its meaning, articulated the sense in which cloning would distort the "moral image" of the family.

Motives and Morality

Thinking about cloning-to-produce-children in terms of the way it would affect the family and the relationship between the generations requires that we think not only of its direct effects, but also of its moral context—the goods that cloning might serve or harm, the attitudes and beliefs about the family and reproduction that cloning would express or embody, and the motives that might draw individuals or families to use cloning to reproduce. Some critics have argued that this approach to the ethics of human cloning amounts to unwarranted speculation. Philosophy professor Allen E. Buchanan, for instance, argues that ethicists like Kass "insinuate that the only reasons most people have for producing a human by cloning are unseemly—for example, to act out a sick fantasy of recreating their dead child from the DNA in a strand of hair or to indulge in their narcissism."[66] As a counterexample, Buchanan offers an unnamed student who told him

> that she would definitely consider cloning—if it were perfectly safe (or at least as safe as ordinary human reproduction)—if she was at the stage of her life when she wanted a child but didn't have a partner.[67]

The student went on to point out the dangers and problems with IVF, and said that "she would rather produce a child with DNA from just one parent than 'borrow' sperm from somebody that wasn't her partner."[68] Though this student is right that IVF poses some serious dangers to women and children, these risks are hardly good reasons to use human cloning, since any remotely plausible cloning technology would involve the same risks to the mother, and would almost certainly pose more serious risks to the future child.[69] What we are left with, then, is the desire to have a child without a "partner," even an anonymous sperm donor. What the young woman seeks to acquire through cloning is precisely what Kass described as "the ultimate 'single-parent child.'"[70]

The ability to satisfy the desire for children without a "partner" is indeed one of the ways cloning would fundamentally transform the nature of human procreation. While contraception and technologies like artificial insemination and IVF have done much to separate sex from reproduction, no reproductive technology other than cloning has actually made it possible to eliminate the need for biological contributions from two human beings to create a child.[71] As the desire of Buchanan's student suggests, this radical transformation of the meaning of the relationship between the generations would not be an unintended consequence of the

use of cloning, but would in many cases be the aim of those using the technology. How would cloning affect the relationship between the generations and the ways we think about the family? A desire for a certain kind of relationship with one's cloned offspring would be an important part of the decision of prospective parents to use cloning to reproduce. Moral reflection on cloning-to-produce-children should be concerned with the question of whether it would contribute to or diminish the well-being of children, parents, and families.

Confounded Kinship Relations and the Weight of Expectations

Those who have sought to debunk the moral objections to cloning-to-produce-children have generally focused on what science tells us about what cloned children might be like. However, no evidence about the biological properties of children created through technologies like cloning could speak to the way the act of manufacturing children using these technologies will shape the relationship between the generations. Human procreation is about more than genetics and physiology; it is also about the link between the generations, between ancestors and descendants, the past and the future.

For example, some supporters of cloning point to the existence of naturally occurring identical twins as proof that we have little reason to worry about cloning. Law professor Kerry Lynn Macintosh, in a recent pro-cloning book, exhibits a sound grasp of the science of human cloning and genetics, and rightly argues that two people who share the same DNA will not possess "the same intellectual, psychological, or behavioral traits."[72] This is correct. Our experience of identical twins shows that individuals with identical genomes are capable of forming their own life plans, their own senses of who they are, and all the rest of the complex psychological and social desiderata that constitute personal identity. They have their own thoughts, beliefs, and actions, and even their own unique sets of fingerprints. The various differences we can see between identical twins provide clear evidence of the limits of genetic determinism.

However, the comparison to identical twins generally skips over an even more important sense in which cloned children will be biologically, psychologically, and socially different from the people from whom they are cloned: the cloned children will be *younger*. Whatever the genetic basis for Lebron James's talent as a basketball player, a clone of Lebron James would certainly not be born with that talent—he would be born

crying and wetting his diapers like any other baby. A baby with a genome identical to that of an adult progenitor would be physiologically, psychologically, and socially much more similar to other babies than to his older "identical twin."

While the difference in age between a cloned child and the person from whom he is cloned is the most obvious reason the two will not have identical biological or psychological properties, this difference in age is also the reason why cloned children will face challenges in forming their own sense of individuality and identity. Unlike identical twins, who grow up simultaneously, the cloned child's elder "twin" will stand as a kind of genetic prophecy, and a source of expectations for how the younger child's life might turn out, even in the unlikely event that those expectations had nothing to do with the choice to produce a clone in the first place.

An individual created through cloning is likely to experience his life quite differently if he knows that he was made to have a genome identical to some other person's—either the person (or one of the people) raising him as a "parent," or some third party selected for exceptional abilities, or a family member, perhaps deceased, whom the parents have chosen to clone. Even if a cloned child is not told of his origins, parents will, in the act of specifying their child's entire genome, be exercising control over their child's origins and identity that will shape the expectations they have for the child that could distort their own openness to the child's developing autonomy and aspirations.

Those who use cloning may *not* want their children simply to follow in the footsteps of the individuals from whom they were cloned. Rather, parents may be on the lookout for specific environmental differences that could allow the cloned children to fulfill the potential that their genetic progenitors possess. As cloning advocate Gregory E. Pence writes, cloning "would be a naturally controlled experiment.... The genome of the ancestor is the control, and variations in genes, environment, or choice will show how things could have been different."[73] Pence's specific examples here include the idea of a cloned child saying to his ancestor, "If only you tried harder, Dad, you could've published your book on James Joyce. You had the ability! After all, I published ten books before I was forty and you had your whole lifetime!"[74] Even those who are open to the idea of their cloned child being different from them will be tempted, Pence writes, to look to their cloned child to "see how things might have been different."[75]

Macintosh dismisses the distinctions between identical twins and clones as "specious," arguing that "twins who grow up together are

exposed to a barrage of information about the traits and talents associated with their shared genome" but that they nonetheless "retain their individuality."[76] But the difference between cloned children and twins is not in the information that the clone might receive about his genetic traits, but in the ways that the act of cloning will shape the expectations surrounding his life, especially the expectations of his parents. Comparisons with identical twins likewise obscure the most important relationship between the person being cloned and the cloned child: the child may be *genetically* an identical twin, but is generationally a *child*, a son or a daughter. That cloning would conflate these two kinds of kinship is a large part of the deep disquiet we feel with the way cloning transforms the basic structure of the family.

Identical twins are siblings—in addition to sharing a genome, they share a genetic mother and a genetic father. A cloned child, on the other hand, does not share a genetic mother and a genetic father with his "twin"; rather, his "twin" will be his sole direct genetic ancestor. That a cloned child will have essentially only a single genetic ancestor is at the heart of the moral meaning of cloning-to-produce-children. But some defenders of human cloning argue that a clone would indeed have two genetic parents—the two genetic parents of the person whose somatic cell nuclei were used for the cloning procedure.[77] There is a certain technical sense in which this is true—the origin of the cloned child's genome will have been the sexual reproduction of the cell donor's parents. (Cloned children could also sometimes be said to have two genetic parents insofar as the cloned child's mitochondrial DNA will be inherited from the egg donor rather than the somatic cell donor.[78] But unlike in sexual reproduction, the egg donor and the somatic cell donor will make vastly unequal genetic contributions to the child.[79])

Identifying parenthood solely with this technical sense of genetic ancestry puts a spotlight on some of the troubling ways cloning would distort the relationship between the generations. The "genetic parents" of a cloned child in this sense could be dead decades before their child is conceived, and the biological connection between them and their new genetic child will be completely mediated by another individual, namely, their child, the person whose genome has been replicated. And of course cloned children could decide one day to clone themselves in turn, further separating the technical sense of genetic parenthood from any actual relationship between the generations. Clones could be created who would be the "identical twins" of their long-deceased ancestors, with their "genetic parents" a distant memory on a bare and branchless family tree.

It is possible to imagine scenarios in which the parents of the person whose genome is replicated would also act as parents to the child created through cloning. For instance, the parents of a young child might choose to clone that child and could raise the resulting second child as if it were a natural sibling of the first. John A. Robertson points to a number of circumstances under which parents might seek to clone one of their minor children, including the desire for a "second child like the first" or one "who could be a source of tissue or organs" or a second child "to replace a dead or dying child with one with its genes."[80] As Robertson articulates it, the right to create clones and rear them is fundamentally a right of adults to define for themselves, on the basis of their own desires and interests, the meaning of the relationship between the generations. This singular emphasis on procreative liberty and self-definition is supposed to trump most other rights and interests. Thus, when it comes to creating a clone of an existing child, Robertson avers that the first child "may have no right to determine whether or not she is cloned," since the child is not herself "reproducing directly"—rather, it is her parents who are reproducing by creating a "later-born identical twin."[81] Likewise, if a person wishes to create a clone of himself, Robertson argues that he need not seek his parents' consent, even though the resulting child will genetically be a child of theirs.[82] Robertson acknowledges the risk of "confusing kinship and family relations," but he expects that with a little counseling, even those risks can be managed.[83]

As with many existing reproductive technologies, cloning undermines the connection between biological and social parenthood. Already surrogacy and the anonymous provision of egg and sperm allow prospective parents to decide whether a given biological relationship should matter to the child. These reproductive techniques are often accompanied by contractual arrangements among the various involved parties (though not, of course, the child), with the commissioning parents deciding such matters as whom the child will call "mother" and whom "father." Cloning takes this power to define the relationship between mother, father, and child even further, by allowing the prospective parent altogether to deny the child either a biological father or a genetic mother.

Concerns with Manufacturing

Another serious concern about the relationship between the generations is the way cloning would transform procreation into a *manufacturing* process. Even more than other reproductive technologies, cloning would

involve children being made by doctors and technicians in accordance with the designs and wishes of parents. This is often a theme in pop-culture depictions of cloning, with many science fiction movies featuring scenes of rows upon rows of cloned children, often growing in vats.[84] However, there is a more serious, less cartoonish objection to turning procreation into manufacturing. As the President's Council on Bioethics wrote in its report on human cloning:

> By using the terms "making" and "manufacture" we are not claiming that cloned children would be artifacts made altogether "by hand" or produced in factories. Rather, we are suggesting that they would, like other human "products," be brought into being in accordance with some pre-selected genetic pattern or design, and therefore in some sense "made to order" by their producers or progenitors.[85]

Some advocates of human cloning misunderstand and mischaracterize the argument that cloning turns procreation into manufacturing. For instance, Kerry Lynn Macintosh labels as the "artifact fallacy" the idea that "animals (or, potentially, humans) born through cloning are necessarily the flawed products of a technological process and can never be functional members of their species."[86]

Macintosh is mistaken to describe serious criticisms of human cloning in this manner. She quotes some of the Council's discussion about how cloning could result in family relations that "would differ from all existing family arrangements" because of the "unique, one-sided, and replicative biological connection to only *one* progenitor"[87]—but she then badly mischaracterizes that discussion: "This is another way of saying that the technology is unnatural and leads to unnatural results."[88] Macintosh's drastic simplification of the Council's argument would not be entirely false if the "unnatural results" were understood to be the relationships that would exist between the parents and the cloned child. But she claims that the Council's objection to cloning implies that any children "born through the technology must also be unnatural—that is, abnormal, strange, and artificial."[89]

Macintosh goes on to write that concerns over the idea of manufacturing children have "no justification in biology,"[90] but this is missing the point. As we discussed above, there are serious concerns that the use of cloning technology will result in medically harmful side effects for children, but the chief problem with the idea of transforming reproduction into a manufacturing process is *not* that this will result in the children being "flawed." The problem is that cloning would transform the meaning of the relationship between parents and children by changing the

process of reproduction from one of *begetting* to one of *making*.[91] This concern is with *how* cloning would bring children into the world (that is, by manufacturing) not with *what* the cloned children will be (that is, artifacts). Whether it is true that cloning would transform procreation into a process of manufacturing cannot be determined by examining the biological characteristics of children created through cloning. Rather, we must look to the meaning of the act itself, and how it differs from natural human procreation.

In natural procreation, children are a result not of *making*, but an outgrowth of *doing*—of sexual union between a man and a woman. Because the fruitfulness of natural procreation is not entirely under the control of the would-be parents, hope is the attitude cultivated in couples toward the prospect of children. The child can therefore be seen as a gift to be accepted in a spirit of gratitude and openness, or can at least be encountered as a new and unique being whose characteristics and future are unknown. But when made through technologically mediated processes, children can be seen by parents and doctors as products to be shaped and controlled, accepted or rejected. To some extent, this is already a problem with IVF, which gives would-be parents power over whether there will be a child; the problem is exacerbated by such "quality-control" procedures as preimplantation genetic diagnosis, which give parents a limited ability to make and select the child they want, the child that fits their plans, goals, and desires. Cloning takes the moral problems associated with these technologies much further. It puts parents in a position to specify the entire genome of the child by selecting a cell donor. Whether parents using cloning choose to clone themselves, a relative, or some other person whom they believe possesses exceptional genetic traits, the child's genome will be deliberately *chosen* by the parents. Of course, selecting the genome of a child is not a fully reliable way of determining the child's biological traits or properties, but it represents an unprecedented level of control: by creating a child with only one genetic parent, cloning allows for exact determination of a child's lineage.

By exercising this kind of control over the genetic ancestry and the genetic properties of children, cloning would undermine parents' openness toward what is novel in the next generation. Cloning would replace the attitude of unconditional parental love and acceptance with one of mastery, transforming the family into an arrangement ordered toward satisfying the desires of adults at the expense of the interests of children, rather than an institution meant to subordinate the desires of adults to the interests of children.

Macintosh argues that when cloning critics talk about cloning as manufacture, they open the door to stigmatizing and dehumanizing the children created through cloning.[92] However, as we stated above, the chief moral problems with cloning-to-produce-children are not with the cloned children themselves, but with the effects that the act of cloning will have on the relationship between the generations. *Clearly, if children are produced through cloning, they should be treated in accordance with the human rights and human dignity they share with all other human beings.*

Conclusion: Two Images of the Family

The debate over cloning-to-produce-children is chiefly a debate about a moral vision of the family that is increasingly widely held, one in which reproduction is seen as a freely chosen project of autonomous adults—supplanting the traditional image of the family in which romantic love between a man and a woman is tied together with marriage and the begetting of children.

The new moral image of the family, based on a doctrine of reproductive liberty, is an appealing one for a liberal society. The importance of freely made choice in this image of the family reflects the way philosophers sometimes imagine the structure and origins of liberal society: as autonomous individuals freely entering into contracts with one another to advance or defend their interests. This image of the family was perhaps most evocatively expressed in the Supreme Court's 1992 *Planned Parenthood v. Casey* ruling that extolled the importance of every individual being able to "define one's own concept of existence, of meaning, of the universe, and of the mystery of human life"[93] through access to technologies and techniques that add to their reproductive autonomy (in that particular case, abortion).

The central feature of this image of the family is adults freely choosing to "have a child." Thanks to biotechnology, what it means to "have a child" is increasingly becoming radically open: legal contracts allow prospective parents to choose which individuals with which biological relationships will be considered the child's parents (whether a particular woman is a "surrogate" or the recipient of a "donor embryo" is a matter of choice, not biology). Reproductive technologies increasingly allow parents to choose and control the kind of biological relationship they will have with their children.

Unlike political liberalism, however, the struggle for reproductive freedom is to a large extent not about ending systematic political or

social oppression, but is rather aimed at "ending reproductive roulette," or progressing from "chance to choice" or from "chance to purpose," to borrow from the titles of three books.[94] Reproductive technologies can allow couples who happen to be affected by the accidents of infertility or genetic disease to have healthy children. But these technologies can also dramatically expand the range of choices individuals can make about reproduction—allowing single individuals to have children without involving a husband or wife, or allowing couples or individuals to choose to have children who will possess a specific set of genetic properties by using DNA from some exceptional individual.

Of course, not all those, or for now not even very many of those, who find aspects of this vision of the family appealing endorse or even approve of cloning-to-produce-children. Many people in a liberal society believe that it is better for parenthood to be planned than for it to be "accidental," and that it is good for children to be "wanted." But few people, outside a handful of professional bioethicists, believe that autonomous choice and rational control are all there is to the family. Some technologies that allow individuals to plan their families, like contraception, are approved by the vast majority of Americans, while others like abortion are deeply divisive, and technologies like cloning and genetic engineering are widely condemned.[95]

The widespread opposition to human cloning and the controversies over other reproductive technologies are signs that Americans still find meaning in a different moral image of the family—one in which children are seen as gifts to be accepted with gratitude and in a spirit of openness to their fundamental *newness*. In this image of the family, the relationships and moral obligations of parents and children are not freely chosen, but are embedded in their biological and social contexts. This image of the family, and its place in the natural and social order was perhaps best articulated by Edmund Burke, in a famous passage:

> Dark and inscrutable are the ways by which we come into the world. The instincts which give rise to this mysterious process of nature are not of our making. But out of physical causes, unknown to us, perhaps unknowable, arise moral duties, which, as we are able perfectly to comprehend, we are bound indispensably to perform. Parents may not be consenting to their moral relation; but consenting or not, they are bound to a long train of burthensome duties towards those with whom they have never made a convention of any sort. Children are not consenting to their relation, but their relation, without their actual consent, binds them to its duties; or rather it implies their consent

> because the presumed consent of every rational creature is in unison with the predisposed order of things. Men come in that manner into a community with the social state of their parents, endowed with all the benefits, loaded with all the duties of their situation.[96]

In this image of the family, moral duties arise from the natural relationship of parents to children, duties that are not autonomously chosen or made in contracts. In our liberal society, where we enjoy so much freedom to choose those with whom we will associate in work, politics, and friendship, the family, for the most part, is a place of unconditional obligations. We rightly value our freedom to seek a "social state" other than that of our parents, but the obligations of love and support that parents owe to their children and the obligations of honor and respect that children owe to their parents remain truly obligatory, not matters of free choice.

The appeal of this understanding of the family surely helps explain why most Americans find the idea of human cloning morally repugnant. More than any other reproductive technology, cloning would undermine the "giftedness" of children, and because there are so few substantive reasons for using cloning-to-produce-children—cloning is more likely to cause harm to babies than to ensure their health—moral approval for cloning represents an extreme commitment to reproductive autonomy for its own sake.

But autonomy is a powerful force in our culture, so we should not imagine that cloning-to-produce-children will forever remain anathema to the American public. Other foundations of family life that have been held as common sense since time immemorial have been increasingly eroded by advocates of unfettered autonomy in a remarkably short time. Taking a stand against cloning now, while there is still a consensus among Americans that cloning is profoundly wrong, will be an essential part of a defense of the family in coming years.

But while it is important that we prohibit cloning-to-produce-children to prevent the long-term degradation of the family, we cannot do so without also making a strong case against the much more immediate threat posed by cloning-for-biomedical-research. It is to that case we now turn.

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Part Three

The Case Against Cloning-for-Biomedical-Research

While there is currently widespread agreement that cloning-to-produce-children would be unethical, and even fairly broad support for its prohibition, public opinion is much more divided on the moral acceptability of cloning-for-biomedical-research.[1] This fact is partly attributable to confusion and partly to the different moral arguments that apply to the different ends cloning may serve.

Disputes over terminology surely compound the confusion. Some of the laws proposed to prohibit cloning-to-produce-children while permitting cloning-for-biomedical-research identify the act of "cloning" not with the creation of a cloned human embryo for research purposes, but only with the transfer of such an embryo to the uterus of a woman.[2] By contrast, many scientists, ethicists, and advocates use the term "cloning" for both practices—calling one "therapeutic cloning" and the other "reproductive cloning." Though both these terms use the word "cloning," they are still not entirely accurate. So-called "therapeutic cloning" will not be therapeutic for any patients in the near future, and will never be therapeutic for the cloned embryo, which will be destroyed. Furthermore, the distinction between the two implies that "therapeutic" cloning is not "reproductive," when both are in fact forms of reproduction—both create new human life.

Unlike cloning-to-produce-children, which would be pursued only by those with a distorted understanding of the goods of procreation and family, cloning-for-biomedical-research serves a noble aim—the discovery of new knowledge that might make possible new modes of healing. But, like cloning-to-produce-children, and arguably to an even greater extent, cloning-for-biomedical-research involves immoral *actions*. In cloning-to-produce-children, after the embryo is cloned, it is transferred to a woman's uterus so that it can develop into a child and be born, while in cloning-for-biomedical-research, the embryo is destroyed.

The availability of morally acceptable alternatives makes cloning-for-biomedical-research less justifiable. In the following pages, we show what is at stake in the debate over cloning-for-biomedical-research, and why it is important to reject human cloning whatever its purpose is.

Exploitation of Embryos

The central moral objection to cloning-for-biomedical-research is that it involves the deliberate killing of human embryos. Much of the debate over cloning-for-biomedical-research therefore concerns the question of the moral status of the embryo. Is the embryo "one of us," despite its apparent lack of distinctively human features and capacities? Do these youngest of human beings deserve our care and protection, or are there purposes that are sufficiently important to warrant killing them or using them in experiments?

We maintain that, because human embryos are human beings, they must "never be used as a mere means for the benefit of others."[3] Human embryos are members of the human species at the earliest stage of biological development. They are tiny in size and unfamiliar in appearance, but they are unmistakably individual human organisms—they do not become human at some later developmental stage. Occasionally scientists will aver that "science does not offer a hard-and-fast answer to the question of when human life begins."[4] The notion that it is impossible for science to answer the question of when human life begins, or even that the question is meaningless, can be convenient for scientists who want to use embryos as raw materials in their technological projects, but it also represents an abdication of the responsibility of science to provide us not only with technological power over nature but also with answers to questions about nature, including answers that might make us reconsider the moral implications of some of our growing technological power over nature.

Cloning is not the only area of research that involves the deliberate destruction of human embryos. Most other forms of embryo-destroying research rely on embryos originally created for reproductive purposes left unused, stored frozen in IVF clinics.[5] But in the case of cloning-for-biomedical-research, human embryos are created for a purpose that requires their destruction. While the abandonment of one's embryonic offspring represents one of the most morally vexing aspects of modern reproductive technologies, the creation of new human lives solely to produce biomedical research materials is a further, distinctive form of human exploitation.

Cloning-for-biomedical-research is a deeper violation of the meaning of the procreative act and the obligations we owe to future generations than cloning-to-produce-children. Both involve seeing offspring as products of our will, made to serve our purposes. But the direct aim of creating human lives in cloning-for-biomedical-research is the destruction of those lives, and the transformation of their bodies into biomedical research

supplies. It literally involves manufacturing and commodifying human life: biotech companies advertise human embryonic stem cells as having been "derived under current Good Manufacturing Practice (cGMP) conditions."[6] Advocates of such embryo-destroying research speak not of "embryos" but of the "products" of techniques like IVF or cloning.[7] In cloning-for-biomedical-research, the act of human reproduction is transformed entirely into a means of satisfying the desires and furthering the projects of autonomous adults, in complete indifference to the interests of the new human beings created.

As we will argue below, there are other serious moral problems associated with cloning-for-biomedical-research, including the exploitation of women who will be needed to provide eggs. And cloning-for-biomedical-research will lay the technical and practical groundwork for cloning-to-produce-children and a number of other morally troubling acts. But we should not forget that cloning-for-biomedical-research is already at the bottom of the slippery slope—it is an act of deliberately creating human beings solely so that they can be destroyed for the benefit of others.

Ethics of Egg Procurement

Procuring human egg cells for cloning research is both practically complicated and ethically problematic. Unlike some forms of human embryo research that can use embryos donated by fertility patients, cloning-for-biomedical-research involves the manufacture of embryos, which requires collecting oocytes from women—a process with significant medical risks to women that inherently exploits and commodifies women's bodies.

Collecting eggs from women requires stimulating their ovaries to release more than one egg cell during ovulation. Women are prescribed a regimen of hormones that induce superovulation.[8] This procedure can result in a condition called ovarian hyperstimulation syndrome; researchers estimate that 3 to 10 percent of the egg-retrieval procedures performed in IVF clinics result in moderate or severe forms of the syndrome.[9] Severe cases can result in nausea; ovarian cysts; the enlargement of ovaries; changes in the viscosity, volume, or coagulation rate of blood; thromboembolism;[10] and even death.[11] The surgical procedure used to extract eggs also poses risks of pelvic infections and injuries, and internal bleeding.[12] Women providing eggs for research may be at lower risk for some of these complications than women undergoing fertility treatment,[13] but they are also undertaking these risks not as part of a course of treatment but for the sake of scientific research.

Obtaining human egg cells is an obstacle for cloning researchers, since it is not easy to find women willing to undergo the risk-laden and onerous procedures necessary to provide eggs. Whether or not scientists should be permitted to pay women for their eggs is one of the more hotly disputed policy questions concerning cloning-for-biomedical-research, since such payments may provide an inducement for women, especially poor women, to take on medically unnecessary risks. For that reason, some jurisdictions and institutions have placed limits on whether or how much scientists can pay women to provide eggs. While there are no federal laws in the United States restricting payments for egg donors (beyond limits on when and how federal dollars can be spent), some states have laws prohibiting payments for anything beyond reimbursement for direct expenses.[14] The National Academy of Sciences guidelines for stem cell research also endorse compensating women "only for direct expenses incurred as a result of the [egg-procurement] procedure,"[15] though these guidelines are not binding.

Guidelines from other professional associations, however, have been more permissive. The American Society for Reproductive Medicine guidelines allow that egg providers may be paid as much as $10,000 to "reflect the time, inconvenience, and physical and emotional demands associated with the oocyte donation process," whether the women are providing eggs for fertility treatments or research.[16] The International Society for Stem Cell Research guidelines suggest that the research-oversight bodies at each institution decide for themselves whether to permit compensation,[17] on the grounds that such groups are able "to distinguish undue inducements from payments that appropriately acknowledge the interests of the subject."[18] (For a brief survey of the policy debates over egg donation, see "Regulation of Egg Collection" in Part Four of this report.)

Some scientists and bioethicists who endorse cloning-for-biomedical-research have sought to loosen or eliminate restrictions on payments to women for eggs. Many human research subjects are compensated for their participation, and many women who provide eggs for fertility treatments are also paid for their eggs. So, the argument goes, for the sake of consistency women providing eggs for research should also be paid.[19] But the fact that human egg cells have been commodified in one instance does not justify their further commodification in other instances.

Advocates of cloning-for-biomedical-research also argue that payments do not represent "undue inducement" for women to undergo egg-collection procedures.[20] But it is somewhat disingenuous to downplay the incentive effect of payments, since the presence of payments clearly makes

a difference in the decisions women make about whether or not to provide eggs: researchers report that it is difficult to find women willing to provide eggs if they will not be compensated, and women cite the absence of compensation as a chief reason for their decision not to undergo egg-collection procedures.[21] A survey of 230 women enrolled in a Columbia University program that paid them each $8,000 for their eggs found that just 2 percent of the women said they would have been willing to provide eggs without getting paid.[22]

Ethicists who endorse payment for eggs argue that following procedures for informed consent and limiting the amount of money paid for eggs can allow scientists to avoid exploiting women.[23] But as bioethicists Françoise Baylis and Carolyn McLeod argue in a critique of payment-for-eggs schemes, in practice it is impossible to eliminate exploitation, especially of the poor.[24] "There simply is no way to ensure, and no reason to expect, equitable participation in egg selling by rich and poor women," they write.[25] Doing so would require researchers or review boards to track the economic situations of all egg sellers and ensure an impartial distribution, because simply showing that recruitment methods do not *intentionally* target poor women would not be enough to prevent the exploitation of the economically vulnerable.[26] The fact that a woman may freely consent to egg retrieval in full knowledge of its risks does not prevent undue inducement and exploitation, because the woman would most likely not have chosen to take on such risks had she been more financially secure. Exploitation of women providing eggs for fertility treatments is already too common, and more extensive commodification of eggs for research will only aggravate this problem.[27]

It is also necessary to respond to the claim that women are not being paid for their eggs but rather are being compensated for the risks and stress they undergo. For example, the American Society for Reproductive Medicine recommends that

> Compensation based on a reasonable assessment of the time, inconvenience, and discomfort associated with oocyte retrieval can and should be distinguished from payment for the oocytes themselves. Payment based on such an assessment is also consistent with employment and other situations in which individuals are compensated for activities demanding time, stress, physical effort, and risk.[28]

But this argument, that it is the time and effort and not the eggs themselves that are being compensated for, is just a bit of rhetorical drapery obscuring the real purpose of the financial payments: securing more

eggs. What researchers want is not the active participation of women in a shared research enterprise, but to extract valuable resources from women's bodies—the raw materials for a biotechnological manufacturing process.

Future Prospects

Cloning-for-biomedical-research is itself a grave moral evil, but if it is actively pursued it will also make possible a host of other evils.

Most obviously, cloning-for-biomedical-research will lay the foundations for cloning-to-produce-children. The process of creating cloned embryos is the most technically challenging part of cloning-for-biomedical-research and also of cloning-to-produce-children. The act of transferring a cloned embryo to a woman's uterus so that it can grow to term is likely to be little different from the act of transferring any embryo produced through IVF (although as of now, because of embryonic defects associated with cloning, cloned human embryos transferred to a uterus may not be able to survive to term[29]). So progress in the practice of cloning-for-biomedical-research necessarily contributes to expertise in cloning-to-produce-children. Furthermore, were cloning-for-biomedical-research allowed to progress, prohibitions on cloning-to-produce-children would become increasingly difficult to justify. It is safe to assume that some individuals and scientific organizations that support the prohibition of cloning-to-produce-children do so today in order to allay public concerns about cloning in general; their motivation to support such a ban would subside as cloning-for-biomedical-research advances and becomes entrenched. At the same time, it is difficult to imagine that, in a world in which cloned human embryos were being created for research in ever-growing numbers, no one would begin to implant them in wombs to bring babies to term. Indeed, were cloned embryos to become a commonplace part of biomedical research, not only would it be practically difficult to enforce laws or regulations prohibiting their transferal to wombs, especially in the largely unregulated U.S. assisted reproduction industry, but such laws or regulations would be morally odious, since they would consign all cloned human beings to death. (The immorality of these "clone-and-kill" laws is discussed further in Part Four.)

If research on human cloning were to become more acceptable to Americans and more engrained in the careers and projects of the scientific community, other biotechnological developments, as we shall see, may come to be regarded as permissible, desirable, or even necessary.

The existence and acceptance of scientific techniques influences moral sensibilities about future techniques, and is often used as justification for setting aside moral objections. (For example, as mentioned above, many ethicists who advocate paying women for eggs point to the precedent of buying and selling eggs for fertility treatments as a justification for the further commodification of eggs for research.)

While it is worth exercising caution in appealing to the distant consequences of cloning research, the stakes in bioethical debates of this kind are high enough to justify taking seriously even some speculative worries. As the philosopher Hans Jonas argued in an essay on the implications of biological engineering:

> Since no less than the very nature and image of man are at issue, prudence becomes itself our first ethical duty, and hypothetical reasoning our first responsibility. To consider the consequences before taking action is no more than common prudence. In this case, wisdom bids us to go further and to examine the use of powers even before they are quite ready for use. One conceivable outcome of such an examination could be the counsel not to let those powers get ready in the first place, i.e., to stop certain lines of inquiry leading to them, considering the extreme seducibility of man by whatever power he has.[30]

In the subsections that follow, we examine several morally troubling scientific and technological possibilities that may follow on cloning-for-biomedical-research and prove too seductive for humankind to resist.

Creeping extensions of embryo research. One of the medical possibilities most commonly cited as a rationale for pursuing cloning-for-biomedical-research is the prospect of using cloning as a large-scale source of patient-specific embryonic stem cells for cell-replacement therapies. The use of cloned human embryos for biological spare parts might become as regular a part of medicine as bone marrow transplantation is today. Even if some versions of such a future—like the possibility of "personalized biological repair kits" for every American[31]—seem exaggerated, that such a hypothetical is proposed at all by advocates is telling.

However, embryonic stem cells, taken from very young human embryos, are not the only possible medical applications of human cloning research. Scientists could grow cloned embryos in laboratories for longer periods in order to perform experiments on embryonic and fetal development, or to aid in the creation of technologies for growing fetuses outside the womb, or to develop organ primordia for transplantation.

Since the early days of the embryo debates, there has been a broad consensus among researchers and ethicists that embryos should not be experimented upon more than fourteen days after fertilization (discounting days spent frozen in storage). Countries that have used the fourteen-day limit in their laws and regulations governing research on human embryos include Australia,[32] Canada,[33] India,[34] Japan,[35] and the United Kingdom.[36] While the United States has no national laws prohibiting research on human embryos beyond fourteen days, professional societies[37] and the National Academies of Sciences[38] have adopted the fourteen-day limit as a guideline. (California's state stem cell research agency uses a twelve-day limit for its funding decisions, on the same principle as the fourteen-day limit.[39])

The basis for this fourteen-day limit is that this is roughly when *gastrulation* occurs, a process after which the cells of the embryo lose their pluripotency, making it no longer possible for the embryo to split into identical twins. According to an influential 1984 British government report on human fertilization and embryology, the formation of the primitive streak in the embryo, a sign that gastrulation has taken place, "marks the beginning of individual development of the embryo."[40]

The widespread adoption of this standard is somewhat surprising, considering its flimsy moral and scientific basis. Embryos are individual human beings from fertilization on—they do not acquire individuality with the emergence of new cell types or the first visible signs of a vertebrate body plan, or even with the loss of the ability to give rise to an identical twin.[41] The fact that early embryos can at times split into two genetically identical embryos does not mean that the embryo was not a single individual prior to becoming two individuals. The divisibility of early embryos is one of their unique biological features, comparable in some respects to the ability of animals like flatworms to grow as distinct individuals when cut in two.[42] As unusual as such biological divisibility may seem, there need be no confusion about whether a flatworm is a single biological individual prior to its being cut in two, just as there need be no confusion about the biological individuality of an embryo that has the potential to divide into genetically identical twins.

The British government's report itself admitted that "biologically there is no one single identifiable stage in the development of the embryo beyond which the *in vitro* embryo should not be kept alive"[43] and that the decision to demarcate a limit was made "in order to allay public anxiety."[44] So the fourteen-day limit on embryonic research is largely arbitrary, both morally and scientifically. And notwithstanding its wide adoption, it is not legally

enforced in the United States. If promising research opportunities were to emerge that required experimenting on older embryos, it is likely that the ethical standards of the scientific community in the United States would shift to accommodate them, accepting research on older and older embryos.

Embryonic and fetal farming. One of the longstanding goals of regenerative medicine is to build organs from pluripotent stem cells. But growing organs from stem cells is an extremely complex matter, even more so than the difficult task of differentiating stem cells into particular cell types. Instead of deriving organs from stem cells, it may be more technically straightforward to culture embryos for longer periods of time. There are already biotechnology companies developing methods for transplanting organs from aborted fetuses,[45] but using cloning to produce genetically identical fetuses could well be a more attractive option. Cloned embryos could be grown past the fourteen-day limit to yield organ primordia, tissues, or stem cells that could be used for transplantation.

This possibility is less strange than it may seem. From a medical perspective, one reason to go in this direction is that transplantation of organ primordia to replace diseased organs seems to have therapeutic advantages over replacing diseased organs with healthy mature organs (such as in kidney transplants).[46] Researchers have explored this possibility by harvesting kidney primordia from aborted human fetuses and implanting them in immunodeficient mice, demonstrating that the organ primordia developed into semi-functioning kidneys.[47] The viable time to transplant kidney progenitors has been determined to be between 7 and 14 weeks of development.[48] There have already been several animal studies in which tissue from fetuses was harvested for the purpose of treating diseases in mature animals.[49] Considering the pressing need for viable human kidneys—there are more than 100,000 names on the U.S. waiting list as of this writing[50]—it is conceivable that in the future we will see increasing pressure to create cloned fetuses for the purpose of harvesting organs.

In 2006, Congress passed the Fetus Farming Prohibition Act to prohibit the deliberate production of fetuses for the sake of harvesting tissues or organs for medical or research purposes.[51] However, the law prohibits the use of fetuses *gestated* for research purposes, and so if researchers developed the means to grow embryos to the fetal stage *in vitro*, this law would likely not prohibit such actions.

Ectogenesis. The idea of growing prenatal human beings outside of the womb, or ectogenesis, is often associated in the public mind with science

fiction, but in recent years it has been inching toward reality, as scientists have improved the ability to keep unborn human beings alive outside of the womb.[52] On the early side of the developmental spectrum, researchers have invented culturing methods that enable the growth of human embryos up to the fourteen-day limit.[53] And on the other side, we already have incubators for caring for premature infants born as early as 22 weeks.[54] Much of the research today is focused on developing technologies to save the lives of babies born prior to 24 weeks, before which the survival rate using existing incubators greatly decreases. However, some people are interested in developing artificial wombs to allow women who are unable to have children to do so without requiring a surrogate—or simply to allow women to have children without undergoing the burdens and inconveniences of biological pregnancy.[55]

Progress in cloning-for-biomedical-research could accelerate the move toward ectogenesis. The desire to obtain patient-specific organs for transplantation could make it attractive to grow cloned fetuses outside the womb. The Fetus Farming Prohibition Act, mentioned above, does not in fact prohibit growing fetuses outside of the womb in order to harvest their organs for research or transplantation.[56] Even if the law were repealed entirely, however, developing ectogenesis technologies may be easier than finding surrogates willing to become pregnant for the gruesome task of supplying doctors with spare parts.

If artificial womb technologies are developed significantly further, there would be far more harvesting of fetal tissues and organs, as the key technical obstacle to "fetal farming" would be removed. Further, the development of artificial wombs would potentially encourage people to argue that, in the interest of saving the lives of patients, we ought to permit the cloning and artificial cultivation of fetuses for the purpose of harvesting tissues.

Deliberately creating headless babies. It is with some trepidation that we raise the next scenario—already realized in animal experimentation—that might arise in an era of widespread cloning-for-biomedical-research: the possibility that cloning may lead to the deliberate creation of headless humans for growing organs.

The creation of headless clones as a source of organs seems gruesome and fantastic. But it also conforms all too well to some of the dominant attitudes in our society concerning the exploitation of prenatal human life. It is not hard to imagine a day when growing demand for sources of cells and organs for transplantation could lead to the creation of not just

embryos but fetuses and infants; the deliberate engineering of these clones to lack human brains may be seen as a compassionate measure. Biologist and futurist Lee Silver endorsed the creation of headless clones in 1997, saying that he saw "nothing wrong, philosophically or rationally," with the practice.[57]

This prospect may seem very far from any reputable scientific work, and indeed, it is far from clear that it will ever be feasible, technically. But scientists have spent decades studying the genes necessary for development, and in some cases the disruption of just one gene can prevent the development of whole organs or parts of the body. In 1995, scientists were able to create headless mouse fetuses by knocking out a single gene,[58] and research on the genetic basis of the development of the brain and head has continued in the years since.[59] Much of this work, conducted on animals, could provide medically useful knowledge of developmental disorders,[60] but it could also, at least theoretically, be used to produce headless human clones as well. So it is not inconceivable that scientists could create embryos that would be unable to develop certain organs or features that are taken by some to be definitive of human personhood, such as the brain, despite the fact that headless fetuses may sound like mere science fiction.

These entities would presumably lack many of the higher capacities of human beings, and might be thought by Silver and others as being less than human and having less than the moral standing of human fetuses, infants, or adults. In fact, this is one of the common arguments in favor of destroying embryos for research—embryos are clumps of cells that have not yet developed the brain functions necessary for thought and sensation that some see as underlying moral standing, and so it is morally justifiable to kill them to provide patients with medical treatments.[61] If it turns out that fetuses or infants are a more effective source of cells and organs for therapy, then ensuring that these fetuses will lack the capacities to think or feel will presumably, in this calculus, make them morally equivalent to the embryos we are already willing to kill in the name of medical research.

The repugnant thought of creating headless clones and the unsettling similarity of such an idea to how we already treat unborn human beings should give us reason to strengthen our commitment to the protection of unborn life by rejecting all forms of embryo exploitation now, before such grotesque possibilities come to seem more plausible.

Interspecies cloning. If cloning research programs continue to be frustrated by the lack of human egg cells, scientists may turn to creating

cloned embryos by combining human cells with enucleated animal cells. Cell lines that showed quite similar properties to human embryonic stem cells have already been generated by transferring human somatic nuclei into rabbit oocytes, as long ago as 2003.[62] This kind of technique would result in embryonic stem cells that have the nuclear DNA of a human and the mitochondrial DNA of an animal.

Since interspecies cloning could potentially provide a means of producing patient-specific embryonic stem cells, many researchers have already proposed its use to make up for the difficulty of procuring human egg cells.[63] Interspecies cloning has also been suggested as a research tool to provide a better understanding of nuclear-mitochondrial interaction and to provide *in vitro* models to study late-onset diseases (such as Parkinson's).[64]

It is still not clear if this kind of cloning will be an effective source of embryonic stem cells for either research or medicine. A report of the President's Council on Bioethics in 2004 pointed out that more research would be required to know if mitochondrial proteins from animals persist in interspecies embryonic stem cells.[65] A 2009 study involving interspecies cloning using human neural stem cell nuclei and goat oocytes found that human mitochondrial proteins were expressed in the resulting cells, but that the incompatibility of the human genome with the goat cytoplasm meant the cells were not able properly to express genes necessary for mitochondrial function.[66]

Whether such methods could be effective or not, would they be morally better or worse than human cloning? Creating and killing human embryos is always wrong. The mixture of human and non-human life is in itself disturbing, although there are some cases in which mixing human and non-human cells or DNA can be morally acceptable. (A full moral analysis of interspecies research is beyond the scope of this report.) However, creating cloned embryos with uncertain standing as members of the human species in order to avoid the moral problems of human cloning is deeply troubling. Overcoming our sense of repugnance at the idea of creating human-animal hybrids only to use the creation of such hybrids as an excuse to overcome our moral judgments about the sanctity of human life would be not a form of sophisticated moral progress but would rather an example of moral evasion.

Artificial gametes. Another development that cloning-for-biomedical-research will both facilitate and increase the demand for is the creation of "artificial gametes"—egg and sperm cells, made to order. Researchers

have laid out three potential applications for artificial gametes: to create *in vitro* models for the study of how human gametes develop and of germline diseases, to enable genetic manipulations of the human germ line, and to create a supply of gametes to use in research and assisted reproductive therapy.[67] But like interspecies cloning, the production of artificial gametes would provide a way to overcome the limited number of human eggs available for cloning research.

Already, researchers have used mouse embryonic stem cells to derive "sperm-like" and "egg-like" cells *in vitro*.[68] Researchers have also been able to derive cells that express markers similar to mature germ cells from human embryonic stem cells.[69] More recently, researchers were able to transform bone marrow stem cells into sperm-like cells.[70] Based on these studies and others, it is quite possible within the next several years that researchers will be able to derive large quantities of gamete cells from stem cells (either embryonic or induced pluripotent stem cells) *in vitro*.

While there are many related concerns about what such a technique might lead to, it is worth highlighting one in particular here. *In vitro* gametogenesis (IVG) increases our ability to design and produce the most genetically desirable gametes and embryos, because it greatly increases the quantity of gametes (especially oocytes) that can be used for IVF. Using such a technique to produce an embryo and create a human being would be a form of eugenic selection. Some bioethicists have instead proposed calling this kind of selection "procreative beneficence," and have argued that "the ability to create large numbers of eggs or sperm through IVG greatly increases our capacity to select the best child possible."[71] They point out that the mass production of artificial gametes would greatly increase the number of embryos available for selection. If gametes were used to create 10,000 embryos, they write, it is virtually guaranteed that parents will find an embryo that has their desired selection of, say, twenty different single-gene traits.[72]

Even if embryos are not created and destroyed on this scale, artificial gametes would still represent a significant increase in the eugenic ability to select desired traits in comparison to today's techniques of IVF and preimplantation genetic diagnosis. And the use of artificial gametes in this way would result in the creation of untold thousands of embryos that will be discarded as failing to meet genetic quality-control standards.

Genetically engineered children. Creating genetically engineered children would be made much easier if cloning were a widely available technology. Cloning is already used by scientists to create genetically

engineered animals, particularly large animals like pigs and cows.[73] One of the major challenges of producing genetically engineered animals is introducing specific genetic modifications into embryos without damaging or destroying them.[74] It is easier to introduce genetic modifications into somatic ("adult") cells, and those modified somatic cells could be used through cloning to produce genetically modified offspring. For instance, scientists could keep cultures of skin cells in a dish and use genetic-modification techniques to introduce specific genetic changes, and then test the resulting cells to see if the genetic modifications have been successful—that is, to see whether the targeted genes have been modified and whether other sites in the genome may have been inadvertently modified. After this process of genetic modification and testing, the scientists could then use the modified somatic cells to create cloned embryos with specific desired genetic changes.

With the development of new genetic-modification techniques that offer increasingly precise means of editing the genome, demand may grow to use them to produce genetically modified children. In April 2015, Chinese researchers announced that they had for the first time genetically modified human embryos using a technique called CRISPR-Cas9,[75] and though the experiment was condemned by many in the scientific community,[76] some scientists have expressed a willingness to consider genetically engineering human beings with these methods.[77]

Genetic modification will always be a highly risky experiment—the human genome is immensely complex, and deliberately changing one gene is likely to have unpredictable effects. A full analysis of the risks and ethical implications of genetic-modification technology is beyond the scope of this report, but if the technology improves alongside research on human cloning, more and more scientists may be tempted to use the two in conjunction to produce genetically engineered children.

Another quite strange application of cloning combined with genetic engineering has been proposed by bioethicist Carson Strong in order to overcome ethical concerns arising from the fact that cloned children will not have unique genomes. In a 2005 article, Strong argued that by genetically modifying embryos, "the objection [to cloning] based on lack of uniqueness would no longer be applicable."[78] Strong went on to speculate that genetic modification could be used "to give the child a nuclear DNA relationship to both members of an infertile couple" by introducing genetic modifications that would "duplicate certain selected genetic characteristics of the other member of the couple, such as hair or eye color," so that "the child would possess nuclear genetic characteristics of both

parents."[79] This argument, however, fails to respond to cloning critics' actual concerns. As we argued in Part Two, what is most repugnant about human cloning is the way it puts control over the genetic properties into the hands of the adults who choose to create them and distorts the relationship between the generations; Strong's proposal to perform genetic modifications would only aggravate this problem.

Cloning and genetic engineering might also be combined with the creation of IVF embryos and embryonic stem cells. Consider this scenario: A couple who want a genetically modified child first use IVF to produce embryos, which they then destroy to derive embryonic stem cells, which can in turn be genetically modified and used to produce cloned offspring. Embryonic stem cells are already more efficient than ordinary somatic cells for cloning,[80] and the resulting cloned children would be genetically related to both "parents" (though, in some sense, the couple initiating this grisly reproductive procedure would be better understood to be the child's grandparents, with the destroyed embryo from which the child is cloned being its parent).

Alternatives to Cloning-for-Biomedical-Research

Human cloning once appeared to be an essential part of the promising field of regenerative medicine. Without cloning, it was argued, researchers would be unable to create patient-specific stem cell lines, making it difficult to produce tissues for therapy or for studying particular diseases. As we described in our previous report *The Stem Cell Debates: Lessons for Science and Politics*, both the urgency and the promise of regenerative medicine were notoriously overhyped during the period from 2001 to 2006.[81] But that supposed urgency and promise put critics of embryo-destructive research in a difficult position: approving of cloning-for-biomedical-research would mean condoning the ethically unacceptable exploitation of women and of embryonic human life, but stopping cloning would mean forgoing a promising route toward treatments for numerous serious diseases and conditions.

This moral dilemma was never entirely stark—cloning was never more than a promising tool for research, not a certain source of cures. And there was always some hope that alternative forms of research that did not require the creation or destruction of embryos would be developed. Shinya Yamanaka's 2006 discovery of a way to make induced pluripotent stem (iPS) cells in mice[82] (followed by their discovery in humans the next year[83]) gave the world hope that the medical promise of regenerative

medicine could be achieved without pursuing ethically troubling research on human cloning.

And yet, while the availability of iPS cells has dampened interest in human cloning,[84] research on human cloning has not ceased (as shown by scientists' successes in 2013 and 2014 in creating stem cells from cloned human embryos[85]).

Here we examine some of the reasons scientists have offered to justify continuing work on human cloning despite the availability of alternatives, and we show why the comparative advantages of pursuing human cloning are so minimal that they cannot surmount the ethical problems associated with that research.

Supposed advantages of cloning. Some scientists and advocates of embryo-destroying research believe that embryonic stem cells represent the "gold standard" for stem cell research.[86] Some have argued that cloning "mimics human physiology more faithfully" than the methods used to create iPS cells, because cloning "emulates normal fertilization."[87] Two major studies were published in 2014 comparing stem cells produced through cloning to iPS cells; the first found that iPS cells were more likely to have epigenetic abnormalities,[88] but the second found that there were no significant epigenetic differences between iPS cells and embryonic stem cells produced through cloning.[89]

Cloning reprograms cells much faster than the methods for creating iPS cells, with cloning transforming the somatic cell into an embryo within hours, whereas iPS cells generally take weeks to reprogram.[90] Whether or not this makes iPS cells more vulnerable to the accumulation of genetic defects is largely unknown.[91] Some scientists have suggested that, because the production of iPS cells involves many rounds of cell division, iPS cells may have a higher risk of proliferating like cancerous cells than stem cells produced through cloning.[92] This higher risk of cancerous proliferation for iPS cells remains largely speculative, however.[93] And as shown by a recent study reporting that iPS cells and cloning-derived stem cells have similar numbers of mutations,[94] the risk of becoming cancerous may not be substantially different between iPS cells and stem cells produced through cloning.

Advantages of iPS cells over cloned stem cells. The difficulty of procuring human eggs means that cloning-based therapies may never be viable as mainstream medical treatments. Extrapolating from recent experiments, it appears that roughly a dozen or more eggs would be required

to use cloning to create a single stem cell line.[95] And because each cycle of egg-retrieval procures an average of around twelve eggs,[96] about one retrieval procedure would be required for there to be enough eggs to give a good chance of deriving a therapeutic stem cell line to treat one patient. Further research may improve the efficiency of this process, but working from this fairly conservative calculation, in order for cloning to become the basis for widespread stem cell therapies—say, providing personalized stem cells to 100,000 patients per year—there would have to be approximately 100,000 egg-retrieval procedures per year. This would likely only be possible if there were a massive market for human eggs, on the order of hundreds of millions of dollars per year.[97] Alternatively, artificial eggs might someday be produced, as discussed above. Either of these scenarios would be morally troubling and practically complex, and unlikely to come to pass without major scientific and social changes.

The impracticality of a medical cloning enterprise of course does not provide justification for eschewing cloning research *per se*; it merely implies that we should not dedicate our medical resources toward cloning-derived stem cell therapies. It makes much more sense to dedicate those resources to therapies based on iPS cells, which do not require human eggs, thus avoiding the risks to women and concerns about exploitation that an egg market would entail. The potential for widespread availability is one of the most significant practical and moral advantages of iPS cells.

From a therapeutic perspective, a further advantage of iPS cells over cloning-derived stem cells is that the latter may have a higher chance of triggering an immune response.[98] Even though cloning-derived stem cells used for therapy would have the same nuclear DNA as the patient, they would have different mitochondrial DNA, and a recent study in mice showed that this difference in mitochondrial DNA can cause immune reactions.[99] (While iPS cells also sometimes cause immune responses, they would not have immune problems connected to differences in mitochondrial DNA.) Relatedly, there may be immune reactions and other problems resulting from "heteroplasmy" in stem cells derived from cloning—mitochondrial DNA incidentally brought along with the somatic-cell nucleus that differs from the bulk of the mitochondrial DNA found in the egg cell.[100]

Do we need to pursue both lines of research? When iPS cells were discovered, some scientists expected that cloning, in the words of one journalist, "may one day become a history lesson."[101] However, with the first successful derivation of stem cells from human cloning in 2013, the

scientific community has once again come to see cloning as an important research program,[102] a view reinforced by the successful cloning experiments in 2014.[103] Many scientists believe that both lines of research should be pursued, arguing that cloning could improve our understanding of how to produce iPS cells.[104]

One reason that has been given in support of simultaneously pursuing cloning and iPS cell research is that the former might indirectly make the latter more effective. Research on cloning could, some scientists have argued, be used to improve the techniques for producing iPS cells.[105] This stands to reason: there are obvious similarities between the fields, both of which involve reprogramming cells, and it would be surprising if there weren't at least *some* findings of value to both.

Still, the crossover of knowledge between cloning research and iPS cell research should not be overstated. In a 2011 paper, bioethicist Insoo Hyun claimed that Shinya Yamanaka, the first researcher to produce iPS cells, may have used results of cloning research to identify factors that can be used to improve iPS cell reprogramming.[106] But the influence of the cloning study on the Yamanaka paper in question was minimal.[107] (In fact, the insights about cloning that Yamanaka depended on could justly be attributed to knowledge that dates back to the early 1960s, when John Gurdon first performed cloning experiments with frogs; as we noted in Part One, Yamanaka and Gurdon shared a Nobel Prize in 2012 for their discoveries related to cell reprogramming.) Moreover, in the Yamanaka study Hyun points to, the scientists who were supposedly dependent on the findings of cloning research still needed to go through a library of 1,473 transcription factors to identify a particularly effective factor for reprogramming somatic cells[108]—so it is difficult to believe that advances in cloning research contributed much to that work on iPS cells.

The idea that cloning research is necessary for progress in iPS cell research is something of a convenient myth. If all cloning research stopped, iPS cell research would hardly grind to a halt. And of course, if only *human* cloning research were stopped, the basic science of reprogramming could still be studied through animal cloning—indeed, the cloning study Hyun refers to which supposedly influenced Yamanaka was conducted with mice, not humans.

The issue of whether to pursue both iPS cell research and cloning research must hinge on whether the potential knowledge acquired through cloning overrides the ethical concerns raised by cloning, including especially the destruction of human embryos.

If we regard embryos as having inherent value—a dignity or sanctity linked to their status as human organisms at the earliest stage of life—then we ought to be committed at least to the claim that there should be no unnecessary destruction of human embryos. It is worth noting that this point has been acknowledged even by some supporters of embryonic research. For instance, the Ethics Advisory Board counseling the U.S. government on embryo research in 1979 wrote that "the human embryo is entitled to profound respect."[109] An influential 1984 British report on embryo research also found that "the human embryo is entitled to some added measure of respect beyond that accorded to other animal subjects."[110] Although this concept of "respect" is notoriously fuzzy and often has been used merely as rhetorical cover,[111] supporters of embryo research will sometimes gesture at its practical consequences. To give but one example, the bioethicist Dan W. Brock, a supporter of embryo-destroying research including cloning-for-biomedical-research, has written that

> human embryos could be shown the special respect that [their] intermediate moral status requires by limiting their use to equally important human purposes. That special respect would justify guidelines limiting embryos' use and destruction to research with reasonable promise of alleviating serious human disease and suffering.[112]

Anyone who accepts the position that the human embryo has at least *some* intrinsic value can only condone the destruction of human embryos if it is necessary for achieving some good of greater value. Since some say that the future medical benefit of stem cells provides such a value, this potential benefit is usually taken to justify the destruction of human embryos in scientific research.

However, in iPS cells we have a means of developing stem cell therapies that does not require the destruction of embryos. While iPS cells may have certain limitations, as reviewed earlier in this section, those limitations do not appear to undermine the merit of the technique. Anyone who regards the human embryo as having some kind of non-instrumental value must recognize that cloning-for-biomedical-research should not continue.

Altered nuclear transfer. Another widely discussed alternative to cloning-for-biomedical-research is altered nuclear transfer (ANT), a proposal developed Dr. William B. Hurlbut as an outgrowth of his work as a member of the President's Council on Bioethics.[113] As the name suggests, ANT is similar to somatic cell nuclear transfer, the technique used for cloning,

but it would involve modifications either to the oocyte, the somatic-cell nucleus, or both, so that the nuclear transfer operation would produce a biological artifact that could serve as a source of pluripotent stem cells, but would not be an embryo. Hurlbut prefers to call the products of ANT simply "entities" instead of embryos, and has said that they would lack the moral status of a human embryo since they would have "no inherent principle of unity, no coherent drive in the direction of the mature human form."[114] If he is correct to say that these entities lack the integrated organization of a living being—that they are equivalent to disordered collections of cells that result from failed fertilization like teratomas or hydatidiform moles[115]—then ANT could offer a morally acceptable alternative to cloning for producing genetically identical pluripotent stem cells, since it would not require the destruction of human embryos.

The methods of ANT were designed through a combination of moral reasoning and philosophical and scientific reflection about the meaning of embryonic human life. ANT therefore offers not only a promising alternative to the particular moral problems of cloning-for-biomedical-research, but also holds out the promise of cooperative dialogue between scientists and moral philosophers, recognizing that moral philosophy concerning human life must be informed by science, and also that, to borrow medical ethicist Paul Ramsey's remark about physicians, scientists "must in greater measure become moral philosophers."[116]

Not everyone agrees with Hurlbut that the products of ANT are not embryos. In a 2004 letter to the *New England Journal of Medicine*, three Harvard-based stem cell researchers argued that the presence of defects could not settle the ethical question concerning the moral status of the embryo.[117] They argue that the inherent principle of unity and coherent organismal drive that Hurlbut cited "are ill-defined concepts with no clear biologic meaning."[118] Whether or not these concepts are scientifically meaningful is at the crux of the debate over ANT, and indeed of the debate over human embryo research more generally. Can science tell us whether embryos are biological individuals with lives that begin at conception, or must an empirical biological science reject such questions about what biological entities *are* as scientifically meaningless and focus only on what can be *done* with biological materials?

In principle, by modifying key developmental genes in the oocyte and in the somatic cell, ANT could produce an entity that will not have the organized unity of a human embryo. As biologist Maureen L. Condic has argued, ANT results in the production of entities unable to undertake "the first globally coordinated event in human development, the formation of

trophoblast and inner cell mass lineages," which is "the earliest act of the embryo *qua* embryo."[119] Addressing gravely important considerations like these, which arise from a confrontation with the question of what the embryo is, should be a much higher priority for developmental biologists and embryologists as they seek to develop new biotechnological powers over human life.

As of this writing, no attempts at ANT have yet been reported with humans, although there have been some attempts involving animals. In 2006, biologists Alexander Meissner and Rudolf Jaenisch attempted to use one ANT method with mice. The researchers noted that the products of ANT were "inherently unable to implant into the uterus" because they lacked the ability to form the outer layer of the embryo necessary for implantation.[120] The authors also observed that the products of ANT lacked a number of features necessary for embryonic development.[121] The scientists were nonetheless able to derive pluripotent stem cells, holding out the promise that, should there ever be general acceptance that the products of ANT are not embryos, ANT could be a useful and morally acceptable alternative to cloning.[122]

Are embryonic stem cells a "gold standard"? Many writers and scientists describe embryonic stem cells as the gold standard for stem cells.[123] Because cloning-derived stem cells come from embryos, the notion of the gold standard is sometimes taken to imply that they are of a higher quality than iPS cells.[124]

Both of those assumptions—that embryonic stem cells represent a gold standard for comparison and that cloning-derived stem cells are functionally superior to iPS cells—are scientifically dubious. To understand why, let us begin by pointing out that the term "embryonic stem cells" is something of a misnomer. Unlike somatic ("adult") stem cells, which are found in the body—so, for example, neural stem cells can be found in the brain—embryonic stem cells are not found in the embryo. As Rudolf Jaenisch stated at a meeting of the President's Council on Bioethics in 2003, embryonic stem cells "have no counterpart" in actual animal embryos.[125] Rather, they are *made out of* cells found in embryos. It would be more precise to call them "embryo-derived stem cells."[126] This terminology would highlight the fact that what we refer to as "embryonic stem cells" do not occur in nature—they are artificially produced. Extracting cells from the inner cell mass and culturing them in an artificial tissue-culture environment induces changes to the cells. As some developmental biologists have emphasized, the notion that embryonic

stem cells represent an *in vitro* equivalent to cells of the inner cell mass is unjustified, since embryonic stem cells have a number of important properties not found in any cells of the early embryo.[127]

One such useful property is long-term self-renewal. In a natural bodily setting, no embryonic cell demonstrates long-term self-renewal.[128] But embryonic stem cells (and iPS cells) in their artificial environment do. As one review put it,

> embryonic cells, once brought into tissue culture, are exposed to numerous extrinsic signals to which they never would be exposed… *in vivo*. ES [embryonic stem] cells certainly adapt to selective tissue culture conditions and acquire novel functions that allow them to proliferate in an undifferentiated state indefinitely, and, because of this, ES cells are in some sense tissue-culture artifacts.[129]

The exposure to artificial tissue-culture conditions is an inevitable aspect of embryonic stem cells (as well as iPS cells). Embryonic stem cells are not somehow more natural than iPS cells; both are shaped in important ways by technical intervention.

Furthermore, there is little reason to treat embryonic stem cells produced through cloning as a gold standard for patient-specific stem cells. Cloning-derived stem cells and iPS cells should be compared on dimensions pertinent to medical therapy, such as the immune reactions they instigate and their ability to successfully differentiate into various useful cell types. While the degree of similarity between embryo-derived and non-embryo-derived stem cells may turn out to be an indicator of these qualities, the degree of similarity itself cannot be the ultimate basis for evaluating the therapeutic prospects of stem cells.

Evidence from studies looking at the clinically relevant features of stem cells suggests that iPS cells could be effective replacements for embryonic stem cells. For example, in a paper published in 2014, researcher Douglas Melton and his colleagues reported developing a method for making insulin-producing cells on the scale necessary to treat type 1 diabetes. Melton's team was able to use both human embryonic stem cells and iPS cells to generate these insulin-producing cells, indicating that iPS cells were at least adequate for this clinical purpose.[130] In September 2014, scientists in Japan began clinical trials for a treatment for macular degeneration, a condition that can lead to blindness, using cells derived from human iPS cells.[131] While the results of these trials have not yet been published, data from pre-clinical studies on the safety and quality of iPS cells is promising, with experiments in animal models showing that

iPS cells seem not to cause tumors or immune rejection, two of the main safety concerns.[132] The actual use of iPS cells in therapy and in research strongly suggests that they represent a viable alternative to using cloning to produce patient-specific stem cells.

Conclusion: Scientific Research and the Need for Ethics

The discovery of human embryonic stem cells in 1998, just a year after the cloning of Dolly was announced, transformed the debate over human cloning. The project of regenerative medicine seemed to give cloning a morally serious purpose, moving it from the controversial fringes of reproductive autonomy to the heart of the medical research enterprise. By 2004, although scientific success with human cloning was still very limited, prominent supporters of embryonic stem cell research were calling for the mass-production of cloned human embryos for spare parts.[133] Although the discovery of induced pluripotent stem cells in 2006 seemed to have eliminated the need for cloning-for-biomedical-research, and numerous scientists turned away from cloning in favor of the more practical and ethical new technique, scientific work on human cloning did not cease, as the experiments in 2013 and 2014 demonstrate. For scientists who believe that the destruction of human embryos is morally acceptable, cloning remains another promising avenue of research. For such scientists, even if human cloning no longer seems necessary, so long as it is possible it should still be pursued.

While the availability of alternative sources of pluripotent stem cells makes cloning-for-biomedical-research unnecessary, it does not make prohibitions against human cloning unnecessary—rather, it makes the decision to prohibit human cloning easier. We no longer face the hard choice of either forgoing promising medical research or maintaining some level of commitment to the sanctity of human life. Scientific progress has, in this case, given us the opportunity to draw apart the goods of medical progress from the harm of destroying human life, but we must take advantage of this opportunity with resolute political action—prohibiting all forms of human cloning now. Doing so will require careful attention to the past two decades of policy and political debates over cloning legislation and regulation, a matter to which we turn next.

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Part Four

Cloning Policy in the United States

American cloning policy is something of a patchwork. There is no federal law prohibiting human cloning; as of today, federal laws and regulations only address funding and other issues indirectly connected to cloning. At the state level, however, there are laws directly prohibiting or explicitly permitting different forms of cloning.

The controversies relating to federal and state cloning policies have focused on three main issues: first, whether different kinds of cloning should be governed differently; second, whether taxpayer dollars should be used to fund cloning-related research; and finally, whether women may be paid by scientists for supplying eggs, and other questions related to the regulation of egg procurement. In this chapter, we survey the efforts of policymakers to regulate cloning in the United States and we analyze some of the relevant legal and constitutional arguments. We begin with an overview of the history of attempts to pass cloning laws at the national level.

Congressional Cloning Legislation

Following the cloning of Dolly the sheep, there was a flurry of legislative activity as members of Congress from both parties sought to restrict the practice of human cloning. None of the proposed bills was enacted into law.

The first congressional effort to prohibit human cloning was introduced in the House of Representatives in early March 1997, just days after the Dolly news broke. Sponsored by Representative Vernon Ehlers (R.-Mich.), the short bill proposed to make it "unlawful for any person to use a human somatic cell for the process of producing a human clone," with violators liable to a civil penalty of up to $5,000.[1] A second bill, introduced in late January 1998 by Senator Ben Nighthorse Campbell (R.-Col.), proposed to make it "unlawful for any person to…clone a human being," whether for research, therapy, or to initiate a pregnancy.[2] The bill would also have made it illegal to "conduct research for the purpose of cloning a human being or otherwise creating a human embryo," suggesting that it would have strictly limited IVF research as well.[3] This bill, too, proposed a civil penalty of up to $5,000.[4] Just a few days later, Senator Dianne

Feinstein (D.-Cal.) introduced a bill that would have made it "unlawful for any person or other legal entity, public or private" to "implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus."[5] The bill, which would have sunset after ten years, included a $1,000,000 fine.[6] It also explicitly carved out a protection for the use of human cloning techniques for research or therapy.[7]

None of these bills even came up for a vote in the House or Senate. But their differing answers to the question of how best to restrict cloning prefigured the divide that to this day has prevented any such legislation from achieving enough support to become law. Some bills, generally supported by Republicans, have sought to outlaw the use of cloning techniques whether for research or to produce children. Other bills, generally supported by Democrats, have sought to outlaw the use of cloning to produce children while ignoring or expressly permitting the creation of cloned human embryos for research. As in Feinstein's proposal, these latter bills have usually sought to prohibit not the *creation* of cloned human embryos, but rather the act of transferring cloned embryos to women's uteri. Critics have condemned these as "clone-and-kill" laws, since the only thing researchers could do after creating a cloned embryo if they could not implant it in a womb would be to freeze it in perpetuity or destroy it. Such legal arrangements would, as Gilbert Meilaender pointed out in 2002, "create a class of human beings whose destruction is mandated by law."[8]

Over the years, support for a few cloning bills did not break down along the usual party lines. For example, in 2001, Representative James Greenwood (R.-Penn.) sponsored a bill that would have prohibited cloning-to-produce-children for ten years while permitting registered researchers to engage in cloning-for-biomedical-research; the bill, which garnered support from several Democrats, never came up for a vote.[9] Senator Orrin Hatch (R.-Utah) repeatedly introduced unsuccessful bills that would have banned cloning-to-produce-children but approved, with some restrictions, cloning-for-biomedical-research.[10] His legislation attracted significant support from Senate Democrats but was never voted on. In 2009, Representative Bart Stupak (D.-Mich.) put forth a bill banning both cloning-to-produce-children and cloning-for-biomedical-research; it was cosponsored by sixty Republicans and only two of his fellow Democrats.[11] It, too, never reached the House floor for a vote.

A unique proposal in 2001 by Representative Brian D. Kerns (R.-Ind.) sought to find a middle ground between a complete ban and the so-called "clone-and-kill" measures, stating that, "It shall be unlawful for a person

to engage in a human cloning procedure with the intent of implanting the resulting cellular product into a uterus."[12] Kerns's legislation therefore did not speak to what must be done with cloned embryos—their destruction by scientists would not have been prohibited, but unlike in the "clone-and-kill" bills, their destruction would not have been *required*.

Although President Bill Clinton had called for swift congressional action following the Dolly announcement[13] (and the subsequent declaration of a Harvard-educated physicist that he wanted to open a cloning-based fertility clinic),[14] it was not until July 2001 that either chamber of Congress approved any kind of human cloning ban. Representative Dave Weldon (R.-Fla.) sponsored a bill that would have entirely banned the creation of cloned embryos.[15] It passed in the House by a vote of 265 to 162, with 63 Democrats joining the "yeas" and 19 Republicans voting with the "nays."[16] However, the counterpart to Weldon's bill, drafted by Senator Sam Brownback (R.-Kans.), never made it the Senate floor for a vote.[17] The House passed Weldon's bill once again in 2003, but again the Senate took no action.[18] Attempts by Weldon and Brownback to pass the legislation in 2005[19] and 2007[20] made even less progress.

Meanwhile, bills resembling the one originally proposed by Senator Feinstein (except without the sunset provision) were proposed by Senator Tom Harkin (D.-Iowa) in 2001,[21] Senator Byron Dorgan (D.-N.D.) in 2002,[22] and Representative Diana DeGette (D.-Col.) in 2007.[23] Of these, only DeGette's bill was voted on; it was defeated 204 to 213 in the House.[24]

As of this writing, the most recent congressional bill proposed to address human cloning directly was introduced by Representative Andy Harris (R.-Md.) in May 2013. Like Weldon's proposal, it would prohibit both cloning-to-produce-children and cloning-for-biomedical-research.[25]

Even without specific legislation addressing human cloning, the Food and Drug Administration asserted its regulatory authority over cloning in a 1998 guidance letter.[26] The letter stated that existing federal law gives the FDA jurisdiction over cloning-to-produce-children, and that any researcher wishing to use "cloning technology to create a human being" must apply to the agency for permission—which it would deny, on the grounds that "there are major unresolved safety questions" relating to cloning.[27] The FDA's letter was only addressed to institutional review boards associated with research institutes and medical centers, and it resulted in no follow-up action.

The lack of a comprehensive national policy restricting cloning puts the United States behind the curve compared with many other

countries.[28] In 2002, the German government forbade, "as a matter of principle, the importation and utilization of embryonic stem cells" as well as the derivation of stem cells.[29] A 2004 Canadian law declared, "No person shall knowingly create a human clone by using any technique," and barred payment to providers of sperm, eggs, or embryos.[30] Italy has some of the strictest cloning and embryo laws in Western Europe. It is illegal there to create human embryos for the purpose of research or experimentation, and all embryos created through IVF in Italy are required to be implanted in the recipient mother—thus preventing any leftover embryos from being used in research laboratories.[31] By 2005, over thirty countries around the world had banned all forms of human cloning.[32] That year, the United Nations General Assembly adopted a declaration calling on its member nations to "prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."[33] The declaration was ratified by 84 countries, including the United States, Mexico, Italy, and Germany. Notable countries to vote against the measure included the United Kingdom, which in 2001 became the first country explicitly to permit (with regulations) cloning-for-biomedical-research;[34] India, where national guidelines for the accreditation of fertility clinics state that "stem cell cloning and research on embryos (less than 15 days old) needs to be encouraged";[35] and South Korea, where women were coerced into donating their eggs for Hwang Woo Suk's fraudulent cloning research.[36]

Proposed language for laws prohibiting cloning in the United States almost always uses a technical definition of human cloning, focusing on restricting specific procedures, in contrast to the more expansive, conceptual definitions often found in other countries. The recent Harris bill, to choose just one representative example, defines the term "human cloning" as

> human asexual reproduction, accomplished by introducing the nuclear material of a human somatic cell into a fertilized or unfertilized oocyte whose nucleus has been removed or inactivated to produce a living organism (at any stage of development) with a human or predominantly human genetic constitution.[37]

Contrast that technical language with Canada's Assisted Human Reproduction law, which makes it a crime to

> create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device.[38]

"Human clone" is defined in the Canadian law as

> an embryo that, as a result of the manipulation of human reproductive material or an *in vitro* embryo, contains a diploid set of chromosomes obtained from a single—living or deceased—human being, foetus or embryo.[39]

This definition does not specify the technique of somatic cell nuclear transfer for prohibition, so the law encompasses other existing cloning technologies like induced twinning, as well as more speculative cloning technologies that might arise in the future.

Embryo Research and Federal Funding

While there are no federal laws that prohibit human cloning, there are some restrictions on the use of taxpayer dollars for cloning and related research. In December 1994, President Clinton used his executive authority to bar federal funding for embryos created specifically for research purposes.[40] Congress followed the next year by passing the Dickey-Wicker Amendment, which prohibited federal funding for "the creation of a human embryo or embryos for research purposes" or for research "in which embryos are created or destroyed."[41] The original text of the Dickey-Wicker Amendment included embryos produced through "cloning" in its funding prohibition; in 1997, the law's language was tweaked to address even more specifically the cloning technique used to make Dolly.[42] The Dolly announcement also prompted President Clinton to send a memorandum to the heads of executive departments and agencies in which he directed that no federal funds "shall be allocated for cloning of human beings."[43]

A congressional effort to write President Clinton's executive policy into law was never voted on.[44] Another legislative approach, which would have prohibited the federal government from entering into any contract whatsoever with organizations that performed cloning-for-biomedical-research in the preceding year, was repeatedly proposed by Representative Ron Paul (R.-Tex.), but it went nowhere.[45]

In 2001, President George W. Bush announced that his administration would permit federal funding of research conducted on human embryonic stem cell lines that had already been derived before his policy was announced.[46] This meant that even if privately funded researchers succeeded in deriving stem cells through cloning, research using those stem cells would have been ineligible for federal funding during the Bush

administration. In 2005 and again in 2007, Congress passed legislation, primarily with Democratic support, that would have overturned the Bush policy and made federal funds available for research on embryonic stem cells (including stem cells derived from privately funded cloning research), but President Bush vetoed both bills.[47]

In March 2009, President Barack Obama put in place a new policy authorizing the director of the National Institutes of Health (NIH) to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law."[48] In announcing his policy, President Obama stated that cloning-to-produce-children "is dangerous, profoundly wrong, and has no place in our society or any society."[49] A few months later, the NIH spelled out the details of the new policy, including a stipulation that research using stem cells derived from human cloning would not be eligible for government funding.[50] Of course, when President Obama crafted his stem cell funding policy there were no embryonic stem cell lines from cloned embryos, and it was not clear at that time if there ever would be. Their exclusion from eligibility for funding was therefore relatively easy. If, however, a president someday sought to fund research on stem cell lines derived from human embryos created through privately funded cloning, there is at present no legal obstacle preventing such a move.[51]

It is worth noting that the NIH currently has no restrictions on funding for cloning research involving non-human primates. According to the Center for Research Integrity, the NIH gave out over three dozen grants from 1991 to 2004 for cloning-related research on non-human primates.[52] Such research is one of the last steps on the road to cloning humans. Though one of Shoukhrat Mitalipov's close colleagues said in 2004 that "I wouldn't buy the argument that establishing cloning technology in monkeys is going to impact reproductive human cloning technology,"[53] after the 2007 breakthrough that allowed Mitalipov's team to make cloned embryos from adult monkeys, that same researcher declared, "It's proof of principle for human therapeutic cloning"[54]—and indeed this work did provide the foundation for "therapeutic cloning" in 2013. Recall, too, that Mitalipov and his colleagues have also sought to perform "reproductive cloning" with non-human primates, and announced some partial successes in that research in 2010, when they reported that a cloned rhesus monkey embryo developed enough for the scientists to detect a heartbeat before the pregnancy miscarried after 81 days.[55] Each incremental discovery can be understood as bringing us closer to cloning-to-produce-children.

Regulation of Egg Collection

Federal law prohibits the buying and selling of human organs.[56] However, this restriction does not apply to bodily materials such as blood, sperm, and eggs. While blood donors are typically uncompensated, gamete providers are typically compensated by IVF clinics, with egg providers typically paid around $5,000 per cycle.[57]

Two broad questions can be separated regarding egg collection: whether it should be outlawed because of the risks it poses to women, and whether remuneration should be allowed. With respect to the former, Japan fully bans collecting eggs from women because of the risks involved.[58] Most countries, however, permit egg collection for research and reproductive purposes as long as informed consent and other procedural conditions are satisfied.

Regarding the question of whether egg providers ought to be paid, some countries (such as Sweden[59]) prohibit remuneration for egg donation for anything other than direct expenses, and some states (as noted below) similarly prohibit payment when the eggs are used for research rather than reproductive purposes. Additionally, some national and state scientific funding agencies require that funded research be performed only using eggs from donors who did not receive payment for anything other than direct expenses, a policy endorsed by the National Academy of Sciences.[60]

State Policies Related to Cloning

Cloning policies at the state level vary widely, ranging from generous funding for cloning-for-biomedical-research to criminal prohibitions against it to no official policy whatsoever. As we describe in detail in the Appendix to this report, seven states (Arizona, Arkansas, Michigan, North Dakota, Oklahoma, South Dakota, and Virginia) ban all forms of human cloning, while ten states (California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Missouri, Montana, New Jersey, and Rhode Island) have so-called "clone-and-kill" laws. More than half of the fifty states currently have no laws addressing cloning.

Numbers do not tell the whole story, however, because arcane or unspecific language leaves laws in several states open to interpretation. For example, a 1973 statute in Minnesota would seem to forbid the destruction of cloned human embryos for research. It reads:

> Whoever uses or permits the use of a living human conceptus for any type of scientific, laboratory research, or other experimentation except

> to protect the life or health of the conceptus, or except as herein provided, shall be guilty of a gross misdemeanor.[61]

Although that law is on the books, it is not understood by the state's research community to prohibit embryo-destroying research.[62]

Funding practices also vary widely across the states. Five states (Arizona, Indiana, Louisiana, Michigan, and Nebraska) ban public funding for any kind of cloning research. Some states officially authorize public funding for cloning-for-biomedical-research, such as California (where a 2004 initiative created a ten-year, $3 billion commitment to stem cell research, including cloning-for-biomedical-research)[63] and New York (where the state government has given more than $300 million to fund stem cell research since 2007).[64] Meanwhile, other states have not passed funding bans simply because the legislatures there would be unlikely to approve such expenditures anyway, so a ban would be considered unnecessary. Missouri does not have a permanent statutory ban on funding for cloning research, but since 2007, the legislature has regularly included language in each appropriations bill restricting funding for human cloning.[65]

Oregon, where the first successful human cloning experiments were conducted in 2013, has no laws restricting, explicitly permitting, or funding human cloning.

State laws regarding compensation for egg collection also vary widely, even among states that strongly support cloning-for-biomedical-research. California prohibits compensation beyond reimbursement for direct expenses to women who provide eggs for research.[66] For this reason, publicly funded labs in California have not been able to use the cell lines created by Mitalipov's lab, which paid egg providers up to $5,000.[67] Massachusetts has also adopted a policy that prohibits any payments to women providing eggs for research.[68] New York, by contrast, permits compensation to egg providers in its publicly supported facilities.[69]

As described in the previous sections, opponents of human cloning in the United States have understandably been inclined to pursue a federal law prohibiting cloning nationally. However, it is important to pursue similar laws at the state level as well, in case federal courts strike down federal laws on constitutional or other grounds.

Cloning and the Constitution

Before turning to our policy recommendations in Part Five, it is important to consider the matter of legal and constitutional authority. Prohibiting

private individuals from engaging in scientific or medical activities, even a project as morally unacceptable as human cloning, requires constitutional justification. What provisions of the United States Constitution give the national government power to prohibit cloning-to-produce-children and cloning-for-biomedical-research? We here briefly consider several constitutional mechanisms for prohibiting human cloning and for legislating on human embryo research more generally.

Regulating commerce.

> The Congress shall have Power…To regulate Commerce with foreign Nations, and among the several States…[70]

Congress's broad enumerated power to regulate interstate commerce could be used to prohibit human cloning. That power has been interpreted by the Supreme Court to permit the regulation not only of the "channels" and "instrumentalities" of interstate commerce, but also of "activities that substantially affect interstate commerce."[71] To satisfy the requirement of "substantially" affecting interstate commerce, an activity that Congress wishes to regulate must be economic in nature and must be linked to interstate commerce through a causal chain that is not attenuated.[72] Cloning-to-produce-children would involve transactions with clients; cloning-for-biomedical-research would involve funding (even in nonprofit, educational research settings); both would presumably involve purchases of equipment from out-of-state vendors.[73]

There are precedents under the commerce clause for national regulation of activities related to reproduction. In 1994, Congress passed and President Clinton signed into law the Freedom of Access to Clinic Entrances Act, which restricts the ability of activists to protest near abortion clinics.[74] The U.S. Court of Appeals for the Seventh Circuit upheld the law, rejecting the argument that "Congress lacked authority to regulate activities affecting reproductive health services" and concluding that "the finding that reproductive health facilities are engaged in interstate commerce is rational" since such clinics "obviously purchase, use, and distribute goods from other States."[75] This rationale would also be applicable in the case of human cloning. Another relevant precedent is the Partial-Birth Abortion Ban Act, passed by Congress and signed into law by President Bush in 2003.[76]

Cloning could also be prohibited under Congress's enumerated power to regulate foreign commerce. Although this power has been the subject

of less judicial analysis than the interstate commerce power, "there is little reason to think that the meaning of 'commerce' should change across clauses."[77] While cloning-to-produce-children might not be said to be an activity that substantially affects commerce with foreign nations, cloning-for-biomedical-research, and indeed many other forms of research on human embryos, certainly would: embryonic stem cell lines derived from cloned embryos could be sold or shipped across the country and around the world (as stem cell lines derived from non-cloned sources already are), where they could be used for a variety of medical and commercial purposes.

Conditional funding.

> The Constitution empowers Congress to "lay and collect Taxes, Duties, Imposts, and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States."…Incident to this power, Congress may attach conditions on the receipt of federal funds, and has repeatedly employed the power "to further broad policy objectives by conditioning receipt of federal moneys upon compliance by the recipient with federal statutory and administrative directives."[78]

Another mechanism by which a nationwide prohibition on cloning could be implemented would be for the federal government to withhold certain forms of funding from states that engage in or do not forbid human cloning. Congress has used its spending power in this way to achieve a wide range of policy aims, most famously to create what amounted to a national 55-mile-per-hour speed limit[79] and a national minimum age for purchasing or possessing alcohol.[80] Such restrictions must be in pursuit of the general welfare, must be unambiguous, must be constitutional, must not be coercive, and must be reasonably related to the purpose of the expenditure.[81]

In the case of cloning, Congress could require that the Department of Health and Human Services (HHS) not approve funding through the National Institutes of Health for biomedical research projects in states in which cloning is being practiced or in which cloning or other forms of embryo-destroying research have not been expressly forbidden by law. By limiting the funding restriction to biomedical research through NIH (instead of also restricting funding for state-level work related to the Food and Drug Administration, the Centers for Disease Control and Prevention, or other agencies of HHS), Congress could ensure that the law would satisfy the requirements of not being coercive and of being reasonably related to the expenditure.

Such a law would not guarantee that all states would prohibit human cloning; some might elect to forgo NIH funding in order to continue permitting cloning. But states with major research universities—such as California, which received $3.4 billion from NIH in fiscal year 2014, Massachusetts, which received $2.4 billion, and New York, which received $2.1 billion—might be inclined to prohibit cloning in order to keep the federal dollars flowing.[82] Oregon, where the 2013 cloning experiments were performed, received $300 million from NIH in 2014,[83] a figure likely sufficient for the state's government to consider halting early forays into this unethical area of research.

Intellectual property.

> The Congress shall have Power…To 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.…[84]

Congress's enumerated power over the instruments of intellectual property could be used to prohibit patents relating to human cloning, thereby reducing the financial incentive to engage in cloning activities. The United States Patent and Trademark Office (USPTO) is already forbidden, under a measure that has been approved in each congressional appropriations cycle since 2004, from issuing patents "directed to or encompassing" human organisms (including embryos).[85] There has been some confusion about whether this provision might apply to human cloning. Representative Lamar Smith (R.-Tx.) has said that "It's directed at preventing the [USPTO] from approving inventions related to human cloning."[86] But the author of the provision, Representative Dave Weldon (R.-Fla.), has specified that while it prohibits patents directly on human organisms, it "should not be construed" to prohibit patents on "methods for creating, modifying, or treating human organisms, including but not limited to methods for creating human embryos through in vitro fertilization, somatic cell nuclear transfer, or parthenogenesis."[87] Congress could expand this provision by prohibiting USPTO from issuing patents for methods of creating human embryos through cloning techniques like somatic cell nuclear transfer, or even by prohibiting USPTO from issuing patents for *any* methods of creating human embryos. Such a prohibition could also apply to the products of cloning or of embryo-destroying research, including embryonic stem cell lines.

(Interestingly, a recent ruling suggests that specific cloned *animals*, too, may not be patentable. The U.S. Court of Appeals for the Federal

Circuit ruled in 2014 that "Dolly's genetic identity to her donor parents renders her unpatentable," since the cloned sheep is not "markedly different" from sheep found in nature.[88] However, the *method* used to clone Dolly was legitimately patented.[89] In general, the legality of biological patents is governed by a still-evolving body of policy promulgated by the USPTO in response to several court rulings—a complicated subject beyond the scope of this report.)

Prohibiting patents on human cloning methods would likely reduce the incentive for those who might hope to profit from the adoption of cloning by the fertility industry. And prohibiting patents on the products of cloning would likely reduce the incentives to engage in cloning-for-biomedical-research. As of this writing, human embryonic stem cell lines can be patented,[90] and U.S. patents have been granted for embryonic stem cells derived through cloning (including, ironically, the stem cell line falsely claimed to have been derived from cloned embryos made by Korean stem cell fraudster Hwang Woo Suk).[91]

One could argue that prohibiting patents on human cloning methods might have the unintended effect of encouraging some parties to engage in cloning, since they will not have to pay to use others' intellectual property related to cloning. This argument assumes that the cost of licensing patented methods would represent a significant barrier to entering the field, which seems unlikely to us. However, this argument does suggest that the intellectual-property approach to restricting cloning ought to be seen as an addition, not an alternative, to the other approaches described here.

Equal protection.

> [N]or shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.… The Congress shall have power to enforce, by appropriate legislation, the provisions of this article.[92]

The Fourteenth Amendment gives Congress power to enact laws ensuring that states do not deprive "any person" of life without due process, and that states do not deny to "any person" the equal protection of the laws.[93] Since human embryos (cloned or otherwise) are human organisms at the earliest stage of life, and so can arguably be considered "persons" deserving of this protection, Congress could pass laws forbidding the intentional destruction of human embryos by states.[94] Using this power, Congress could prevent embryo-destructive research, including

cloning research, from being conducted in state-operated laboratories and from being conducted with state funds. Congress could also use this power to strike down the "clone-and-kill" laws now on the books in ten states, laws that legally prohibit cloned embryos from being implanted in a woman's uterus, thereby depriving persons of life.

We mention in passing one other possible constitutional mechanism for legislation: the Thirteenth Amendment's prohibition of slavery and involuntary servitude.[95] While not directly relevant to human cloning as it seems likely to develop in the near future, this prohibition could be used as justification for legally proscribing some of the scenarios we described in Part Three, such as the intentional creation of human beings for the purpose of harvesting their organs.

Potential Constitutional Challenges to a National Cloning Prohibition

Supporters of human cloning might claim that a prohibition on cloning violates putative constitutional rights. Here we proleptically address two such potential objections.

Would prohibiting cloning violate a right to "reproductive freedom"? Now that human embryos have been successfully created through cloning, we may be approaching a day—perhaps in just the next few years—when some fertility clinics might choose to offer cloning as a reproductive option to clients, or when would-be parents might request cloning as a reproductive service. In such circumstances, judicial challenges to restrictions on human cloning may become a serious policy matter, so it is worth reviewing previous court decisions that may bear on the question of whether cloning may be protected under a constitutional right to reproductive freedom.

Federal jurisprudence in this area is notoriously contentious. In 1965, the Supreme Court struck down a state contraception ban on the grounds that it violated the "right to marital privacy."[96] A subsequent ruling, also related to contraception, was even more expansive: "If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[97] *Roe v. Wade* in 1973 placed "a woman's decision whether or not to terminate her pregnancy" under the same "right of privacy."[98] In *Planned Parenthood v. Casey*, a 1992 case that reaffirmed the "essential holding" of

Roe, the Court put an individual's decisions over procreative matters in the broadest possible context:

> These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.[99]

Lower courts have drawn on the Supreme Court's jurisprudence about contraception and abortion (technological ways to not have a baby) in deciding cases related to assisted reproduction (technological ways to have a baby). In the first American court case addressing surrogacy arrangements, the Supreme Court of New Jersey declared in 1988 that "the right to procreate very simply is the right to have natural children, whether through sexual intercourse or artificial insemination."[100] A federal court in Illinois ruled in 1990 that IVF is constitutionally protected, stating "It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included . . . the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."[101] In 1991, a federal court in Ohio ruled in favor of a teacher who sued her school district after being fired for using artificial insemination, noting, "A woman has a constitutional privacy right to control her reproductive functions. Consequently, a woman possesses the right to become pregnant by artificial insemination."[102] These and many other precedents are often taken together to suggest that there exists a constitutionally protected right to reproductive freedom; they could be used to support an argument for permitting a right to cloning-to-produce-children.

However, even today reproductive freedom is not unlimited. For example, under current Supreme Court jurisprudence, Congress and the states can enact laws restricting abortion so long as those laws do not impose an "undue burden" on access to abortion.[103] And, in an intriguing analogy to cloning suggested by law professor Lori B. Andrews, we also restrict incest.[104] Incest involves some risk of physical harm to offspring, as well as the confounding and perversion of generational and other familial relationships. Restrictions on cloning-to-produce-children can be defended on both those same grounds.

Would prohibiting human cloning infringe on the "right of scientific inquiry"? Some policymakers and legal analysts have argued that prohibiting cloning-for-biomedical-research would violate an amorphous right under the First Amendment to engage in scientific experimentation.

During the first wave of cloning debates in the late 1990s, Senator Tom Harkin (D.-Iowa) argued that there are no "appropriate limits to human knowledge. None, whatsoever.... To my friends Senator Bond and President Clinton who are saying 'Stop, we can't play God,' I say 'Fine. Take your ranks alongside Pope Paul V, who in 1616 tried to stop Galileo.'"[105] According to law professor R. Alta Charo, some experiments can be protected under the First Amendment. "If the questions you ask and the science you do really challenges or explores cultural or religious or political norms," she has said, "that in itself is an act of rebellion, and this is exactly the sort of thing that fits comfortably in the spirit of the First Amendment."[106] An extreme version of the argument for a constitutionally protected right to research was articulated in 1978, by law professor John A. Robertson. If the First Amendment "serves to protect free trade in the dissemination of ideas and information," he wrote, "it must also protect the necessary preconditions of speech, such as the production of ideas and information through research."[107]

These arguments in favor of a First Amendment right to research conflate science's role as a source of and a way of communicating knowledge with the actions that scientists take in pursuit of knowledge. Some actions can indeed be counted as speech and therefore protected under the First Amendment; they must be "sufficiently imbued with elements of communication," which can be determined by asking whether "an intent to convey a particularized message was present, and [whether] in the surrounding circumstances the likelihood was great that the message would be understood by those who viewed it."[108] It is difficult to imagine cases when scientific research *qua* research could justifiably be considered that kind of expressive conduct. However, as scientist and attorney Steve Keane has argued, the presence of "public or governmental disapproval" could ironically create a situation in which a scientist could claim that engaging in certain kinds of scientific research might qualify as expressive conduct, "with the expression owing its existence to the external factor of public disapproval."[109] Yet (as Keane himself notes), that is not the end of the story: even scientific research that is expressive can be restricted so long as the restriction is "within the constitutional power of the government"; "furthers an important or substantial governmental interest"; the asserted interest is "unrelated to the suppression of free

expression"; and "the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest."[110] It is unlikely that any of those criteria could be used to challenge on First Amendment grounds the sorts of proposed laws and regulations prohibiting human cloning that we discuss in these pages.

Finally, it is worth noting that there are already many examples of restrictions on scientific research today, most obviously laws and regulations protecting human research subjects and the welfare of animals used in experiments.[111]

The Moratorium Option and Its Flaws

A measure sometimes suggested for legislating on human cloning—and often suggested as a compromise between doing nothing and passing a law prohibiting cloning outright—is a moratorium set to expire ("sunset") after some length of time. If, the argument goes, a moratorium on all forms of human cloning could be passed, this would put a stop to ongoing research, without the troubling moral consequences of "clone-and-kill" laws that some states have adopted. The distinction between a temporary moratorium and a permanent prohibition is not clear-cut, since Congress can revisit and overturn past laws or can indefinitely renew any temporary moratorium.

Some policymakers may find a cloning moratorium attractive because it would imply that the justification for a prohibition may change in the future. But the most important reasons for outlawing human cloning are not historically relative. The chief arguments against cloning—that it would warp the relationship between the generations and that it is an unjust and destructive exploitation of human life—will not lose their force no matter what scientific or cultural developments take place in the coming years, and the first experimental use of cloning-to-produce-children will always be an unethical form of human experimentation. Furthermore, there is no reason to suppose that we will have better conditions for reasoning about the morality of human cloning in the future than we do today.

Conclusion: Cloning Policy

Despite widespread agreement in the wake of the Dolly announcement that at least cloning-to-produce-children should be prohibited, and despite many efforts from legislators to enact such a prohibition, there is no nationwide prohibition on cloning in the United States. But laws

and regulations prohibiting cloning can be crafted to comport with the Constitution, and to overcome objections related to reproductive freedom and the First Amendment. In the final section of this report, we recommend policies that can be implemented to put a stop to human cloning.

Part Five

Recommendations

Cloning-to-produce-children is inherently unethical. It would confound family structures and badly distort the relationship between the generations; transform procreation into manufacturing; and accelerate the dangerous trend toward treating children as products that can be made to order instead of as new and unique beings. Furthermore, the first instances of cloning-to-produce-children would be dangerous and unpredictable experiments that are medically unnecessary for the human subjects—the children being created—and to which they could not consent.

Cloning-for-biomedical-research is also inherently unethical, involving as it does the intentional creation of embryonic human beings for the purpose of destroying them by using them as a source of research material. Cloning research requires the harvesting of large numbers of egg cells, which means subjecting women to dangerous hormone treatments. And it risks sending us down a path toward fetal farming, artificial wombs, genetic engineering, and other immoral activities.

The justification for engaging in cloning-for-biomedical-research is weaker than ever before, thanks to the availability of viable alternative sources of pluripotent stem cells. And yet experiments have continued, bringing us closer to the day when a pregnancy can be initiated with an embryo created through cloning. The practice of science in a free society is not exempt from democratic oversight, and in the case of cloning, such oversight is urgently needed. The time to act is now.

I. Congress Should Prohibit All Forms of Human Cloning and the Creation of Embryos for Research

Congress should pass and the president should sign legislation that:

> **(1) makes it unlawful for any person or entity, public or private, in or affecting interstate or foreign commerce, knowingly to clone a human being (defined as the act of creating an embryo that, as a result of the manipulation of human reproductive material, including any human cells, genes, or their parts, or an *in vitro* embryo, contains a diploid set of chromosomes obtained from a single—living or deceased—human being, fetus or embryo);**

[The measure above would effectively prohibit both cloning-to-produce-children and cloning-for-biomedical-research. The conceptual definition provided here would prohibit cloning by somatic cell nuclear transfer, the most common method used for human cloning today, as well as other existing techniques for cloning, such as the deliberate splitting of embryos, and also speculative techniques for human cloning such as tetraploid complementation—but without prohibiting ethically acceptable research that scientists sometimes identify as "cloning," such as the "cloning" of DNA molecules or human cells.]

(2) makes it unlawful for any person or entity, public or private, in or affecting interstate or foreign commerce, knowingly to create a human embryo (defined as any organism that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells) or embryos for research purposes;

[The measure above would effectively prohibit the creation of embryos for research—which is always an unethical exploitation of human life, lays the groundwork for many of the same unethical technologies that human cloning might make possible, and requires the collection of human egg cells, putting women at risk.]

(3) prohibits the Department of Health and Human Services from providing funds for the creation of a human embryo or embryos for research purposes, or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed under existing federal regulations and codes governing research involving pregnant women or fetuses;

[The measure above would make the Dickey-Wicker Amendment, which today must be renewed with each federal appropriations cycle, permanent. While this measure would to some extent be redundant with previous portions of our recommendations, it would provide an additional means of preventing unethical research if the other portions of the legislation recommended here were struck down. Subsequent congressional appropriations specifying funding contrary to this measure would override it, but unless such appropriations were enacted, this measure would hold.]

(4) prohibits the Department of Health and Human Services from funding biomedical research in any state in which all forms of human cloning have not been prohibited;

[Although this measure, too, might seem redundant in light of the general prohibition recommended above, it would provide an incentive for state governments to pass legislation restricting human cloning, thereby reducing the possibility that cloning could proceed on an intrastate basis.]

(5) prohibits the United States Patent and Trademark Office from issuing patents on claims directed to or encompassing a human organism (at whatever stage of development), for methods of creating human embryos (including cloning), and for any products derived from or necessitating the destruction of human embryos (including embryonic stem cell lines), and voiding any such patents already issued.

[This measure would extend current restrictions on the U.S. Patent and Trademark Office in the America Invents Act of 2011 and in the Weldon Amendment, which today is renewed with each federal appropriations cycle. While this measure may seem largely redundant given the preceding portions of these recommendations, it would provide an additional means of discouraging human cloning and embryo research in case other measures in these recommendations were struck down.]

The constitutional authority for these provisions is discussed in Part Four of this report.

II. States Should Also Prohibit Human Cloning and the Creation of Embryos for Research

State governments should enact laws that:

(1) make it unlawful for any person or entity, public or private, knowingly to clone a human being (defined as the act of creating an embryo that, as a result of the manipulation of human reproductive material, including any human cells, genes, or their parts, or an *in vitro* embryo, contains a diploid set of chromosomes obtained from a single—living or deceased—human being, fetus or embryo); and

(2) make it unlawful for any person or entity, public or private, knowingly to create a human embryo (defined as any organism that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells) or embryos for research purposes.

As described in this report's Appendix, several states have already passed laws that permit the creation through cloning of human embryos but that forbid the transfer of such embryos to women's uteri. Such an approach is tantamount to a legal requirement that human embryos created through cloning must be frozen indefinitely or destroyed. Legislators in states that have adopted such "clone-and-kill" laws should repeal and replace them. While comprehensive laws prohibiting human cloning, of the sort outlined here, are ideal, even altering some of the language in state laws prohibiting cloning-to-produce-children could make them less morally troubling. As noted in Part Four, a bill in the U.S. House of Representatives sponsored by Representative Brian D. Kerns in 2001 would have prohibited creating cloned embryos with the intent of implanting them into a uterus. Such a law would not prohibit the cloning or destruction of human embryos for research, but it would likewise not require the destruction of cloned embryos. Although we do not endorse this proposal, it is a less morally problematic way to prohibit cloning-to-produce-children than through "clone-and-kill" laws.

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Appendix

State Laws on Human Cloning

There are no federal laws regulating human cloning in the United States, with the exception of laws and policies restricting the federal government from funding human cloning research. However, many states have passed laws on human cloning. Of the states with cloning laws,

- 7 states (Arizona, Arkansas, Michigan, North Dakota, Oklahoma, South Dakota, and Virginia) clearly prohibit both cloning-to-produce-children and cloning-for-biomedical-research;

- 10 states (California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, Missouri, Montana, New Jersey, and Rhode Island) prohibit cloning-to-produce-children while permitting cloning-for-biomedical-research, therefore legally requiring any cloned human embryos to be frozen in perpetuity or destroyed (so-called "clone-and-kill" laws); and

- 1 state (Minnesota) has a statute that would *seem* to prohibit cloning-for-biomedical-research while not addressing the issue of cloning-to-produce-children.

Other states have laws that indirectly address human cloning, either by providing or prohibiting government funding for cloning research, or by explicitly protecting doctors who object to human cloning on grounds of conscience.

Alabama. There are currently no laws in Alabama that prohibit human cloning, whether for biomedical research or to produce children.

Alaska. There are currently no laws in Alaska that prohibit human cloning, whether for biomedical research or to produce children.

Arizona. All forms of human cloning have been prohibited in Arizona since 2010, when the state amended its statutory code to forbid any "attempt to create an *in vitro* human embryo by any means other than fertilization through the combining of a human egg with a human sperm."[1]

The law also states that "a person shall not intentionally or knowingly engage in destructive human embryonic stem cell research."[2] The state also prohibits public funds from being used for "somatic cell nuclear transfer, commonly known as human cloning."[3]

Arkansas. All forms of human cloning are banned in Arkansas. In 2003, the state passed a law prohibiting the production, purchase, sale, and transportation of human clones. The law defines "cloning" as "human asexual reproduction, accomplished by introducing the genetic material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism, at any stage of development, that is genetically virtually identical to an existing or previously existing human organism."[4]

In addition, the law makes it illegal to "ship, transfer, or receive, in whole or in part, any oocyte, embryo, fetus, or human somatic cell, for the purpose of human cloning."[5] The law still permits research using nuclear transfer for producing "molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans," as well as for conducting IVF and other reproductive techniques, so long as the procedures are not used for the intentional "gestation or birth" of human clones.[6]

California. Cloning-to-produce-children is illegal in California, while cloning-for-biomedical-research is protected under the state's constitution and is funded by a state agency. The state originally passed a cloning law in 1997, amending its Health and Safety Code to make it illegal to "clone a human being."[7] The law defined cloning as "the practice of creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human egg cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being."[8] The 1997 law included a sunset provision by which the law would expire on January 1, 2003.[9]

An amended version of the 1997 law was enacted in 2002.[10] The new law made it illegal to "clone a human being or engage in human reproductive cloning," and slightly amended the definition of cloning to include the use of "nonhuman" as well as human egg cells.[11] (This change was presumably made in order to ensure that the law will prohibit interspecies cloning at least for reproductive purposes.) "Human reproductive cloning" was defined as "the creation of a human fetus that is substantially

genetically identical to a previously born human being,"[12] though the state's Department of Health Services was given authority to "adopt, interpret, and update regulations, as necessary, for purposes of more precisely defining the procedures that constitute human reproductive cloning."[13]

In 2004, the Proposition 71 ballot initiative was approved by the state's voters, amending California's constitution to protect explicitly cloning-for-biomedical-research: "Pluripotent stem cells may be derived from somatic cell nuclear transfer."[14] Proposition 71 also established the California Institute for Regenerative Medicine, which provides funding for stem cell research, including cloning-for-biomedical-research.[15]

It is worth noting that California law prohibits cloning *for the purpose of* initiating a pregnancy, rather than prohibiting *the actual initiation of* a pregnancy by transferring cloned embryos to a woman's uterus. This means that California does not expressly require the destruction of all cloned human embryos, as some states do, but given that cloning-for-biomedical-research is expressly protected by the state's constitution, the result is effectively the same: researchers can create embryos through cloning, but can only do so if they intend to destroy them to create embryonic stem cells.

California law prohibits researchers from paying for egg cells,[16] and the state's stem cell research guidelines do not allow research on stem cell lines derived from cloned embryos created using egg cells that have been paid for by scientists.[17]

Colorado. There are currently no laws in Colorado that prohibit human cloning, whether for biomedical research or to produce children.

Connecticut. Cloning-for-biomedical-research is legal in Connecticut, while cloning-to-produce-children is against the law. In 2005, Connecticut passed a law prohibiting human cloning, somewhat bizarrely defining cloning as "inducing or replicating a living human being's complete set of genetic material to develop after gastrulation commences."[18] The law defines gastrulation as "the process immediately following the blastula state when the hollow ball of cells representing the early embryo undergoes a complex and coordinated series of movements that results in the formation of the three primary germ layers, the ectoderm, mesoderm and endoderm."[19] Under these definitions, Connecticut law prohibits cloning-to-produce-children but permits cloning-for-biomedical research.

Delaware. There are currently no laws in Delaware that prohibit human cloning, whether for biomedical research or to produce children.

Florida. There are currently no laws in Florida that prohibit human cloning, whether for biomedical research or to produce children.

Georgia. There are currently no laws in Georgia that prohibit human cloning, whether for biomedical research or to produce children.

Hawaii. There are currently no laws in Hawaii that prohibit human cloning, whether for biomedical research or to produce children.

Idaho. Idaho state law currently does not include any statutes prohibiting either cloning-for-biomedical-research or cloning-to-produce-children. However, in 2010, Idaho enacted a conscience-protection law that includes "human embryo cloning" among the "health care services" to which health care professionals may object on grounds of conscience.[20]

Illinois. It is legal to conduct cloning-for-biomedical-research in Illinois, but cloning-to-produce-children is outlawed in the state. The Stem Cell Research and Human Cloning Prohibition Act of 2008 makes it illegal "to transfer to a uterus or attempt to transfer to a uterus anything other than the product of fertilization of an egg of a human female by a sperm of a human male for the purpose of initiating a pregnancy that could result in the creation of a human fetus or the birth of a new human being."[21] By prohibiting the transfer of a cloned human embryo to the uterus of a woman, this law would require embryos created through cloning—or through some other experimental techniques—to be either frozen in perpetuity or destroyed. The 2008 law also explicitly permits public funds to be used to support cloning-for-biomedical-research.[22]

Indiana. Indiana law does not directly prohibit human cloning either for the purposes of biomedical research or to produce children, though the state does have laws that indirectly restrict all forms of cloning. In 2005, Indiana passed a law on stem cell research and cloning[23] that declared cloning to be "against public policy,"[24] prohibited state funding for human cloning, and prohibited state educational institutions or employees from participating in cloning.[25] Furthermore, any hospital that knowingly allows its facilities to be used for human cloning or its employees to participate in human cloning will have its license revoked by the state's health

commissioner.[26] Indiana law defines "cloning" as "the use of asexual reproduction to create or grow a human embryo from a single cell or cells of a genetically identical human."[27]

Indiana's cloning law is somewhat ambiguous, since the law is directed primarily against hospitals and state educational institutions. Researchers at a private university, biotechnology company, or assisted reproduction clinic not licensed as a hospital may not face legal consequences for engaging in either cloning-for-biomedical-research or cloning-to-produce-children.

Iowa. Iowa prohibits cloning-to-produce-children but permits cloning-for-biomedical-research. In 2007, the state enacted the Iowa Stem Cell Research and Cures Initiative, which prohibits "human reproductive cloning."[28] The law defines human reproductive cloning as "human asexual reproduction, using somatic cell nuclear transfer, for implantation or attempted implantation into a woman's uterus or substitute for a woman's uterus."[29] The Iowa law's definition of "human reproductive cloning" also explicitly states that the term's meaning does not include "somatic cell nuclear transfer performed for the purpose of creating embryonic stem cells."[30] This means Iowa law permits the creation of cloned human embryos for the purpose of stem cell research, but requires that cloned human embryos be frozen in perpetuity or destroyed.

Kansas. There are currently no laws in Kansas that prohibit human cloning, whether for biomedical research or to produce children.

Kentucky. There are currently no laws in Kentucky that prohibit human cloning, whether for biomedical research or to produce children.

Louisiana. There are currently no laws in Louisiana that directly prohibit human cloning, whether for biomedical research or to produce children. In 1999, Louisiana did enact a law that prohibited cloning-to-produce-children while permitting cloning-for-biomedical-research, but that law included a sunset provision, and it expired without being renewed in 2003.[31] In 2008, Louisiana amended its statutory code to prohibit the state from providing funding for somatic cell nuclear transfer, effectively barring the state from funding either cloning-for-biomedical-research or cloning-to-produce-children.[32] A 2009 Louisiana conscience-protection law also includes "human embryo cloning" among the health care services that "no person shall be required to participate in."[33]

Maine. There are currently no laws in Maine that prohibit human cloning, whether for biomedical research or to produce children. The state does, however, prohibit the "use [of]…any live human fetus, whether intrauterine or extrauterine…for scientific experimentation or for any form of experimentation."[34] While this law prevents research on cloned human fetuses, it does not prohibit the destruction of cloned human embryos to create stem cells.

Maryland. Maryland prohibits cloning-to-produce-children while permitting cloning-for-biomedical-research. In 2006, the state enacted the Maryland Stem Cell Research Act,[35] establishing a fund for stem cell research[36] and prohibiting "human cloning."[37] The law defines human cloning as "the replication of a human being through the production of a precise genetic copy of nuclear human DNA or any other human molecule, cell, or tissue in order to create a new human being or to allow development beyond an embryo."[38] The law further stipulates that "nothing in this part may be construed to prohibit the creation of stem cell lines to be used for therapeutic research purposes,"[39] making it clear that cloning-for-biomedical-research is permitted in the state. The law also specifies that anyone conducting state-funded research shall not "engage in any research that intentionally and directly leads to human cloning."[40]

Massachusetts. Massachusetts prohibits cloning-to-produce-children while permitting cloning-for-biomedical-research. In 2005, Massachusetts enacted a law prohibiting "reproductive cloning" without specifically defining the term.[41] While the state prohibits the creation of human embryos through fertilization for research purposes, it explicitly allows "the creation of a pre-implantation embryo by somatic cell nuclear transfer, parthenogenesis or other asexual means for research purposes."[42] The state also prohibits payment for gametes, including human egg cells.[43]

In its practical effect, the Massachusetts law is not very different from most of the "clone-and-kill" laws enacted elsewhere, and by prohibiting scientists from creating embryos for research in some cases, it arguably reduces the opportunities for the exploitation of human life. However, in another respect, the law represents an even more troubling variation of the "clone-and-kill" model. In most other states with "clone-and-kill" laws, the implicit principle justifying the exploitation of embryos for research is that they are developmentally immature and so lack the requisite moral status for protection. Under the Massachusetts law, however, the moral status of

an embryo depends on the method through which it was created; embryos created through experimental techniques such as cloning are singled out for destructive exploitation.

Michigan. Michigan prohibits both cloning-for-biomedical-research and cloning-to-produce-children. In 1998, Michigan amended its public health law to prohibit human cloning, defining cloning as "the use of human somatic cell nuclear transfer technology to produce a human embryo," with human embryo defined as "a human egg cell with a full genetic composition capable of differentiating and maturing into a complete human being."[44] The state also passed a law in 1998 that prohibited the use of state funds for human cloning.[45]

Minnesota. While there are no Minnesota state laws that explicitly prohibit either cloning-to-produce-children or cloning-for-biomedical-research, the state's 1973 Human Conceptus Statute *may* prohibit cloning-for-biomedical-research (though not cloning-to-produce-children). The law prohibits "the use of a living human conceptus for any type of scientific, laboratory research or other experimentation except to protect the life or health of the conceptus," and makes it illegal "to buy or sell a living human conceptus."[46] The law defines "human conceptus" as "any human organism, conceived either in the human body or produced in an artificial environment other than the human body from fertilization through the first 265 days thereafter."[47] "Fertilization" is not defined in the law, so there is some ambiguity as to whether the law would apply only to embryos created through the union of sperm and egg cells, or also to embryos created through other means such as cloning.

In 2009, lawmakers amended the state's higher education appropriations act to prohibit the University of Minnesota from using state funds for cloning research.[48]

In 2011, the state legislature passed the Human Cloning Prohibition Act, which would have prohibited human cloning, defining cloning as "human asexual reproduction accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism at any stage of development that is genetically virtually identical to an existing or previously existing human organism."[49] However, the bill was vetoed by Governor Mark Dayton,[50] who also vetoed a bill that would have prohibited the state from funding cloning research.[51]

Mississippi. There are currently no laws in Mississippi that prohibit human cloning, whether for biomedical research or to produce children.

Missouri. Missouri prohibits cloning-to-produce-children but permits cloning-for-biomedical-research. In 2006, Missouri amended Article III of its constitution with section 38(d), titled the "Missouri Stem Cell Research and Cures Initiative."[52] This change to the Missouri constitution made it illegal to "clone or attempt to clone a human being,"[53] where cloning means "to implant in a uterus or attempt to implant in a uterus anything other than the product of fertilization of an egg of a human female by a sperm of a human male for the purpose of initiating a pregnancy that could result in the creation of a human fetus, or the birth of a human being."[54] The Missouri constitution thus requires that all human embryos created through cloning or through other experimental technologies must be frozen in perpetuity or destroyed. The constitution also prohibits the creation of human embryos solely for research, but only if those embryos are created through fertilization—leaving scientists free to create embryos through techniques like cloning solely for the purpose of exploitative research.[55]

However, the constitution does make it illegal to "purchase or sell human blastocysts or eggs for stem cell research,"[56] a measure that is sure to make it difficult for cloning-for-biomedical-research to proceed in the state.

Montana. Montana prohibits cloning-to-produce-children but permits cloning-for-biomedical-research. The state enacted a law in 2009 prohibiting any attempt "to perform reproductive cloning,"[57] defining reproductive cloning as "human cloning intended to result in the gestation or birth of a child who is genetically identical to another conceptus, embryo, fetus, or human being, living or dead."[58] The law explicitly carves out an exception for "research into the use of nuclear transfer or other cloning techniques to produce molecules, deoxyribonucleic acid, tissues, organs, plants, cells other than human embryos, or animals other than humans."[59]

The law is ambiguous: it mentions human embryos only to exclude them from the list of explicitly permitted uses of nuclear transfer, but the law does not actually *forbid* the creation of human embryos through nuclear transfer. The state seems to permit cloning-for-biomedical-research. However, the law does not explicitly require that cloned human embryos be kept frozen in perpetuity or destroyed, but rather prohibits the act of creating cloned human embryos with the intention to transfer them to a woman's uterus to produce a child.

Nebraska. Nebraska has no laws directly prohibiting either cloning-for-biomedical-research or cloning-to-produce-children, but a 2008 law does prohibit the Nebraska government from funding somatic cell nuclear transfer, which effectively prohibits state funding for any form of human cloning.[60]

Nevada. There are currently no laws in Nevada that prohibit human cloning, whether for biomedical research or to produce children.

New Hampshire. There are currently no laws in New Hampshire that prohibit human cloning, whether for biomedical research or to produce children.

New Jersey. New Jersey permits cloning-for-biomedical-research and prohibits cloning-to-produce-children. Under a 2004 New Jersey law, "cloning of a human being" is defined as "the replication of a human individual by cultivating a cell with genetic material through the egg, embryo, fetal and newborn stages into a new human individual."[61] However, the law permits "research involving the derivation and use of human embryonic stem cells, human embryonic germ cells and human adult stem cells, including somatic cell nuclear transplantation."[62] The law does not expressly prohibit the act of transferring cloned embryos to a woman's uterus; rather, the law employs the more vague language of "cultivating a cell."[63] Nonetheless, New Jersey's law requires all cloned human embryos to be either kept frozen in perpetuity or destroyed. In 2007, the citizens of New Jersey voted down a ballot initiative to establish a stem cell research fund, which would have funded cloning-for-biomedical-research by issuing $450 million in bonds.[64]

New Mexico. There are currently no laws in New Mexico that prohibit human cloning, whether for biomedical research or to produce children.

New York. New York law does not directly prohibit cloning-to-produce-children or cloning-for-biomedical research. In 2007, the state created the Empire State Stem Cell Board, a panel that guides the state's expenditures on stem cell research; the board is prohibited from funding research on "reproductive cloning."[65] In 2009, the board decided to permit funding for research on stem cell lines derived from embryos that had been created using eggs paid for by researchers.[66]

North Carolina. There are currently no laws in North Carolina that prohibit human cloning, whether for biomedical research or to produce children.

North Dakota. North Dakota prohibits all forms of human cloning. In 2003, North Dakota amended its statutory code to prohibit human cloning, where "'human cloning' means human asexual reproduction, accomplished by introducing the genetic material of a human somatic cell into a fertilized or unfertilized oocyte, the nucleus of which has been or will be removed or inactivated, to produce a living organism with a human or predominantly human genetic constitution."[67] The inclusion of the phrase "predominantly human genetic constitution" presumably is intended to ensure that the law will prohibit interspecies cloning.

Ohio. There are currently no laws in Ohio that prohibit human cloning, whether for biomedical research or to produce children.

Oklahoma. Oklahoma prohibits all forms of human cloning. In 2009, the state amended its statutory code to prohibit human cloning, defining human cloning as "human asexual reproduction, accomplished by introducing the nuclear material of a human somatic cell into a fertilized or unfertilized oocyte whose nucleus has been removed or inactivated to produce a living organism (at any stage of development) with a human genetic constitution."[68] The law also makes it illegal to "ship, transfer, or receive the product of human cloning for any purpose" and to "import the product of human cloning for any purpose."[69]

Oregon. There are currently no laws in Oregon that prohibit human cloning, whether for biomedical research or to produce children.

Pennsylvania. There are currently no laws in Pennsylvania that directly prohibit cloning, whether for biomedical research or to produce children.

Rhode Island. Rhode Island permits cloning-for-biomedical-research while prohibiting cloning-to-produce-children. The state has in fact passed three cloning laws, each with sunset provisions. The first, passed in 1998, was due to expire in 2003.[70] The law was renewed in 2002, but that law expired in 2010[71] before a new law was again passed in 2013; it is set to expire in 2017.[72] The current law makes it illegal to use "somatic cell nuclear transfer for the purpose of initiating or attempting to initiate

a human pregnancy"; it also prohibits the creation of "genetically identical human beings by dividing a blastocyst, zygote, or embryo."[73] The prohibition against dividing embryos is likely meant to forbid doctors from using embryo-splitting techniques to induce twinning in IVF embryos, a form of cloning-to-produce-children that is often ignored by legislators. However, the law explicitly permits somatic cell nuclear transfer, making it mandatory in Rhode Island for scientists either to freeze in perpetuity or to destroy any cloned embryos they create.

South Carolina. There are currently no laws in South Carolina that prohibit human cloning, whether for biomedical research or to produce children.

South Dakota. South Dakota prohibits all forms of human cloning. A 2004 law makes human cloning illegal, defining human cloning as "human asexual reproduction accomplished by introducing the nuclear material of a human somatic cell into a fertilized or unfertilized oocyte whose nucleus has been removed or inactivated to produce a living organism, at any stage of development, with a human or predominantly human genetic constitution."[74] This law therefore prohibits all forms of human cloning; its inclusion of organisms with a "predominantly human constitution" is presumably intended to ensure that the law will prohibit interspecies cloning.

Tennessee. There are currently no laws in Tennessee that prohibit human cloning, whether for biomedical research or to produce children.

Texas. There are currently no laws in Texas that prohibit human cloning, whether for biomedical research or to produce children.

Utah. There are currently no laws in Utah that prohibit human cloning, whether for biomedical research or to produce children.

Vermont. There are currently no laws in Vermont that prohibit human cloning, whether for biomedical research or to produce children.

Virginia. Virginia prohibits cloning-for-biomedical-research as well as cloning-to-produce-children. Virginia law is unusual insofar as its prohibitions against cloning appear to be redundant, and its prohibition of cloning-to-produce-children includes language commonly found in "clone-and-kill" laws.

A state law enacted in 2001 prohibits human cloning, which it defines as "the creation of or attempt to create a human being by transferring the nucleus from a human cell from whatever source into an oocyte from which the nucleus has been removed."[75] Under this definition, the law would appear to prohibit all forms of human cloning.

The law also makes it illegal to "ship or receive the product of a somatic cell nuclear transfer in commerce for the purpose of implanting the product of somatic cell nuclear transfer into a uterine environment so as to initiate a pregnancy" and illegal to "possess the product of human cloning."[76]

The law also prohibits implanting or attempting to implant "the product of somatic cell nuclear transfer into a uterine environment so as to initiate a pregnancy."[77] This language is similar to that found in other states' "clone-and-kill" laws, but given Virginia's prohibitions against creating or possessing cloned embryos, this provision does not have the same effect as in other states; it seems to be a redundant measure.

The law also explicitly permits the use of "somatic cell nuclear transfer or other cloning technologies to clone molecules, including DNA, cells, or tissues"—an apparent conflation of different meanings of the term "cloning."[78]

Washington. There are currently no laws in Washington that prohibit human cloning, whether for biomedical research or to produce children.

West Virginia. There are currently no laws in West Virginia that prohibit human cloning, whether for biomedical research or to produce children.

Wisconsin. There are currently no laws in Wisconsin that prohibit human cloning, whether for biomedical research or to produce children.

Wyoming. There are currently no laws in Wyoming that prohibit human cloning, whether for biomedical research or to produce children.

Territories, Protectorates, and the District of Columbia. Neither in the U.S. territories and protectorates nor in the District of Columbia are there currently any laws that prohibit human cloning, whether for biomedical research or to produce children.

Notes

Preface: Cloning Then and Now

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3. Rob Stein and Michaeleen Doucleff, "Scientists Clone Human Embryos To Make Stem Cells," National Public Radio, May 15, 2013, http://npr.org/blogs/health/2013/05/15/183916891/scientists-clone-human-embryos-to-make-stem-cells.

4. *Ibid.*

5. "OHSU research team successfully converts human skin cells into embryonic stem cells" (press release), Oregon Health & Science University, May 15, 2013, http://www.ohsu.edu/xd/about/news_events/news/2013/05-15-ohsu-research-team-succe.cfm.

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7. Wesley J. Smith, "Human Cloning Obfuscation 6: German Style" (blog post), *National Review Online*, May 20, 2013, http://www.nationalreview.com/human-exceptionalism/348874/human-cloning-obfuscation-6-german-style.

8. For example, a search for the phrase "human cloning" in the LexisNexis database of English-language newspapers gives 85 results for the week following the announcement of Mitalipov's cloning paper (May 15 to May 22, 2013) and only another 150 for the rest of 2013 (May 23 to December 31, 2013). (See endnote 11 below for comparison.)

9. National Bioethics Advisory Commission (NBAC), *Cloning Human Beings*, Rockville, Md., 1997, available at https://bioethicsarchive.georgetown.edu/nbac/pubs/cloning1/cloning.pdf.

10. William J. Clinton, "Remarks Announcing the Prohibition on Federal Funding for Cloning of Human Beings and an Exchange With Reporters," *Public Papers of the Presidents of the United States: William J. Clinton (1997, Book I)*, March 4, 1997, Washington, D.C., 230, http://www.gpo.gov/fdsys/pkg/PPP-1997-book1/pdf/PPP-1997-book1-doc-pg230.pdf.

11. A search for the phrase "human cloning" in the LexisNexis database of English-language newspapers gives 208 results for just the first week following Wilmut's announcement (February 22 to March 1, 1997). The following month (March 2 to March 31,

1997) gives another 403 results. For the remainder of that year (April 1 to December 31, 1997), there are another 501 results. Calendar year 1998 gives another 1,080 results, and calendar year 1999 gives 623. A search of the Library of Congress online catalogue for the phrase "human cloning" gives nine books published in 1997, fifteen published in 1998, and seventeen in 1999. (See endnote 8 above for comparison.)

12. Lee M. Silver, *Remaking Eden*, (New York: Avon Books, 1997), 151.

13. Pope John Paul II, "Dialogue Between Cultures for a Civilization of Love and Peace," January 1, 2001, http://w2.vatican.va/content/john-paul-ii/en/messages/peace/documents/hf_jp-ii_mes_20001208_xxxiv-world-day-for-peace.html.

14. United Nations General Assembly, Fifty-ninth session, Resolution 59/280 "United Nations Declaration on Human Cloning" (adopted March 8, 2005), http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/59/280. For more information on the UN deliberations, see the online archives of the Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings, available at http://www.un.org/law/cloning/.

Part One: Scientific and Historical Background

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2. Irving L. Weissman *et al.*, *Scientific and Medical Aspects of Human Reproductive Cloning*, National Research Council (Washington, D.C.: National Academy Press, 2002), 6.

3. The Human Genetics Advisory Commission and The Human Fertilization and Embryology Authority, *Cloning Issues in Reproduction, Science and Medicine*, December 1998.

4. Elizabeth Landau, "Cloning stem cells: What does it mean?," CNN.com, May 20, 2013, http://www.cnn.com/2013/05/18/health/stem-cells-cloning/.

5. Mitsutoshi Yamada *et al.*, "Human oocytes reprogram adult somatic nuclei of a type 1 diabetic to diploid pluripotent stem cells," *Nature* 510 (June 26, 2014): 533–538, http://dx.doi.org/10.1038/nature13287.

6. Herbert J. Webber, "New Horticultural and Agricultural Terms," *Science* 18 (October 16, 1903) 502, http://dx.doi.org/10.1126/science.18.459.501-b.

7. See entries for "clone, n.," "clone, v.," "cloned, adj.," and "cloning, n." in the *Oxford English Dictionary* (OED Online), Oxford University Press, http://oed.com.

8. In certain areas of biology, the term "clone" is more often used to describe a *group* of molecules, cells, or organisms, rather than individuals.

9. Jacques Loeb, "On the Nature of the Process of Fertilization and the Artificial Production of Normal Larvae (Plutei) from the Unfertilized Eggs of the Sea Urchin," *American Journal of Physiology* 31 (1899): 135–138, http://ajplegacy.physiology.org/content/3/3/135.

10. Jacques Loeb, *The Mechanistic Conception of Life: Biological Essays* (Chicago: University of Chicago Press, 1912), 5–14, https://archive.org/details/mechanisticconce1912loeb.

11. Loeb quoted in "Creation of Life," *Boston Herald*, November 26, 1899, 17.

12. This is how the French zoologist Yves Delage described the content of letters he received "signed with women's names." Yves Delage and Marie Goldsmith, La parthénogénèse naturelle et expérimentale (Paris: Ernest Flammarion, 1913), 302. English translation from Philip J. Pauly, Controlling Life: Jacques Loeb and the Engineering Ideal in Biology (New York: Oxford University Press, 1987), 105.

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29. *Ibid.*, 528.

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54. For an account of the congressional reactions to the cloning news, see Andrea L. Bonnicksen, *Crafting a Cloning Policy: From Dolly to Stem Cells* (Washington, D.C.: Georgetown University Press, 2002): 34–37.

55. Constance A. Morella, Biotechnology and the Ethics of Cloning (hearing), United States House of Representatives Committee on Science, Subcommittee on Technology, 105th Congress, 1st Session, March 5, 1997, Washington, D.C.: Government Printing Office, http://commdocs.house.gov/committees/science/hsy064170.000/hsy064170_0.htm.

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57. National Bioethics Advisory Commission (NBAC), *Cloning Human Beings* (Rockville, Md., 1997), iii, https://bioethicsarchive.georgetown.edu/nbac/pubs/cloning1/cloning.pdf.

58. *Ibid.*, iv.

59. *Ibid.*, 109.

60. *Ibid.*, 32.

61. *Ibid.*, 109.

62. James A. Thomson *et al.*, "Embryonic Stem Cell Lines Derived from Human Blastocysts," *Science* 282, no. 5391 (1998): 1145–1147, http://dx.doi.org/10.1126/science.282.5391.1145.

63. Martin J. Evans and Matthew H. Kaufman, "Establishment in culture of pluripotential cells from mouse embryos," *Nature* 292 (1981): 154–156, http://dx.doi.org/10.1038/292154a0.

64. National Institutes of Health, *Report of the Human Embryo Research Panel*, 76. The report recommends restricting embryonic stem cell research to "embryos resulting from IVF treatment for infertility or clinical research that have been donated with the consent of the progenitors."

65. See, for example, Gina Kolata, "Congress is Cautioned Against Ban on Human-Cloning Work," *New York Times*, March 13, 1997, B11, http://www.nytimes.com/1997/03/13/us/congress-is-cautioned-against-ban-on-human-cloning-work.html.

66. *Ibid.*, 30.

67. *Department of Labor Appropriations Act 1998*, Public Law No. 105-78, 111 Stat 1467 (1997), http://www.gpo.gov/fdsys/pkg/PLAW-105publ78/pdf/PLAW-105publ78.pdf.

68. The most notable of these unsavory characters were Brigitte Boisselier (a member of the Raëlian cult and the leader of its Clonaid cloning project), Panayiotis Zavos (who claimed to have transferred several cloned embryos to wombs), and Severino Antinori (who claims he helped give birth to three cloned children).

69. Hwang Woo Suk *et al.*, "Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst" (retracted January 12, 2006), *Science* 303, no. 5664 (2004): 1669–1674, http://dx.doi.org/10.1126/science.1094515; Hwang Woo Suk *et al.*, "Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts" (retracted January 12, 2006), *Science* 308, no. 5729 (2005): 1777–1783, http://dx.doi.org/10.1126/science.1112286.

70. Kitai Kim *et al.*, "Recombination Signatures Distinguish Embryonic Stem Cells Derived by Parthenogenesis and Somatic Cell Nuclear Transfer," *Cell Stem Cell* 1, no. 3 (2007): 346–352, http://dx.doi.org/10.1016/j.stem.2007.07.001.

71. Ministry for Health, Welfare and Family Affairs, Republic of Korea, *The National Bioethics Committee's Report on Bioethical Problems in Hwang Woo-Suk Research*, Seoul: National Bioethics Committee, (November 2006) http://www.nibp.kr/xe/?module=file&act=procFileDownload&file_srl=3233&sid=59733db99b6ebb74a9782b1d8f5c9085.

72. Jose B. Cibelli *et al.*, "Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development," *e-biomed: The Journal of Regenerative Medicine* 2 (November 26, 2001): 25–31, http://dx.doi.org/10.1089/152489001753262168.

73. Stojkovic Miodrag *et al.*, "Derivation of a human blastocyst after heterologous nuclear transfer to donated oocytes," *Reproductive Biomedicine Online* 11, no. 2 (2005): 226–231, http://dx.doi.org/10.1016/S1472-6483(10)60962-5.

74. Andrew J. French *et al.*, "Development of Human Cloned Blastocysts Following Somatic Cell Nuclear Transfer with Adult Fibroblasts," *Stem Cells* 26, no. 2 (2008): 485–493, http://dx.doi.org/10.1634/stemcells.2007-0252.

75. Yong Fan *et al.*, "Derivation of Cloned Human Blastocysts by Histone Deacetylase

Inhibitor Treatment After Somatic Cell Nuclear Transfer with β-Thalassemia Fibroblasts," *Stem Cells and Development* 20, no. 11 (2011): 1951–1959, http://dx.doi.org/10.1089/scd.2010.0451.

76. Scott Noggle *et al.*, "Human oocytes reprogram somatic cells to a pluripotent state," *Nature* 478, no. 7367 (2011): 70–75, http://doi.org/10.1038/nature10397.

77. For example, Dieter Egli and some of his colleagues accompanied the publication of their 2011 cloning research with a letter to the journal *Cell Stem Cell* reporting on a questionnaire given to prospective egg donors they had attempted to recruit for their study. Egli and his colleagues found that the most common reason given for *not* participating in the research was the absence of financial compensation. Dieter Egli *et al.*, "Impracticality of Egg Donor Recruitment in the Absence of Compensation," *Cell Stem Cell* 9, no. 4 (2011): 293–294, http://dx.doi.org/10.1016/j.stem.2011.08.002.

78. A team of researchers led by Japan's Shinya Yamanaka first produced mouse iPS cells in 2006. (Kazutoshi Takahashi and Shinya Yamanaka, "Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors," *Cell* 126, no. 4 [2006]: 663–676, http://dx.doi.org/10.1016/j.cell.2006.07.024.) The following year, the same Japanese team and a Wisconsin-based team led by James Thomson reported nearly simultaneously that they had produced human iPS cells. (Kazutoshi Takahashi *et al.*, "Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors," *Cell* 131, no. 5 [2007]: 861–872, http://dx.doi.org/10.1016/j.cell.2007.11.019 and Junying Yu *et al.*, "Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells," *Science* 318, no. 5858 [2007]: 1917–1920, http://dx.doi.org/10.1126/science.1151526.)

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83. Shoukhrat M. Mitalipov *et al.*, "Rhesus monkey embryos produced by nuclear transfer from embryonic blastomeres or somatic cells," *Biology of Reproduction* 66, no. 5 (2002): 1367–1373, http://dx.doi.org/10.1095/biolreprod66.5.1367.

84. J. A. Byrne *et al.*, "Producing primate embryonic stem cells by somatic cell nuclear transfer," *Nature* 450, no. 7168 (2007): 497–502, http://dx.doi.org/10.1038/nature06357.

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87. See Te-Yu Lu and Clement L. Markert, "Manufacture of diploid/tetraploid chimeric mice," *Proceedings of the National Academy of Sciences* 77, no. 10 (1980): 6012–6016, http://dx.doi.org/10.1073/pnas.77.10.6012.

88. Masahito Tachibana *et al.*, "Generation of Chimeric Rhesus Monkeys," *Cell* 148, no. 1–2 (2012): 285–295, http://dx.doi.org/10.1016/j.cell.2011.12.007.

89. *Ibid.*, 287.

90. *Ibid.*

91. *Ibid.*

92. *Ibid.*, 291–292.

93. See especially Jennifer Nichols and Austin Smith, "Naive and Primed Pluripotent States," *Cell Stem Cell* 4, no. 6 (2009): 487–492, http://dx.doi.org/10.1016/j.stem.2009.05.015.

94. For example, tetraploid complementation, a special type of chimera-formation that has been used to clone mice from pluripotent stem cells, is unlikely to be possible for humans—allaying concerns about using iPS cells in human cloning, at least for now. Bernard Lo *et al.*, "Cloning Mice and Men: Prohibiting the Use of iPS Cells for Human Reproductive Cloning," *Cell Stem Cell* 6, no. 1 (2010): 16–20, http://dx.doi.org/10.1016/j.stem.2009.12.004.

95. By chimerically combining cloned and non-cloned embryos, researchers can track which sorts of tissues the cloned embryos are unable to contribute to, knowledge that could be used to refine methods for cloning-to-produce-children.

96. Michelle L. Sparman, Masahito Tachibana, and Shoukhrat M. Mitalipov, "Cloning of non-human primates: the road 'less traveled by,'" *International Journal of Developmental Biology* 54, no. 11–12 (2010): 1671–1678, http://dx.doi.org/10.1387/ijdb.103196ms. Why clone monkeys? The researchers say that creating cloned monkey offspring would benefit biomedical research, since "the production of genetically identical monkeys would significantly reduce the number of animals utilized in biomedical research" and "would allow for the production of genetically modified primates, including gene knockout models, to study gene function and human diseases." *Ibid.*, 1675.

97. A minor controversy followed the publication of Mitalipov's 2013 cloning paper, when anonymous scientists noticed that some of the images in the paper were duplicated and mislabeled. Many of these scientists also questioned whether *Cell*, the journal that published the paper, had rushed through the editorial-review process because of the importance of the paper's findings. Unlike the notorious fraud perpetrated by Hwang Woo Suk in the previous decade, however, the presence of duplicated images in

Mitalipov's paper did not cast serious doubt on the central scientific findings; the erroneous images were not central to the paper's scientific claims. After a brief investigation, the problem was found to have been the result of errors during the preparation of the paper, and not to have had any bearing on the paper's conclusions. (David Cyranoski, "Fallout from Hailed Cloning Paper," *Nature* 497 [May 30, 2013]: 543–544, http://dx.doi.org/10.1038/497543a; Adam Marcus, "*Cell* attributes image problems in to paper to 'minor errors,' sees no impact on conclusions," Retraction Watch [blog] May 23, 2013, http://retractionwatch.com/2013/05/23/cell-attributes-image-problems-in-cloning-paper-to-minor-errors-sees-no-impact-on-conclusions/.)

98. See, for example, Alan Colman and Alexander Kind, "Therapeutic cloning: concepts and practicalities," *Trends in Biotechnology* 18, no. 5 (May 2000): 192–196, http://dx.doi.org/10.1016/S0167-7799(00)01434-7.

99. Tachibana *et al.*, "Human Embryonic Stem Cells Derived by Somatic Cell Nuclear Transfer," *Cell* 153, no. 6 (2013): 1232, http://dx.doi.org/10.1016/j.cell.2013.05.006. However, the total efficiency of Mitalipov's experiments was substantially lower than one stem cell line per five eggs.

100. *Ibid.*, 1235.

101. *Ibid.*

102. Yamada *et al.*, "Human oocytes reprogram adult somatic nuclei of a type 1 diabetic to diploid pluripotent stem cells," *Nature* 510 (June 26, 2014): 533–538, http://dx.doi.org/10.1038/nature13287.

103. Young Gie Chung *et al.*, "Human Somatic Cell Nuclear Transfer Using Adult Cells," *Cell Stem Cell* 14 (2014): 777–780, http://dx.doi.org/10.1016/j.stem.2014.03.015.

104. Yamada *et al.*, "Human oocytes reprogram adult somatic nuclei of a type 1 diabetic to diploid pluripotent stem cells," 535; Chung *et al.*, "Human Somatic Cell Nuclear Transfer Using Adult Cells," 800.

105. Yamada *et al.*, "Human oocytes reprogram adult somatic nuclei of a type 1 diabetic to diploid pluripotent stem cells," 535–536.

Part Two: The Case Against Cloning-to-Produce-Children

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2. Daniel Callahan, *False Hope* (New York: Simon and Schuster, 1998), 141.

3. President's Council on Bioethics (PCBE), *Human Cloning and Human Dignity: An Ethical Inquiry* (Washington, D.C., 2002), https://bioethicsarchive.georgetown.edu/pcbe/reports/cloningreport/.

4. Yuval Levin, "Putting Health in Perspective," *The New Atlantis* 36 (Summer 2012): 23–36, http://www.thenewatlantis.com/publications/putting-health-in-perspective.

5. For example, National Bioethics Advisory Commission, *Cloning Human Beings* (Rockville, Md.: National Bioethics Advisory Commission 1997), iv, https://bioethicsarchive.georgetown.edu/nbac/pubs/cloning1/cloning.pdf; and National Academy of Sciences, *Scientific and Medical Aspects of Human Reproductive Cloning* (Washington, D.C.: National Academy Press, 2002), 5, http://www.nap.edu/openbook.php?isbn=0309076374.

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13. According to one theory, SCNT may not fully or reliably "reprogram" the nuclei of differentiated adult cells. This is suggested by the fact that, from the earliest days of SCNT in the 1950s, the procedure has been more efficient when the nuclei have come from embryonic rather than adult cells. This suggests that the adult-cell nuclei used in SCNT do not come to express the genes necessary for embryonic development. Scientists have found that important developmental genes are not always expressed in cloned blastocysts, either because of incomplete reprogramming or because of the ways eggs and embryos are manipulated and cultured in SCNT. (Paul A. De Sousa *et al.*, "Evaluation of gestational deficiencies in cloned sheep fetuses and placentae," *Biology of Reproduction* 65, no. 1 [2001]: 23–30, http://dx.doi.org/10.1095/biolreprod65.1.23; Susan M. Rhind *et al.*, "Human cloning: can it be made safe?," *Nature Reviews Genetics* 4, no. 11 [2003]: 855–864, http://dx.doi.org/10.1038/nrg1205.)

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16. Up to 50 percent of pregnancies with cloned animal embryos reach the stage at which a fetal heartbeat can be detected, but the survival rate of fetuses decreases after early pregnancy, with high rates of miscarriage. A study of cloned bovine embryos found that between 50 and 100 percent of pregnancies that had reached the stage of a detectable fetal heartbeat miscarried, compared to miscarriage rates of between 2 and 10 percent for natural pregnancies and 16 percent for IVF. (J. L. Edwards *et al.*, "Cloning adult farm animals: a review of the possibilities and problems associated with somatic cell nuclear transfer," *American Journal of Reproductive Immunology* 50, no. 2 [2003]: 113–123, http://dx.doi.org/10.1034/j.1600-0897.2003.00064.x.)

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21. Susan M. Rhind *et al*, "Human cloning: can it be made safe?," *Nature Reviews Genetics* 4, no. 11 (2003): 855–864, http://dx.doi.org/10.1038/nrg1205. Another study linked LOS to placental abnormalities, suggesting that such problems as enlarged hearts or enlarged umbilical cords may be consequences of placental dysfunction. F. Constant, "Large offspring or large placenta syndrome? Morphometric analysis of late gestation bovine placentomes from somatic nuclear transfer pregnancies complicated by hydrallantois," *Biology of Reproduction* 75, no. 1 (2006): 122–130, http://dx.doi.org/10.1095/biolreprod.106.051581.

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and telomere length in animals cloned from senescent somatic cells," *Science* 288, no. 5466 (2000): 665–669, http://dx.doi.org/10.1126/science.288.5466.665; X. Cindy Tian *et al.*, "Normal telomere lengths found in cloned cattle," *Nature Genetics* 26, no. 3 (2000): 272–273, http://dx.doi.org/10.1038/81559; Norikazu Miyashita *et al.*, "Remarkable differences in telomere lengths among cloned cattle derived from different cell types," *Biology of reproduction* 66, no. 6 (2002): 1649–1655, http://dx.doi.org/10.1095/biolreprod66.6.1649. The latter study found that telomere length in cloned cattle is highly dependent on the type of cell that provides the donor nucleus, with fibroblast nuclei resulting in a clone with low telomere length, and muscle cell nuclei resulting in a clone with normal telomere length. Other studies have reported on cloned pigs that display normal telomere length and cloned sheep with abnormally short telomeres. Shiels *et al.*, "Analysis of telomere lengths in cloned sheep," *op. cit.*; Jiang Le *et al.*, "Telomere lengths in cloned transgenic pigs," *Biology of Reproduction* 70, no. 6 (2004): 1589–1593, http://dx.doi.org/10.1095/biolreprod.103.022616.

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57. Center for Genetics and Society staff, "CGS Summary of Public Opinion Polls" (online publication), February 4, 2014, http://www.geneticsandsociety.org/article.php?id=401; Rebecca Riffkin, "New Record Highs in Moral Acceptability," Gallup.com, May 30, 2014, http://www.gallup.com/poll/170789/new-record-highs-moral-acceptability.aspx.

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64. Hilary Putnam, "Cloning People," in *Philosophy in an Age of Science* (Cambridge, Mass.: Harvard University Press, 2012), 328.

65. *Ibid.*, 334.

66. Allen Buchanan, *Better Than Human* (New York: Oxford University Press: 2011), 62.

67. *Ibid.*

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69. A woman could use cloning to have a child while avoiding the risks of egg collection and pregnancy by using a donor egg and a surrogate, but transferring these health risks to other women would hardly be an example of an ethically respectable reason for choosing cloning.

70. Kass, "The Wisdom of Repugnance," 18.

71. Although the cloning technique SCNT could involve two individuals' genetic material—chromosomal DNA from the individual supplying the nucleus and mitochondrial DNA from the individual supplying the egg—the technique could also be used by a woman to clone herself using her own eggs. In such a case, the woman would be the sole genetic parent of her cloned child.

72. Kerry Lynn Macintosh, *Human Cloning: Four Fallacies and Their Legal Consequences* (Cambridge, U.K.: Cambridge University Press, 2012), 27.

73. Gregory E. Pence, *Cloning After Dolly: Who's Still Afraid?* (Lanham, Md.: Rowman & Littlefield 2004), 4.

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78. As remarked above, this qualification does not apply to women who clone themselves using their own eggs, and who would therefore be the sole genetic parents of their cloned children.

79. Embryos and children produced through new methods of "mitochondrial replacement" are often said to have three genetic parents since they will have inherited mitochondrial DNA from the woman who provided an egg cell for the procedure, as well as the standard complement of chromosomal DNA from the providers of the sperm and the other egg. As with cloning, the egg provider has a genetic relationship with the child that is unprecedented in nature, and she makes a contribution to the child's biology that is in most respects far less significant than that made by the child's two other parents. Whether children produced through cloning can be said to have one or two genetic parents, or whether children produced through these mitochondrial replacement technologies have two or three genetic parents are difficult questions, but it is clear that the genetic relationships between these children and their ancestors is complicated and confounded by the use of these technologies.

80. Robertson, "Liberty, Identity, and Human Cloning," 1393.

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87. President's Council on Bioethics, *Human Cloning and Human Dignity*, 110.

88. Macintosh, *Human Cloning*, 113.

89. *Ibid.*

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Part Three: The Case Against Cloning-for-Biomedical-Research

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Part Four: Cloning Policy in the United States

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72. *Ibid.*, 559–561. See also *United States v. Morrison*, 529 U.S. 598 (2000), 615–616, http://www.supremecourt.gov/opinions/boundvolumes/529bv.pdf. An additional requirement is that the regulation should contain "an express jurisdictional element which might limit its reach" to cases of the regulated activity that have "an explicit connection with or effect on interstate commerce." *Lopez*, 562; *Morrison*, 611–613.

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74. *Freedom of Access to Clinic Entrances Act of 1994*, Public Law No. 103-259, 108 Stat. 694, enacted May 26, 1994, 18 U.S.C. §248, http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap13-sec248.pdf.

75. *United States v. Wilson*, 73 F.3d 675 (7th Cir., 1995), http://caselaw.findlaw.com/us-7th-circuit/1306989.html. The same court later rejected the argument that the regulation in question violates the First Amendment protection of free speech. *United States v. Wilson*, 154 F.3d 658 (7th Cir., 1998), http://caselaw.findlaw.com/us-7th-circuit/1253692.html.

76. *Partial-Birth Abortion Ban Act of 2003*, Public Law No. 108-105, 117 Stat. 1201, enacted November 5, 2003, 18 U.S.C. §1531, http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap74-sec1531.pdf. The Supreme Court has upheld the law (although it has not addressed the specific question of whether the law is a permissible exercise of Congress's power to regulate interstate commerce). *Gonzales v. Carhart*, 550 U.S. 124 (2007), http://www.supremecourt.gov/opinions/boundvolumes/550bv.pdf. On the question of the commerce clause, notice the concurrence of Justice Thomas, *ibid*., 168–169.

77. Anthony J. Colangelo, "The Foreign Commerce Clause," *Virginia Law Review* 96, iss. 5 (2010), 984, http://www.virginialawreview.org/volumes/content/foreign-commerce-clause.

78. *South Dakota v. Dole*, 483 U.S. 203 (1987). The excerpted passage quotes the United States Constitution, Article I, Section 8, Clause 1 and *Fullilove v. Klutznick*, 448 U.S. 448 (1980), 474.

79. *Emergency Highway Energy Conservation Act*, Public Law No. 93-239, 72 Stat. 892, 1046, enacted January 2, 1974, http://uscode.house.gov/statutes/pl/93/239.pdf.

80. *National Minimum Drinking Age Act of 1984*, Public Law No. 98-363, 98 Stat. 435, enacted July 17, 1984, 23 U.S.C. §158, http://www.gpo.gov/fdsys/pkg/USCODE-2011-title23/pdf/USCODE-2011-title23-chap1-sec158.pdf.

81. *South Dakota v. Dole*, 483 U.S. 203 (1987), http://laws.findlaw.com/us/483/203.html. On the matter of "reasonably related," see also *Massachusetts v. United States*, 435 U.S. 444 (1978), 461, http://laws.findlaw.com/us/435/444.html. On the matter of coercion, see also *National Federation of Independent Business v. Sebelius*, 567 U.S. ___ [132 S. Ct. 2566] (2012), http://www.supremecourt.gov/opinions/11pdf/11-393c3a2.pdf.

82. NIH Research Portfolio Online Reporting Tools (RePORT), "NIH Awards by Location & Organization," http://report.nih.gov/award/index.cfm?ot=&fy=2014&state=&ic=&fm=&orgid=&distr=&rfa=&om=n&pid=#tab1.

83. *Ibid.*

84. United States Constitution, Article I, Section 8, Clauses 1 and 8.

85. The "Weldon Amendment," named for Representative Dave Weldon (R.-Fla.) who sponsored it in 2003, first went into effect in fiscal year 2004; it has been renewed in subsequent appropriations bills. It reads: "None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism." See, for example, *Consolidated Appropriations Act, 2004*, Public Law No. 108-199, https://www.congress.gov/108/plaws/publ199/PLAW-108publ199.pdf. Representative Weldon succeeded in incorporating similar language in the America Invents Act, a law passed in 2011, after he left Congress: "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism." *Leahy-Smith America Invents Act*, Public Law No. 112-29, https://www.congress.gov/112/plaws/publ29/PLAW-112publ29.pdf.

86. 157 Cong. Rec. H4451 (June 22, 2011), http://www.gpo.gov/fdsys/pkg/CREC-2011-06-22/pdf/CREC-2011-06-22-house.pdf.

87. 149 Cong. Rec. H12840–12841 (December 8, 2003), http://www.gpo.gov/fdsys/pkg/CREC-2003-12-08/pdf/CREC-2003-12-08-pt1-PgH12766-2.pdf, quoted in 157 Cong. Rec. E1180 (June 23, 2011), http://www.gpo.gov/fdsys/pkg/CREC-2011-06-23/pdf/CREC-2011-06-23-extensions.pdf. See also Joe Matal, "A Guide to the Legislative History of the America Invents Act: Part I of II," *Federal Circuit Bar Journal* 21, no. 3 (March 2012), 510–511, http://www.uspto.gov/sites/default/files/aia_implementation/guide-to-aia-p1.pdf.

88. *In re Roslin Institute (Edinburgh)*, 13-1407 (Fed. Cir. May 8, 2014), 7, http://cafc.uscourts.gov/images/stories/opinions-orders/13-1407.Opinion.5-6-2014.1.PDF.

89. *Ibid.*, 3.

90. A recent challenge to patents for human embryonic stem cells was rejected by the U.S. Court of Appeals for the Federal Circuit on the grounds that the plaintiffs lacked standing. (*Consumer Watchdog v. Wisconsin Alumni Research Foundation*, 13-1377 [Fed. Cir. June 4, 2014], http://cafc.uscourts.gov/images/stories/opinions-orders/13-1377.Opinion.6-2-2014.1.PDF.) An appeal is currently pending. (Lisa Schuchman, "Will Supreme Court Step in on Stem Cell Patents?" [press release], Consumer Watchdog, November 3, 2014, http://www.consumerwatchdog.org/story/will-supreme-court-step-stem-cell-patents.)

91. Andrew Pollack, "Disgraced Scientist Granted U.S. Patent for Work Found to be Fraudulent," *New York Times*, February 14, 2014, http://www.nytimes.com/2014/02/15/science/disgraced-scientist-granted-us-patent-for-work-found-to-be-fraudulent.html.

92. Fourteenth Amendment to the United States Constitution, Sections 1 and 5.

93. *Ibid.*

94. It is worth noting that some critics of abortion have argued that the Fourteenth Amendment could also be used to restrict abortion, despite Supreme Court jurisprudence limiting Congress's enforcement power under the amendment to "state action," not private conduct. *United States v. Morrison*, 529 U.S. 598 (2000), 621, http://www.supremecourt.gov/opinions/boundvolumes/529bv.pdf; Robert A. Burt, "Constitutional Constraints on the Regulation of Cloning," *Yale Journal of Health Policy, Law, and Ethics* 9 supplement (2009): 502–503, http://digitalcommons.law.yale.edu/yjhple/vol9/iss3/2; Ramesh Ponnuru, "Can the Federal Government Regulate Abortion?," National Review Online, May 14, 2015, http://www.nationalreview.com/corner/418399/can-federal-government-regulate-abortion-ramesh-ponnuru; Ramesh Ponnuru, "Yes, It's Constitutional for Congress to Pass Abortion Laws," National Review Online, January 23, 2015, http://www.nationalreview.com/article/412681/yes-its-constitutional-congress-pass-abortion-laws-ramesh-ponnuru; Robert P. George, "Reflections of a Questioner: The Palmetto Freedom Forum Revisited," *Public Discourse*, October 3, 2011, http://www.thepublicdiscourse.com/2011/10/4055/.

95. Thirteenth Amendment to the United States Constitution, Section 1.

96. *Griswold v. Connecticut*, 381 U.S. 479 (1965), http://laws.findlaw.com/us/381/479.html.

97. *Eisenstadt v. Baird*, 405 U.S. 438 (1972), http://laws.findlaw.com/us/405/438.html.

98. *Roe v. Wade*, 410 U.S. 113 (1973), http://laws.findlaw.com/us/410/113.html.

99. *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), 851, http://www.supremecourt.gov/opinions/boundvolumes/505bv.pdf.

100. *In the Matter of Baby M*, 109 N.J. 396 (1988), 537 A.2d 1227, http://law.justia.com/cases/new-jersey/supreme-court/1988/109-n-j-396-1.html.

101. *Lifchez v. Hartigan*, 735 F. Supp. 1361 (1990), http://law.justia.com/cases/federal/district-courts/FSupp/735/1361/1459541/.

102. *Cameron v. Board of Education of Hillsboro*, 795 F. Supp. 228 (1991), http://law.justia.com/cases/federal/district-courts/FSupp/795/228/2596441/.

103. *Planned Parenthood v. Casey*, *op. cit.*

104. Lori B. Andrews, "Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning," *Harvard Journal of Law and Technology* 11, no. 3 (Summer 1998): 669, http://jolt.law.harvard.edu/articles/pdf/v11/11HarvJLTech643.pdf.

105. 144 Cong. Rec. S508 (February 9, 1998), http://www.gpo.gov/fdsys/pkg/CREC-1998-02-09/pdf/CREC-1998-02-09-senate.pdf.

106. Brian Alexander, "Free to Clone," *New York Times Magazine*, September 26, 2004, 26, http://www.nytimes.com/2004/09/26/magazine/26IDEA.html.

107. John A. Robertson, "The Scientist's Right to Research: A Constitutional Analysis," *Southern California Law Review* 51, no. 6 (September 1978), 1217–1218.

108. *Spence v. Washington*, 418 U.S. 405 (1974), http://laws.findlaw.com/us/418/405.html.

109. Steve Keane, "The Case Against Blanket First Amendment Protection of Scientific Research: Articulating a More Limited Scope of Protection," *Stanford Law Review* 59, iss. 2 (November 2006): 526–527, http://www.stanfordlawreview.org/sites/default/files/articles/Keane.pdf.

110. *Ibid.*, 533, quoting *United States v. O'Brien*, 391 U.S. 367 (1968), http://laws.findlaw.com/us/391/367.html. See also Keane, 535, where he specifically addresses the example of a cloning law.

111. On human research subjects in U.S. regulations, see 21 CFR §§50, 56, and 58 (http://www.ecfr.gov/ecfrbrowse/Title21/21cfrv1_02.tpl) and 45 CFR §46 (http://www.ecfr.gov/ecfrbrowse/Title45/45cfr46_main_02.tpl). On animal welfare, see 9 CFR §1 (http://www.ecfr.gov/ecfrbrowse/Title09/9cfrv1_02.tpl).

Appendix: State Laws on Human Cloning

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2. SCR 1044, Arizona Revised Statutes §36-2313 (2010), http://azleg.gov/ars/36/02313.htm.

3. H.B. 2221, Arizona Revised Statutes §35–196.04 (2005), http://www.azleg.gov/ars/35/00196-04.htm.

4. *An Act to Prohibit Human Cloning*, S.B. 185, §20-16-1001 (2003), http://www.arkleg.state.ar.us/assembly/2003/R/Acts/Act607.pdf.

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6. *Ibid.*, 2–3.

7. S.B. 1344, California Health and Safety Code §24185 (1997), https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=20.&title=&part=&chapter=1.4.

8. *Ibid.*

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18. Connecticut General Statutes §32-41jj, http://www.cga.ct.gov/current/pub/chap_581.htm#sec_32-41jj.

19. *Ibid.*

20. S.B. 1353, Idaho Code Annotated §18-611 (2010), http://www.legislature.idaho.gov/idstat/Title18/T18CH6SECT18-611.htm.

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22. *Ibid.*

23. *An Act to amend the Indiana Code concerning health*, S. B. 2005 (2005), http://www.in.gov/legislative/bills/2005/PDF/SE/SE0268.1.pdf.

24. P.L. 126–2005 S.B. 268, Indiana Code §16-34.5-1-1 (2005), https://iga.in.gov/static-documents/8/b/a/3/8ba3c3f9/TITLE16_title16.pdf#page=599.

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30. *Ibid.*

31. H.B. 370, Louisiana Revised Statutes §40:1299.36.1 (1999), https://www.legis.la.gov/legis/Law.aspx?p=y&d=97221.

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