

F.2. HUMAN GENETIC MODIFICATION

The items in this section are edited versions of material prepared by the [Center for Genetics and Society](#).

F.2.a. GENE EDITING FOR HUMAN REPRODUCTION - June 2017

Introduction

The decade from 2004 to 2014 was a period of relative quiet about human germline modification. That changed in 2014-2015 as an inexpensive, easy-to-use, more accurate set of genetic engineering techniques became available. These were collectively known as “gene editing,” tools, with CRISPR by far the best known.

Human gene-editing proposals were made to address scores of conditions that had previously been out of reach. CRISPR-using researchers began floating the prospect of “gene drive,” a technique to genetically modify an entire population of short-generation organisms – e.g. disease-bearing mosquitoes – in a very short time period.

Scientists were aware that CRISPR could be used to genetically alter human gametes or embryos. In April 2015 researchers from Sun Yat-sen University announced that they had edited the genomes of non-viable human embryos.

The advent of CRISPR has significantly reduced the technical barriers to making human germline modification clinically practicable. While there are many prominent scientists, biotech industry figures, academics and advocates who have been and remain opposed to human germline modification, others are forging ahead with new enthusiasm.

1. SOBERING DEVELOPMENTS

- Although by most medical standards it would still be too risky to use CRISPR in clinical tests, some scientists are arguing that it is “safe enough,” especially in “last resort” situations, and that argument is getting traction.
- Advances in prenatal testing could make it easier to monitor pregnancies established with altered embryos, so that fetuses developing in anomalous ways could be terminated.
- There is little awareness that germline editing is unnecessary to prevent the transmission of serious inherited diseases in nearly all cases. News reports on gene-editing developments rarely mention the current availability of such techniques. See this study by the [Center for Genetics and Society](#) on media coverage.
- News coverage and commentary regarding germline gene editing continues to frame the issue as one of scientific breakthroughs and life-saving cures being opposed by fearful Luddites and religious zealots, and frequently concluding that “like it or not – it’s inevitable.”
- Some highly visible researchers, physicians and bioethicists have begun asserting that it is a social and medical duty to use germline editing to fulfill the desire of the very small number of people who, for technical reasons, cannot use embryo screening to have a child both unaffected by the disease they carry and also fully genetically related to both members of a heterosexual couple. Some go even further and say that it a *moral duty* to use any high-tech means to *enhance* future generations. This was considered a bizarre, off-the-reservation position just a few years ago; now it has become normalized, even if it’s still a minority view.
- A high-level report, authored by a committee of the US National Academies of Sciences, recommends proceeding with reproductive use of gene editing under certain conditions. (See the [Center for Genetics and Society press statement](#).) This is the first time *in human history* that a body of this stature has advocated

human germline modification. It was no surprise, however. The individuals leading the initiative are known to support human germline modification, and have been preparing the way for this for literally decades; some played key roles in the early 1970s efforts by the scientific community to clear the way for the first recombinant DNA experimentation.

- New York-based fertility doctor John Zhang recently “pioneered” the rogue use of a technique that, while it does not alter genes per se, is a form of germline modification. Zhang used nuclear transfer to reconstruct an embryo, and went to Mexico to impregnate a woman with it. He explained that he did this because “there are no rules” in Mexico; although this is not actually true, neither Mexican nor US authorities appear to have appetite for enforcing existing policies that at least arguably prohibit it. Zhang has now launched a start-up called Darwin Life to commercialize the technique for women affected by general age-related infertility. He has published no peer-reviewed evidence, but his presentation about the technique at a large medical congress, available online, is set to the music of Chariots of Fire. In spite of all this, criticism from researchers and physicians has been quite sparse. This open flouting of regulations and professional guidelines, and the absence of subsequent sanctions, is unprecedented and represents a dangerous turn in the evolving relationship of the scientific community and the larger human community.
- The “Transhumanist” subculture is growing in numbers, visibility, and legitimacy, and are increasingly vocal and explicit about their advocacy of designer babies and a post-human future. Their ideas have entered the mainstream in Silicon Valley and much of the tech sector. See more on transhumanism, eugenics and the Tech sector in **Attachment F.3**.

2. ENCOURAGING DEVELOPMENTS

- A number of noted scientists and biotech industry figures openly oppose using gene editing for human reproduction; some are willing to play a public role in making this case. Examples:
 - “Don’t Edit the Human Germ Line,” an opinion piece published in *Nature*.
 - UC Davis stem cell researcher Paul Knoepfler’s Dec 2015 book *GMO Sapiens: The Life-Changing Science of Designer Babies* is highly critical of human gene editing for reproduction.
 - Emmanuelle Charpentier, one of the three CRISPR developers usually named as a potential Nobelist, has made it clear that she opposes human germline modification.
- During the Obama administration several US agencies ruled out human germline modification or warned about it:
 - April 2015: Francis S. Collins, Director of the National Institutes of Health, released a Statement saying that the NIH would not fund gene editing for reproduction.
 - Dec 2015: President Obama signed the federal omnibus budget bill, which contained a rider that effectively prevents clinical uses of human germline modification (it bars the FDA from using any funds to consider any such applications). The sponsor, Rep. Robert Adherholt (R-AL), intends to add the language in subsequent years.
 - Feb 2016: James Clapper, Director of U.S. National Intelligence, added genome editing to the list of “weapons of mass destruction and proliferation.”
- The international consensus against human germline modification appears to be holding (despite counter-initiatives in several countries).
 - The Council of Europe has reaffirmed the Oviedo Convention’s prohibition of human germline modification in December 2015.
 - UNESCO’s International Bioethics Committee updated its Report on the Human Genome recommending a “moratorium on genome editing of the human germline.”

- A December 2015 “International Summit on Human Gene Editing” was of mixed import. This 3-day, 500-person meeting in Washington DC, organized by the US National Academies of Sciences and Medicine, the UK Royal Society, and the Chinese Academy of Sciences, is considered a landmark event. A concluding statement by the organizing committee said that it would be “irresponsible to proceed” with human germline modification unless and until a “broad societal consensus” had been reached.
- In public opinion studies, sentiment against germline modification for enhancement purposes appears to be holding steady, although it’s well known that question wording can elicit strikingly different responses:
 - STAT-Harvard poll: Americans say no to ‘designer babies’, *STAT* (February 11th, 2016): Most Americans oppose using powerful new technology to “alter the genes of unborn babies,” according to a new poll, even to prevent serious inherited diseases.
 - U.S. Public Wary of Biomedical Technologies to ‘Enhance’ Human Abilities, Pew Research Center (July 26, 2016): A new survey suggests Americans are more worried than enthusiastic about using gene editing, brain chip implants and synthetic blood to change human capabilities. Focus groups talked about unequal access and social inequality.
 - The Public and the Gene-Editing Revolution, *New England Journal of Medicine* (April 14, 2016): A problematic analysis of a selection of 17 studies over 30 years leads the authors to argue that a majority of Americans approve of gene editing aimed at preventing one’s children from inheriting certain diseases.
- Projects recently completed or underway by scholars, scientists and advocates opposed to human germline modification include:
 - A new anthology, *Beyond Bioethics: Toward a New Biopolitics*, by Marcy Darnovsky and Osagie Obasogie of the Center for Genetics and Society, was published by UC Press in Spring 2018.
 - Stuart Newman and Tina Stevens are writing *Biotech Juggernaut: Hope, Hype, and Hidden Agendas of Entrepreneurial BioScience*, to be published by Routledge.
 - *A Dangerous Idea: Eugenics, Genetics and the American Dream*, produced by Andy Kimbrell of the International Center for Technology Assessment, is a feature-length documentary featuring Robert Reich and Van Jones, among others.
 - Other recent relevant documentaries include: *DNA Dreams* (BGI’s cloning and cognitive research project), *Future Baby* (surrogacy, egg freezing, etc), *State of Eugenics* (how North Carolina came to compensate survivors of its eugenic sterilization program), *Fixed* (disability and enhancement), *Made in India* (cross-border surrogacy), *No Más Bebés* (involuntary sterilization in 1970s Los Angeles of Latinas), *Surviving Eugenics* (sterilizations in Canada).

F.2.b. ADDITIONAL DEVELOPMENTS AND EVENTS RELEVANT TO THE POLITICS OF HUMAN GENETIC MODIFICATION [June 2017]

1. Several “3-person IVF” babies born via nuclear transfer techniques, which do not alter genes but are a form of germline modification
2. Synthetic biology developments, including HGP-Write, a high-profile project to synthesize the complete human genome. Bad publicity about an initial secretive meeting at Harvard. Has some DARPA funds.
3. Direct-to-consumer genetic testing: FDA restricts then partly relaxes tests for health risks
4. Dramatic fall in sequencing prices (\$1K genome in 2014)
5. Police DNA databases & familial searching, with predictable abuses
6. Gametogenesis: creation of sperm and eggs from stem cells, which would allow creation of large numbers of gametes or embryos that could be modified and tested. Hank Greely predicts “easy PGD” – gametogenesis plus embryo screening – in his recent *The End of Sex and the Future of Human Reproduction*, now getting a fair amount of play in the media and on the lecture circuit.
7. Gene drives: technique that uses gene editing to force an alteration throughout an entire population of short-generation organisms (e.g. yeast, insects)
8. “De-extinction” proposals, including in the name of environmentalism, for species including passenger pigeon, woolly mammoth, and Neanderthals
9. Very high pricing of early gene editing-based therapies (> \$1M)
10. CRISPR patent fight; CRISPR startups acquired by Big Biotech and Pharma companies
11. BGI fails to deliver the “genius genes” (but this year a research team claims to have found 52 genes with effects on “IQ”)
12. Genetic scientists acknowledge the “missing heritability” in many common conditions; physicians question the value of whole-genome sequencing for most people
13. Supreme Court victory (partial but important) against Myriad re patents on human genes
14. Fraudulent stem cell clinics proliferate in many countries, including hundreds in the US
15. Human cloning all but disappeared as an issue, though human embryos now can be cloned. (In mid 2000s, Hwang Woo Suk’s celebrated claim to have cloned human embryos turned out to be a fraud; also he embezzled government research funds and put ~20 egg “donors” in hospital.)
16. Cross-border surrogacy: numbers of treatments and agencies continues to rise, as does media attention
17. A number of destination countries (India, Thailand, Cambodia, more) pass laws limiting the practice, often restricting surrogacy arrangements to citizens, sometimes in unfortunately discriminatory ways (e.g., only heterosexual married couples)
18. Egg freezing via a new fast-freeze method; Silicon Valley first and other companies later offer it as an employee perk
19. Marketing juggernaut for early-pregnancy non-invasive prenatal tests
20. More and more US fertility clinics openly offer non-medical sex selection
21. LA fertility doctor offers embryo screening for “hair, eye & skin color” (and is forced to put the program on hold at least temporarily)
22. 23andMe’s “designer baby” patent revealed and disavowed

F.2.c. KEY READINGS ON CONSEQUENTIAL DEVELOPMENTS REGARDING HUMAN GENETIC MODIFICATION 2015-2018

2015

- Engineering the Perfect Baby, Antonio Regalado, *MIT Technology Review* (March 5, 2015)
Scientists are developing ways to edit the DNA of tomorrow's children. Should they stop before it's too late?
- Don't Edit the Human Germ Line, Edward Lanphier et. al., *Nature* (March 12, 2015)
Heritable human genetic modifications pose serious risks, and the therapeutic benefits are tenuous.
- Human Germline Genetic Modification, Lisa Ikemoto and Paul Knoepfler, *Knoepfler Lab Stem Cell Blog* (March 23, 2015): "The call for a moratorium [is] a game changer" that creates an opportunity for open exchange.
- A Prudent Path Forward for Genomic Engineering and Germline Gene Modification, David Baltimore et. al., *Science* (April 3, 2015): Recommendations include "clinical applications in humans" of germline gene editing "while societal, environmental, and ethical implications of such activity are discussed...".
- Who's Getting Rich Off Your Genes?, Patricia J. Williams, *The Nation* (April 3, 2015)
The post-war aversion to eugenics... has eroded.
- Human Genetic Engineering Demands More Than a Moratorium, Sheila Jasanoff, J. Benjamin Hurlbut and Krishanu Saha, *The Guardian* (April 7, 2015)
Expert calls for a moratorium on germline gene engineering are not a substitute for richer public debate.
- Brave New Genome, Eric S. Lander, *New England Journal of Medicine* (June 3, 2015) It has been only about a decade since we first read the human genome. We should exercise great caution before we begin to rewrite it.
- Can We Cure Genetic Diseases Without Slipping Into Eugenics?, Nathaniel Comfort, *Nation* (July 16, 2015).
CRISPR gene editing could correct genetic mutations for serious illnesses. Will it also create a new eugenics?
- Better Babies, Nathaniel Comfort, *Aeon* (November 17, 2015)
The long, peculiar history of designer humans, from Plato's citizen breeders to Nobel sperm banks and CRISPR.
- Human gene editing is a social and political matter, not just a scientific one, Marcy Darnovsky, *The Guardian* (December 4, 2015): The organizing committee kicked the can down the road, leaving the door open for gene editing for human reproduction.

2016

- Should you edit your children's genes?, Erika Check Hayden, *Nature News* (February 23, 2016)
In the fierce debate about CRISPR gene editing, it's time to give patients a voice.
- The Return of Eugenics, Fraser Nelson, *The Spectator* [UK] (April 2, 2016) Emerging prenatal genetic screening technologies are creating a "new" eugenics not so ideologically different from that of the past.
- Will Modern Genetics Turn Us Into Gene "Genies"?, by Marcy Darnovsky, Dan Sarewitz, Samuel Weiss Evans, Arvis Sulovari, Eric A. Widra, *Zócalo Public Square* (May 24, 2016) Contributors discuss their stances on the dangers and potential benefits of gene manipulation.
- Considering Gene Editing, Jef Akst, *The Scientist* (July 12, 2016) "Given the world as we know it, germline genetic enhancement could exacerbate the already obscene gap between the 'haves' and the 'have nots.'"
- Pro and Con: Should Gene Editing Be Performed on Human Embryos?, John Harris (Pro); Marcy Darnovsky (Con), *National Geographic* (July 15, 2016): Harris: "Research on Gene Editing in Humans Must Continue." Darnovsky: "Do Not Open the Door to Editing Genes in Future Humans."

2017

- [Human Germline Gene Editing: An 'Impressive' Sleight of Hand?](#), Françoise Baylis, *Impact Ethics* (Feb 17, 2017)
- [Human germline genome editing and broad societal consensus](#), Françoise Baylis, *Nature* (May 8, 2017): Baylis advocates for setting aside the 2017 NAS/NAM report that recommends permitting germline gene editing for therapeutic purposes, and makes a wider call to embrace the challenge of seeking broad societal consensus.
- [Genome editing: That's the way the CRISPR crumbles](#), Nathaniel Comfort, *Nature* (May 31, 2017): Review of Jennifer Doudna's *Crack in Creation*.
- [Fixing genes won't fix us](#), Jim Kozubek, *Boston Globe* (June 1, 2017): Kozubek argues that efforts to engineer genes often attribute social problems to biological sources.
- [The illusion of control in germline-engineering policy](#), Harald König, *Nature* (June 7, 2017)
- [The Fertility Doctor Trying to Commercialize Three-Parent Babies](#), Emily Mullin, *MIT Technology Review* (June 13, 2017): John Zhang's start-up, Darwin Life, plans to commercialize experimental nuclear transfer techniques as an age-related fertility treatment. Zhang wants to combine the technique with gene editing for IQ.
- [CRISPR, human genetic modification, & a needed course correction](#), Paul Knoepfler, *The Niche* (June 26, 2017): Paul Knoepfler of UC Davis advocates more assertive policy stances by scientists to prevent threats to society.
- [DNA variants that are bad for health may also make you stupid](#), Michael Le Page, *New Scientist* (June 20, 2017)
- [Who will pay for CRISPR?](#), Jim Kozubek, *STAT* (June 26, 2017): Insurance companies are already excluding CRISPR treatments from coverage. Will only the wealthy be able to access them?
- [Jennifer Doudna: 'I have to be true to who I am as a scientist'](#), Hannah Devlin, *The Guardian* (July 2, 2017): Interview in which Doudna says that CRISPR to edit embryos "shouldn't be used clinically today, but in the future possibly. That's a big change for me."
- [The Brave New World of Gene Editing](#), Matthew Cobb, *New York Review of Books* (July 13, 2017). Review of *The Gene Machine* by Bonnie Rochman, *DNA Is Not Destiny* by Steven J. Heine, and *A Crack in Creation* by Jennifer A. Doudna and Samuel H. Sternberg.

2018

[in preparation]

F.2.d. HUMAN GENETIC MODIFICATION: TECHNIQUES & APPLICATIONS / POLITICS AND POLICIES - 2000-2017

Edited from material prepared by [The Center for Genetics and Society](#)

Technologies & Applications	Politics & Policies
2000	2000
<ul style="list-style-type: none"> • First successful somatic gene therapy trial, for X-SCID. • Human genome mapped (Collins, Venter). • Nematodes engineered for double life-span. • First cloned pigs. • Genetically modified fluorescent rabbit created as artwork. • Mice genetically modified to resist obesity. • Birth of first "savior sibling," Adam Nash (UK). 	<ul style="list-style-type: none"> • Controversy over 1999 death of Jesse Gelsinger following gene therapy experiment. • Bill Joy cites dangers of genetic engineering, nanotech & robotics in <i>Wired magazine</i>. • Major European bank bans loans to companies promoting human genetic modification. • Japan, Netherlands ban cloning and inheritable genetic modification (IGM). • AAAS report opens doors to IGM. • Council for Responsible Genetics issues "Genetic Bill of Rights."
2001	2001
<ul style="list-style-type: none"> • First attempt to clone an endangered ox, a Gaur; it dies. • First cloned cat (Genetic Savings and Clone). • First ooplasmic transfers: children with 3 genetic parents. • First genetically modified primate. 	<ul style="list-style-type: none"> • UK allows creation of clonal human embryos. • President Bush OKs federal funds for research on existing stem cell lines. • World Conference on Racism condemns human genetic engineering. • US House passes ban on all cloning. • France and Germany call for UN to draft global cloning treaty. • First World Transhumanist Association international assembly.
2002	2002
<ul style="list-style-type: none"> • Covert attempts to clone human embryos at Stanford, UCSF. • Polio virus synthesized using mail-order DNA. • Craig Venter announces intention to create first true artificial life. • Cloning hoaxes: Raelians, Antinori, Zavos. • Chinese researchers claimed to have created human clonal embryos. 	<ul style="list-style-type: none"> • UN launches process for international convention to ban human cloning. • World Olympics Committee bans gene doping. • German Foreign Minister J. Fischer calls for global accord on human genetics. • California bans reproductive cloning, allows cloning-based stem cell research. • US Senate deadlocked on cloning.

2003	2003
<ul style="list-style-type: none"> • First genetically modified animal to be sold as a pet, the "Glofish" • First synthetic virus. • Scientists create human embryo that is both male and female. • Gene therapy trials cause leukemia in French children. • UK women screen embryos to ensure birth of a deaf child. 	<ul style="list-style-type: none"> • US Congress passes bill banning all human cloning. • <i>Enough: Staying Human in an Engineered Age</i>, by Bill McKibben. • ETC Group publishes <i>The Big Down</i>; first activist attention to nanotechnology. • Spread of commercial advertisements for sex selection. • Many US states initiate stem cell programs.

2004	2004
<ul style="list-style-type: none"> • In Korea, Hwang Woo Suk claims stem cells extracted from clonal human embryos. • First parthenote mouse: two female genetic parents, no male parent. • UK scientists begin attempts to create clonal human embryos. • Genetics Savings & Clone offer commercial cat cloning @ \$30,000 ea. • "Savior siblings" created to provide stem cells for ill siblings. 	<ul style="list-style-type: none"> • Canada, France, New Zealand approve legislation banning SCNT & germline. • First Synthetic Biology conference held, at MIT. • \$100 million donation to Oxford U. to program promoting transhumanism. • US President's Bioethics Council releases <i>Reproduction and Responsibility</i>. • California voters approve Proposition 71 to fund stem cell research (59%-41%).
2005	2005
<ul style="list-style-type: none"> • First cloned dog (Korea). • First face transplants (France, US). • Korean cloning claims found to be fabricated. • Researchers create chimeric mice with human nervous system. • Gene sequence for virulent 1918 influenza virus published online. 	<ul style="list-style-type: none"> • UN ends debate on human cloning treaty with inconclusive resolution. • Committee of UK Parliament supports heritable genetic modification. • Connecticut, Illinois, and New Jersey approve stem cell research funding. • US National Council of Churches approves policy banning human germline. • US National Academies publishes permissive stem cell research guidelines.

2006	2006
<ul style="list-style-type: none"> • Hwang Woo Suk disgraced amid scandal of false data, embezzlement, etc. • UK scientists produce mice from sperm derived from embryonic stem cells. • Survey finds ~ half of US fertility clinics offer non-medical sex selection. • Harvard begins work towards cloning-based stem cell research. • ACT complains that it is unable to get women to provide eggs for SCNT. 	<ul style="list-style-type: none"> • Media attention to "Synthetic Biology"; civil society protests. • "Hinxtan Group" of international bioethicists and scientists call for minimal stem cell regulations. • AAAS convenes supporters of human "enhancement" to plan strategy. • President Bush vetoes Castle-DeGette stem cell bill.

2007	2007
<ul style="list-style-type: none"> • Craig Venter replaces bacterial genome, key step towards artificial life. • Harvard unable to get women to provide eggs for cloning research. • Genes for skin color identified and proposed for general use by consumers. • Texas fertility center offers "custom designed" embryos. • Controversy over death in gene therapy experiment in Illinois. • Egg freezing increasingly available and promoted. • 23andMe to offer full personal genomic sequencing; Google invests. 	<ul style="list-style-type: none"> • UK approves creation of human-animal hybrid embryos for research. • Bill to restrict human gene patents introduced in US Congress. • Craig Venter files patent for first artificial life. • Synthetic biologists outline plan for self-regulation; civil society protests. • Intern'l Society for Stem Cell Research releases permissive guidelines. • <i>The Case Against Perfection</i>, by Harvard professor Michael Sandel. • UK bill allows genetically modified human embryos for research.
2008	2008
<ul style="list-style-type: none"> • Prenatal test for hundreds of genetic conditions under development. • Gene test for children's athletic tendencies marketed to parents. • Study: IVF greatly increases birth defects. • First ovary transplant. • Eggs grown from five-year-old girls' ovarian tissue. • DIY biology widely promoted. • Ian Wilmut quits cloning-based stem cell research. • First clonal human embryo. • First genetically modified human embryo reported. • Commercial dog cloning revived. 	<ul style="list-style-type: none"> • Renewed push for cognitive enhancement. • Media reports that economic downturn leads to more women offering eggs, surrogacy. • UNESCO committee considers re-introducing treaty to ban reproductive cloning. • Under pressure, Google, Microsoft pull ads for sex selection. • Consumer genetic testing companies face regulators in California, New York. • Australia, Japan approve cloning-based stem cell research. • Netherlands government almost collapses over PGD. • US Genetic Information Nondiscrimination Act becomes law. • Push for payments for eggs for stem cell research in California, Singapore.
2009	2009
<ul style="list-style-type: none"> • DNA contamination of swabs confused German police for 15 yrs. • First transgenic dogs created in Korea, and marmosets in Japan. • Genome sequencing cost continues to fall; \$1000 genome in 2 yrs. • Live mice are produced from induced pluripotent stem cells. • At least two companies apply for permission to conduct clinical trials using human ESCs. • Efforts continue to use cloning and/or genetic modification to save endangered species or revive extinct ones.. • Three more teams of researchers create cloned human embryos. 	<ul style="list-style-type: none"> • A Los Angeles woman gives birth to octuplets after IVF, is quickly dubbed "Octomom" by the media, and provokes a debate about guidelines & regulation. • Los Angeles fertility clinic will screen embryos for eye, hair, skin color; backs down after a storm of protest. • "Singularity University" announced. • Consumer market for genetic tests continues to grow. • NIH issues guidelines for federal funding of embryonic stem cell research, allowing use of embryos created but not needed for fertility treatment. • Laws against reproductive human cloning renewed in Israel. • NY stem cell program approves payments for women's eggs for stem cell research.

2010	2010
<ul style="list-style-type: none"> • Scientists turn skin into nerve cells without any intermediate step. • Continued discussion of re-creating Neanderthals, etc. • US horse racing authorities refuse to allow registration of clones. • Unexpected deaths of genetically modified cows that were intended to generate human follicle stimulating hormone. • Craig Venter team synthesizes a complete bacterial genome and uses it to take over a cell. • DTC gene test accuracy questioned after reports of lab mistakes. • 10 yrs after Human Genome Project announcement, some are disappointed with the lack of medical treatments derived from it. • Reproductive tourism continues globally, drawing increased attention but little regulation. • Cost of full-genome sequencing drops below \$10,000. • First patient treated in clinical trial based on embryonic stem cells. 	<ul style="list-style-type: none"> • Sex ratios clearly affected by selection in many countries especially in East Asia. • Laws against reproductive human cloning renewed in Russia. • Federal district court rules that human genes cannot be patented. • Doubts are raised about the validity of stem cell patents owned by WARF and licensed by Geron; they are upheld, then overturned, and remain in question. • Walgreens plans to sell DTC test kits until FDA complains. • GAO investigation of DTC gene testing industry concludes that companies mislead customers. • UC Berkeley offers controversial gene tests to incoming students. Calif Health Department rules they can't release results to students and the program is scaled back. • EU temporarily bans animal cloning for food production. • Robert Edwards wins Nobel Prize for development of IVF. • Presidential Bioethics Commission holds hearing on synthetic biology.
<ul style="list-style-type: none"> • Geron Corp. abandoned the field of embryonic stem cell research and the first clinical trial ever approved. CIRM had authorized a \$25m loan to pursue the trial, the \$6m spent was paid back. • A new cloning technology to make ESCs was announced. Like previous methods, it would require large numbers of women's eggs. • Research continued on induced pluripotent stem cells, though reports of compatibility issues and unexpected mutations dampened optimism. • First success reported in gene therapy for hemophilia; also, resistance to HIV infection in mice was reported. • "Proof of principle" for testing fetal genomes via maternal blood tests very early in pregnancy; prenatal test for Down Syndrome on sale. • A California fertility clinic offers PGD for sex selection without requiring that the family already have at least one child of the other sex. • Human DNA contamination seen in nonhuman genome databases. • Using synthetic biology, a Harvard team efficiently altered <i>E. Coli</i>'s genetic code; synthetic DNA was added to yeast cells. 	<p style="text-align: center;">2011</p> <ul style="list-style-type: none"> • Cross-border commercial surrogacy controversy draws continued attention. • FBI uncovered a baby-selling scheme involving prominent surrogacy lawyers. • The rights of "donor offspring" and gamete donor anonymity became a public issue, sparked by disclosure of sperm donors with up to 150 children. • Controversy in the US over collecting DNA from people arrested but not convicted. Familial searching boosted by success in California, and for its minor role in identifying Osama bin Laden. • The President's bioethics commission reviewed international clinical trials, following up on scandal in Guatemala. • An FDA panel recommended that genetic testing always be under a doctor's supervision, but firm rules have not been implemented. • Proposals to compensate victims of eugenic sterilizations in North Carolina gained national attention. Eugenics archives in both Philadelphia and London were published online. • An appeals court reversed a lower court ruling against Myriad in the gene patent lawsuit, but ACLU and others are appealing to the Supreme Court. In Europe, the Court of Justice denied patents for some stem cell techniques.

2012	2013
<ul style="list-style-type: none"> • The Nobel Prize in Physiology or Medicine went to John Gurdon for cloning a frog and to Shinya Yamanaka for discovering how to reprogram adult cells into induced pluripotent stem cells. • Mitinori Saitou and colleagues in Kyoto created mice by using sperm and eggs grown from iPS cells. • Scientists in Oregon, NYC and the UK refined techniques to combine genes from three parents to create a viable human embryo. • Whole genome sequencing became cheaper and more viable.. • Non-invasive prenatal diagnostic testing, via fetal DNA circulating in the mother's blood early in pregnancy, was shown to be feasible. • The number of IVF babies worldwide reached five million. • Reproductive tourism continued to grow, esp in India and the US. 	<ul style="list-style-type: none"> • The White House unveiled a "National Bioeconomy Blueprint" relying heavily on synthetic biology. • Over 100 civil society organizations developed Principles for the Oversight of Synthetic Biology. • North Carolina's Senate blocked payments supported by the governor and approved by the House for victims of eugenic sterilizations. • Many countries and U.S. states greatly expanded their DNA police databases, by taking DNA from everyone who is arrested even if not convicted. • The American Society for Reproductive Medicine removed its experimental label from egg freezing, for women at risk of losing their fertility due to medical treatments. • In the UK, the HFEA held a public consultation about the social and ethical implications of allowing mitochondrial replacement techniques to move to human clinical trial. • The Institute of Medicine issued a report criticizing the California Institute for Regenerative Medicine for conflicts of interest in the agency's governance structure. • Stem cell scams were common, with Celltex, RNL Bio and Celltex mired in controversy • The Supreme Court agreed to hear a challenge to human gene patents held by Myriad Genetics in a suit brought by the ACLU
<ul style="list-style-type: none"> • The Nobel Prize in Physiology or Medicine went to John Gurdon for cloning a frog and to Shinya Yamanaka for discovering how to reprogram adult cells into induced pluripotent stem cells. • Mitinori Saitou and colleagues in Kyoto created mice by using sperm and eggs grown from iPS cells. • Scientists in Oregon, NYC and the UK refined techniques to combine genes from three parents to create a viable human embryo. • Whole genome sequencing became cheaper and more viable.. • Non-invasive prenatal diagnostic testing, via fetal DNA circulating in the mother's blood early in pregnancy, was shown to be feasible. • The number of IVF babies worldwide reached five million. • Reproductive tourism continued to grow, esp in India and the US. 	<ul style="list-style-type: none"> • 23andMe is awarded a "designer baby" patent that would let users investigate the kinds of children they might have with each other. • The CRISPR/Cas system attracts attention as a more precise gene editing tool; Editas Medicine launches to commercialize it. • Oregon scientists successfully create first human embryonic stem cells using cloning technique, somatic cell nuclear transfer. • Synthetic artemisinin and vanilla marketed; "glowing plants" offered as part of a Kickstarter campaign. • Researchers clone an extinct frog, but the embryos die after several days. • State and federal DNA police databases expand; more states opt for including arrestees or people convicted of low-level crimes. • Stem cell scams unfold in Texas, Italy & the Philippines. • The BGI seeks to "uncover" the genetic basis of intelligence. • Non-invasive prenatal genetic testing is heavily marketed; disability rights advocates raise concerns. • Google launches Calico to extend the human life span; hires Ray Kurzweil as a Director of Engineering. • UK researchers genetically modify mouse sperm & find functional changes persisting through 3 generations. • Early success in gene therapy trials to repair heart damage and blood cancers.
<ul style="list-style-type: none"> • US Supreme Court rules unanimously in <i>Molecular Pathology v. Myriad Genetics</i> that naturally occurring human genes cannot be patented but that cDNA can. • US Supreme Court declines to intervene to block federal funding of embryonic stem cell research. • A California bill that would have expanded the market for women's eggs is vetoed by Governor Brown. • FDA orders 23andMe to stop making health predictions. • UK Dept of Health says it will draft regulations to change UK law against human inheritable genetic modification to allow "mitochondrial replacement" techniques. • FDA plans to discuss the feasibility of the same techniques moving to human clinical trials. • Professional organizations ACMG, AAP, ACOG and NSGC release controversial policy statements on genetic testing of children, reporting of incidental findings in genetic tests, and guidelines for noninvasive fetal gene tests. • A consortium called the global alliance of 69 institutions in 13 countries was created to promote the free flow of genetic information. • Investigation reveals nearly 150 women illegally sterilized in California prisons between 2006 and 2010. • Australian-based Virtus Health becomes first IVF company to be publicly traded on the stock market. • Anti choice policy makers introduce sex-selective abortion bans to undermine women's reproductive rights. 	<ul style="list-style-type: none"> • US Supreme Court rules unanimously in <i>Molecular Pathology v. Myriad Genetics</i> that naturally occurring human genes cannot be patented but that cDNA can. • US Supreme Court declines to intervene to block federal funding of embryonic stem cell research. • A California bill that would have expanded the market for women's eggs is vetoed by Governor Brown. • FDA orders 23andMe to stop making health predictions. • UK Dept of Health says it will draft regulations to change UK law against human inheritable genetic modification to allow "mitochondrial replacement" techniques. • FDA plans to discuss the feasibility of the same techniques moving to human clinical trials. • Professional organizations ACMG, AAP, ACOG and NSGC release controversial policy statements on genetic testing of children, reporting of incidental findings in genetic tests, and guidelines for noninvasive fetal gene tests. • A consortium called the global alliance of 69 institutions in 13 countries was created to promote the free flow of genetic information. • Investigation reveals nearly 150 women illegally sterilized in California prisons between 2006 and 2010. • Australian-based Virtus Health becomes first IVF company to be publicly traded on the stock market. • Anti choice policy makers introduce sex-selective abortion bans to undermine women's reproductive rights.

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<ul style="list-style-type: none"> • A series of much-publicized abuses leads Thailand's Parliament to ban all commercial surrogacy in the country. • A white Ohio woman sues her sperm bank, alleging that the company mistakenly gave her vials from an African-American donor. • An FDA expert committee considers "3-person IVF" and concludes it could take decades to confirm its safety and efficacy. • The next day, the UK government issues proposed regulations to allow the techniques to be used. The House of Commons and Parliament's Science & Technology Committee later debate the issue, and at year's end draft regulations await a vote. • No. Carolina becomes first US state to compensate its victims of eugenic sterilizations. • California Gov. Jerry Brown signs SB 1135 into law, providing protection against sterilization abuses in California prisons. • The Federal Trade Commission charges GeneLink, which served 30,000 customers, for making claims not based on science and failing to protect consumer information. • Myriad Genetics continues to suffer setbacks in its legal battles over its BRCA gene patents in the US; Australia chooses to uphold Myriad's patents. • A California court decides unanimously that the practice of requiring people arrested for felonies to submit samples of their DNA to police violates the state constitution. • The FBI is preparing to accelerate the collection of DNA profiles for the government's massive new biometric identification database, and is hoping to use a machine that can scan DNA in 90 minutes. • CIRM celebrates its 10th anniversary without having any cures close to the clinic. Its recently departed President, Alan Trounstein, provokes a conflict-of-interest scandal. 	<ul style="list-style-type: none"> • Stem cells move into clinical trials, mostly with adult stem cells but also with iPSC-based trial. • Facebook and Apple announce a \$20,000 benefit for their female employees toward elective egg freezing; informational "egg-freezing parties" take place in New York and California. • A study of 300,000 births finds slightly greater risk of complications for IVF babies; several medical associations push for elective single embryo transfers to reduce risks. • The first baby is born following a womb transplant. • An assessment of 5 early prenatal gene test labs finds a need for better quality control. • The first baby is born after having his whole genome sequenced in utero. Proposals for whole-genome newborn testing gain steam. • GenePeeks uses sperm donor and recipient DNA to create "virtual babies" with desirable traits. • Concrete evidence emerges of errors in DTC gene test interpretation causing potential harm. • 23andMe launches its tests (including ones now prohibited in the US) in Canada and the UK. • The long-awaited \$1,000 genome is announced by Illumina with help from the US government. • Craig Venter forms Human Longevity Inc; goal: sequence 500K human genomes in 5 years. • Google sets up a cloud for your DNA, joins with Global Alliance, continues move into the healthcare business. • CRISPR continues to gain attention, awards and funding as various parties vie for patents. • Scientists seriously consider "gene drives" to alter genes and then deliberately spread them through the entire population of a species. • Efforts to "humanize" pigs via genetic engineering to make organs for transplant into humans. • US Dept of Defense creates a unit to pursue synthetic biology. • First gene therapy drug is announced, with a record price tag of \$1.4 million. 	<p style="text-align: center;">2015</p> <ul style="list-style-type: none"> • Chinese researchers report using CRISPR to edit the genomes of non-viable human embryos, with large number of "off target" effects. • CRISPR-produced super-dogs, micro-pigs, and hornless cows make headlines. • The first application to pursue CRISPR/Cas9 genome-editing research in viable human embryos is submitted to the UK's fertility regulator. • CRISPR gene-editing technology continues to develop, in thousands of labs producing hundreds of papers. • Gene drive, a technology by which genetic modifications might take over entire populations (e.g. of mosquitoes) becomes a pressing concern. • Synthetic biology becomes a mainstream topic attracting investment by the Defense Advanced Research Projects Agency (DARPA), among others. • Uterine transplants receive approval in the UK, and the Cleveland Clinic also plans to perform them.
<p style="text-align: center;">2015</p> <ul style="list-style-type: none"> • Statements by researchers, biotech industry figures, et al in <i>Nature</i> and <i>Science</i> warn of rumored human germline modification and propose different kinds of moratoria. • NIH, UNESCO, the White House, and others publicly oppose altering the human germline. • US House of Representatives holds first Congressional committee hearing on genetically engineered human DNA. • UK approves an exception to its ban on germline modification to allow nuclear transfer or "3-person IVF" in efforts to prevent transmission of an uncommon mitochondrial disease. • FDA clears 23andMe to sell carrier tests, while cracking down on other medical tests. • Gene therapy advances, but treatments look to be extremely expensive. • Stem cell therapy scams continue to come to public attention and official concern. • Commercial surrogacy banned in several countries that had become cross-boarder hubs. • The International Summit on Human Gene Editing, co-organized by US, UK and Chinese researchers, is held in December in DC. The organizing committee's concluding statement says it would be "irresponsible to proceed" with human germline editing in the absence of "broad societal consensus." • A rider is inserted into the US federal budget appropriations bill that bars FDA from using any funds to consider research applications that involve modifying human embryos. 	<p style="text-align: center;">2015</p> <ul style="list-style-type: none"> • Statements by researchers, biotech industry figures, et al in <i>Nature</i> and <i>Science</i> warn of rumored human germline modification and propose different kinds of moratoria. • NIH, UNESCO, the White House, and others publicly oppose altering the human germline. • US House of Representatives holds first Congressional committee hearing on genetically engineered human DNA. • UK approves an exception to its ban on germline modification to allow nuclear transfer or "3-person IVF" in efforts to prevent transmission of an uncommon mitochondrial disease. • FDA clears 23andMe to sell carrier tests, while cracking down on other medical tests. • Gene therapy advances, but treatments look to be extremely expensive. • Stem cell therapy scams continue to come to public attention and official concern. • Commercial surrogacy banned in several countries that had become cross-boarder hubs. • The International Summit on Human Gene Editing, co-organized by US, UK and Chinese researchers, is held in December in DC. The organizing committee's concluding statement says it would be "irresponsible to proceed" with human germline editing in the absence of "broad societal consensus." • A rider is inserted into the US federal budget appropriations bill that bars FDA from using any funds to consider research applications that involve modifying human embryos. 	<p style="text-align: center;">2015</p> <ul style="list-style-type: none"> • Statements by researchers, biotech industry figures, et al in <i>Nature</i> and <i>Science</i> warn of rumored human germline modification and propose different kinds of moratoria. • NIH, UNESCO, the White House, and others publicly oppose altering the human germline. • US House of Representatives holds first Congressional committee hearing on genetically engineered human DNA. • UK approves an exception to its ban on germline modification to allow nuclear transfer or "3-person IVF" in efforts to prevent transmission of an uncommon mitochondrial disease. • FDA clears 23andMe to sell carrier tests, while cracking down on other medical tests. • Gene therapy advances, but treatments look to be extremely expensive. • Stem cell therapy scams continue to come to public attention and official concern. • Commercial surrogacy banned in several countries that had become cross-boarder hubs. • The International Summit on Human Gene Editing, co-organized by US, UK and Chinese researchers, is held in December in DC. The organizing committee's concluding statement says it would be "irresponsible to proceed" with human germline editing in the absence of "broad societal consensus." • A rider is inserted into the US federal budget appropriations bill that bars FDA from using any funds to consider research applications that involve modifying human embryos.

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<ul style="list-style-type: none"> A baby conceived via nuclear transfer ("3-person IVF") is born in Mexico, to Jordanian parents at risk of transmitting an uncommon form of mitochondrial disease, after the procedure is conducted by a New York fertility doctor who acknowledges his evasion of US regulations. Two "3-person IVF" pregnancies are announced, in Ukraine, and both said to be for infertility rather than to avoid transmission of disease. Reports suggest that another "3-parent" baby had been born, in China. A research team in Sweden is revealed to be using CRISPR gene editing on viable human embryos. The Cleveland Clinic announces the first successful "womb transplant" in the US, using a uterus from a deceased donor. George Church, Andrew Hessel et al. are developing "HGP-Write" to create a human genome from scratch. The project is discussed at an invitation-only meeting at Harvard that generated much negative reaction. 	<ul style="list-style-type: none"> US National Academy of Medicine report on 3-person IVF to prevent mitochondrial disease recommends that it be ethically permissible under certain conditions, among them a restriction to implanting only male embryos in order to limit risks to future generations. The report acknowledges that 3-person IVF "does not address a medical need" as it "would not treat an existing person for a disease, illness, or condition." The UK's Human Fertilisation and Embryology Authority (HFEA) rejects the male embryo limitation and later announces it will accept applications from fertility clinics to use the technique. An attempt in the California legislature to overturn a law prohibiting payment for eggs for research (beyond expenses) fails. Surrogacy, especially as a transnational industry, received more attention, much of it critical. Cambodia became the latest industry target and banned commercial surrogacy. 570 stem cell clinics in the U.S. selling unapproved procedures are identified and publicized. 	<ul style="list-style-type: none"> CRISPR and related research continue intensively, though new questions are raised about "off-target" genome edits. Chinese scientists use CRISPR to modify viable human embryos with limited success but acknowledge that ethical and technical issues remain. Sangamo Therapeutics announces clinical trials of <i>in vivo</i> human gene editing (using zinc finger nucleases, not CRISPR technology). The project to write a complete human genome changes its name to GP-Write (to allow for non-human genomes) but not its goals. GP-Write fails to reach its \$100 million funding goal, but gets a modest grant from DARPA, the Defense Department research arm. A research paper suggesting that gene editing with CRISPR may cause unexpected changes is met with heavy backlash after causing stocks to plummet. New York fertility doctor John Zhang launches a start-up offering to "rejuvenate" older women's eggs and "cure" infertility. He explicitly states that he intends to progress towards designer babies. 	<ul style="list-style-type: none"> US National Academies publishes <i>Human Genome Editing: Science, Ethics, and Governance</i>, recommending that germline gene editing for reproduction be permitted, with limitations. This is a major departure from long-standing global consensus that human germline should remain off limits. The FDA licenses 23andMe to sell direct-to-consumer tests for 10 disease risks (including Parkinson's, Alzheimer's, and celiac disease) and strongly implies more permissions are forthcoming. "De-extinction" continues to attract some scientists. Other scientists, environmentalists, and public interest advocates continue to criticize the project. Three women become blind from stem-cell treatments they thought would improve their vision after paying \$5000 each to take part in what they mistook for a clinical trial. It was revealed that least four patients died in a stem-cell clinical trial, some of which had not been reported to the FDA in a timely manner. A Singapore court establishes a novel legal standard by ruling that parents have a strong interest in "genetic affinity" with their children, in a case involving an IVF mix-up. Ancestry.com is criticized for its terms and conditions clause, which permits company ownership of consumers' and their relatives' DNA. Daily Mail exposes scandal in IVF clinic, offering cash-for-eggs. John Zhang offers free IVF by lottery and announces winners through Facebook Live.