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The Architectures of the Designed Human: A Legal and Scientific Analysis of Germline Genome Editing

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ABSTRACT

The convergence of reproductive biology and genomic engineering has birthed a legal and ethical singularity: the potential to design the genetic constitution of future human generations. This research paper, situated at the intersection of *Law and Emerging Technology*, provides an exhaustive examination of the phenomenon colloquially termed the "designer baby"—specifically, the application of Heritable Human Genome Editing (HHGE). We traverse the molecular intricacies of CRISPR-Cas9 mediated double-strand breaks and homology-directed repair, establishing the scientific baseline necessary for legal adjudication. The analysis proceeds to dissect the regulatory vacuum exposed by the He Jiankui affair, contrasting the "illegal medical practice" verdict with the subsequent amendment to the Criminal Law of the People's Republic of China (Article 336-1). A comparative legal framework scrutinizes the permissive licensure model of the United Kingdom's Human Fertilisation and Embryology Authority (HFEA), the funding-based prohibition in the United States, and the dignity-based bans of the European Oviedo Convention. Centrally, this report evaluates the Indian legal landscape, interrogating the applicability of the Environment (Protection) Act, 1986, to human biological materials and analyzing the constitutional tension between reproductive privacy under Article 21 and the state's *parens patriae* interest in preserving the unadulterated human gene pool. We conclude that current statutory frameworks are ill-equipped to manage the transition from negative selection (PGD) to positive modification, necessitating a *sui generis* biomedical jurisprudence.

INTRODUCTION: THE TRANSITION FROM CHANCE TO CHOICE

The history of human reproduction has, for millennia, been a game of genetic roulette. The combination of parental gametes—sperm and egg—has traditionally been governed by the randomness of meiotic segregation, a biological lottery that determines everything from eye color to susceptibility to fatal neurodegenerative diseases. The emergence of the "designer baby" concept marks the termi-

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nation of this era of biological chance and the commencement of an era of biological choice. For the legal scholar, this transition fundamentally alters the subject of the law: the human being is no longer merely a "given" entity but potentially a "manufactured" one.

In the domain of *Law and Emerging Technology*, the term "designer baby" serves as a colloquial catch-all for a spectrum of reproductive interventions[1]. However, precision is required. We are not merely discussing the selection of embryos, a practice already entrenched in clinical reality, but the active rewriting of the genetic code—Human Germline Genome Editing (HHGE). This technology enables the alteration of the DNA sequences in germ cells (sperm and eggs) or early zygotes, ensuring that the changes are heritable and passed down to all subsequent generations of that lineage. The legal implications of such trans-generational modification are profound, challenging the very notions of bodily integrity, parental rights, and the state's power to regulate the future of the human species[2].

The Definitional Matrix: Therapy, Enhancement, and the "Designer" Label

To regulate effectively, the law must distinguish between distinct biotechnological interventions. The spectrum of "design" can be categorized into three distinct tiers:

Tier 1: Negative Selection (Pre-implantation Genetic Diagnosis - PGD). Currently legal in many jurisdictions, including India (with restrictions on sex selection), PGD involves screening embryos created via In Vitro Fertilization (IVF) for specific genetic defects. Parents may choose to implant an embryo free of Thalassemia or Cystic Fibrosis. This is a process of *selection*, not modification; it can only select traits already present in the parents' genetic pool.

Tier 2: Therapeutic Germline Editing. This involves the active use of gene-editing tools like CRISPR-Cas9 to correct a pathogenic mutation in an embryo. For example, correcting the *HBB* gene mutation responsible for Sickle Cell Anemia to the wild-type (healthy) sequence. Proponents argue this is merely "curative medicine" applied at the earliest possible stage.

Tier 3: Genetic Enhancement. This involves inserting genes to confer traits that are within the normal human range but superior to what the parents could naturally provide (e.g., enhanced muscle mass, higher cognitive function, or resistance to viral infection as attempted by He Jiankui)[3]. This crosses the boundary from therapy to eugenics, raising severe constitutional questions regarding equality.

The legal dilemma lies in the porosity of the border between "therapy" and "enhancement." A genetic intervention to boost immune function could be argued as therapeutic (preventing disease) or enhancing (creating a "super-immune" human)[4]. The law currently lacks the semantic precision to distinguish these intent-based categories effectively.

The Technological Imperative and the Law of Lag

The "Law of Lag" posits that technological capability grows exponentially while legal frameworks evolve incrementally. The discovery of CRISPR-Cas9[5] in 2012 by Jennifer Doudna and Emmanuelle Charpentier served as the catalyst for this disparity. Prior to CRISPR, gene editing was reliant on Zinc Finger Nucleases (ZFNs) and TALENs—tools that were expensive, difficult to engineer, and inefficient. CRISPR[6] democratized the ability to edit the genome, reducing the cost and complexity by orders of magnitude.

This democratization means that the capability to create a designer baby is no longer restricted to state-sponsored megaprojects but is theoretically accessible to private fertility clinics and even well-funded rogue actors. The legal system, designed to regulate finished products (drugs) or professional conduct (medical negligence), struggles to address a technology where the "product" is a human being and the "negligence" might not manifest for generations. This report analyzes how current laws are straining under this weight and proposes the necessary architectural shifts for a robust regulatory future.

The Molecular Engines of Creation: Scientific Procedures and Mechanisms

For a law student to critically engage with bioethics, a nuanced understanding of the underlying science is non-negotiable. One cannot regulate the risks of "off-target effects" without understanding the biochemical affinity of the Cas9 enzyme. Genome editing is not a magical "find and replace" function in a word processor; it is a physical intervention into the molecular structure of life.

2.1 The Evolution of Editing: Zinc Fingers to CRISPR-Cas9

The journey to high-precision editing began with protein-based recognition systems. **Zinc Finger Nucleases**

(ZFNs)[7] and **Transcription Activator-Like Effector Nucleases (TALENs)** were the pioneers[8]. In these systems, scientists had to engineer a specific protein for every new DNA target they wished to cut. This protein engineering was labor-intensive, costly, and had a high failure rate.
CRISPR-Cas9 (Clustered Regularly Interspaced Short Palindromic Repeats) changed the paradigm by switching from protein-based recognition to **RNA-based recognition**. It was adapted from the adaptive immune system of bacteria (specifically *Streptococcus pyogenes*). When bacteria are attacked by viruses, they capture snippets of viral DNA and store them in their own genome (CRISPR arrays) as a memory bank. If the virus attacks again, the bacteria produce RNA segments that match the viral DNA, guiding an enzyme (Cas9) to cut and destroy the invader.

2.2 The Cas9 Endonuclease and Guide RNA Complex

The CRISPR system consists of two primary components that function as "molecular scissors":

1. **Cas9 Enzyme:** This is the endonuclease, the protein that physically cuts the DNA. It acts as the blade.
2. **Guide RNA (gRNA):** This is a synthetic RNA molecule designed by the scientist. It comprises a "scaffold" sequence that binds to the Cas9 protein and a "spacer" sequence (approx. 20 nucleotides) that matches the target DNA sequence in the human genome.

The Procedure: When introduced into a human cell (e.g., a zygote via microinjection), the Cas9-gRNA complex scans the genome. It looks for a specific sequence called the **Protospacer Adjacent Motif (PAM)**[9]. Once it finds a PAM, it unzips the DNA to check if the sequence matches the gRNA. If a match is found, the Cas9 enzyme undergoes a conformational change and cleaves both strands of the DNA, creating a **Double-Stranded Break (DSB)**[10].

2.3 The Repair Dilemma: Non-Homologous End Joining (NHEJ) vs. Homology-Directed Repair (HDR)

The creation of the DSB is merely the catalyst. The actual "editing" is performed by the cell's own DNA repair machinery, which rushes to fix the break [11]. The outcome depends entirely on which repair pathway acts first, a variable that is notoriously difficult to control in human embryos.

Repair Pathway	Mechanism	Outcome for "Designer Babies"
Non-Homologous End Joining (NHEJ)	The cell's "emergency" repair crew. It simply grabs the two broken ends of DNA and stitches them back together. This is a sloppy process that often adds or deletes random bases (indels) at the junction.	**Gene Disruption (Knockout).** This is useful if the goal is to *break* a gene (e.g., disabling the *CCR5* gene to prevent HIV, as He Jiankui attempted). It is *not* useful for correcting a gene or inserting a new trait.
Homology-Directed Repair (HDR)	The cell's "precision" repair crew. It looks for a homologous template (a backup copy) to copy from to repair the break. Scientists hijack this by injecting a synthetic DNA template containing the desired genetic sequence.	**Gene Correction/Insertion.** This allows for the precise rewriting of letters (e.g., changing an 'A' to a 'T'). This is required for most therapeutic applications and all enhancement applications.

The Scientific Hurdle: In human embryos, NHEJ is the dominant pathway. HDR is generally active only during the late S and G2 phases of the cell cycle (when the cell is preparing to divide). In the early zygote stage, inducing HDR is extremely inefficient. If the cell chooses NHEJ instead of HDR, the embryo will not have the corrected gene but a random mutation—a failed experiment.

2.4 Advanced Modalities: Prime Editing and Base Editing

Recognizing the risks of double-stranded breaks (which can shatter chromosomes), new iterations of the technology are emerging:
Base Editing: Uses a modified Cas9 that does not cut both strands but chemically converts one DNA letter to another

[1] Harvard University. (2019). Harvard researchers share views on future, ethics of gene editing. https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/
[2] The Regulatory Review. (2024). Editing the human genome. https://www.theregreview.org/2024/06/01/editing-the-human-genome/
[3] NCBI. (n.d.). Article on gene editing. https://pmc.ncbi.nlm.nih.gov/articles/PMC8524470/
[4] National Institutes of Health. (n.d.). Preimplantation genetic diagnosis: Prenatal testing for embryos finally achieving its potential. https://pmc.ncbi.nlm.nih.gov/articles/PMC4449675/
[5] National Institutes of Health. (n.d.). Mechanism and applications of CRISPR/Cas-9-mediated genome editing. https://pmc.ncbi.nlm.nih.gov/articles/PMC4449675/

(e.g., C to T) without breaking the helix. This reduces the risk of indels.

Prime Editing: Often described as a "search-and-replace" word processor. It fuses a Cas9 "nickase" (which cuts only one strand) with a reverse transcriptase enzyme. It uses a prime editing guide RNA (pegRNA) to both find the target and write the new genetic information directly at the site[12]. This method is safer and more precise, representing the likely future of any clinical application of designer babies.

Clinical Architectures: Reproductive Technologies as Delivery Systems

Genome editing tools are useless for reproduction without a delivery mechanism. The "designer baby" is created not in a petri dish alone, but through the infrastructure of Assisted Reproductive Technology (ART)[13].

3.1 In Vitro Fertilization (IVF) and the Pre-implantation Genetic Diagnosis (PGD) Paradigm

The foundation of all germline intervention is IVF. The process involves:

1. **Ovarian Stimulation:** The mother undergoes hormonal treatment to produce multiple eggs.
2. **Retrieval and Fertilization:** Eggs are harvested and fertilized with sperm in the lab.
3. **Culture:** The resulting zygotes grow into blastocysts (Day 5-6 embryos).

PGD/PGT (Pre-implantation Genetic Testing) is the current gold standard for preventing genetic disease[14].

- **Biopsy:** Embryologists remove 3-10 cells from the **trophectoderm** (the outer layer that becomes the placenta). The **Inner Cell Mass** (which becomes the fetus) is left untouched to minimize risk.
- **Analysis:**
- **PCR (Polymerase Chain Reaction):** Used for single-gene disorders (PGT-M) like Sickle Cell or Cystic Fibrosis. It amplifies the DNA to detect specific mutations.
- **FISH (Fluorescence In Situ Hybridization):** Used for counting chromosomes (PGT-A) to screen for Down Syndrome (Trisomy 21).
- **NGS (Next-Generation Sequencing):** Allows for comprehensive screening of all chromosomes and multiple gene defects simultaneously.

PGD is a filter; it can only select the best of what exists. If both parents are homozygous for a recessive disease (i.e., they only have disease genes to pass on), PGD cannot help. This is where genome editing becomes the only option for a healthy biologically related child.

3.2 Mitochondrial Replacement Therapy (MRT): The "Three-Parent" Precedent

MRT occupies a unique legal niche. It is the only form of heritable modification currently permitted in the UK and Australia. It targets mitochondrial DNA (mtDNA), which is separate from the nuclear genome and inherited solely from the mother. Mutations in mtDNA can cause fatal metabolic disorders.

Procedure:

- **Maternal Spindle Transfer (MST):** The nucleus is removed from the mother's egg (containing unhealthy mitochondria). It is inserted into a donor egg that has had its nucleus removed but retains healthy mitochondria. The reconstructed egg is then fertilized.
- **Pronuclear Transfer (PNT):** Both the mother's and donor's eggs are fertilized first. The pronuclei (nuclear DNA) are removed from the mother's zygote and transferred into the donor's enucleated zygote.

The resulting child has nuclear DNA from the mother and father (determining appearance, personality, etc.) and mtDNA from the donor (providing cellular energy). This "germline modification" is permitted by regulators like the HFEA because it does not alter the "genetic identity" or nuclear traits of the child, a distinction critical to its legality.

3.3 The Germline Editing Protocol: Zygote Microinjection and Timing

For nuclear genome editing (the true "designer baby" scenario), the CRISPR components (Cas9 protein and gRNA) are usually microinjected directly into the zygote **at the single-cell stage[15]**, often simultaneously with the sperm during Intra-Cytoplasmic Sperm Injection (ICSI)[16].

[6]CRISPR Therapeutics. (n.d.). Gene editing. https://crisprtx.com/gene-editing

[7]Nature. (n.d.). Article on genetics. https://www.nature.com/articles/nrg2842

[8]PubMed. (n.d.). Article on genetics. https://pubmed.ncbi.nlm.nih.gov/23508559/

The Timing Criticality: The edit must occur *before* the first cell division (mitosis). If the edit happens *after* the DNA has replicated or the cell has divided, the embryo becomes a mosaic (discussed below). The window of opportunity is extremely narrow—a matter of hours[17].

Biological Uncertainties and Risk Assessment

While the mechanics of CRISPR are well understood in cell lines, applying them to human embryos introduces chaotic variables. The "precision" of CRISPR is often overstated in the context of embryology.

4.1 The Chimera in the Clinic: Mosaicism and Developmental Heterogeneity

Mosaicism is perhaps the most significant barrier to the clinical safety of designer babies. It occurs when the CRISPR edit is not uniform across all cells of the embryo. If the Cas9 enzyme acts slowly, the zygote may divide into two cells before the edit happens. The edit might then occur in only one of the two cells.
As the embryo develops into a fetus and then a baby, it will be a "mosaic"—an organism composed of two or more genetically distinct populations of cells.

- **Scientific Data:** Studies in human embryos have shown high rates of mosaicism. One study indicated that 100% of embryos injected with Cas9 mRNA were mosaic. Another found unintended outcomes in 16% of cells.
- **Consequences:** If the "designer" trait was HIV resistance (CCR5 deletion), a mosaic baby might have resistance in their skin cells but not in their immune cells (T-cells), rendering the "design" useless. Worse, if the edit was to correct a fatal disease, the baby might still suffer from the condition in affected tissues.

4.2 Off-Target Mutagenesis: The Precision Paradox

The human genome contains 3 billion base pairs. A guide RNA targets a sequence of 20 bases. Statistically, similar sequences exist elsewhere in the genome. Cas9 can sometimes bind to these "look-alike" sequences and cut them, causing **off-target mutations**.

- **Risk:** An off-target cut could disable a tumor suppressor gene (like *p53*), essentially programming the baby to develop cancer. Alternatively, it could disrupt a developmental gene, causing congenital malformations.
- **Detection:** Detecting these errors is difficult. Standard PGD (biopsy of 5 cells) cannot sequence the entire genome of the remaining embryo cells to guarantee that no off-target cuts occurred.

4.3 On-Target Chaos: Large Deletions and Chromosomal Rearrangements

Even when CRISPR hits the correct target, the repair process can be destructive. Recent studies on human embryos (specifically targeting the *POU5F1* gene) revealed that the double-strand breaks often lead to **large deletions** (thousands of letters missing) or **chromosomal rearrangements** (part of one chromosome breaking off and attaching to another).

- **Impact:** This level of genomic damage, known as chromothripsis, typically results in embryo arrest (death) or severe developmental disorders incompatible with life. The assumption that CRISPR makes a "clean cut" and a "clean repair" has been proven false in the context of early human embryos.

The He Jiankui Watershed: A Socio-Legal Case Study

Theoretical debates about designer babies collided with reality in November 2018 with the announcement of the birth of twin girls, "Lulu" and "Nana," in China. This event serves as the primary case study for the failure of soft-law regulations and the necessity of criminal statutes[18].

5.1 The CCR5 Experiment: Rationale and Execution

He Jiankui, a biophysicist at the Southern University of Science and Technology in Shenzhen, recruited couples where the male partner was HIV-positive and the female was HIV-negative. His goal was not to cure an existing disease in the embryo, but to *prevent* future infection—a form of "preventative enhancement."
The Target: He targeted the *CCR5* gene. A naturally occurring mutation, *CCR5Δ32*, makes individuals resistant to

[9]Portland Press. (n.d.). Beginner's guide to CRISPR-Cas9-based gene editing. https://portlandpress.com/biochemist/article/43/4/36/229007/Beginner-s-guide-to-CRISPR-Cas9-based-gene-editing

[10]Wikipedia. (n.d.). Double-strand break repair model. https://en.wikipedia.org/wiki/Double-strand_break_repair_model

HIV infection (as HIV uses the CCR5 receptor to enter T-cells). He used CRISPR-Cas9 to induce a similar deletion in the embryos.

Scientific Failure:

1. **Mosaicism:** The data released showed that the twins were mosaic. Not all their cells carried the protective mutation.
2. **Novel Mutations:** The edits did not perfectly replicate the natural *CCR5Δ32* mutation[19]. Instead, they created novel, unstudied mutations whose health effects were unknown.
3. **Lack of Necessity:** The risk of HIV transmission from an HIV-positive father to a child can be effectively eliminated through sperm washing and standard ART, making the risky genetic intervention medically unnecessary.

5.2 The Regulatory Failure and Global Scientific Reaction

The experiment proceeded despite a consensus in the scientific community (articulated at the First International Summit on Human Genome Editing in 2015) that germline editing should not be attempted clinically.

- **Ethical Dumping:** The experiment highlighted the risk of "medical tourism" or lax oversight. He forged ethical review documents and misled the hospital ethics committee.
- **Reaction:** The global community, including the organizers of the Second International Summit in Hong Kong, condemned the experiment as "irresponsible" and a violation of international norms.

5.3 Legal Retribution: From "Illegal Medical Practice" to Criminal Law Amendment XI

At the time of the experiment, China lacked a specific criminal statute banning gene editing.

- **The Verdict:** In December 2019, He Jiankui was sentenced to three years in prison under **Article 336** of the Criminal Law for "illegal medical practice." The court ruled he practiced medicine without a license and violated relevant regulations.

Legislative Response: Recognizing the gap, the Standing Committee of the National People's Congress passed **Amendment XI to the Criminal Law** in December 2020[20].

- **New Article 336-1:** This article explicitly criminalizes "the implantation of genetically edited or cloned human embryos into the body of a human being or animal."
- **Penalty:** Up to 3 years imprisonment for serious circumstances, and 3-7 years for "especially serious" circumstances.

This amendment represents a pivotal shift: the creation of a designer baby is no longer just a regulatory violation in China; it is a specific statutory crime.

Global Legal Frameworks: Comparative Jurisprudence

The governance of germline editing is characterized by a "patchwork" of national laws, ranging from permissive regulation to constitutional bans.

6.1 United Kingdom: The HFEA and the Licensed Exception Model

The UK is widely regarded as having the most robust and adaptable framework, centered on the **Human Fertilisation and Embryology Act 1990 (HFE Act)**[21].

- **The Regulator:** The **Human Fertilisation and Embryology Authority (HFEA)** is an independent statutory body that oversees all fertility clinics and embryo research.
- **The Prohibition:** Section 3(3) of the Act prohibits placing an embryo in a woman unless it is a "permitted embryo." A permitted embryo is defined as one whose nuclear DNA has not been altered. This effectively bans CRISPR babies.
- **The Flexibility:** The Act allows Parliament to amend the definition of "permitted embryo" through secondary legislation (regulations) rather than a full new Act. This power was used in 2015 to legalize Mitochondrial Replacement Therapy (MRT). The UK remains the only country with a clear legal pathway to

[11]In Vivo BioSystems. (n.d.). HDR vs. NHEJ. https://invivobiosystems.com/crispr/hdr-vs-nhej/

[12]Genetic Literacy Project. (n.d.). Gene editing regulations tracker: United Kingdom germline embryonic. https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/united-kingdom-germline-embryonic

[13]Wikipedia. (n.d.). Assisted reproductive technology. https://en.wikipedia.org/wiki/Assisted_reproductive_technology

[14]UCSF Health. (n.d.). Pre-implantation genetic diagnosis. https://www.ucsfhealth.org/treatments/pre-implantation-genetic-diagnosis

[15]NCBI. (n.d.). Article on genetic diagnosis. https://pmc.ncbi.nlm.nih.gov/articles/PMC6733984

[16]Cleveland Clinic. (n.d.). Intracytoplasmic sperm injection. https://my.clevelandclinic.org/health/treatments/22463-intracytoplasmic-sperm-injection

license specific forms of germline modification if they are proven safe.
- **Research:** The HFEA regularly licenses CRISPR research on embryos (up to 14 days), such as Dr. Kathy Niakan's work on the *OCT4* gene, ensuring scientific progress continues under strict oversight.

6.2 United States: The FDA, Appropriations Riders, and the "Regulatory Tangle"

The US approach is less a coherent policy and more a bureaucratic blockade.
- **FDA Authority:** The FDA asserts that gene-edited embryos are "drugs" or "biological products" under the **Public Health Service Act** and the **Federal Food, Drug, and Cosmetic Act**. Therefore, any clinical use requires an Investigational New Drug (IND) application.
- **The Aderholt Amendment:** Since 2015, Congress has attached a "rider" to the FDA's annual budget appropriations bill. This rider explicitly forbids the FDA from acknowledging or reviewing any submission for a clinical trial involving heritable genetic modification.
- **Implication:** This creates a *de facto* ban. Even if a scientist had a safe, perfect technique, the FDA is legally barred from even reading their application.
- **The Loophole:** Unlike the UK and many EU nations, there is no federal law in the US that criminalizes the *creation* of a gene-edited baby if it were done with private funding and without FDA approval (though this would be a violation of the FD&C Act regarding unapproved drugs, it is not a specific "bioethics crime").

6.3 European Union: The Oviedo Convention and the Dignity Doctrine

Europe adopts a "human rights" approach rooted in the concept of human dignity.
- **The Oviedo Convention (1997):** This is the only binding international treaty on bioethics. **Article 13** states that an intervention on the human genome "may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."
- **Effect:** This constitutes an absolute ban on heritable germline editing. Most EU countries (e.g., France, Spain, Switzerland) have ratified this or have domestic laws mirroring it. It reflects a "bioconservative" view that the human germline is inviolable.

The Indian Legal Landscape: Constitutional and Statutory Analysis

For an Indian law student, understanding the domestic framework is critical. India occupies a unique position: it has high-tech fertility capabilities (a massive IVF market) but a regulatory framework that is largely guideline-based rather than statutory regarding gene editing[^22].

7.1 Constitutional Provisions: Article 21, Reproductive Autonomy, and the Right to Science

Article 21 (Right to Life and Personal Liberty) is the font of bioethical jurisprudence in India.

- **Reproductive Autonomy:** In *Suchita Srivastava v. Chandigarh Administration* (2009)[^23], the Supreme Court held that "reproductive autonomy" is a dimension of personal liberty under Article 21. This includes the right to make choices regarding procreation.
- **Privacy:** In *K.S. Puttaswamy v. Union of India* (2017)[^24], the Court reaffirmed privacy as a fundamental right. A litigant could argue that the genetic composition of their child is a private family matter, protected from state interference.
- **Counter-Argument (Public Order/Health):** However, Article 21 is not absolute. The state can restrict rights for "compelling state interests." The preservation of the human gene pool and the prevention of eugenic inequality would likely be accepted by the courts as valid grounds to restrict the right to create designer babies.
- **Right to Health:** If gene editing is the *only* way for a couple to have a healthy child (e.g., both parents

[17]National Human Genome Research Institute. (n.d.). Mitosis. https://www.genome.gov/genetics-glossary/Mitosis
[18]Stanford Law School. (2022). CRISPR: He Jiankui v. Science. https://law.stanford.edu/wp-content/uploads/2022/05/25-STLR-290-2022_CRISPR-People-He-Jiankui-v.-Science_Macintosh.pdf
[19]Wikipedia. (n.d.). He Jiankui affair. https://en.wikipedia.org/wiki/He_Jiankui_affair
[20]MPS. (n.d.). Content on gene editing. https://www.mps.gov.cn/n2255079/n6865805/n7355748/n7913217/c7917775/content.html
[21]UK Legislation. (n.d.). Human Fertilisation and Embryology Act 1990. https://www.legislation.gov.uk/ukpga/1990/37/contents

homozygous for a dominant genetic disease), a ban might be challenged as violating the "Right to Health" implied in Article 21.

7.2 The Statutory Void: Environment (Protection) Act, 1986 and the Definition of "Organism"

India does not have a "Human Genome Editing Act." Instead, regulation is shoehorned into environmental law.

- **Rules 1989:** The *Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989*, notified under the **Environment (Protection) Act (EPA), 1986**[^25], are the primary legal text.

Definitions:

- **"Genetically Engineered Organism" (GEO):** The Rules define this broadly. While intended for GMO crops and bacteria, the text covers "cells" and "organisms." Technically, a human zygote modified by CRISPR is a "Genetically Engineered Cell" under Rule 2.
- **The GEAC:** Under these rules, the **Genetic Engineering Appraisal Committee (GEAC)**[^26] is the competent authority to approve uses of GEOs. However, the GEAC sits under the Ministry of Environment and is designed for environmental safety (biosafety), not medical ethics. It is structurally unsuited to regulate human clinical trials.

7.3 The ICMR Guidelines (2017 & 2019): Ethical Codes vs. Enforceable Law

The **Indian Council of Medical Research (ICMR)** attempts to fill the statutory gap with guidelines[^27].

1. **National Guidelines for Stem Cell Research (2017):**

- **The Ban:** Explicitly states that "research related to human germline gene therapy and reproductive cloning" is prohibited.
- **The 14-Day Rule:** Permits in vitro research on embryos only up to 14 days or primitive streak formation.

2. **National Guidelines for Gene Therapy Product Development and Clinical Trials (2019):**

- Defines "Gene Therapy Products" (GTPs) as "New Drugs" under the **New Drugs and Clinical Trials Rules, 2019**.
- **Reiteration of Ban:** States: "Due to ethical and social reasons, germline gene therapy is banned in India."
- **Regulatory Pathway:** For somatic therapies, it establishes a hierarchy involving the **Gene Therapy Advisory and Evaluation Committee (GTAEC)**, the **CDSCO** (Drug Controller), and Institutional Ethics Committees.

The Enforceability Problem: While the *New Drugs Rules 2019* have statutory force (under the Drugs and Cosmetics Act), the specific prohibition on germline editing is contained in the *Guidelines*. In Indian administrative law, guidelines do not always have the full force of a statute unless explicitly backed by one. A rogue clinic could theoretically challenge the ban, arguing that "germline editing" is not a "drug" in the traditional sense. However, the classification of GTPs as "new drugs" closes much of this gap, requiring CDSCO approval, which would be denied based on the guidelines.

7.4 The Judicial Role: Developing a Jurisprudence of Genetic Integrity

Unlike the US Supreme Court, which has not ruled directly on gene editing, the Indian Supreme Court has a history of proactive intervention in environmental and health matters (e.g., *M.K. Ranjitsinh* case on the Great Indian Bustard, invoking Article 21 for environmental protection). It is likely that any future challenge to gene editing regulations would see the Court invoking the "Precautionary Principle" to uphold the ban on designer babies, prioritizing the collective safety of the human gene pool over individual reproductive liberty.

Ethical Jurisprudence: The Philosophy of Genetic Governance

The legal regulation of designer babies is ultimately an expression of ethical philosophy.

[22]Cyril Amarchand Mangaldas. (2025). Designer babies in India: Ethical dilemma and legal roadblocks. https://corporate.cyrilamarchandblogs.com/2025/04/designer-babies-in-india-ethical-dilemma-and-legal-roadblocks/

[23]Dhyeya Law. (n.d.). Suchita Srivastava v. Chandigarh Administration and ors. (2009). https://www.dhyeyalaw.in/suchita-srivastava-v-chandigarh-administration-and-ors-2009-13-scr-989

[24]Supreme Court of India. (n.d.). Judgment on gene editing. https://digiscr.sci.gov.in/view_judgment?id=NjEwMg==

[25]India Code. (n.d.). The Environment Protection Act, 1986. https://www.indiacode.nic.in/bitstream/123456789/4316/1/ep_act_1986.pdf

[26]GEAC India. (n.d.). About GEAC India. http://geacindia.gov.in/about-geac-india.aspx

8.1 Liberal Eugenics vs. Authoritarian Eugenics[^28]

20th-century eugenics was **Authoritarian**: the state coercing individuals (forced sterilization) to improve the "national stock." The modern "Designer Baby" movement is termed **Liberal Eugenics** (by philosophers like Nicholas Agar). It argues that eugenics is permissible if:

1. It is voluntary (parental choice).
2. It is state-neutral (the government doesn't define the "good" genome).
3. It does not harm the child.

However, critics argue that individual choices aggregate into social coercion. If 90% of parents enhance their children's intelligence, the remaining 10% are effectively disabled by society's new standard. This leads to the "Gattaca" scenario—a society stratified not by race or class, but by genetic validity.

8.2 The Right to an Open Future and Intergenerational Consent

A central legal-ethical objection is the lack of consent. A fetus cannot consent to genetic modification. Philosopher Joel Feinberg's concept of the **"Right to an Open Future"** argues that parents hold rights in trust for the child. They must keep the child's future options open until the child is an adult.

- **Violation:** If parents genetically engineer a child to be a "perfect musician" or "deaf" (as in the case of deaf parents wanting a deaf child), they violate the child's right to an open future. Germline editing is an irreversible bio-physiological determination of the child's life trajectory.

8.3 Distributive Justice: The Threat of a Genetically Stratified Society

In a market-driven system (like the US or India's private healthcare sector), gene editing would be a luxury good. This poses a threat to the constitutional value of equality.

- **The "Genorich":** If the wealthy can purchase genetic immunity to disease, higher IQ, and physical longevity, biological differences will reinforce economic class.
- **Article 14 (India):** The state has a duty to prevent such radical inequality. A complete ban or strict price control/public access model would be the only ways to align designer babies with egalitarian constitutional principles.

Future Horizons: Polygenic Scores and Ectogenesis

While regulators focus on CRISPR, other technologies are bypassing the ban.

- **Polygenic Embryo Screening:** Companies like Orchid Biosciences now offer PGD that screens not just for single diseases, but for "Polygenic Risk Scores" (PRS)—calculating an embryo's genetic risk for diabetes, heart disease, or schizophrenia based on thousands of genetic markers. This allows for "soft" design (selection) without "hard" editing[29].
- **Ectogenesis (Artificial Wombs):** Research into growing fetuses outside the body is advancing. This challenges the "viability" framework of abortion law and could theoretically allow for extensive genetic monitoring and intervention during gestation, requiring a complete overhaul of prenatal law.

Conclusion and Legislative Recommendations

The "designer baby" has moved from the realm of science fiction to the docket of the legislature. The scientific reality—defined by the mechanics of CRISPR-Cas9, the risks of mosaicism, and the inevitability of technological improvement—demands a legal response that is nuanced, enforceable, and globally harmonized.

Summary of Findings:

1. **Scientific Immaturity:** The technology is currently too risky for clinical application (mosaicism, off-target effects).
2. **Regulatory Fragmentation:** The world is divided. China has criminalized it; the UK regulates it; the US blocks it via funding; India bans it via guidelines.

[27]Indian Council of Medical Research. (2019). Guidelines for preimplantation genetic diagnosis. https://www.icmr.gov.in/icmrobject/uploads/Guidelines/1724844182_icmr_pripe2019.pdf

[28]Stanford Encyclopedia of Philosophy. (2014). Eugenics. https://plato.stanford.edu/archives/fall2014/entries/eugenics/

[29]Orchid Health. (n.d.). Polygenic embryo screening and your family. https://guides.orchidhealth.com/post/polygenic-embryo-screening-and-your-family

3. **The Indian Gap:** India's reliance on the Environment Protection Act and ICMR Guidelines is insufficient. The lack of a specific "Biomedical Technology Offenses" statute creates a vulnerability to rogue actors.

RECOMMENDATIONS:

- **For India:** Enact a **Biomedical Technology Regulation Act**. This Act should:
- Explicitly define the legal status of the human embryo.
- Create a statutory body (modeled on the UK HFEA) specifically for human genetic research, separate from the environmental GEAC.
- Criminalize unauthorized heritable genome editing with specific penal provisions, mirroring China's Article 336-1.
- **Global:** Establish an international treaty (beyond the soft law of UNESCO) that defines a "safe harbor" for therapeutic research while enforcing a moratorium on reproductive enhancement.

The law must not merely react to technology; it must shape the conditions of its emergence. In the case of the designer baby, the law is the only barrier between the dignity of the human species and the vagaries of the genetic marketplace.