Ethical Issues in Biotechnology

For Mains: Ethical concern related to different methods of the biotechnology

What is Biotechnology?

Biotechnology stands at the forefront of scientific advancement, offering transformative solutions in **medicine**, **agriculture**, and **environmental sustainability**. However, the rapid development and application of biotechnological methods such as in **stem cell research**, **cloning**, and **genetic engineering**, raise significant ethical concerns.

- Biotechnology represents a rapidly evolving field with profound implications for healthcare, agriculture, and environmental management. While its advancements promise significant benefits, they also raise critical ethical concerns that require careful examination.

What are the Ethical Concerns Associated with Biotechnology?

- **Stem Cell Research**
  - **About:**
    - Stem cell research studies the basic building blocks of life to learn about health, disease, and develop new treatments. Stem cells can treat blood conditions and **cancers**, and are being studied for their potential to help with other diseases.
  - **Ethical issues Associated:**
    - **Destruction of Embryos:** One of the most contentious ethical issues in stem cell research is the destruction of **human embryos**.
      - Proponents argue that research on embryos can lead to significant medical breakthroughs, while opponents view the destruction of embryos as morally equivalent to taking a life.
      - The **US National Institutes of Health (NIH)** reports that stem cell research has the potential to provide cures for diseases such as **Parkinson's disease, diabetes**, and **spinal cord injuries**. However, the use of embryonic **stem cells** remains controversial due to the ethical implications of embryo destruction.
    - **Informed Consent and Exploitation:** The process of obtaining stem cells often involves **consent from donors,** particularly in cases where surplus embryos from **in vitro fertilization (IVF)** are used.
      - Concerns arise about whether donors are fully informed about how their embryos will be used and the potential for exploitation of vulnerable populations.
      - Ethical frameworks, such as the **Belmont Report,** emphasize the importance of informed consent and respect for persons, raising questions about whether current practices sufficiently safeguard donor rights.
        - The Belmont Report is a set of ethical principles and guidelines for research involving human subjects, created by the US-based body **National Commission for the Protection of Human**

Subjects of Biomedical and Behavioral Research in 1978.
        - The report's three basic ethical principles are **respect for persons, beneficence,** and **justice**. Its purpose is to help resolve ethical issues that arise from research with human subjects, recognizing the limitations of previous codes and providing a basis for establishing rules for research.
    - **Equity and Access:** The **commercialization of stem cell therapies** raises ethical concerns regarding equitable access. Advanced therapies may be accessible primarily to affluent individuals, exacerbating existing health disparities.
        - A 2019 study published in US-based journal **Health Affairs** indicates that access to advanced medical treatments is often linked to socioeconomic status, highlighting the need for policies that ensure fair distribution of biotechnological innovations.

- **Cloning**
    - **About:**
        - Cloning is a process that **creates genetically identical copies** of an organism by **replicating an individual's genetic blueprint.**
        - The clones are **produced asexually** and are **identical to their parent** in both physical and genetic makeup.
    - **Types:**
        - **Reproductive Cloning:**
            - It is a technique used to **create an organism that is genetically identical** to the donor organism. This involves **transferring the nucleus of a somatic cell into an enucleated egg cell,** which is then implanted into a surrogate mother.
            - **Example:** The most famous example is **Dolly the Sheep**, the first mammal cloned using **somatic cell nuclear transfer (SCNT)**.
        - **Therapeutic Cloning:**
            - It is aimed at **generating embryonic stem cells** for research or medical treatment by creating a cloned embryo and harvesting stem cells from it.
            - It aims to **develop treatments for degenerative diseases** such as **Parkinson's, Alzheimer's, and diabetes** or to regenerate damaged tissues.
            - **Example:** Stem cells derived from cloned embryos have been studied for their potential in regenerative medicine, such as creating patient-specific stem cell lines.
        - **Gene Cloning (Molecular Cloning):**
            - It is the process of **creating multiple copies of a specific gene or DNA segment.** This involves **inserting the desired DNA into a vector** (e.g., plasmids) and introducing it into host cells, usually bacteria, where it replicates.
            - It is widely used in **genetic research, biotechnology, and medicine** for producing proteins, studying genes, or creating genetically modified organisms.
            - **Example**: Insulin production is a classic example where a human **insulin gene** is cloned into **E. coli bacteria** to produce insulin on a large scale for diabetic patients.
        - **Embryo Cloning (Artificial Twinning):**
            - It is the process of **splitting an early-stage embryo (blastocyst)** into two or more identical embryos. Unlike reproductive cloning, this **mimics the natural process** of creating identical twins.
            - It is mostly used in **agricultural and livestock breeding** to produce animals with desirable traits.
            - **Example:** Artificial twinning has been used to **clone cattle**, such as producing identical calves with superior genetic qualities for milk production or disease resistance.
    - **Associated Ethical Issues:**
        - **Identity and Individuality:**
            - Cloning, especially **reproductive cloning,** raises profound ethical

questions regarding identity. If a clone is genetically identical to another individual, issues surrounding personal identity, individuality, and rights become critical.
- Philosophers such as David Hume have argued that individuality is not solely defined by **genetics** but also by experiences and personal development. **Cloning** may undermine the uniqueness of an individual.

- **Health Risks:**
  - Cloning poses significant health risks, not only to the cloned individual but also to the surrogate mother. Cloned animals often exhibit health problems, and the success rate of cloning remains low.
  - For example, **Dolly the sheep**, the first cloned mammal, lived a shorter life than typical sheep, suffering from various health issues before her death. Such outcomes raise ethical questions about the well-being of clones.
- **Exploitation of Animals:**
  - The use of cloning for agricultural purposes can lead to the exploitation of animals, raising ethical concerns about their treatment and welfare.
  - For Example, Surrogate animals in cloning processes often undergo **multiple invasive procedures,** causing significant stress and health risks. For example, in cloning prize-winning horses, **surrogate mares are repeatedly used for embryo implantation**, raising concerns about their physical and emotional well-being.
  - Cloning often results in **high rates of failure, miscarriages, and stillbirths** in animals. For example, in the process of cloning **Dolly the Sheep,** 277 attempts were made, resulting in 29 viable embryos, only one of which developed into a healthy lamb, highlighting the toll on surrogate animals and embryos involved in the process.
  - Animal welfare organizations have also argued that cloning may lead to **increased suffering and exploitation** in pursuit of agricultural efficiency, challenging the ethical justification of such practices.

- **Genetic Engineering**
  - **About:**
    - **Genetic engineering** is the process of **manipulating an organism's genetic material,** typically by **inserting or deleting specific genes,** to **achieve desired traits or characteristics**.
    - It holds immense promise for **agriculture, medicine, and environmental** conservation.
  - **Genetic Engineering Technologies:**
    - **CRISPR/Cas9 Technology**
      - **CRISPR-Cas9** is a **gene-editing tool** that enables **precise modifications in the DNA** of living organisms.
      - It consists of two key components:
        - **CRISPR**: A guide RNA that directs the **Cas9 enzyme** to a specific DNA sequence.
        - **Cas9:** A **molecular "scissors"** that cuts the DNA at the target location.
      - **Applications:**
        - **Agriculture:** Developing **pest-resistant crops** and enhancing crop yield.
          - **Example:** Rice edited using CRISPR to **resist bacterial blight.**
        - **Medicine**: Treating **genetic disorder**s and infectious diseases.
          - Example: CRISPR is being used to **edit defective genes** responsible for **sickle cell anemia** and **cystic fibrosis.**
        - **Conservation:** Reviving extinct species or saving endangered species.
          - **Example**: Attempts to use CRISPR to edit **elephant DNA** for traits similar to the **wooly mammoth.**
        - **Ethical Concerns:**

        - Risk of **unintended mutations (off-target effects)**.
        - Concerns over **germline editing** and **designer babies.**
    - **Gene Silencing/ Gene Knockdown**
        - **Gene silencing or knockdown** refers to **techniques used to suppress or reduce the expression of a specific gene**.
        - It is achieved through mechanisms like **RNA interference (RNAi), antisense oligonucleotides**, or **CRISPR interference (CRISPRi).**
        - **Applications:**
            - **Disease Treatment:** Silencing genes involved in disease pathways.
                - **Example**: **RNAi-based drugs** like **Patisiran**, approved for treating **hereditary transthyretin-mediated amyloidosis,** silence the gene responsible for producing the faulty protein.
            - **Research:** Understanding gene function by observing the effects of reduced gene expression.
                - **Example:** Gene knockdown in mice to study the role of **tumor suppressor genes** in cancer.
            - **Agriculture**: Creating **crops resistant to pests and pathogens**.
                - **Example**: Gene silencing to develop **plants resistant to the papaya ringspot virus.**
    - **Ethical and Safety Concerns:**
        - Possibility of **unintended gene interactions.**
        - **Environmental risks**, such as altered ecological balance in agriculture.
- **Associated Ethical Concerns:**
    - **Playing God:**
        - Genetic engineering raises concerns about humanity's role in altering life forms. The ability to manipulate genes can be seen as overstepping natural boundaries.
        - The possibility of creating **"designer babies"** through genetic modification raises ethical concerns related to **eugenics** and **social inequality.** The capacity to select specific traits may reinforce societal inequalities, creating a divide between those who can afford genetic enhancements and those who cannot.
        - This challenges the moral authority of nature and questions the limits of scientific intervention in biological processes.
        - A 2020 report from the American Association for the Advancement of Science cautions against the socio-economic implications of genetic modification, emphasizing the risk of creating a genetically stratified society.
    - **Informed Consent:**
        - The complexity of genetic technologies may hinder individuals' understanding of the implications of genetic modifications.
        - Thus, ensuring informed consent, particularly in **genetic testing** and therapies, is crucial. Individuals must fully understand the risks and benefits involved.
    - **Biodiversity and Ecological Impact:**
        - Genetic engineering in agriculture, particularly the use of **Genetically Modified Organism (GMO)** raises environmental ethical issues. The release of GMOs into ecosystems may lead to unintended consequences, including loss of biodiversity and the emergence of resistant pests.
        - There is a moral responsibility to protect ecosystems and consider the long-term effects of introducing **genetically modified organisms (GMOs).**
        - The **United Nations** **Food and Agriculture Organization (FAO)** highlights concerns about the long-term ecological impact of GMOs, suggesting that comprehensive risk assessments are necessary before widespread adoption.
    - **Equity and Access:**
        - **Genetic engineering** technologies may exacerbate existing inequalities,

as access to these advancements could be limited to wealthy individuals or nations.
- Ensuring equitable access to genetic technologies is vital to prevent a divide between those who can afford enhancements and those who cannot.
- The potential for misuse of genetic information raises concerns about discrimination in employment, insurance, and social services.

Way Forward

- **Establishing Ethical Guidelines:** Comprehensive **ethical frameworks** should emphasize **respect for human dignity, informed consent, and equitable access** to biotechnological innovations.
    - The **Nagoya Protocol** adopted in **2010**, aims to promote the **fair and equitable sharing of benefits** arising from the utilization of **genetic resources.**
- **Investing in Independent Research**: Independent research helps **evaluate long-term effects and unintended consequences,** ensuring responsible progress. Transparent research practices foster **public trust** and enable **informed decision-making**.
- **Implementing Stringent Safety Measures**: Robust safety protocols must be enforced to **minimize risks and prevent harmful outcomes**.
    - Responsible practices in **genetic engineering** are essential to safeguard human health and the environment.
- **Preventing Discrimination:** Regulations must prohibit the misuse of biotechnology for discriminatory purposes, including **genetic discrimination**.
    - Strict **anti-discrimination policies** can ensure ethical and equitable applications of genetic engineering.
- **Ensuring Equitable Access:** Biotechnological innovations should be **accessible to all,** regardless of socioeconomic status, to **avoid disparities and maximize societal benefits.**
    - The **Cartagena Protocol on Biosafety** is an international agreement that aims to ensure the **safe handling, transport, and use of living modified organisms (LMOs)**. The protocol was **adopted in 2000** as a supplementary agreement to the **Convention on Biological Diversity (CBD).**
- **Promoting International Cooperation:** Given the global nature of biotechnological challenges, harmonized ethical standards are crucial. International cooperation through organizations like the **World Health Organization (WHO)** and the **World Trade Organization (WTO)** can address cross-border issues and **promote equitable access** to biotechnology.
- **Ensuring Sustainable Development**: Ethical considerations play a pivotal role in ensuring that biotechnology contributes to **sustainable development goals (SDGs).** By addressing ethical dilemmas, biotechnology can help tackle global challenges like **food security, health crises**, and **environmental sustainability.**

UPSC Civil Services Examination, Previous Year Question (PYQ)

Mains

Q. Dr. Srinivasan is a senior scientist working for a reputed biotechnology Company known for its cutting-edge research in pharmaceuticals. Dr. Srinivasan is heading a research team working on a new drug aimed at treating a rapidly spreading variant of a new viral infectious disease. The disease has been rapidly spreading across the world and the cases reported in the country are increasing. There is huge pressure on Dr. Srinivasan's team to expedite the trials for the drug as there is a significant market for it, and the company wants to get the first-mover advantage in the market. During a team meeting, some senior team members suggest some shortcut for expediting the clinical trials for the drug and for getting the requisite approvals. These include manipulating data to exclude some negative outcomes and selectively reporting positive results foregoing the process of informed consent and using compounds already patented by a rival company, rather than developing one's own component. Dr. Srinivasan is not comfortable taking such shortcuts, at the same time he realizes meeting the targets is impossible without using these means. (2024)

(a) What would you do in such a situation?

(b) Examine your options and consequences in the light of the ethical questions involved

(c) How can data ethics and drug ethics save humanity at large in such a scenario?