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Innovation and Challenges in Biotechnology

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ABSTRACT

This brief analyses the regulatory, security and ethical challenges facing states and the international community regarding emerging technologies in biotechnology, focusing on the CRISPR/Cas9 gene editing system and artificial gene synthesis. It highlights the inadequacy of current mechanisms such as export control regimes to regulate these emerging technologies because of a fundamental shift in the nature of challenges posed and an altered global landscape. The brief also underlines the need for an inclusive mechanism to facilitate discussions on the ethical issues, and suggests possible solutions to the manifold dilemma.

Key Words: the CRISPR/Cas9, artificial gene synthesis, Regulatory, Security and Ethical challenges,

INTRODUCTION

Emerging technologies are often categorized as either new, or continuing advancement of existing ones which will be widely available within a couple of years. Globally, the rapid climb within the field of biotechnology has led to the emergence of newer technologies that have the potential to impact various aspects of people's lives. Technologies like gene therapy, gene editing, synthetic biology, and nanobiotechnology are getting used to deal with a spread of challenges like treating genetic disorders, eliminating tropical diseases like malaria, and using targeted medicine to treat cancer[1]

At an equivalent time, however, these technologies present unique regulatory and bioethical conundrums. Emerging technologies usually undergo a period of familiarization and experimentation during which scientists test their limits and develop promising new applications. During this course of technological maturity, these technologies often challenge existing ethical and regulatory norms, primarily thanks to their novelty. it's difficult to manage them at this stage, because their broader implications on health, the environment, and national security are yet to be fully understood. Regulatory apparatuses eventually catch up and replacement equilibrium is established. However, adequate caution must be exercised during this intervening maturity period which, for a few emerging technologies may last several years.

This brief examines two of the foremost promising advances within the field of biotechnology: the CRISPR/Cas9 gene-editing system, and artificial gene synthesis technology. These technologies illustrate how regulatory and ethical grey-areas are often exploited in ways in which are detrimental to both science and society. Past experience with emerging technologies can help create an understanding of the effectiveness of traditional regulatory approaches and explore alternatives better fitted to the present challenges.

Potential Threats: Two Case Studies

CRISPR/Cas9 Gene Editing Technology

Developments in biotechnology are facilitating significant innovation across the world, especially within the fields of drugs, environment, and agriculture. One with many potential is that the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR/Cas9) system.[2] it's a gene editing technology which was invented almost a decade ago but has revolutionised the sector of medical research and

biotechnology due to its simplicity, efficiency, and cost-effectiveness.
The essence of CRISPR/Cas9 gene-editing system is straightforward enough: It finds the target DNA sequence within the cell and performs desired edits to the gene sequence, all by itself. This functionality also can be wont to turn segments of genes on or off without altering the target DNA sequence. As compared to other gene editing techniques, CRISPR is quick, easy, and extraordinarily cost-efficient. this system are often applied directly in embryo also, reducing the time required to switch target genes as compared to the normal method of using embryonic stem (ES) cells.

CRISPR is already getting used during a sort of ways to deal with contemporary challenges. a number of its applications include development of custom-made gene drives in wild type mosquito populations with potential to eliminate deadly tropical diseases like malaria;[3] making newborns freed from disease by editing out dangerous mutations at the embryonic stage that cause genetic disorders like mongolism and Huntington's disease;[4]and improving the efficiency and production of biofuels by creating strains of algae that produce twice the maximum amount fat, which are then wont to produce biofuels.[5]

To make certain, CRISPR-Cas9 can revolutionise the fields of immunotherapy and gene therapy, among others. However, its simplicity and cost-effectiveness could also enable its use for potentially unethical research, especially because it currently falls in an ethical and regulatory grey-area. In 2018, Chinese scientist, He Jiankui, announced the birth of the world's first-ever 'CRISPR twins'.[6]He used CRISPR technology to edit the genome of human embryos and take away undesirable mutations within the CCR5 gene that creates the cell vulnerable to Human Immunodeficiency Virus (HIV).[7] it had been a surprising and concerning development because CRISPR technology remains at an experimental stage and germline editing has not been approved in humans.

[a] The second- and third order-effects of such genetic edits, that too in genomes of live humans, are unpredictable. What concerned the worldwide scientific community further was that such a consequential experiment was conducted clandestinely, and therefore the result was publicly announced only after the babies were born.[8] Even experiments involving mosquito gene drives that seek to eliminate malaria are being done under controlled conditions precisely because their potential impact on the environment is unknown. The birth of the 'CRISPR twins' lays bare the deficiencies in oversight procedures, both at the worldwide and Chinese-government level that allowed such an experiment to be conducted within the first place.[9]

Artificial Gene Synthesis

Artificial gene synthesis is that the production of gene-length double-stranded DNA fragments through
chemical synthesis of oligonucleotides. Unlike natural DNA synthesis in living cells, artificial gene synthesis doesn't require a template DNA, allowing almost any sequence to be synthesised.[10] The technology makes it possible to supply DNA molecules that don't exist naturally in living organisms. Gene synthesis isn't a replacement technology, and DNA fragments are synthesized in laboratories since the 1970s. However, earlier methods were time-consuming, prohibitive, and susceptible to errors. Commercial gene-synthesis services available today have shorter turnaround times, are costeffective,
and are virtually error-free. this is often fast becoming an enabling technology for contemporary biology. This technology provides several advantages during the research and development process. Gene synthesis is employed to form custom plasmids,[b] optimize organic phenomenon,[c] produce recombinant antibodies,[d] study mutant genes and even design and synthesize DNA vaccines. It provides greater flexibility to scientists in choosing target sequences for his or her experiments. However, as is that the case with many emerging technologies, artificial gene synthesis, if unregulated, can become a national security and public health risk.

The accessibility and advantages of this technology makes it a potentially attractive instrument, for instance, for bioterrorism. In accordance with international treaties like the Biological Weapons Convention (BWC), several microbiological agents, including specific strains of bacteria and viruses are strictly regulated thanks to their potential to be used as ingredients of biological weapons. These include causative agents of deadly diseases like tuberculosis, anthrax, rinderpest, and botulism. To mitigate the likelihood of non-state and malicious actors using these strains for a biological warfare, their use in biomedical research is tightly regulated by countries.[11] However, availability of low-cost gene-synthesis services is testing the bounds of this regulatory approach.

Many of the precise virulent or infectious strains restricted under the BWC have their non-lethal, non-infectious and commonly found counterparts. For instance, several strains of E. coli are often found within the typical human gut—they are harmless, and exist during a symbiotic state in our large intestines providing resistance against pathogenic organisms. However, a selected strain of E. coli like the Shiga-toxin producing one, can cause bloody diarrhoea and renal failure. it's the potential to make a public health scare or disrupt agricultural supply chains. Most worrying is that only a couple of specific genes determine whether an E. coli is going to be harmless and harmful: this might be exploited by a trained biologist to convert a commonly available variant into a virulent one. While such risks have existed in theory for several decades, traditional gene synthesis methods in use were prohibitive and not considered as explanation for concern. However, recent advancements in gene editing technologies alongside cheap, commercially available gene-synthesis services[e] have converted a once theoretical threat into a true one.[12]In 2017, David Evans and his team at the University of Alberta announced that they used synthetic biology tools to recreate the extinct horsepox virus, which is closely associated with the smallpox virus that causes smallpox.[13] They purchased multiple overlapping DNA fragments from a billboard German gene-synthesis company and stitched together a functional 212,000-base-pair horsepox virus genome in their laboratory. Furthermore, they were ready to grow, sequence and characterize the synthetic sequence along the lines of predicted natural sequence. This led to concern among the scientific community that this experiment could even be

replicated to synthetically recreate the smallpox virus, given its close relation with horsepox.[14]More recently, there are concerns raised by several governments, scientists and national security experts regarding the origin of the SARS-CoV-2 virus that causes Covid-19. The theories include an accidental leak of an artificial corona virus, and a genetically-edited corona virus that 'escaped' from a laboratory.[15]Investigations into the origins of SARS-CoV-2 are still ongoing and are fraught with geopolitical implications of their own.[f] However, the pandemic experience highlights that existing regulatory procedures at the national and international level are inadequate to deal with the emerging biosafety and biosecurity risks posed by emerging technologies.

Balancing Alarmism and Regulation

Historically, emerging technologies are often developed with either beneficial or harmful intent. The challenge for the worldwide community is to develop regulations that don't stifle innovation and protect scientific freedom, while ensuring enough checks and balances to minimize risks posed by the misuse of such advancements. The potential for technologies like CRISPR/Cas9 and artificial biology to profit humanity far exceeds the risks their misuse may pose. Both these technologies have also been at the forefront of tackling the Covid-19 pandemic. Several vaccines that have either been developed or are under development, including mRNA vaccines have used both of those technologies in their vaccine development process.[16]Furthermore, extensive collaboration between scientists from across the world wouldn't are possible without the free flow of data. Extremely restrictive regulations would have added more months to the vaccine development process—something that the planet couldn't afford.

However, information asymmetry between the scientific community and therefore the general public, alongside the role of media, often results in alarmism and impulsive policymaking. this is often true also for emerging technologies. The scientific community bears a singular responsibility to uphold the very best standards of biosafety and ethical probity because a couple of isolated incidents of misuse and negligence can negatively affect public perception and hamper growth prospects of the emerging technology. The 1999 case of Jesse Gelsinger from us is sort of instructive during this regard. Gelsinger was the primary person to be publicly identified as having died during a clinical test for gene therapy. [17]He had a rare genetic disease and took part during a gene therapy trial for an equivalent disease at the University of Pennsylvania. He died at the age of 18, of complications from an inflammatory response triggered by his body shortly after receiving a dose of the experimental adenovirus vector. The investigation conducted by us Food and Drug Administration (USFDA) concluded that the scientists involved within the trial broke certain rules of conduct. This was a grave setback for the gene-therapy technology. Following the incident, all gene therapy trials within the us was halted for a few times. Funding for gene therapy research dried up and deep scepticism developed among the general public and policymakers regarding the technology.[18]Indeed, it took quite a decade for the sector to get over this setback.[19]Given the complicated, technical, and unpredictable nature of scientific experimentation, better regulatory mechanisms should be devised to tackle contemporary challenges. At an equivalent time, these measures shouldn't stifle scientific freedom nor cause unnecessary alarm among the general public or policymakers.

Current Regulatory Landscape

Global

National governments tend to enact domestic regulations when emerging technologies reach a desired threshold to be used, adoption or commercial viability. Similarly, as global health, biosecurity, and ethical implications of certain emerging technologies start becoming apparent, involves multilateral regulatory frameworks also strengthen.

Historically, technologies with potential national security implications are subjected to regulations aimed toward limiting their spread and monitoring their use. This has been attempted by institutionalizing export control regimes and thru legislative or executive actions at the extent of individual states. for instance, the Australia Group (AG) is an export-control organization that compiles an inventory of technologies, equipment, and pathogens with the potential to be used for chemical or biological weapons development. This list is employed by nations to harmonise their own export-control regulations. Similarly, there are international treaties like the Cartagena Protocol on Biosafety to the Convention on Biological Diversity that govern movement of living modified organisms (LMOs) resulting from modern biotechnology from one country to a different. But countries still retain significant freedom to formulate their own regulations.

Ethical standards for research and development (R&D) activities are usually enforced through legislations or guidelines issued by national governments. there's no global multilateral institution that issues binding guidelines on the moral aspects of innovation, although some international conventions detail broad bioethical principles that countries can use as a template to border their own guidelines. for instance, UNESCO's Universal Declaration on Bioethics and Human Rights (2005) as adopted by the United Nations General Assembly (UNGA) outlines "universal standards within the field of bioethics with due regard for human dignity and human rights and freedoms, within the spirit of cultural pluralism inherent in bioethics."[20]Furthermore, intergovernmental organizations like the UN Inter-Agency Committee on Bioethics (UNIACB) are constituted to facilitate discussions on bioethics. It is incumbent upon national governments to manage these emerging technologies through domestic legislations or guidelines. Several countries[g] have already issued detailed guidelines which will regulate emerging technologies within the biotechnology field, including regulations and guidelines on bioethics. India.

In India, the Ministry of Environment, Forest, and global climate change (MoEFCC), Ministry of Science and Technology (MoST) and Ministry of Health and Family Welfare (MoHFW) are liable for regulating different aspects of R&D in biotechnology.

For R&D of genetically modified organisms (GMOs), the overarching regulatory framework has been notified under the Environment (Protection) Act, 1986 through 'Rules for manufacture, use/import/export & storage of hazardous

microorganisms/genetically engineered organisms or cells, 1989.' These rules are to be jointly implemented by MoEFCC, Department of Biotechnology (DBT) under MoST and respective state governments. As per these rules, six committees are constituted (See Table 1).

Table 1: Regulatory committees and functions

Regulatory Committee	Function
Recombinant DNA Advisory Committee (RDAC)	An advisory body that takes note of developments in field of biotechnology at national and international level
Institutional Biosafety Committee (IBSC)	Any institution that intends to engage in research activity that involves genetic manipulation of microorganisms, plants or animals is mandated to constitute an IBSC. It also ensures that necessary guidelines are properly implemented within the research institution.
Review Committee on Genetic Manipulation (RCGM)	A regulatory body that monitors safety related aspects of research projects involving genetically engineered organisms.
Genetic Engineering Appraisal Committee (GEAC)	The apex regulatory body housed under the MoEFCC. It approves activities involving large scale use of hazardous microorganisms and recombinant products such as commercial introduction of GMO crop varieties.
State Biotechnology Coordination Committee (SBCC)	Acts as monitoring body that ensures compliance of relevant guidelines by research institutions at the state level and coordinates with DLCs within its jurisdiction.
District Level Committees (DLC)	Acts as monitoring body that ensures compliance of relevant guidelines by research institutions at the district level.

Source: BMC Proceedings[21]

For research involving human participants and clinical trials, a separate framework by the Central Drugs Standard Control Organization (CDSCO) under the MoHFW is applicable. The Drugs and Cosmetics Act, 1940 is that the governing legislation under which Indian Good Clinical Practice Guidelines for Clinical Trials, 2001 and New Drugs and Clinical Trials Rules, 2019[22] are notified. CDSCO has mandated that Clinical trials should be registered online in Clinical Trials Registry–India (CTR-I), a national public record system for registration of clinical trials. The rules also mandate that every research institution establish an Institutional ethics panel (IEC). Quite 1200 Ethics Committees have already been established by various institutions and registered with CDSCO.[23]

The National Apex Committee for somatic cell Research and Therapy (NAC-SCRT) is constituted by MoHFW to oversee the activities within the field of somatic cell research in India. The committee examines the scientific, technical, ethical, legal and social issues involving somatic cell research and therapy. All institutions completing research on human stem cells are mandated to constitute an Institutional Committee for somatic cell Research (IC-SCR) and register it with the NAC-SCRT.

The Indian Council of Medical Research (ICMR) alongside Department of Biotechnology (DBT) has also published National Guidelines for somatic cell Research, 2017. The rules restrict genome modification including gene editing by CRISPR-Cas9 technology of stem cells, germ-line stem cells or gamete and human embryos to in-vitro studies only.[24]the rules also prohibit culturing of genome modified human embryos beyond 14 days of fertilization. Furthermore, ICMR has also published National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. These are applicable to all or any biomedical, social, and behavioral science research for health conducted in India involving human participants, their biological material, and data.

At the worldwide level, India is signatory to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and India's domestic export control regulations are fully aligned with guidelines of the Australia Group (AG). However, there's need for better coordination and collaboration between countries at regional and global level regarding these guidelines.

Challenges with Current Regulatory Mechanisms

The transnational nature of biotechnology research makes it increasingly difficult for both scientists and corporations to stick to different regulatory norms in several countries. Countries like Germany, the United Kingdom and therefore the US each have their well-developed biotechnology sector with the potential to manufacture cutting-edge laboratory equipment like gene sequencers, gene synthesisers, advanced experimental kits, and reagents. Meanwhile, countries like India, Israel and lots of in Asia, Africa and South America need to rely exclusively on imports of such equipment. Collaborations between scientists of various countries have also increased thanks to the decentralized nature of biomedical research. Given the bioethical and national security implications of the many emerging technologies, it's imperative that a multilateral regulatory system is developed.

Traditionally, export control regimes have regulated technologies with implications on global and national security. Export control regimes are multilateral institutions that seek to stop proliferation of technologies which will be wont to develop nuclear, chemical, or biological weapons. These institutions have played a crucial role in regulating cross-border flow of probably dangerous dual-use technologies. However, there are significant challenges

involved in regulating emerging technologies in biotechnology through export controls.

First, it's difficult to manage the worldwide flow of data concerning these technologies thanks to the open and collaborative nature of research project. Many of those techniques use commonly available reagents and laboratory equipment that might be practically impossible to manage through export controls. Furthermore, tight export control regulation would only contribute to stifling research and development (R&D) activities as these technologies are fast becoming the cornerstone of biomedical research across various fields. For instance, the CRISPR technology is actually a variant of natural self-defense mechanism in bacteria that has been tweaked to be used as a gene editing tool. The biological principle underpinning the technology is general knowledge and a trained biologist would face little difficulty in conducting experiments using CRISPR anywhere within the world. Furthermore, commercially available CRISPR kits have only simplified the experimental process. It makes it harder to formulate a selected criterion to label certain technologies as dual use and recommend their inclusion within the export control lists.

Second, in stark contrast to the amount between 1960s-1980s when the primary export control regimes were established, cutting-edge R&D activities are not any longer the exclusive domain of select few industrialized or advanced economies. This complicates efforts to manage emerging technologies using export controls. for instance, only a couple of nations or private corporations could afford to take a position in nuclear technology—this constraint reduced the danger of widespread proliferation once these countries agreed to cooperate on non- proliferation measures. In biomedical research, however, its trans-national nature presents a singular challenge. The heightened role of non-state actors and rogue individuals in spreading terrorism is another factor complicating regulation through export controls.

Finally, for any export control regulations to be effective, they might get to command support from the key geopolitical players of the day and from countries with significant industrial and scientific base. For instance, crucial players within the biotechnology sector like Russia, China and Israel aren't members of the Australia Group (AG). This suggests that any efforts at regulation under the aegis of AG would be ineffective. Furthermore, export control regimes are seen by non-members as a way to deny them access to advanced technologies. Therefore, export controls are unlikely to become the framework to manage currently emerging technologies within the field of biotechnology.

The role of geopolitics

No aspect of up to date world is immune from the reach of worldwide geopolitics and regulation of emerging technologies is not any exception. Historically, developed nations just like the US, Russia and therefore the European Union are the dominant force in institutionalizing global regulations. Through their technological and economic prowess, they need ensured that the planet adopted their standards of regulation, and sometimes keeping in mind their country's parochial interests. However, as a more Multi-polar world takes shape, this equilibrium has began to shift: there's significant lack of trust between governments, especially between biotechnology powerhouses like the US and China. This Trend has been further accelerated by the geopolitical fallout of the Covid-19 pandemic.

Similarly, regional powers like India and therefore the countries of Association of Southeast Asian Nations (ASEAN) alongside other developing countries also are asserting themselves and posing for a seat at the regulatory high-table. This has led to a churn at several international institutions including export control organizations and therefore the UN, especially on matters concerning emerging technologies. One recent example is that the success of India in getting its own 5G standard referred to as '5Gi' approved for final evaluation to become a part of global 5G standards set to be approved by International Telecommunications Union (ITU) in 2021.[25]

Given the trans-national nature of biotechnological research, both in terms of cutting-edge research and manufacturing of laboratory equipment, geopolitics would definitely gain prominence during discussions seeking to manage this field. Consistent with a realist approach to geopolitics, countries with significant edge up the biotechnology industry would like regulations that maintain their technological lead while preventing other countries from catching up. To stop itself from being at the receiving end of this geopolitical dynamic, India should cooperate with its partners and participate in international discussions or working groups as an advocate for its interests alongside those of the developing world. International Institutions are under strain, and building a broad consensus on emerging technology regulation would be a huge challenge. there's an urgent got to develop an alternate deliberative approach that's both more inclusive than export controls and fewer fragmented than individual national regulations.

A Way Forward

The UN remains the foremost representative forum for discussion involving all relevant Stakeholders. Therefore, an Open-ended working party (OEWG) created under the resolution of the UN General Assembly (UNGA) is often considered as a possible forum for discussions on this issue.

An OEWG found out by UNGA in 2018 is already deliberating another globally contentious issue: the Appliance of law of nations in cyberspace. It's been ready to successfully conduct several rounds of discussions. An identical mechanism is often devised to debate other globally contentious issues like the regulatory aspects of emerging technologies in biotechnology. An OEWG is that the least restrictive
And most deliberative choice to facilitate discussions among civil society members, NGOs, and subject matter experts additionally to representatives from UN member states. The proposed OEWG can prefer to start deliberations supported the background paper released by 'Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing' found out by the planet Health Organization (WHO) in 2019 to supply an

summary of governance issues around human genome editing.[26]Similarly, the 2015 report submitted by 'The Independent Advisory Group on Public Health Implications of Synthetic Biology Technology associated with Smallpox' to the Director-General of WHO can act as a basis for broader deliberations on dual use aspects of synthetic biology.[27]Discussions at the worldwide level often takes time to materialize into relevant conventions, treaties, or guidelines. It's going to take several additional years across jurisdictions to develop adequate procedures to manage emerging technologies. Within the meantime, the scientific community and personal enterprise should step in to fill within the global regulatory gap. There are several precedents for an equivalent.

In 1975, the Asilomar Conference on recombinant deoxyribonucleic acid was convened in California that included lawyers, journalists, officialdom, and scientists from different parts of the planet. The participants considered the difficulty of regulation of biotechnology and formulated voluntary guidelines to make sure the security of recombinant deoxyribonucleic acid technology which was as revolutionary and novel a technology then, as CRISPR is now. These guidelines served as a template for subsequent guidelines issued by the National Institutes of Health and other regulatory bodies.[28] The initiative by the scientific community to self-regulate in response to a revolutionary yet unpredictable technology can function a template for present times. The global scientific community should consider stringent self-regulation regarding controversial aspects of emerging technologies like human genome editing using CRISPR until a broader consensus are often developed. There are some encouraging efforts during this regard: UNESCO's International Bioethics Committee (IBC) in 2015 updated its guidelines on the Human Genome and Human Rights. Workshops and discussions associated with bioethics are organized at International Summit on Human Gene Editing in 2015 and 2018. The He Jiankui incident highlighted the importance and urgency of such initiatives and therefore the got to encourage all members of the worldwide scientific community to stick to those guidelines. it's significant to notice that after international backlash, including at the 2018 International Summit on Human Gene Editing, Chinese regulators proposed legislative changes and issued fresh guidelines to stop a repeat of such incidents.[29]

The private sector has also tried to self-regulate the utilization of potential dual-use technology within the absence of multilateral guidelines. for instance, several multinational companies providing commercial gene-synthesis services have formed the International Gene Synthesis Consortium (IGSC). IGSC members together represent 80 percent of the world's commercial gene synthesis capacity. The organization has published its own Harmonized Screening Protocol (HSP) to screen gene synthesis orders across jurisdictions for sequences that have dual-use potential or are restricted under national or export-control regulations.[30]The protocol also encourages IGSC members to coordinate with and share information with local and national enforcement and intelligence authorities to stop the potential misuse of synthetic genes. this technique is predicated on guidelines issued by the US Department of Health and Human Services (DoHHS) that mandate gene synthesis companies to undertake comprehensive screening of the customer, the sequence ordered to be synthesized and do a follow-up screening to verify the legitimacy of the customer.[31]

Initiatives taken by gene-synthesis companies can become a template for other multinational corporations across countries to formulate a standard reporting mechanism for his or her sector to be employed by manufacturers, exporters, and importers of sensitive and potential dual-use technologies to stay a record and verify credentials of consumers. they will also work with willing national regulators to further refine this mechanism.

CONCLUSION

Over time, the increasing pace of technological innovation ensures that newer and better technologies still be developed. Often, it's the regulators that have got to play catch-up with scientific and technological developments. Advancements in technology are happening at a way faster pace today than almost the other time in human history. Increased global literacy, globalization, rapid climb in information technology services, automation, and AI are all contributing to the accelerated the pace of innovation. In the initial onslaught of the Covid-19 pandemic, governments round the world significantly increased investments in healthcare, with corresponding investments by the private sector also. this is able to certainly provide an impetus to R&D, spur innovation, and help the evolution of existing technologies. rather than playing catch-up with technological developments of the day, a proactive approach by governments may be a far better alternative to deal with contemporary challenges. This approach should involve regular deliberations between scientists, civil society, and therefore the private sector, and may be more beneficial than resorting to ad-hoc regulatory arrangements.

Endnotes

[a] In germline editing, edited genome of an individual becomes heritable. This contrasts with somatic cell editing where only the patient being treated is affected. Regulatory agencies in many countries allow somatic gene editing but not germline editing in humans.

[b] Plasmids are small, circular pieces of DNA mainly found in bacteria. They are used in genetic engineering to amplify copies of certain genes and in molecular cloning, they are used to transport foreign genetic material from one cell to another.

[c] Gene expression is the process through which the instructions in DNA are converted into a functional product, such as a protein.

[d] Recombinant antibodies are antibodies that are generated in a laboratory using synthetic genes.

[f] China has repeatedly refuted the accidental leak theory. It will suffer significant reputational damage if it is determined that origin of SARS-CoV-2 virus was indeed an accidental leak from a laboratory. This revelation will only exacerbate the geopolitical realignment currently underway in response to China's rise.

[g] Regulatory authorities in India, European Union, United States, and United Kingdom among others have issued domestic guidelines on bioethics.

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