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Summary

Like all countries, India faces the reality that modern biotechnology is unlocking many advances in healthcare, food and energy security, and environmental conservation. At the same time, these same breakthroughs are ushering in a host of potential threats, including biological warfare and irreversible alterations to the human gene pool.

To navigate this complex policy landscape, India needs to craft a more streamlined regulatory system and take other concrete steps to support growth in its domestic biotech sector. Doing so would likely help New Delhi—a much-needed voice from the developing world—vie for a chance to play a leading role in discussions on global governance, as nations begin formulating responsible global standards in response to recent biotech innovations.

The Promise and Pitfalls of India's Biotech Sector

- India's indigenous biotech sector has risen rapidly in recent years, with the country's biopharmaceuticals industry leading the charge. Given increasing private investment in R&D, and the sector's relatively low starting point, there remains immense potential for future growth, especially in biopharmaceuticals, bioservices, and bioagriculture.
- Yet India's convoluted regulatory system is plagued with bureaucratic bottlenecks and redundancies that delay or prevent new products from securing government approval. This problem is compounded by highly politicized public opposition to biotechnology, which lacks a serious empirical or scientific basis and further impedes the sector's growth.
- New Delhi must take proactive steps to strengthen and streamline its biotech regulatory apparatus; support the commercialization of biotech advances; and foster an inclusive domestic dialogue to build greater public knowledge about biotechnology, appropriate norms, and baseline practices.

Prospects for the Global Governance of Biotechnology

- There are gaps in the current patchwork of international legal agreements that shape the global governance of biotechnology, particularly related to

the protection of intellectual property rights, the nonproliferation of biological weapons, and equitable terms for the cross-border movement of biotech products. Even more stark is the absence of global norms that outline responsible practices for new advances in the biotech sector, especially in the cases of big data analytics and genetic engineering.

- Developing and developed countries should begin collaborating to try to craft guiding principles for responsible innovation in the biotech sphere. India should start positioning itself as a strong voice in the discussions that will help define and set these emerging global standards. For instance, India and the rest of the international community need to rethink and possibly overhaul the existing global regimes for biodiversity and patenting.

Introduction

If physics and chemistry drove the industrial transformations of the twentieth century, biology promises to generate groundbreaking technological applications in the present one. Humanity's growing ability to map, mimic, and manipulate the genetic code of organisms is opening up new possible applications of biology in areas ranging from agriculture and medicine to information technology (IT) and warfare.

Recent breakthroughs in biotechnology foreshadow profound, both positive and negative, societal effects around the world. Optimists claim that biotechnology offers the potential for advances in fields including healthcare, agriculture, and environmental conservation. As a massive emerging economy that bills itself as a promising hub for such innovation, India is no exception. Biotechnology has great potential in India, where cutting-edge product development and research is under way despite a nascent market and industry. Three areas in particular—biopharmaceuticals, bioagriculture, and bioservices—have significantly driven growth in India's biotech sector. Yet some fear that burgeoning forms of biotechnology may lead to the spread of new types of biological weapons, new ethical challenges, and other risks.

Recent breakthroughs in biotechnology foreshadow profound, both positive and negative, societal effects around the world.

In any case, India will face considerable challenges in securing its national interests amid this unfolding biological revolution. While New Delhi has taken some initial steps to encourage biotech research and commercial applications, inefficiencies in the country's current regulatory mechanisms and political opposition to biotechnology spawned by public misgivings have sometimes constrained the sector's economic potential. Addressing such regulatory shortcomings and political hurdles may help India become a more competitive economic player and more influential international actor in this rapidly changing field.

The State of Play in Biotechnology

Modern biotechnology is defined as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."[1] The subdiscipline of synthetic biology involves the design, redesign, and/or construction of biological entities such as enzymes, genetic circuits, and cells.[2] Alongside breakthroughs in biotechnology itself, complementary advances in physics, chemistry, and the computational and material sciences have further expanded the horizons of such research.

Applications of Biotechnology

The discovery of double-stranded deoxyribonucleic acid (DNA), molecules that contain organisms' genetic blueprints, laid the groundwork for modern biotech research. In recent years, the development of a breakthrough technology called Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) and its associated Cas9 enzyme has revolutionized the field of genome editing, making it possible to snip out small pieces of harmful DNA and replace it with normal sequences.[3] Biotechnology is not only confined to tinkering with DNA sequences but also has expanded to explore the potential of single-stranded ribonucleic acid (RNA). The latter is necessary for the expression of DNA and has already been the subject of extensive research, especially in areas such as RNA interference (RNAi) and anti-sense technology. Both RNAi and anti-sense technology allow scientists to exert control over the expression of specific genetic traits through a technique known as gene silencing without changing the sequence of the target gene. This advance has enormous significance as it changes the terms of the worldwide debate over the safety of genetically modified organisms (GMOs). In the healthcare sector, for instance, such techniques also may provide a potential alternative to gene therapies, making these tools easier to use reliably and safely compared to DNA-based technologies.[4]

Rapid innovations in the field have the potential to improve the lives of people around the world.

Rapid innovations in the field have the potential to improve the lives of people around the world in at least five areas, including agriculture, environmental conservation, healthcare and disease treatment, big data–driven bioinformatics, and industrial biotechnology. Relevant areas of inquiry include stem cell research, embryo research, genetic engineering, synthetic biology, and tissue engineering.

First, agricultural biotechnology can help meet the world's food supply needs as populations increase. Scientific advances have produced new genes that can fortify crops to withstand natural calamities, pests, and diseases (including crops like Bacillus thuringiensis or Bt cotton) or to provide higher nutritional value (as with golden rice). One technique is to employ RNA-based

gene-silencing sprays to make crops more viral-resistant or drought-resistant.[5] CRISPR, meanwhile, provides a targeted alternative approach for improving plants' genetic traits that is easier and generally cheaper than traditional breeding techniques.[6] Genetic engineering technologies have also been used to improve the quality and quantity of fish reared in aquaculture.[7] Similar advances can help improve the quality and quantity of milk, eggs, and meat, as well as produce healthier, faster-growing animals.[8]

Second, biotechnology can be used to reduce carbon emissions and otherwise promote environmental conservation efforts. Using microbes, oil-based raw materials in the plastics industry can be replaced with more ecofriendly raw materials like sugars.[9] One application of bioremediation involves the use of microorganisms like Pseudomonas and Mycobacterium to treat sewage. The chemicals conventionally used for this purpose can be augmented with these beneficial bacteria to control the spread of pathogenic bacteria, in turn helping reduce the transmission of cholera, typhoid, and other waterborne diseases.[10] This type of technology can also be employed to mitigate environmental hazards, including oil spills and radioactive waste.[11]

Third, biotechnology has led to new ways of treating a variety of human diseases. Clinical trials involving gene therapy have successfully prevented the further development of Alzheimer's in mice suffering from the initial stages of the disease,[12] and gene therapy reversed sickle-cell anemia for the first time in a French teenager.[13] A gene therapy product made by Renova Therapeutics for congestive heart failure is also currently at the third stage of clinical trials.[14] In addition, there are a number of diseases that gene therapy has the theoretical potential to treat, like cystic fibrosis and even some forms of cancer.[15] The versatility of CRISPR and the Cas9 enzyme suggests that this breakthrough, too, is a promising theoretical avenue to other potential forms of gene therapy for those suffering from other debilitating hereditary diseases.[16] In October 2016, a China-based research team took the unprecedented step of successfully injecting and delivering cells modified using CRISPR and Cas9 into the body of a person suffering from lung cancer, and clinical trials involving CRISPR are also planned in the United States.[17]

Biotech advances in the healthcare space are also spurring revolutions in the development of drugs.[18] The mapping of genetic variations among individuals has opened new possibilities in the field of personalized medicine, potentially enabling physicians to prescribe drugs tailored to patients' genetic profiles to maximize their therapeutic effects. To cite one example, such pharmacogenetic testing has already become an integral part of breast cancer treatment.[19]

Information obtained from next-generation gene-sequencing techniques and advancements in targeted gene editing could even go beyond treating diseases. In the future, this knowledge could possibly also be exploited to microengineer the intelligence, strength, speed, health, and other traits of individuals as embryos, perhaps eventually spawning designer babies with tailored genomes

through assistive reproductive technologies.[20] Some experts predict that in about twenty years, techniques that reprogram human bodies to amplify intellectual capacity, improve physical capabilities, and even enhance emotional well-being may be available.[21]

Fourth, the twin fields of genomics and bioinformatics are also poised to revolutionize healthcare, by coupling the advances of biotechnology with the collection and analysis of huge volumes of genetic and biological big data. Genomics is a large, interdisciplinary field that focuses on studying the genome as a whole,[22] while bioinformatics uses computer programming and information storage to study biological data.[23] Companies such as 23andMe in the United States, the Beijing Genomics Institute in China, and Mapmygenome in India have made it possible to test individual proclivities for certain diseases and tailor treatments for individuals' specific needs.[24] Although these developments are promising in the case of diseases caused by a single defective gene, it does not seem to be as readily applicable to ones involving multiple genes, like diabetes, hypertension, and cancer. This use of big data extrapolates vital medical information from individual genetic data sets. This, in turn, could theoretically facilitate earlier detection of diseases such as cancer from a single blood test, a feat that a company called GRAIL is currently attempting.[25] Big data can also help researchers and pharmaceutical companies like Roche monitor the efficacy of drugs.[26]

Despite all this promise, however, some aspects of biotechnology are raising profound ethical and political dilemmas that must be addressed, particularly related to the alteration of genetic material. The most important concern is unintended, potentially harmful genetic mutations.

Fifth, industrial biotechnology employs complete microbial cells or cellular enzymes to generate products for industrial use. Industrial biotechnology involves the manufacturing of chemicals, biodegradable plastics, food additives, biofuels, or other enzyme-based products. One example is the use of recombinant DNA technology to make BioSteel; genes isolated from a silk-spinning spider are inserted into the genome of a goat egg prior to fertilization to produce a highly resilient silk product. This type of transgenic goat, once mature, creates a spider silk–based protein through its milk that can be used to manufacture athletic shoes and other products.[27] Another example involves the production of biorubber using sugar rather than traditional hydrocarbons, thereby providing a reliable and sustainable alternative to the raw materials typically used in the rubber and plastics industries.[28]

Risks of Biotechnology

Despite all this promise, however, some aspects of biotechnology are raising profound ethical and political dilemmas that must be addressed, particularly related to the alteration of genetic material. The most important concern is unintended, potentially harmful genetic mutations. For instance, the possible medical applications of CRISPR pose a fresh round of ethical and legal

quandaries for the world.[29] While this technology is intended to treat debilitating hereditary diseases, it can interfere with cellular signaling pathways or be used to edit genes on the human germ line. Changes to the latter would be passed down to subsequent generations, permanently altering the human gene pool with potentially dangerous consequences.[30] Another point of contention is intentional gene drives, that is to say, efforts to genetically enhance specific traits and their chances of being inherited by future generations, which could lead to a loss of human genetic diversity.[31] Furthermore, while big data applications in the fields of genomics and bioinformatics have immense potential, such innovations also raise fundamental questions about data privacy, particularly regarding how to protect individuals' genetic information and how to govern the commercial use of such private genetic data.

Aside from these ethical and safety questions surrounding genetic alterations, some potentially dual-use aspects of biotechnology have other troubling national security implications. Developments in genetic engineering and advances in computational power are opening the door to new forms of biological weapons that could further challenge the existing international regimes that govern the development and spread of biotechnology.[32] Hence, new developments in biotechnology, in turn, are raising fresh questions about norms, arms control, and nonproliferation.

Beyond the challenges of governing genetic alterations responsibly and preventing the proliferation of biological weapons, many developing countries like India are also concerned about the inequitable global distribution of biotech capacity. Many developing nations are far behind developed ones in terms of both research capabilities and industry size in this emerging frontier. This grim situation is attributed to a confluence of factors, including limited funding, a shortage of skilled human capital, and more tenuous linkages between industry actors and academic institutions in the developing world compared to those in advanced economies.

India's Biotech Landscape

As a major emerging economy with a burgeoning biotech sector, India has a strong interest in global trends in this field. In India, biotechnology is best considered a sunrise industry with a lot of growth potential, given the country's wealth of biodiversity, the traditional knowledge of indigenous communities, recent policy initiatives to promote the sector, and the emergence of private players driving the sector's growth. According to Renu Swarup, the managing director of the Biotechnology Industry Research Assistance Council (BIRAC), India has only scratched the surface when it comes to areas like bioagriculture and bioinformatics.[33] Biotechnology is one of the fastest growing knowledge-based sectors of India's economy, garnering about $11 billion in revenue during the 2015–2016 fiscal year.[34] The industry is expected to grow at a compound

annual rate of nearly 30.5 percent to reach the $100 billion mark by 2025 if the country's business and regulatory environment is favorable.[35]

Like in other countries, India's biotech sector includes a range of areas. Biopharmaceuticals—comprising vaccines, therapeutics, and diagnostics—is the largest biotech subsector in India. In 2016, it accounted for 64 percent of the industry's total revenue. Aside from this, bioservices—including clinical research and contract manufacturing—brought in 18 percent of the industry's revenue; bioagricultural products—such as hybrid seeds, genetically modified (GM) crops, biofertilizers, and biopesticides—stood at 14 percent; bioindustry, predominantly from enzyme manufacturing, constituted 3 percent; and bioinformatics—dealing primarily with the maintenance of extensive electronic databases, stood at 1 percent.[36] Thus, India's biotech sector offers opportunities for economic growth and job creation in various industries. Organizations like BIRAC have been working closely with industry players to drive these outcomes.

But while the Indian biotech sector holds a lot of promise, India also has a lot of ground to make up in this space compared with other countries. India currently accounts for 2 percent of the global biotech industry.[37] The investor community has shied away from early-stage biotech ventures due to long gestation periods before commercialization, bureaucratic delays related to government approvals for new products, and India's multilayered regulatory structures. In addition, while India produces a large number of biotech graduates and postgraduates annually, most are not job-ready—this highlights a significant skill gap in the sector.[38]

Still, India's biopharmaceuticals sector in particular has enormous opportunities for growth. This stems from the country's large population, along with substantial predicted revenue growth from medical tourism.[39] The sector counts vaccines, diagnostics, and recombinant therapeutics among its major drivers of growth.[40] Starting with the days of vaccine production by the Haffkine Institute in Mumbai and the Pasteur Institute of India in the early 1900s,[41] this sector has produced globally acclaimed Indian companies, including the Serum Institute of India, Biocon, and Shantha Biotechnics. India helps supply vaccines to international institutions, such as the World Health Organization and the United Nations International Children's Emergency Fund (UNICEF).[42]

Indian biopharmaceutical firms have also made impressive advances in recent years. While efforts to develop a vaccine for the Zika virus are under way at multinationals like the French firm Sanofi and the Japanese firm Takeda, Bharat Biotech, an Indian firm, has become the first to file for a relevant patent.[43] Another example is that Regenerative Medical Services, another Indian company, has become the fourth in the world to receive regulatory approval from the Indian government to administer a new treatment called chondron autologous chondrocyte implantation to repair damaged cartilage in patients' knee and hip joints.[44]

India could potentially build on its existing competencies to emerge as a hub for biosimilars—the generic equivalent of biologic drugs. Considering India's remarkable achievements in the generic drugs industry, domestic pharmaceutical firms like Zydus Cadila and Dr. Reddy's Laboratories have initiated research programs to capture this emerging space. However, designing and testing viable biological compounds, given their complex structures, requires more intensive, technically demanding research than traditional small-molecule drugs do. There is indeed a long road ahead for Indian firms that are still playing catch up in this area.[45]

Bioservices—which comprise contract research, manufacturing services, and clinical trials—constitute another important area for sectoral expansion in India. The high cost of drug development in highly regulated markets, such as the United States and the European Union (EU), encourage pharmaceutical companies to look for cheaper alternatives. India, with drug development costs that are significantly lower than those of the United States and nearly half as much as those in the EU,[46] could conceivably serve as an attractive destination for contract manufacturing. This cost factor could significantly drive investments in this sector in combination with other factors—such as India's young, diverse population; the impending expirations by 2020 of patents for many drugs with annual global sales in excess of $1 billion;[47] and regulatory waivers granted by the Indian government's Drug Technical Advisory Board (DTAB) for advanced clinical trials of certain drugs.[48] Contract manufacturing firms like Jubilant Life Sciences, Dishman, and Divi's Laboratories have become suppliers of active pharmaceutical ingredients used in drug formulas.[49] Syngene International is an affiliate of the Indian biotech firm Biocon that conducts contract research and plans to launch a pharmaceuticals research and development center in Bengaluru for U.S. biotech company Amgen.[50]

India, with drug development costs that are significantly lower than those of the United States and nearly half as much as those in the EU, could conceivably serve as an attractive destination for contract manufacturing.

Bioagriculture is the third largest contributor to the Indian biotechnology space, and it holds great potential considering India is still predominantly an agricultural economy. As the NITI Aayog, a government think tank, points out in its latest three-year action plan, GM seeds have emerged as a powerful new technology that promises high productivity; improved quality; and lower use of fertilizers, weedicides, and pesticides.[51] Among crops, Bt cotton is the only GM crop currently approved for production and commercialization in India. Mahyco Monsanto Biotech, a joint venture between Monsanto and an Indian biotech firm called Mahyco, has developed cutting-edge Bollgard technologies to protect Bt cotton against destructive bollworm infections,[52] while Nuziveedu Seeds has become the largest Bt cotton seed company in India.[53]

Biofuels, biofertilizers, and biopesticides have also contributed significantly to the Indian bioagriculture sector. India has a huge supply chain of

biofertilizers, including companies like Gujarat State Fertilizers and Chemicals, Madras Fertilizers, and Rashtriya Chemicals and Fertilizers. Complementing conventional forms of agricultural biotechnology, marine biotechnology, too, can help meet impending challenges like securing sustainable food supplies and energy resources. For example, the Center for Conservation and Utilization of Blue Green Algae at the Indian Agricultural Research Institute has been developing algal strains as biofertilizers.[54] Private firms like Geomarine Biotechnologies, Parry Nutraceuticals, and Mangalore Biotech Laboratory have also been active in formulating marine-based biotech products.[55] This is a promising, yet underexplored, area where India can target market expansion.

A sound regulatory environment and a flourishing domestic biotech sector, in turn, would help India build a foundation to emerge as a more prominent voice in international conversations about biotech-related issues.

Meanwhile, industrial biotechnology in India covers products such as microbial enzymes and microorganisms themselves, which can be used in food products, pharmaceuticals, textiles, and even for bioenergy and bioremediation purposes. These products provide an alternative to chemicals used in these industries, thereby addressing environmental hazards. Private players, such as Novozymes and Sea6 Energy, have made considerable progress in this sector. The former offers a new technology to produce biodiesel, while the latter has optimized a technology to derive biofuel from marine biomass.[56]

Meanwhile, bioinformatics is an emerging area that deploys mathematical, statistical, and computer models to analyze biological data. The Indian bioinformatics space is fragmented with a large number of small and mid-sized players, the most notable of which are Strand Life Sciences, Ocimum Biosolutions, and Molecular Connections.[57] Large overseas IT firms like IBM and Intel also have expanded to capture shares of this world market.[58]

In short, India's private biotech industry may not be as advanced as those of more industrialized countries, but India does have several emerging players in a variety of biotech-related sectors. The right government policies can help create an environment in which they can flourish.

India's Biotech Policies and Regulations

How well India taps into the immense potential of its biotechnology sector depends largely on how well the nation addresses policy and regulatory challenges stemming from the current structuring of its bureaucratic system and from public misconceptions about the negative effects of biotech that have engendered political pressure to oppose its advances. A sound regulatory environment and a flourishing domestic biotech sector, in turn, would help India build a foundation to emerge as a more prominent voice in international conversations about biotech-related issues.

Major Government Actors

There is a fundamental distinction between the U.S. and Indian models for regulating biotech products. While Washington's system has been characterized as a product-driven, innovator-friendly regime that relies on measurable performance and safety standards to evaluate genetically engineered products in comparison to ones that are not genetically modified,[59] in the Indian system, GM products attract regulatory attention at the level of the genetic event and undergo case-by-case biosafety testing.[60] Thus, in India, regulations kick in starting with the process used to introduce a new genetic trait into an organism. The multiple regulatory layers of this system ensure that, in sectors like agricultural biotechnology, approval processes typically take between three and five years, and sometimes even more than ten years.[61]

Governmental and quasi-governmental actors in India's biotech space serve at least three broad functions: providing funding, conducting and supporting research, and monitoring adherence to state regulations. The Department of Biotechnology (DBT), under the Ministry of Science and Technology, is considered the main governmental body vested with state authority on matters pertaining to biotechnology. Set up in 1986, the department promotes research, development, and innovation in biotechnology; oversees some funding activities; and carries out regulatory responsibilities. More specifically, the DBT supports universities, research institutes, and firms working in the biotech field in multiple ways: it provides infrastructural support, helps cultivate skilled human capital, champions related scientific advances, implements biosafety guidelines for recombinant DNA products, and undertakes other related activities.[62]

An assortment of additional bodies—some that are under the DBT umbrella and some that are not—provide funding and other sources of support to commercial actors in India's biotech sector. The DBT's Small Business Innovation Research Initiative supports the early-stage research of small and medium-sized firms.[63] Meanwhile, the BIRAC, set up in 2012 under the DBT, has supported biotech enterprises with a wide range of initiatives, including the Biotech Ignition Grant—which helps scientists and entrepreneurs commercialize their research—and the Biotechnology Industry Partnership Program, which allows private companies involved in high-risk biotech research to reduce their financial burdens through cost-sharing arrangements with public research centers.[64] Other government-led efforts promote start-ups and other entrepreneurial activities in the biotech sector. For instance, several state governments have set up biotech parks and technology incubators with a particular focus on agricultural and healthcare-related biotechnology.[65]

The DBT also fulfills a range of regulatory functions in conjunction with committees that are affiliated with it, including the Review Committee on

Genetic Manipulation (RCGM) and the Genetic Engineering Appraisal Committee (GEAC). The roles of committees accentuate the department's significance as a regulatory institution and are enumerated in a set of rules formulated in 1989 under the Environment Protection Act of 1986. These rules are implemented through a series of DBT and GEAC guidelines that are updated from time to time and touch upon vital areas including recombinant DNA (1990), transgenic seeds (1998), clinical and preclinical data for ribosomal DNA (rDNA) vaccines (1999), genetically engineered crops and plants (2008), and stem cell research (2013).

Under the present framework, state bodies from three different domains—biotechnology, environmental protection, and drug control—wield varying degrees of regulatory power, depending on the nature of a given biotech research activity or resulting products. Broadly speaking, the regulatory system covers three areas: advisory, approval, and monitoring functions. The Recombinant DNA Advisory Committee (RDAC) takes note of national and international biotech developments and recommends suitable technologies and processes accordingly. The RDAC therefore holds an advisory function, and its recommendations carry significant weight when Indian safety regulations are formulated for rDNA research, use, and applications.

The most important approval bodies are institutional biosafety committees (IBSCs), the RCGM, and the GEAC. Of these, IBSCs are the internal approval authorities housed within each organization involved in recombinant DNA activities. Composed of a given institution's head, scientists within the institution engaged in rDNA work, medical experts, and a DBT nominee, IBSCs evaluate whether lab and onsite experiments comply with rDNA safety guidelines and relevant emergency plans. IBSCs have the authority to approve experiments with low risks, conducted in a contained facility with genetic material of microbial, plant, or animal origins considered safe by the guidelines. When experiments carry greater risks, IBSCs make their recommendations known to the RCGM for approval.[66]

The RCGM, which primarily serves as an approval body within the DBT, also has a limited monitoring role to play. Because IBSCs submit reports on the progress of research and share information relating to experiments with the RCGM, the latter is best positioned to monitor the safety of ongoing research projects.[67] It can direct field-trial institutions to generate toxicity, allergenicity, and long-term environmental safety data on transgenic materials, and then it can respond in a data-driven manner. It also has a recommendation-based role, mandating appropriate procedural and guidance manuals as well as proper types of containment facilities and conditions for experimental trials. As an approval body, the RCGM has to grant prior approval for all experiments involving category III risks—that is, those conducted with genetic material of microbial, plant, or animal origins considered capable of altering the biosphere—and all open-field experiments with GMOs. RCGM approval is also

required for the cross-border movement of agents and vectors required to produce GMOs, transgenic microorganisms, and germplasms.[68]

After the RCGM recommends product safety measures on the basis of small-scale trials and preclinical data, the regulatory role of the GEAC—falling under the authority of the Ministry of Environment, Forest, and Climate Change (MoEFCC)—takes effect. The GEAC approves activities involving the large-scale use of hazardous microorganisms and recombinant products in research and industrial production. It also examines data from clinical trials with respect to living modified organisms and grants clearances pertaining to the discharge of genetically engineered organisms from labs and hospitals into the environment.[69]

But the GEAC's approval functions are narrowly confined to the environmental perspective it brings to bear on a given activity. Beyond this, more specialized, domain-specific authorities come into the picture, adding new layers to the regulatory landscape. In the case of GM foods, the Food Safety and Standards Authority of India (FSSAI) is stipulated as the relevant regulatory authority on paper. However, the FSSAI has not yet enacted specific permanent regulations, so the GEAC has been handling this duty for the time being.[70] In 2010, the FSSAI came up with interim regulations and proposed the creation of a GM foods—and food safety—assessment unit within the FSSAI,[71] but no real progress on implementation has been made.

By its own admission, the FSSAI suffers from various hurdles including inadequate infrastructure, a lack of lab or surveillance infrastructure, and limited research support on food science and risk assessment.[72] The FSSAI has also been accused of selectively prioritizing particular regulatory issues while neglecting other important ones; for instance, critics have pointed to the body's haste in seeking to regulate organic foods to substantiate this accusation.[73] In the case of GM crops, small-scale, open-field trials require extensive agronomic evaluations under the supervision of the Indian Council of Agricultural Research or a state agricultural university for at least two crop seasons. However, the field trials can only be done after a no-objection certificate has been obtained from the relevant state government. This additional obligation has limited field trials to only a few crops, such as chickpeas and cotton, thereby hindering growth in the agricultural biotech sector.[74]

By its own admission, the FSSAI suffers from various hurdles including inadequate infrastructure, a lack of lab or surveillance infrastructure, and limited research support on food science and risk assessment.

For firms seeking approval to manufacture and sell biologics or biosimilar drugs,[75] India's drug control authorities also figure into this already complicated regulatory framework. The Central Drugs Standard Control Organization (CDSCO), headed by the drugs controller general of India (DCGI) under the Ministry of Health and Family Welfare, is responsible for the approval of new drugs. In the case of biosimilars, the RCGM recommends clinical trials based on data from preclinical studies. The DCGI then considers these recommendations

and independently decides whether to grant approval for clinical trials and, subsequently, permission for marketing and manufacturing.[76]

In addition, India's federal governing structure also vests regulatory powers in authorities at the state level, so biotech innovators are accountable to multiple levels of authority and compliance regimes. Because biotech products touch upon legislative areas, such as agriculture and the environment, that have both national and local significance, regulatory authorities at the state level and even district level possess vast monitoring and enforcement powers.

The state biotechnology coordination committees (SBCCs) of each Indian state rely on other state bodies, such as pollution control boards and health authorities, to inspect, investigate, and take punitive action in cases of unsafe biotech activities. They monitor research institutions and companies engaged in the genetic manipulation of microorganisms, plants, or animals to examine whether they are following stipulated safety regulations and the conditions tied to GEAC approvals for field and clinical trials. They also do post-release monitoring of GM products for a period of at least three to five years to avoid unforeseen risks. District-level committees do similar work within their respective jurisdictions, visiting biotech installations and regularly submitting reports to SBCCs or the GEAC. Likewise, when it comes to biosimilars, state drug regulatory bodies exercise wide-ranging powers. This is particularly so because in India's drug regulatory regime—while the licensing and approval of drugs and drug imports is within the remit of the central government—the manufacture, sale, and distribution of drugs come under the shared, or even exclusive, regulatory responsibilities of state governments.

Unfortunately, the current Indian regulatory system is characterized by divided roles and responsibilities based on the diverse applications of biotechnology rather than integrated, coordinated action within a holistic, well-tailored ecosystem.

Major Obstacles to Growth in Biotech

India's relatively young efforts to help fund and promote biotech research are laudable and deserve to be scaled up more, but these positive steps will likely not deliver optimal results absent a streamlined, well-resourced regulatory system and a supportive political environment. Regulatory bodies need to coordinate effectively among themselves and must be aware of innovations happening in the biotech space early on, so that appropriate regulatory adjustments can be made in a manner conducive to both innovation and safety.

Unfortunately, the current Indian regulatory system is characterized by divided roles and responsibilities based on the diverse applications of biotechnology rather than integrated, coordinated action within a holistic, well-tailored ecosystem. There was overwhelming evidence of this issue in a 2012 report of the Committee on Agriculture headed by Basudeb Acharia.[77] The committee observed that the roles and responsibilities of the GEAC were not spelled out properly, and much uncertainty persisted regarding its autonomy as

an approval-granting body.[78] Similarly, the committee observed that both the GEAC and RCGM seemed to have underdeveloped organizational structures.[79]

As observed by the expert committee constituted by the Ministry of Health and Family Welfare in 2013, the CDSCO has been plagued by a lack of functional and financial autonomy, poor infrastructure, and the adequate manpower to perform its role as the central drug approval body. Similarly, the pharmacovigilance machinery to inspect the safety of already approved drugs, mostly through state regulatory bodies, is in need of technical and skill upgrades.[80] These gaps have already caused considerable concerns and problems with respect to the small-molecule generics industry, and are likely to stand multiplied in the context of biosimilars due to the fast-evolving nature of this technology, a lack of sufficient resources for creating new kinds of testing labs, and the absence of a talent pool that grasps the science behind these advances and related concerns well enough to effectively regulate them.

Indian biotech firms seeking to establish themselves in rapidly advancing sectors are too often hamstrung by bureaucratic delays and poorly defined regulatory processes.

On top of these barriers, incomplete and sometimes skewed societal understandings of biotechnology and its consequences have contributed to a contentious political atmosphere in India that is often not supportive of the biotech industry.[81] Political actors and civic activists have often turned this environment to their advantage, creating a state of public paranoia about biotechnology, which consequently has sometimes made authorities afraid to take any regulatory initiative.[82]

The way biotechnology has played out in two areas in particular validates this point: GM crops and the exploration of India's biodiversity. Since agriculture comes under the jurisdiction of states in India, state governments wield significant influence over trials and the commercial cultivation of GM crops. Bt cotton, approved for commercial cultivation in 2002, remains to date the only crop to receive such approval. The polarization of views and opinions around biotechnology has left little room for healthy and balanced appraisals.[83]

As a consequence, states long refused to even offer a regulatory pathway for testing other GM crops. For instance, in the case of Bt eggplant, although the GEAC recommended commercial cultivation in October 2009, the MoEFCC announced a moratorium in February 2010.[84] The stated reason for the latter's decision was the absence of long-term studies that established human and environmental safety. But after seven years, the status of Bt eggplant still stands where it was left in 2010, and the GEAC has provided no clear path for securing approval. Recent developments indicate that GM mustard may also be headed in the same direction. A public interest litigation case initiated before the Supreme Court of India by an anti-GM campaigner has delayed approval from the GEAC, which was inclined to approve commercial cultivation of the crop.[85]

Meanwhile, innovation and growth in India's biotech sphere has also been hampered by well-intentioned regulatory efforts to shield India's wealth of

biodiversity from foreign profiteering. India's biodiversity has sometimes been wrongfully misappropriated by foreign actors in the past. Examples abound, including the granting of patents pertaining to the healing properties of turmeric and the fungicidal properties of the neem plant, in the United States and the EU respectively.[86] These patents were subsequently revoked but at considerable cost to the Indian exchequer.

To prevent such situations from recurring, India enacted the National Biodiversity Act, which came into force in 2002 and was meant to govern access to the use of India's bioreserves and make benefit sharing more equitable. Though originally billed as a solution to India's foreign exploitation problem, ambiguities in the act's regulations have unwittingly deterred innovation and investment in biotechnology, a field heavily reliant on biodiversity.

Foreign companies subsequently have found it difficult to access India's wealth of biodiversity, while both Indians and foreign individuals (which include nonresident Indians, according to the act) have found it difficult to commercialize their research findings. Moreover, innovative Indian companies have not been able to raise foreign capital, and criminal penalties for accessing biodiversity resources without "prior-permission" further constrains research and commercial ventures in the biotech space.[87] Both Indians and non-Indians require prior approval from the National Biodiversity Authority (NBA) when seeking intellectual property (IP) rights and transferring research involving Indian bioresources.[88] Meanwhile, insufficiently funded state biodiversity boards have opportunistically relied on this act to compel revenue sharing by Indian companies, despite direct instructions from the NBA to the contrary.[89]

Consequently, this act has painted India as unfriendly toward scientific innovation in the biotech space and even compelled some Indian biotechnology companies to relocate abroad.[90] Shrikumar Suryanarayan, one of India's leading innovators in the industrial biotech space and chairman of Sea6 Energy, says that the Indian approach almost borders on xenophobia. He observes that the National Biodiversity Act has "stall[ed] foreign investment," and he concludes that "outsider skepticism and paranoia surrounding biodiversity exploration has led to inertia by approval authorities."[91]

How to Strengthen India's Biotech Sector

Unless India seeks ways to address the problems plaguing its biotech sphere, growth in this sector will likely continue running into sizable roadblocks. Fortunately, there are steps that India can take that may enhance its biotech sector's prospects for growth and innovation. A flourishing Indian biotech sector supported by a sound regulatory environment and a supportive political atmosphere, in turn, would help New Delhi build a foundation to become a more prominent voice in global governance discussions pertaining to biotechnology.

One promising step would be for New Delhi to strive to create a legal and financial ecosystem that will nurture innovation and growth while limiting

regulatory hold-ups. India needs a proper balance between strategic research, product planning, and the liberalization of regulatory frameworks to support biotech growth. The contributions of science, research, and innovation have to be synchronized within an overall paradigm of inclusive growth and development in order to increase India's chances of establishing itself as a global scientific power.

To improve bureaucratic outcomes, New Delhi must strengthen its regulatory capacity. The best solution may be to establish an independent or statutory body with the authority to regulate biotech research as well as the transporting and importing of biotech products. In the absence of such a sweeping overhaul, the government should at least augment the capacities of and facilitate greater coordination among existing institutional bodies like the RCGM, GEAC, and DCGI so as to minimize bureaucratic delays. In 2005, for instance, the MoEFCC's Task Force on Recombinant Pharma, headed by R.A. Mashelkar, proposed one possible solution when it recommended the creation of an independent National Biotechnology Regulatory Authority (NBRA), which would offer a single professionally managed mechanism for the various clearance processes across different verticals in the biotech industry.[92] An earlier committee headed by Mashelkar also recommended realigning the CDSCO as a central drug authority with regulatory power across the value chain from drug research and development to post-marketing supervision.[93]

As of now, both these ideas remain unimplemented. The NBRA recommendation metamorphosed into a proposed Biotechnology Regulatory Authority of India. There was even a parliamentary bill initiated to create such an entity in 2013, which subsequently lapsed.[94] The central drug authority, though a very good policy innovation that would have streamlined the entire regulatory environment for drugs and biotech, was vetoed by a later parliamentary committee.[95] There are no policy steps currently under way to revive these ideas, though reforms of some kind clearly are necessary in order for India's biotech sector to reach its full potential.

India also needs strong legal and regulatory frameworks to address emerging critical issues arising from new innovations in the biotech space, such as big data analytics. The bioinformatics boom is a function of technological advances in genomics, cloud computing, data analytics, artificial intelligence, and machine learning. At its core is the availability of significant data tranches coupled with analytic capabilities.[96] Public trust in data security and confidence that genetic information shall not be misused or prejudicially used are integral to gathering the requisite volume and variety of data needed for pattern recognition and sound analytics.[97]

Structural regulatory reforms would likely be more impactful if they are accompanied and complemented by broader societal input on issues related to biotechnology. India needs a more expansive domestic discourse on a range of issues that affect biotech governance—from the ethics of deploying new

technologies to flexible efforts to adopt to the changing balance of influence on biotech issues among states and nonstate actors. New Delhi needs to draw in the biotech industry as well as the legal and strategic communities to strengthen interactions with the bureaucratic and political classes to cope with the extraordinary challenges and opportunities that biotechnology is ushering in.

A comprehensive domestic discourse involving a wide range of stakeholders would enable India to chart a path to obtain the greatest possible benefits from these developments in a sustainable and legal manner. A committee on the biotech economy, constituted by the Department of Biotechnology, and comprising researchers, policymakers, industry players, and members of civil society, must be created to enhance synergies and make central- and state-level policies and regulations both coherent and consistent. A bioeconomy information system and observatory, along the lines of a three-year experiment in the EU,[98] may also be established to regularly evaluate research and innovation, the interactions between policies and actors, and market competition across biotech verticals and update strategies accordingly.

The exchange of ideas and information is imperative for ensuring that biotech research and development is carried out in a sustainable manner. Additional outreach efforts such as national biotech conferences should be held regularly to discuss advances in modern biotechnology and regulatory hurdles to researching and commercializing such advances. It is only through ongoing regular dialogues with multiple stakeholders including bioethicists, lawyers, industry players, and researchers that efficient regulatory mechanisms compliant with good manufacturing practices can be formed. This, in turn, could present new avenues for contract research and manufacturing services, which could spark further growth in the bioservices sector.

More energetic public outreach on issues related to biotechnology is also vital. The emphasis must be on communicating about biotechnology with the general public in comprehensible terms. Conducting public awareness campaigns in print and electronic media as well as modifying school curricula may be the initial steps toward making public discourse on biotech issues science-based rather than emotionally driven; this may eventually help lessen public opposition to biotech and the political pressure this can cause.

The Limitations of Global Governance on Biotech Issues

Until India takes domestic steps to address the regulatory impasses and inefficiencies that plague its biotech sector, the country's progress in this emerging technological field will remain constrained. In the meantime, these difficulties will likely hamper New Delhi's potential to become a more influential voice in broader global conversations on how to responsibly govern biotechnology

in ways that take India's interests into account. Aspects of global governance pertaining to biotechnology have become particularly salient as the rapid pace of innovation in India and around the world has also heightened the global challenges that such advances pose.

The issue of how to regulate biotechnology globally came to the fore in the 1970s and, over the years, this has given rise to a number of international legal instruments. These instruments broadly deal with three distinct sets of challenges: the protection of genetic resources and biodiversity, the regulation of biological weapons, and the management of international trade in GM products. Instruments such as the Convention on Biological Diversity (1992), the International Plant Protection Convention (1951), the United Nations Educational, Scientific, and Cultural Organization (UNESCO) International Declaration on Human Genetic Data (2003), and the Nagoya Protocol (2010) pertain to genetics and biodiversity. The 1972 Biological Weapons Convention (BWC) deals with the issue of weaponized forms of biotechnology. And the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (1994) and the WTO Agreement on Technical Barriers to Trade (1994) help govern international trade involving GMOs.[99]

Existing legal instruments have not included adequate enforcement provisions to protect the interests of developing countries.

Broadly speaking, there have been a few successes (especially in the case of biological weapons), but elements of this patchwork of legal instruments suffer from three major shortcomings.[100] First, of particular concern to developing countries like India is the fact that legal provisions governing the cross-border spread of biotechnology have not significantly reduced the uncompensated movement of precious biological and genetic resources—including specific genetic traits and plant DNA—from developing countries to advanced economies.[101] Breakthroughs in genetic engineering have raised concerns over the use and manipulation of genetic resources and the monopolization of their use through indiscriminate patenting by the world's dominant biotech companies, which are primarily based in the West; this has led to charges of biocolonialism from organizations such as the Indigenous People's Council on Biocolonialism.[102]

Existing legal instruments have not included adequate enforcement provisions to protect the interests of developing countries. While the Nagoya Protocol, a supplementary agreement to the Convention on Biological Diversity,[103] does address the issue of fair and equitable sharing of benefits from products developed through genetic manipulation, it has not been as effective as one would hope.[104] The use of ambiguous qualifiers such as "as appropriate," "where applicable," and "as far as possible" throughout the texts, and the absence of any self-standing obligation on the part of user countries to ensure benefit sharing, leaves the implementation of these instruments open-ended.[105]

Moreover, the Convention on Biological Diversity defines genetic material as "any material of plant, animal, microbial or other origin containing functional units of heredity,"[106] a definition subsequently interpreted by the convention's governing body to exclude human genetic resources from the framework of the convention and the Nagoya Protocol.[107] Thus, several advances in modern biotechnology are not even covered by this equitable benefit-sharing framework.

Consequently, while biotechnology can help states move toward achieving economic and environmental sustainability in a globalizing world,[108] there is a fear that a few multinational firms in technologically rich states will enjoy a disproportionate degree of power over access to food and other critical resources. The outsized control of vital biotech innovations by such companies has been a source of significant tension in developing countries, including India. A good example of this is the recent case of Monsanto threatening to reevaluate its business activities in India in the face of a government proposal to cut royalties on Monsanto's vital Bt cotton seeds.[109] Further, as an ongoing patent dispute between two U.S. universities over the revolutionary CRISPR technology shows, it looks as though the future of biotech may be determined largely by the actions of institutions based in the West.[110] This demonstrates the stark economic and technological imbalance between the West and the rest of the world.

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When coupled with the continued commercialization of vital genetic and biological resources of the developing world, this reality has two major implications for global politics:

If the world comes to increasingly rely on seeds and technologies developed and controlled by such companies, the food security achieved in much of the developing world, including India, after immense struggles and investments could be undermined.[111] An increased centralization of genetic resources in the hands of a few Western companies could push the developing world back into a situation of greater dependency on the West, reinforcing global inequalities and potentially ratcheting up tensions.

The second area where global governance must be improved relates to the security dimensions of biotechnology, which existing legal mechanisms may not be in a position to deal with comprehensively.[112] Synthetic biology can be harnessed to create biological weapons, including disease-carrying viruses, in laboratories without the need for existing biological resources. In a worst-case scenario, advances in biotechnology, genetics, and genomics could theoretically result in a new form of militarized eugenics, whereby certain individuals, or a small section of people carrying a certain genetic strain, could be specifically targeted. Furthermore, the falling costs of bioengineering using technologies like CRISPR may level the playing field between states and nonstate actors to a degree. If such technologies were to get into the hands of extremist

or terrorist groups, the nature and scale of potential harm would be almost unimaginable.[113] These challenges pose a wide array of environmental, ethical, political, and social challenges.[114]

The security dilemmas posed by the potential weaponization of biotechnology have already caught the attention of the United States; James Clapper, then U.S. director of national intelligence, highlighted genome editing as a global danger before the Senate Armed Services Committee in 2016.[115] It is only a matter of time before other major powers begin grappling with this issue in an institutional manner. Traditionally, India has taken a hard stance against biological weapons; however, it remains to be seen how New Delhi might react to the possible developments discussed here.

Third, the ability of existing multilateral legal instruments to respond to rapidly emerging biotech-related ethical dilemmas is unproven. Take for example, the recent creation of a pig embryo injected with human stem cells that, when fully developed, will be able to grow organs containing human cells.[116] The medical possibilities of this development are immense, especially for lifesaving organ transplant procedures and for advancing medical research. But the creation of a part-human, part-animal creature throws up a number of fundamental ethical and regulatory questions that cannot be answered by the existing regime. Similar questions are being raised by advances in gene-editing technologies; this may facilitate the genetic modification of embryos, which could eventually lead to the birth of so-called designer babies, in effect allowing people to artificially enhance their capabilities.[117]

These issues of gene editing directly relate to the existing technology gap between a handful of rich nations and the rest of the world. If, for example, gene editing is used to enhance the capabilities of citizens in countries that have the technical and financial resources to do so, then actual biological differences could arise between the citizens of these countries and the rest of humanity. Reconciling these issues under existing international agreements would be very difficult, and the only means of addressing this challenge is likely to provide for new ways of consensus building among relevant actors.[118]

The inadequacies in these current international frameworks underscore the need for a new set of global conversations that not only take into account the evolving issues likely to be faced in the future but also address the leading questions of today. Beyond traditional actors like states, the stakeholders in these new conversations must include pharmaceutical companies, universities, research laboratories, and nongovernmental organizations from both developing and developed countries, along with proprietors of traditional knowledge, including indigenous peoples. Such a multi-stakeholder model would mean acknowledging the diversity of issues present in this field and would allow everyone who has a stake in the outcome of such global discussions to have a voice at the table. The multi-stakeholder model that internet governance is moving toward could possibly be emulated for the case of biotechnology.

At present, however, with biotechnology increasingly being seen as central to countries' economic and national security, having such an inclusive conversation is not going to be an easy task.

India's Role in Shaping Global Biotech Regimes

Given these pressing concerns, India has an urgent interest in shaping new potential global regimes pertaining to biotechnology. As a global biodiversity hotspot, and as a potential beneficiary of these technologies, India must actively engage in shaping governance regimes that account for its interests. These interests primarily include protecting indigenous bioresources and related knowledge, equitably sharing technological know-how, and preventing these technologies from falling into the wrong hands. And, as previously mentioned, India must also focus on providing a stable and open domestic ecosystem for biotech innovations.

In the past, India's approach to global regimes related to emerging technologies has tended to be defensive, and this, in turn, has resulted in all-or-nothing ideological positions that sometimes have isolated New Delhi on the global stage. India's initial idealistic emphasis on total nuclear disarmament and complete nondiscrimination, for example, had made New Delhi increasingly marginal to the evolution of global nuclear technology regimes. To some degree, old thinking on strategic autonomy and a presumed commitment to lead the developing world against advanced economies still endures in India's leadership classes.

Yet, over the last few years, some have begun attempting to correct this orientation, as India has started instead presenting itself as a responsible power seeking to contribute to and manage the global order. India's support for the global nonproliferation regime, its quest for membership in technology regimes, its recent commitment to positive outcomes in climate change negotiations, and its support for a multi-stakeholder approach to internet governance all mark India's new sense of itself as a leading power that will uphold its responsibilities to the international order as well as secure its own economic and political interests.

To this end, beyond the aforementioned ways that India could seek to improve its domestic regulatory environment and convene a comprehensive domestic dialogue on biotechnology, there are other steps that India can take on the international stage to improve its position on issues related to biotechnology.

India's Stance on Global Biotech Standards

For instance, India can try to leverage its position as a major developing country to advocate for a more equitable worldwide distribution of the technical knowledge and potential gains of biotechnology. With the global biotech industry currently focused on accelerating productivity, collaboration is

a plausible way forward for countries faced with resource constraints. With an abundance of high-quality, low-cost, technical human capital and a relatively advanced commercial biotech sector, India could conceivably become a partner of choice for stakeholders from developed and developing countries alike.[119] Though IP rights still present a major hurdle—given that most major Western biotech companies do not consider the Indian IP regime sufficiently protective of their proprietary rights[120]—several Indian companies have managed to overcome this hurdle and work with international partners. The task is to foster an environment that encourages India to continuously improve its domestic strengths in collaboration with others and use that strength to shape global rules of the road.

One issue to keep in mind here is that such international collaboration should not provide an impetus for bio-piracy or the undue transfer of genetic resources outside the country. India has, in the past, been subject to instances of bio-piracy, including infamous examples involving Basmati rice and turmeric.[121] To counter this trend, India launched the Traditional Knowledge Digital Library (TKDL) as a way of documenting and protecting traditional knowledge and preventing bio-piracy and unethical bio-prospecting.[122] Recent reports that indicate a degree of apathy toward the TKDL among policymakers are therefore worrisome.[123] While the TKDL may not have been as successful as some initially hoped,[124] it remains a unique experiment in protecting both traditional knowledge and indigenous genetic resources. Despite its limitations, the TKDL could potentially be at the front lines of ensuring that genetic research collaboration does not take place on terms that are detrimental to India, and therefore the Indian government should consider giving it greater support.

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These problems at least partially stem from a lack of clear biotech-related definitions in international mechanisms for protecting IP. The current vehicle for multilateralism—the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)—is inadequate for dealing with modern advances in biotechnology. Terms such as "microorganism" and "microbiological process," which are considered patent-eligible under TRIPS, unfortunately bear no consistent meaning in scientific and medical literature.[125] Though introduced with the aim of harmonizing standards across countries, the various patent exclusions contained in Article 27 of TRIPS have meant that countries adopt highly divergent eligibility thresholds.[126] Similarly, patent exclusions on the grounds of *ordre public* or morality have provided states with huge leeway to treat biotechnology in widely differing ways for purposes of patent granting.[127] Such flexibility would not be undesirable per se but for the indeterminacy of these expressions and the consequential divergence that undermines the broader goal of harmonization.

A further issue is that these IP protections have expired. It would likely be in India's interest to try and revive them. Tellingly, Article 27(3), which deals with the patentability of microorganisms, was introduced with a short shelf life, and its terms were supposed to come up for review only four years after TRIPS came into effect. That this review never happened indicates strong differences over this issue and the need for clarity as to when renewed negotiations should commence in earnest. Moreover, it would be in India's interest to help lead such multilateral discussions as much as possible because the alternative would likely be rather inimical to its interests. After all, bilateralism between countries that own technology in this space and other countries that do not could accentuate the division between technological haves and have-nots, whereas a multilateral approach would allow developing countries to exercise greater collective negotiating power and perhaps level the diplomatic playing field considerably.

The treatment of data being gleaned from the field of bioinformatics and the intersection of biotechnology and big data would also benefit from having global standards, which India could help shape. There is currently no global framework for vital matters such as nondiscriminatory deep-learning algorithms; privacy-by-design architecture; or norms for data acquisition, storage, distribution, and analysis. Leadership in this arena would help guarantee beneficial, data-driven solutions while hopefully safeguarding against truant actors who may be tempted to handle genetic data irresponsibly.

It may take a great deal of time to improve global standards on various aspects of biotech and the prospects for success are uncertain. In the meantime, India can also do more on its own to spur domestic innovation as a way to reduce its dependence on biotech materials from other countries. For instance, Radhakrishna Pillai, the director of the Rajiv Gandhi Center for Biotechnology, observes that basic biotech research in India still depends almost exclusively on imports of molecular biological enzymes, monoclonal antibodies, cell lines, serums, experimental animals, and key reagents. This dependence is expensive and considerably slows the pace of innovation and research in India. To overcome this limitation, Pillai recommends that the Indian government invest in developing the necessary infrastructure, along with seed capital and tax breaks, to push scientific researchers out of their comfort zones and spur them to develop their own domestic business ventures. A feasible approach, in his opinion, would be to work backward from society's needs to generate research-based solutions in the laboratory, instead of creating new markets for technologies developed in the laboratory.[128]

Hedging Against Biological Weapons

As for the threat of biological weapons, India is party to the 1972 BWC and has stated that it has no intention of developing such weapons.[129] Recognition of the potential militarization of advances in biotechnology led to a round of negotiations between 1995 and 2001 that centered on the insertion of an

additional protocol to the BWC, which would have required member states to annually declare their biological defense facilities and their industrial capabilities and programs. India supported these efforts and expressly mentioned that a "multilaterally agreed mechanism for verification of compliance" would be "critically important" to the effective working of the convention.[130]

The United States, however, presumably fearful of international interference with its own biological defense program, seemingly scuttled these talks and the additional protocol.[131] In fact, the United States has since remained opposed to international oversight at subsequent BWC review conferences, as evidenced by its statement in the recent Eighth Review Conference of the convention, where Washington stressed that "there is no substitute for effective national implementation" and did not mention the word "verification" at all.[132] The U.S. position stands in marked contrast to statements at the same conference by countries like India.

With formal efforts to strengthen and update the BWC effectively stalled, India must not shy away from studying the possible implications of the weaponization of new developments—including CRISPR and gene editing. These advances, by their very nature, are dual-use and cannot be easily equated with more easily distinguishable weaponized applications, such as anthrax. There are potential military and strategic benefits that can be derived from these technologies that may not fall afoul of existing international norms, and India should actively undertake and encourage research on these particular technical aspects until new norms specifically dealing with these developments are adopted.

In all of these areas, it is therefore necessary for an honest and open global conversation to take place on recent developments in this biotech sector among a wide range of stakeholders. A consensus-based approach to the global governance of biotech that is equitable, just, and fair may emerge out of such a conversation. Any such global regimes would need to be necessarily open to further changes, while ensuring that safeguards exist against the potential misuse of these technologies.

Conclusion

Biotechnology is among a handful of technologies, along with artificial intelligence and quantum computing, that will likely redefine human society in the twenty-first century. The avenues it will continue to open up, both positive and negative, are staggering. If India is to become a leading power in the coming decades, it is imperative that it begin to grasp the immense possibilities and implications of recent developments in biotechnology. New Delhi should therefore continue searching for ways to enhance its biotech regulatory system and to foster growth in India's biotech sector, so that the country can position itself to play as prominent a role as possible in global conversations about how to respond to the promise and peril that biotechnology represents.

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