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Bio-Technology in India and Uzbekistan, Its Laws and The Role of Regulatory Body

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I. INTRODUCTION

There is a growing recognition of the potential of life sciences research intended for peaceful purposes and public benefits which can be misused and directed for *bio-warfare and bioterrorism*. This has led to the emergence of what is now known as the "dual use" dilemma and the continuing debate on the *dual use nature of biotechnology research with potentials for biological weapons making*. Dual use potential of biotechnology has been underappreciated by the life sciences and wider communities until recently, when terrorism has increased awareness and concern about it and how it poses a threat to nation's security. This informed range of calls has promoted dual use of biosecurity education and awareness-raising among life scientists, peace and conflict resolution specialists, security agents and policy makers. *Hence life scientists, security professionals, educators and policy makers in the developed nations are giving increased attention to biotechnology and its implications for national security*. Thus bioterrorism, biowarfare, biosecurity education, have become topical issues. This has led to the evolution of web of preventative policies aimed at prohibiting the misuse of the life sciences. *This is embodied in the General-Purpose Criterion of the Biological and Toxin Weapons Convention (BTWC).* Therefor, with this paper an attempt has been made to explain how bio-technology being the most flourishing sector for the development has its own risks attached to it and these threats pertaining to bio-technology must be addressed in different ordeals as discussed further in the paper. Bioweapon threats could include the deliberate release by attackers of an agent that causes one or more of a variety of different diseases. *Public health authorities have developed a system to prioritize biological agents according to their risk to national security*.

1) Category A agents are the highest priority, and these are disease agents that pose a risk to national security because they can be transmitted from person to person and/or result in high mortality, and/or have high potential to cause social disruption. These are anthrax, botulism (via botulinum toxin, which is not passable from person to person), plague, smallpox, tularemia, and a collection of viruses that cause hemorrhagic fevers, such as Ebola, Marburg, Lassa, and Machupo. These disease agents exist in nature (with the exception of smallpox, which has been eradicated in the wild), but they could be manipulated to make them more dangerous.

2) Category B agents are moderately easy to disseminate and result in low mortality. These include brucellosis, glanders, Q fever, ricin toxin, typhus fever, and other agents.

Category C agents include emerging disease agents that could be engineered for mass dissemination in the future, such as Nipah virus. (This index of possible threats from the CDC lists all Category A, B, and C agents. Note that chemical weapons, such as those involving nonbiological substances such as chlorine gas, are not included.)

India today has the largest biological wealth in the world. It has the demographic advantage of having the human resource of 1.3 billion people with 50 per cent below the age of 25 years. The animal wealth is also comparable to the human resource in numbers with more than one billion animals. The country has unparalleled plant wealth. More than 15 per cent of GDP comes from the agriculture sector and 60 per cent of the population is employed in this sector directly or indirectly. *The nation has a rich biodiversity with two hotspots, one in the North East and other in the Western Ghats, having more than 45,000 species of plants many of them having medicinal value. The use of effective vaccines would likely protect lives and limit disease spread in a biological weapons emergency*. Licensed vaccines are currently available for a few threats, such as anthrax and smallpox, and research is underway to develop and produce vaccines for other threats, such as tularemia, Ebola virus, and Marburg virus. *Many bioweapon diseases threats, however, lack a corresponding vaccine, and for those that do, significant challenges exist to their successful use in an emergency situation.*

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With such biological assets, there is a need for formulation of detailed plans and strategies to appropriately respond to any bio-threat to the three major categories of biological wealth. Bio-threats can arise from a natural outbreak transiting to an epidemic or pandemic, from an irresponsible nation venturing into bio-warfare on a large scale which is rather a remote possibility, or from an act of bioterrorism from a non-state actor all of these constituting as a threat towards national security of a nation and also creating a global threat.

II. WHAT IS BIO-TECHNOLOGY?

The technology which is based on biology is known as biotechnology which harnesses cellular and bio molecular processes to develop technologies and products that help improve our lives and the health of our planet. Biotechnology is being used to heal the world, to provide energy to the world and finally to feed the world. It heals the world by reducing the rates of infectious diseases. Further it changes the odds of serious life-threatening conditions affecting millions around the world. *It creates more precise tools for disease detection and combating serious illness and every day threats confronting the developing world.*

When Edward Jenner invented vaccines and when Alexander Fleming discovered antibiotics, they were harnessing the power of biotechnology. And, of course, modern civilization would hardly be imaginable without the fermentation processes that gave us beer, wine, and cheese!

When he coined the term in 1919, the agriculturalist Karl Ereky described *'biotechnology' as "all lines of work by which products are produced from raw materials with the aid of living things."* In modern biotechnology, researchers modify DNA and proteins to shape the capabilities of living cells, plants, and animals into something useful for humans. Biotechnologists do this by sequencing, or reading, the DNA found in nature, and then manipulating it in a test tube or, more recently, inside of living cells. Their work has brought us the powerful cellular tools at biotechnologists' disposal today. *In the coming decades, scientists will use the tools of biotechnology to manipulate cells with increasing control, from precision editing of DNA to synthesizing entire genomes from their basic chemical building blocks.* These cells could go on to become bomb-sniffing plants, miracle cancer drugs etc. And biotechnology may be a crucial ally in the fight against climate change.

But rewriting the blueprints of life carries an enormous risk. To begin with, the same technology being used to extend our lives could instead be used to end them. While researchers might see the engineering of a supercharged flu virus as a perfectly reasonable way to better understand and thus fight the flu, the public might see the drawbacks as equally obvious: the virus could escape, or someone could weaponize the research. And the advanced genetic tools that some are considering for mosquito control could have unforeseen effects, possibly leading to environmental damage. While the risks of biotechnology have been fretted over for decades, the increasing pace of progress from low cost DNA sequencing to rapid gene synthesis to precision genome editing suggests biotechnology is entering a new realm of maturity regarding both beneficial applications and more worrisome risks. *"It is clearly understood by so far that when a person has complete knowledge of what the subject means or what potential it holds the advancement then could be used in any manner"*- This sentence will get a clear view in further reading of the paper.

III. BIO-TECHNOLOGY A "BOON" AS WELL AS "BANE" FOR SOCIETY

Satellite images make clear the massive changes that mankind has made to the surface of the Earth: cleared forests, massive dams and reservoirs, millions of miles of roads. If we could take satellite-type images of the microscopic world, the impact of biotechnology would be no less obvious. The majority of the food we eat comes from engineered plants, which are modified either via modern technology or by more traditional artificial selection to grow without pesticides, to require fewer nutrients, or to withstand the rapidly changing climate. Manufacturers have substituted petroleum-based ingredients with biomaterials in many consumer goods, such as plastics, cosmetics, and fuels. The laundry detergent? It almost certainly contains biotechnology. So, do nearly all of your cotton clothes. These are few of the many examples which in concise form have been sited to showcase how bio-technology has been a boon to the developing society and how certain advancements are being made through the science and technology combination. *But perhaps the biggest application of biotechnology is in human health.* Biotechnology is present in our lives before we're even born, from fertility assistance to prenatal screening to the home pregnancy test. It follows us through childhood, with immunizations and antibiotics, both of which have drastically improved life expectancy. Biotechnology is behind blockbuster drugs for treating cancer and heart disease, and it's being deployed in cutting-edge research to cure Alzheimer's and reverse aging as well. The scientists behind the technology called CRISPR/Cas9 believe it may be the key to safely editing DNA for curing genetic disease. And one company is betting that organ transplant waiting lists can be eliminated by growing human organs in chimeric pigs; these advancements and instances of growth of human mind for developing such great things with use of bio-technology has been a favored subject for all and hence all the developed and developing nations are putting a lot of efforts in order to advance their individual strength when it comes to bio-technology.

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Along with excitement, the rapid progress of research has also raised questions about the consequences of biotechnology advances. Biotechnology may carry more risk than other scientific fields: microbes are tiny and difficult to detect, but the dangers are potentially vast. Further, engineered cells could divide on their own and spread in the wild, with the possibility of far-reaching consequences. *Biotechnology could most likely prove harmful either through the unintended consequences of benevolent research or from the purposeful manipulation of biology to cause harm.* One could also imagine messy controversies, in which one group engages in an application for biotechnology that others consider dangerous or unethical creating a rift.

The biotechnology is also essential to feed the world. It improves crop resistance, enhances crop herbicides and facilitates the use of more environmentally sustainable farming practices. Currently there are more than 250 biotechnology health care products and vaccines available to patients most of them for treatment of previously untreatable diseases. More than 13 million farmers globally use agricultural biotechnology to increase yields, prevent damage from insects and pests as also help to preserve the environment.

Apart from this, there are and have been speculations about misuse of such a technology and genetically engineered material particularly to strengthen military programs by other nations. It is reported that the technology could lead to disasters which could be more dangerous than nuclear accidents. *The reason being genes can replicate, spread and recombine indefinitely*. The cloning of Dolly the sheep was visualized as a step which would lead to human cloning. Initially the United States imposed a five-year ban on human cloning, while the British at that time wanted cloning to be made illegal. Currently in the United States cloning is permitted for bio medical research however, many states have passed laws on human cloning and some of them forbid cloning of children *as all of these can further accelerate the use of bio-technology for destructive purposes making the nation's security vulnerable and risk prone.*

As genetic engineering can boost horizontal gene transfer which is to transfer genes to unrelated species, it may be used to create new pathogenic bacteria and anti-biotic resistance among pathogens. *It is reported that such horizontal gene transfers are already occurring due to improper handling, storage and disposal of genetically engineered material. It has been alleged that previously unknown bacterial strains responsible for outbreak of Streptococcus epidemic and E.coli in Scotland were the result of genetic recombination subsequent to horizontal gene transfer.* According to WHO reports there are at least 30 new diseases including AIDS, Ebola and Hepatitis C which have emerged over the last 30 years. Genes for antibiotic resistance are also believed to have spread horizontally. *Such microbes are cause of concern because infections with these and other similar strains will not respond to known treatments and therefore accidental or intentional release of such genetically engineered organisms into the environment may be disastrous.*

IV. "WEAPONIZING BIOLOGY" IS BECOMING THE BIGGEST BANE

The world recently witnessed the devastating effects of disease outbreaks, in the form of Ebola and the Zika virus but those were natural in origin but the current COVID-19 has its proper share of speculations of being a virus originated with proper planning and agenda. The malicious use of biotechnology could mean that future outbreaks are started on purpose like it is speculated for the current COVID-19. *Whether the perpetrator is a state actor or a terrorist group, the development and release of a bioweapon, such as a poison or infectious disease, would be hard to detect and even harder to stop.* Unlike a bullet or a bomb, deadly cells could continue to spread long after being deployed. The US government takes this threat very seriously, and the threat of bioweapons to the environment should not be taken lightly either. Developed nations, and even impoverished ones, have the resources and know how to produce bioweapons.; which India as a nation is lacking. *For example, North Korea is rumored to have assembled an arsenal containing "anthrax, botulism, hemorrhagic fever, plague, smallpox, typhoid, and yellow fever," ready in case of attack.* It's not unreasonable to assume that terrorists or other groups are trying to get their hands-on bioweapons as well. *Indeed, numerous instances of chemical or biological weapon use have been recorded, including the anthrax scare shortly after 9/11, which left 5 dead after the toxic cells were sent through the mail.* And new gene editing technologies are increasing the odds that a hypothetical bioweapon targeted at a certain ethnicity, or even a single individual like a world leader, could one day become a reality. Activities like these certainly is making the bio-technology a threat towards National security and safety of a nation.

While attacks using traditional weapons may require much less expertise, the dangers of bioweapons should not be ignored. *It might seem impossible to make bioweapons without plenty of expensive materials and scientific knowledge, but recent advances in biotechnology may make it even easier for bioweapons to be produced outside of a specialized research lab. The cost to chemically manufacture strands of DNA is falling rapidly, meaning it may one day be affordable to 'print' deadly proteins or cells at home.* And the openness of science publishing, which has been crucial to our rapid research advances, also means that anyone can freely Google the chemical details of deadly neurotoxins. In fact, the most controversial aspect of the supercharged influenza case was not that the experiments had been carried out, but that the researchers wanted to openly share the details.

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On a more hopeful note, scientific advances may allow researchers to find solutions to biotechnology threats as quickly as they arise. Recombinant DNA and biotechnology tools have enabled the rapid invention of new vaccines which could protect against new outbreaks, natural or man-made. For example, less than 5 months after the World Health Organization declared Zika virus a public health emergency, researchers got approval to enroll patients in trials for a DNA vaccine and similarly the process for vaccine and it's trials are on full swing when it comes to the current COVID-19 pandemic.

Biotechnology doesn't have to be deadly, or even dangerous, to fundamentally change our lives. While humans have been altering genes of plants and animals for millennia first through selective breeding and more recently with molecular tools and chimeras we are only just beginning to make changes to our own genomes (amid great controversy). Cutting-edge tools like CRISPR/Cas9 and DNA synthesis raise important ethical questions that are increasingly urgent to answer. Some question whether altering human genes means "playing God," and if so, whether we should do that at all. For instance, if gene therapy in humans is acceptable to cure disease, where do you draw the line? With such questions we need to re-visit the morale by which the whole process of developing the biology with the technology started and maintain the basic ethics while emerging the new dimensions of a particular attribute of the subject so that it does not become a weapon of destruction instead of being of help and become a menace for a country's security and safety.

V. BIO-TECHNOLOGY IN INDIA, ITS LAWS AND THE ROLE OF REGULATORY BODY

India's biotech sector has attracted significant amount of attention over the past two decades. Several global companies have aggressively joined hands with Indian companies due to India's strong generic biotechnology potential. The Government of India has taken several initiatives to improve the biotechnology sector in the country as well as offer enough scope for research in this field. The prime initiatives taken by the government includes the following: A Network of Technology Centers and promotion of start-ups by Small Industries Development Bank of India (SIDBI) are among the steps taken by the Government of India to promote innovation and entrepreneurship in the Agro-industry proposed by the Ministry of Micro, Small & Medium Enterprises (MSME) in a new scheme. *The Department of Biotechnology (DBT) along with other government funded institutions such as National Biotechnology Board (NBTB) and many other autonomous bodies representing the biotechnology sector, are working together in order to project India as a global hub for biotech research and business excellence*. With the country offering numerous comparative advantages in terms of R&D facilities, knowledge, skills, and cost effectiveness, the biotechnology industry in India has immense potential to emerge as a global key player. India is a most favored nation for the multinational to invest. India is amongst the top 12 biotech destinations in the world and ranks third in the Asia-Pacific region. India has the second highest number of USFDA–approved plants, after the USA. India adopted the product patent regime in 2005. India is the largest producer of recombinant Hepatitis B vaccine. India has the potential to become a major producer of transgenic rice and several genetically modified (GM) or engineered vegetables. India has abundance of highly-skilled and trained pool of talent. Special purpose organization such as Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking of Department of Biotechnology is there to support the industry through funding, mentoring, hand-holding and infrastructure support.The Indian government has entered into a number of biotechnology co-operation agreements with various countries in an effort to foster additional growth in this sector. Several State Governments such as Karnataka, Tamil Nadu, Andhra Pradesh, Maharashtra have taken out their specific policies to boost the biotechnology sector in their respective areas. Some of the key steps taken by the State Governments include: announcing separate Biotechnology Policy for their States, setting up of Task Forces with experts to guide them on policy issues, setting up of exclusive Biotechnology Parks with agriculture and health biotechnology as key areas. The city of Bangalore, located in the State of Karnataka and known as the IT capital of India, is emerging as the hub of Biotechnology industry in India. This is how India as nation is increasing its potential when it comes to bio-technology and its advancements.

VI. REGULATORY FRAMEWORK IN INDIA

Department of Biotechnology [DBT] constituted under the Ministry of Science and Technology is the nodal agency for policy, promotion of R&D, international cooperation and manufacturing activities. Together with DBT, Genetic Engineering and Approval Committee [GEAC] constituted under Ministry of Environment and Forests [MoEF] is the leading regulatory body in the area of Biotechnology in India. Several committees have also been constituted under the said ministries to regulate the activities involving handling, manufacture, storage, testing, and release of genetic modified materials in India. These committees have statutory authority. Most of the committee members are from the scientific community and staff of DBT and MoEF. DBT appoints the members to the committees. The GEAC is supposed to be assisted by the *State Biotechnology Coordination Committees* (SBCC) and *District Level Committees* (DLC).

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The most important committees are:

1) The *Institutional Biosafety Committees* (IBSC), responsible for the local implementation of guidelines,
2) *Review Committee on Genetic Manipulations* (RCGM) responsible for issuing permits;
3) *GEAC* responsible for monitoring the large scale and commercial use of transgenic materials.

The Biotechnology industry in India is governed by the following enactments depending upon their relevance/applicability on case to case basis:

a) *Environment Protection Act, 1986*
b) EXIM Policy
c) Foreign Exchange Management Act, 1999
d) Laws pertaining to Intellectual Property Rights
e) *Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989 notified by Ministry of Environment & Forests on December 5, 1989 under Environment and Protection Act, 1986.*
f) Revised Recombinant DNA Safety Guidelines
g) Guidelines for Research in Transgenic Plants & Guidelines for Toxity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998
h) National Seed Policy, 2002
i) Seeds Act, 1966
j) The Plants, Fruits and Seeds [Regulation of import in India] Order 1989 issued under the Destructive Insects and Pests Act, 1914.
k) Guidelines for Generating Preclinical and Clinical Data for rDNA Therapeutics, 1999
l) Drugs & Cosmetic Act 1940 along with Drugs and Cosmetic Rules
m) Drug Policy, 2002
n) *Biological Diversity Act,2002*

VII. WHY BIO-TECHNOLOGY IS CONSIDERED AS A THREAT TO NATIONAL SECURITY?

Many of biotechnology's benefits are of dual-use as mentioned earlier, it is increasing the possibility that knowledge, skills, and equipment could be adapted for use as biological weapons.

A. *Relationship Biotechnology and Biological Warfare*

Biological Warfare is the use of disease producing agents to harm or kill adversary's military forces, population of a country, food and livestock. This could be delivered by conventional warhead, a human being or other civilian means. The pay load would be any living or non- living virus, microorganism or a bio active substance. *This would result in the initiation and spread of communicable diseases such as anthrax and plague or an epidemic.* Further contamination of food with an herbicide, pesticide or a heavy metal results in food poisoning. There after intentional release of pathogenic organisms can kill crops and destroy buffer stocks of food thereby causing panic and consternation for the adversary. *This is known as anti-crop warfare and could cause famine, malnutrition, decline of economic conditions and unsatiated hunger amongst the people.* Defoliants in the Vietnam War were primarily used to target sweet potatoes, sugar beets, soya beans, cotton, wheat and rice.

The implications of bio technology in warfare have been recognised by several countries. Currently it is reported that 17 countries are suspected of having biological weapons programmes. These are *Canada, China, Cuba, France, Russia, Germany, Iran, Iraq, Israel, Japan, Libya, North Korea, South Africa, Syria, the United Kingdom and the United States.* The progress of bio technology has made biological warfare more effective.

Uzbekistan, as a party to the Convention on the Prohibition of Bacteriological and Toxic Weapons, ensures the prohibition of the production and accumulation of biological weapons. Each State Party to this Convention undertakes to destroy or transfer to peaceful purposes, as soon as possible, but not later than nine months after the entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention that it possesses or which are under its jurisdiction or control. In implementing the provisions of this article, all necessary precautions must be taken to protect the public and the environment.

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Each State Party to this Convention undertakes not to transfer to anyone, directly or indirectly, nor in any way to help, encourage or induce any State, group of States or international organizations to manufacture or acquire any or otherwise any agents, toxins, weapons, equipment or means of delivery referred to in Article I of the Convention.

Currently, many countries visualise that biological weapons could be useful as a poor man's weapon of mass destruction which possibly could deter attacks from stronger nations and the second issue is that it is a relatively cheap force multiplier that can possibly compensate for asymmetry in conventional arsenals. As the same biotechnological equipment is utilised by modern pharmaceutical programme or laboratories associated with state of the art hospitals and can be used to start and run a biological weapons programme. Accordingly, identification of an offensive biological weapons programme would be extremely difficult. To illustrate manufacture of vaccines for human or veterinary use can conceal the production of large quantities of biological weapons. Bio technology has made the biological warfare programmes more complex, target oriented and ineffectual for verification procedures.

B. Offensive Evolution: Leading as national security threat

Attempts to use biological weapons date back to 400 BC. The Scythian archers infected their arrows by dipping them in decomposing bodies or in blood mixed with manure. The Romans were to follow and use biological agents in wars. They used dead animals to foul enemy's water supply to make soldiers sick by drinking the same. Similarly, the Tartars tried to infect the enemy by throwing bodies infected with plague over the walls of the city of Kaffa in the 14th century. *In the First World War the Germans developed anthrax, glanders, cholera and a wheat fungus. They allegedly spread plague in St Petersburg and infected mules with glanders in Mesopotamia*. They also attempted to do the same with the horses of the French Cavalry. *The Geneva Protocol of 1925 was signed by 108 nations. This was the first multilateral agreement that extended prohibition of chemical agents to biological agents.* It is unfortunate that the Geneva Protocol did not include any clause or method for verification of compliance.

During World War II, Japanese forces operated a secret biological warfare research facility (Unit 731) in Manchuria that carried out human experiments on prisoners. They exposed more than 3000 victims to plague, anthrax, syphillis and other agents in an attempt to examine the disease. Autopsies were also performed for greater understanding of the effects of the human body. In 1942, the United States formed the War Research Service which developed biological agents by June 1944 to counter the use by Germany. The British also made similar tests for a possible German offensive.

Post Second World War biological warfare was used in Vietnam sporadically by the United States from 1960 to 1968. The agent was to ensure limited spread of pneumonic plague and this is evident from a report by the World Health Organisation. It resulted in 2158 suspected cases and 107 deaths. It was further alleged that the erstwhile Soviet Union supplied biological weapons mainly Mycotoxins to Government forces, to kill dissident tribal people and enemy soldiers in Laos, Cambodia and Afghanistan. These were issued by the US State Department in 1982 in two major publications. It is reported that Laos had 6504 deaths, Cambodia 981 deaths and the casualties caused in Afghanistan are not known.

Meanwhile, the Biological and Toxin Weapons Convention banned the entire category of Biological and Toxin Weapons on 10 April 1972. This was to be effective from 26 March 1975. It was ratified by 22 countries and signed by 109 countries. Currently, there are 183 countries have joined the Convention and pledged to disavow biological weapons. United States and India have ratified the treaty. Despite this it is easy to produce these weapons due to bio technology. The treaty lacks any significant provisions for enforcement or verification. This has enabled a number of signatories to the treaty have maintained active weapons programmes. Iraq was suspected of having a Biological Warfare programme in 2003 and Libya was persuaded to terminate its biological programme in 2003. It is interesting to comprehend a few issues of the Corona Virus which has become a global pandemic. The present pandemic was preceded by the SARS epidemic which spread from China from the third week of January 2002. SARS was also a contagious disease but the issue was delayed and China informed the World Health Organisation (WHO) on February 07, 2002. Despite the delay the disease was contained and casualties minimised.

'Brahma Chellany' in his article in 'the Times of India on April 19, 2020' calls China a repeat offender. The Communist Party of China (CPC) treated the Covid-19 outbreak in Wuhan in November 2019 as a political embarrassment rather than a public health emergency delaying the start of containment, tracing, testing and treating to January 23, 2020 as per the speculations. Thereby, CPC made two mistakes. First, it turned a local outbreak into a global pandemic and second, they have provided false data of their casualties. The latter has resulted in a lack of effective response to the pandemic. This could lead to serious misunderstanding. China also blocked a discussion of the pandemic in the UN Security Council. There has been a total lack of transparency resulting in the pandemic affecting the entire world. *The impact is greater than the two World Wars and serious thought has to be given to developing intelligence on these issues to avoid further casualties.*

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French virologist and medicine Nobel laureate Luc Montagnier created a scientific firestorm across the world. He claimed that SARS-Cov-2, the virus that led to the global pandemic is manmade as it's the result of an attempt to manufacture a vaccine against the AIDS virus in Wuhan National Biosafety laboratory. He made the statement while being interviewed on a French news channel. He jointly discovered the AIDS virus and bagged the 2008 Nobel award in medicine. He alleged that there was presence of elements of HIV and malaria in the genome of coronavirus. He said it was suspected and the virus could not have arisen naturally. His allegation has come at a time when the US has started a probe into this issue. These attracted criticism from a section of the scientific community. The US Government is carrying out a full investigation and there are questions to be answered by the Chinese despite their repeated denials. The US Government is asking the Chinese Communist Party to allow experts get in to the Wuhan Virology Lab. China on the other hand has responded where they have denied permission and stated they are a victim and not the culprit. The moot point is such disasters need to be correctly investigated to make the process failsafe.

Applications to the Indian Armed Forces and population at large: The path for weakening the national security

The present pandemic of Coronavirus has impacted the Armed Forces of all countries of the world. Currently, the immediate focus is on defensive measures with an aim of keeping personnel fit. Over-all the Indian Armed Forces have to deal with the surveillance, diagnosis, offensive and defensive measures. First of all, we must understand what India's position with regard to this subject is. *During an event organised by the DRDO in July 2018, the former Defence Minister late Manohar Parrikar said India must be well prepared to deal with chemical and biological warfare in the wake of changing threat perception and security reasons.* As a matter of fact, he said we should be prepared for any kind of warfare. The Armed Forces must be prepared for all kinds of threat. During the event DRDO handed over Nuclear, Biological, Chemical Reconnaissance Vehicle and NBC drugs to the Indian Army.

On March 27, 2020, on the occasion of the 45th anniversary of the Biological and Toxin Weapons Convention (BTWC) coming into force, India underlined the need for international cooperation, including institutional strengthening of the World Health Organisation. The Covid-19 issue was discussed in detail and ahead of the ninth Review Conference of the Convention in 2021. *India reiterated its call for putting in place a comprehensive and legally binding protocol having a non-discriminatory, verification mechanism to strengthen norms to deal with biological weapons.*

C. Preparation for Biological Attacks and its prevention- a global perspective

In 2001, before the 9/11 attacks, several U.S. agencies and academic groups conducted a simulated biological attack, codenamed Dark Winter, in which smallpox virus was the weapon. The exercise, which operated on an assumption of about 12 million available doses of smallpox vaccine, based on the then-available stores of smallpox vaccine, "demonstrated serious weaknesses in the public health system that could prevent an effective response to bioterrorism or severe naturally occurring infectious diseases" ("Overview of Potential Agents of Biological Terrorism," Southern Illinois University School of Medicine).

One key weakness exposed in the exercise was a shortage of vaccine; this has since been addressed, at least in the case of smallpox, with the addition of hundreds of millions of doses of smallpox vaccine to U.S. vaccine reserves. Other difficulties exposed were the conflicts between federal and state priorities in managing resources, a shortage of medical infrastructure to deal with mass casualties, and the crucial need for U.S. citizens to trust and cooperate with leaders. The reaction of those exposed to anthrax in the post-9/11 attacks illustrates the challenges embedded in the latter issue: a study published in 2008 suggested that the reticence of many exposed individuals to take the anthrax vaccine reflected their fear of the vaccine's side effects and distrust of medical personnel (Quinn, 2008). In any large-scale bioterror incident, this distrust may be a major hurdle to effective containment of an infectious agent. Authorities hope that disaster planning and the devising of effective medical countermeasures for biological attacks will both minimize the impact of any such attack and also act as deterrent to those who might consider such an attack. If the attack could be easily contained and addressed, then a terrorist or unfriendly nation might have less incentive to initiate one.

VIII. SAFEGAURDS AND WAY FORWARD

India and its Defence Forces must have a fresh look at Biotechnology and undertake the following measures: -

1) A Project should be initiated comprising of three services, DRDO a representative from the ministry of Health a representative from the Ministry of Finance and Representative from the Ministry of Defence.
2) The Project must have the capability of knowing the latest viruses and also details of Case X genetically engineered viruses.
3) The Project must keep in touch with the laboratories to keep ahead of impending biological weapons and genetically engineered products.
4) The Project could suggest innovative ideas on the subject like ducks eating locusts.
5) The Project must be given the same importance as Atomic Energy Commission and ISRO.

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6) The Project could function as a Biological Warfare Commission.
7) It would create a Biological Warfare Doctrine as also measures to be undertaken to develop Offensive and Defensive Biological Warfare.
8) The Institute of Nuclear Medicine and Allied Sciences (INMAS) would actively cooperate with the project for better results.
9) Issues would be emerging as the project formalises and navigates itself in the biological warfare world.

This will enable the nation and its regulatory bodies to be proactive while dealing with Biological Warfare. *It is pertinent to note that the intelligence community in the United States had warned about Coronavirus for the last five years.* Further, they predicted with uncanny accuracy many of the medical supply shortages which are troubling the US Government today. It must be noted that the Biological and Toxin Weapons Convention (BTWC) is still not ratified globally, unlike the Chemical Weapons Convention (CWC) which is administered by the Organization for the Prohibition of Chemical Weapons (OPCW), an intergovernmental organization based in the Hague.

Likewise, one cannot rule out the possibility of a virulent and contagious pathogen making its way out of an advanced microbiology laboratory; or a vaccine development unit that could inadvertently leak the pathogen out of a laboratory or facility that does not practice adequate bio-safety and bio-security safeguards.

All these scenarios re-emphasize the need for a concerted action plan for our nation that should be made operational on a priority basis.

The Defence Research & Development Organization (DRDO) has already developed considerable expertise to deliver a large number of CBRN (chemical, biological, radiological and nuclear) defence technologies and products to our Armed Forces for strengthening the national security. These include field-based diagnostic tools, personal protective equipment (PPE), collective protection at underground field shelters, decontamination devices and materials and medical management. Even a model hospital to handle CBRN victims has been developed. The National Disaster Management Authority (NDMA) has issued Standard Operating Procedure with valuable inputs from DRDO.

A decade ago, DRDO also formulated a blueprint for bio-threat mitigation and initiated a dialogue through inter-ministerial consultation. Now is the most opportune time to give a renewed thrust to all necessary endeavours for bio-threat preparedness.

A national-level mission mode program on bio-threat mitigation may need to be launched with overall coordination by the National Security Advisor (NSA) in the Prime Minister's Office, since bio-threat may impact our comprehensive National Security. A task force at National Security Council Secretariat may be constituted to address this dire need with the focus. Since it involves coordination between multiple ministries such as defence, health, agriculture and others, it is essential to constitute an inter-ministerial steering committee for proper coordination keeping DRDO as the nodal department.

Necessary resources including adequate budget need to be allocated for this important national mission. *Currently, in our country, we have only one BSL- 4 facility at the National Institute of Virology, Pune.* The country would require at least five more such facilities to be established on priority for undertaking advance R&D endeavours to study pathogens, keep a repository of potential bio-threat agents and develop diagnostics and therapeutics.

A large country like ours should strengthen the existing surveillance systems and mechanisms for identifying natural outbreaks. *A reliable database of epidemiological studies on infectious diseases needs to be strengthened to discriminate between the natural outbreak or the onset of an epidemic.* The Government of India needs to make a critical investment for the development of appropriate technologies and products, evolve suitable policies and ensure their practices at the grass-root level by networking with the state. In a federal structure like ours, the involvement and participation of states is an essential perspective of such a national initiative. It is indeed a 'wake-up call for the nation' to respond appropriately and adequately towards any bio-threat considering the emerging scenario.

IX. CONCLUSION

A biological attack by terrorists or an unfriendly nation is a remote possibility that nevertheless demands public health emergency response planning. Several multi-agency simulations have exposed weaknesses in systems designed to respond to biological emergencies. These exercises have helped to focus planning efforts on the need for emergency plans to address the potential for a large bioweapons event to overwhelm medical capabilities, cause widespread illness and death, and lead to economic and social disruption. The successful deployment of vaccines, antibodies, and other medications in a bioweapon event will depend on a number factors, such as how many people the attack has the potential to harm, the stability of the transportation system in an emergency, the availability of viable vaccine and drugs, and the ability of the public health system to communicate with the public and get the vaccines and medications into the people who need them all of these together constituting a menace towards national security pertaining to uses of bio-technology.

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The national security and law enforcement communities should improve communication with the life sciences community about how to mitigate the risks of bioterrorism. It is imperative that the United States conduct its legitimate defensive activities in an open and transparent manner to allow biomedical scientists to contribute to developing measures that will minimize the impact of bioterrorism. The intelligence and law enforcement agencies rely on academic scientists for their expertise about the nature of current agents and the potential for new ones, and for the best advice on limiting the spread of new technologies that would make countermeasures more difficult. *In addition, the national security community needs to establish advisory boards of scientists and clinicians with expertise in viral diseases, bacterial pathogens, biotechnology, immunology, toxins, molecular biology, and public health.* These advisory boards could help members of the intelligence and law enforcement communities stay on top of relevant areas of science and technology and provide a trusted set of advisors to answer technical questions. Any attempt to reduce the risks associated with biotechnology must be international in scope because the technologies that could be misused are being developed around the world. Additionally, international consensus and consistent guidelines for overseeing research in advanced biotechnology are necessary in order to prevent limitations on certain types of research in the United States that would impede the progress of biomedical research and undermine national interests. Therefore, the international policymaking and scientific communities should create an International Forum on Biosecurity to develop and promote coordinated national, regional, and international measures that will provide a counterpart to the system recommended for the countries. Policies to counter biological threats should not be so broad that they prevent the life sciences community from continuing its role of contributing to the betterment of life and improving defences against biological threats. Caution must be taken when adopting policies to respond to this threat so results will be achieved without creating unintended consequences. On the other hand, the potential threat from the misuse of biological research is a challenge to which policymakers and the scientific community must respond. *Only a system of international guidelines and review will ultimately minimize the potential for the misuse of biotechnology and its threat towards the national security of a nation.*

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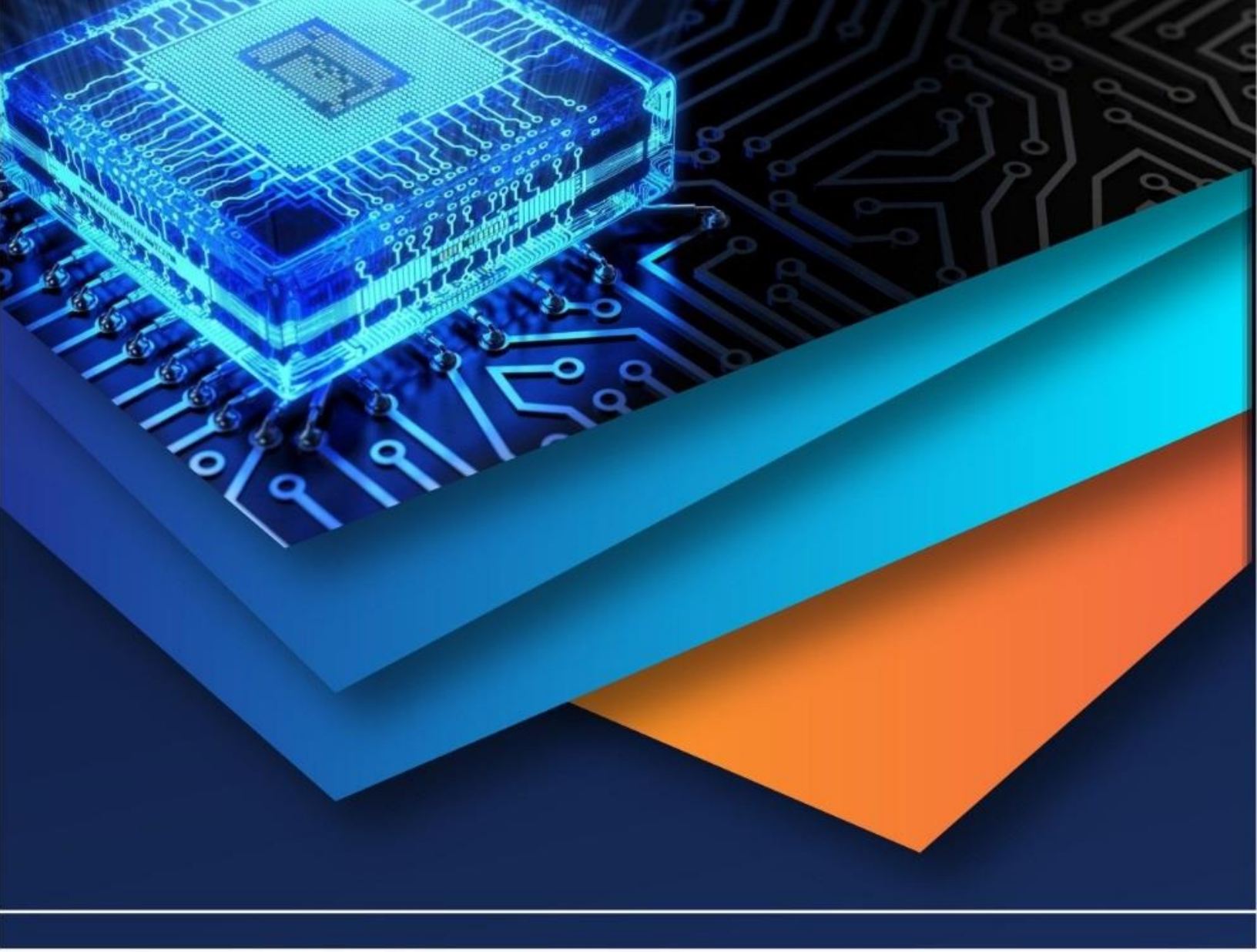

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