6th Legal:
Implications of Biosecurity and Biotechnology

A BEARMUN General Assembly Committee

[1]

Chairs: Gargee Piplani and Adinath Lane

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Letters from Your Chairs

Dear Delegates,

My name is Gargee Piplani (she/her/hers) and I am absolutely delighted to serve as your chair for BEARMUN 6th Legal. My interest in this topic stems from a philosophy class I took in my first semester of college – we discussed morality in many contexts, including medicine. I had never previously questioned the ethics of this field, especially considering how helpful the advancements have been to humans, and was drawn to the complexity behind these constantly developing technologies. I am excited to see how you guys tackle this intricate topic, and diplomatically resolve an issue that our world is facing today.

My MUN career began in my sophomore year of high school and I never abandoned the activity since then. Most of my coursework does not touch on international relations or policy, which I loved to learn about, so I made it a point to pursue these interests by joining MUN in college. I have been competing on the circuit since my first semester on campus, primarily in GA committees, but with conferences, I served as the Chief of Staff External for UCBMUN and a vice chair for Hunger Games at BEARMUN last year.

I'm originally from the East Bay, but spent a lot of my early life moving around places including Mumbai, NYC, Ohio, and Michigan. Currently, I am a junior at UC Berkeley studying Business Administration, Data Science, and Computer Science. Outside of MUN, I am also a part of a hedge fund and Greek life on campus. In my free time, I love going on walks, enjoying a good matcha, cheering on the Golden State Warriors, and side questing around the Bay Area.

Adi and I look forward to an exciting weekend with everyone and welcoming you all to our wonderful campus!

Gargee Piplani
Chair, 6th Legal

Welcome delegates!

My name is Adi Lane (he/him/his), and I am so excited to be your Chair for 6th Legal at BEARMUN 2024! I'm a third-year student at Berkeley majoring in Molecular and Cell Biology as well as Public Health, so the implications of this committee are a subject dear to my heart. How will you balance innovation with communication, ensuring that your policies grant equitable access to new systems without reducing efficacy in the process?

As you prepare for committee, remember not to examine the world of biotechnology in a vacuum; effective change must incorporate a knowledge of community well-being beyond just your medical "bugs and drugs"--keep other determinants of health and innovation in mind! I'll be looking for thoughtful, holistic, and evidence-based suggestions to make sure we apply these technologies for maximal benefit while mitigating risk–I **highly recommend** you look at our "Questions to Consider" section when outlining your position. From a behavioral standpoint, I'll be looking for delegates who can effectively negotiate and cooperate with parties that may have opposing viewpoints–"power delegates" that yell over committee or disregard others will be highly frowned upon.

A little about myself: I've lived in Palo Alto since moving from Gurugram when I was five, but try to go back every year (I'm currently writing this just after landing in Delhi). I was never a part of Model United Nations in high school (go Gunn!), but I'm so happy that I joined UC Berkeley's MUN team in my freshman spring semester—the creativity, talent, and friendliness of everyone on the team is incredible. I'm also the Secretary-General for our February UCBMUN collegiate conference in San Francisco, so I know how hard Sara, Anna, and the rest of your wonderful BEARMUN secretariat worked to make this conference spectacular.

Outside of Model UN, I'm a member of one of Berkeley's premed fraternities, volunteer at a local elementary school, and help fundraise with the Fighting Cancer at Berkeley club. Otherwise, I'm probably walking through Berkeley's dinosaur exhibits, hiking along the Bay's many trails, or sleeping under the sun on Memorial Glade. Feel free to email me at adinathlane@berkeley.edu with questions–Gargee and I can't wait to meet you!

See you soon,

Adinath Paul Wayne Lane
Chair, 6th Legal

The 6th Legal Body (UNESCO BG pw is "BeatMUNXIX!")

The United Nations General Assembly Sixth Committee, also known as the 6th Legal Committee, was established through the General Assembly's mandate to promote the development and management of international law as expressed in the UN Charter [2]. Much of the committee's past work has focused on matters of international security and legislation, including the negotiation of UN conventions, the promotion of justice, drug control, and terrorism prevention. As technology continues to develop, however, the committee has resolved discussions in other fields to ensure that international safety standards are delineated, notably in the 2006 United Nations Declaration on Human Cloning. This committee will focus on the development of international law regarding the rapid changes currently occurring within the field of biotechnology.

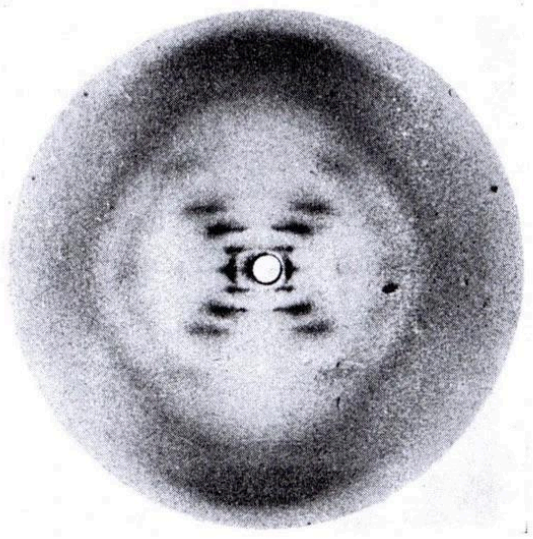
A History of Biotechnology

As a reminder, this committee will not require a deep-level understanding of various biotechnologies; this historical review aims to provide context through which various applications of biotechnology may be more easily understood. The ultimate focus of this committee will be on the international legislation to manage such applications, not necessarily the science involved. Feel free to email us if you have any questions!

In its most general form, **biotechnology** is the use of living organisms to produce certain products or services [3]. By this definition, humans have been practicing biotechnology for millenia through processes such as agriculture, selective animal breeding, and fermentation. For most of human history, however, biotechnology largely remained at the macroorganismal level.

Theories about heredity, development, and evolution began to gain more attention in the 19th century as scientists like Charles Darwin and Gregor Mendel conducted observational and experimental research in nature. The fields of microbiology and biochemistry also began to develop as techniques like cell culture and microscopy were further advanced.

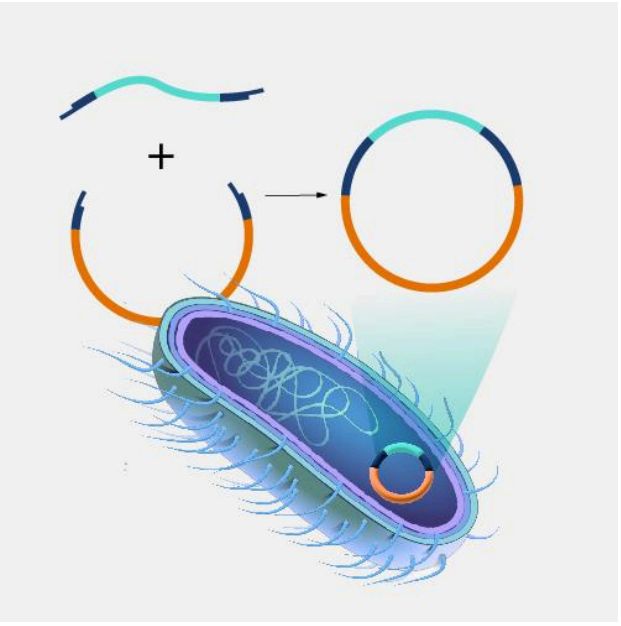
The early 20th century saw the use of biotechnology as a critical tool in war as countries used bacteria to produce animal feed, industrial chemicals, and antibiotics like penicillin at a national scale. A major transition toward *intracellular* biotechnology occurred with the increased focus on the molecular nature of inheritance in the early-mid 20th century. A series of pivotal experiments about **DNA** as a unit of inheritance culminated in James Watson and Francis Crick's discovery of DNA's double-helix structure. The deciphering of DNA's structure was critical in allowing future scientists to understand inheritance and development, kickstarting the field of **molecular genetics** [4].

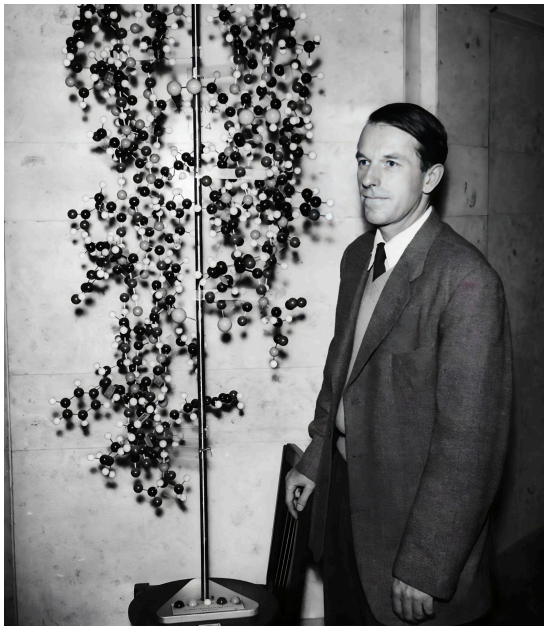


Known as "Photo 51", this x-ray of DNA from Rosalind Franklin's lab was critical in the determination of DNA's double helix structure. Discovering the structure of DNA was a major step in understanding how to interpret and edit DNA sequences. [4]

Modern biotechnology truly found its birthplace in the late 20th century, when biochemist Paul Berg pioneered the concept of **recombinant DNA**, or the introduction of one organism's DNA into another organism's genome. The mass production of these genetically-edited "hybrids" became known as **gene cloning** (AKA molecular cloning), setting the stage for a new innovative age of genetic engineering [5].

The rise of gene cloning came hand-in-hand with the development of the Sanger Sequencing technique, a laboratory method to determine the letter code of a DNA sequence. Sanger's procedure made the field of **gene sequencing** significantly faster and more efficient, and was another critical step toward understanding molecular genetics; by understanding what "code" a specific DNA sequence contained, scientists were able to figure out how different DNA molecules corresponded to different proteins, like insulin. Such discoveries were vital to the pharmaceutical production of these proteins in the future.





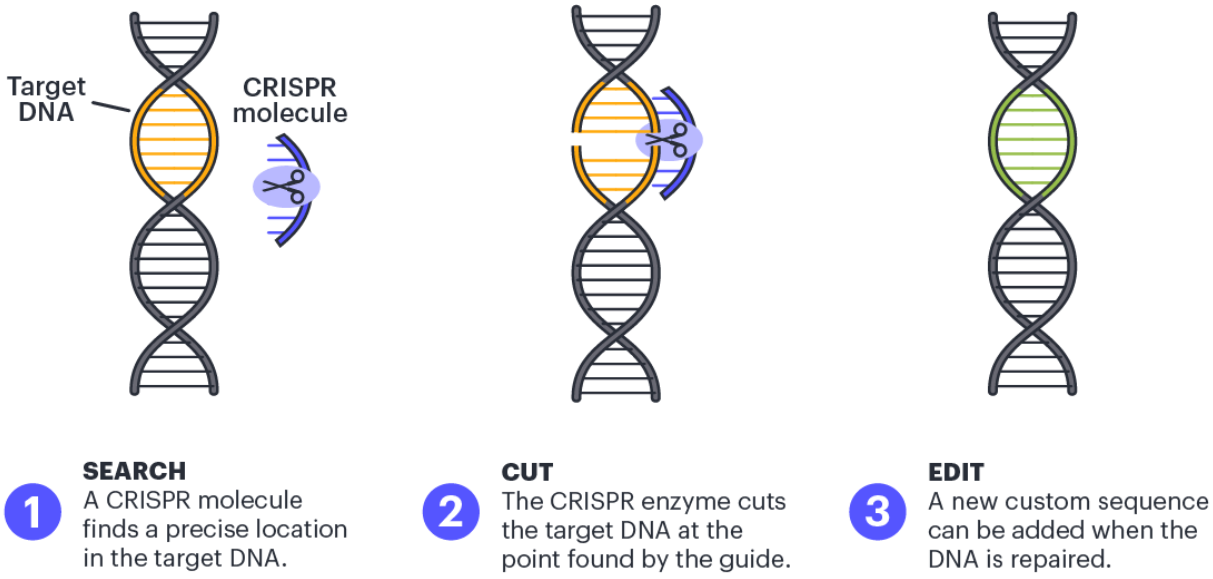
Together, the development of technologies to write (gene cloning) and read (DNA sequencing) genes in the 1970s formed the foundation of modern biotechnology.

Left: An example of bacterial recombinant DNA. Many bacteria have small circular DNA sequences (orange) that can be cut so that foreign DNA (turquoise) can be inserted, allowing these "hybrid" bacteria to make proteins they normally would lack the "code" to produce [6].

Right: Frederick Sanger developed the Sanger sequencing technique to read DNA code [7].

The 21st century has seen many technological advances to make both of these principles (gene cloning and DNA sequencing) significantly faster and cheaper. Advanced next-generation sequencing techniques allow scientists to now break up a DNA sequence and read many parts in parallel, a far faster alternative to the "letter-by-letter" approach in Sanger sequencing [5].

One of the most famous recent developments in biotechnology is the ability to use **CRISPR** systems to edit genes. CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) is an antiviral defense used by many bacteria in nature that allows them to target specific DNA sequences and cut them. In 2012, Emmanuelle Charpentier and UC Berkeley professor Jennifer Doudna won a Nobel Prize after discovering that they could "program" this system to edit genes of their choice. CRISPR technology is one of the most pivotal discoveries in all of biology; not only does it dramatically increase the precision of gene-editing, but it also enables for a variety of genetic modulations in a more cost-effective and affordable manner than ever before [8].



An overview of CRISPR technology. Initially derived from bacteria as a natural antiviral defense system, CRISPR technology allows scientists to target and modify specific regions of DNA code with a high degree of precision [8].

Finally, this time period has seen an increased focus on other processes associated with protein production. In particular, discoveries of RNA's wide array of functions within the cell has led to an "RNA Revolution" that cannot be understated; both the Moderna and Pfizer COVID-19 vaccines are famous examples of new RNA vaccine technology, using RNA to build harmless COVID-19 proteins in cells that "prepare" the immune system for genuine infection. These emerging technologies may not focus on DNA, but they offer scientists exciting ways to produce and regulate a vast array of proteins, often with a higher degree of success than other protein-forming techniques [9].

Rapid advances in gene editing and sequencing, as well as increased research in other aspects of molecular biology, have led to breakthrough advances in modern biotechnology. This background guide aims to review some of the most pertinent applications of these discoveries, as well as major concerns surrounding them. We'll end on a discussion of various attempts at regulating biotechnology throughout history.

Major Applications

The Human Genome Project and Other Databases

The Human Genome Project (HGP) was a hallmark in biological discovery. Running from October 1990 to April 2003 (2 years ahead of its intended completion) and costing over $3B, researchers aimed to comprehensively study and understand all facets of DNA (known as a genome) in a set of organisms. For reference, one copy of the human genome has around 3

billion base pairs of DNA. The project was funded by the Department of Energy and the National Institute of Health, which created the Office for Human Genome Research in 1988. The researchers came from over 20 different universities and research centers across the International Human Genome Sequencing Consortium (United States, United Kingdom, France, Germany, Japan, and China). The project successfully generated the first ever sequence of the human genome, which provided key insights into the human blueprint and has revolutionized the study of human biology ever since [10].

In 1988, a special committee of the US National Academy of Sciences outlined the goals for the Human Genome Project which included sequencing the entire genome of humans, mouse, fruit fly, nematode, baker's yeast, and the bacterium *E. coli*. Most of the original human genome sequence came from volunteers across Buffalo, New York who were drawn by public advertisements to donate blood samples from which their DNA could be extracted. Researchers at the local Roswell Park Center Cancer Institute, some of the most experienced in the country, could then prepare this DNA into a form that could be used for sequencing.

The human genome sequence was made readily available to the public shortly after its discovery due to the "Bermuda Principles" where the researchers agreed to release the sequenced data. This agreement significantly increased the awareness and willingness to share data in the field of medicine, making it one of the greatest legacies of the Human Genome Project. Today, the genome is used around the world to make groundbreaking medical discoveries. For example, the Genome Function Laboratory at the Francis Crick Institute in the UK is able to sequence the DNA in several cancerous tumors repeatedly to see which ones actually lead to cancer-inducing mutations [11].

Every year, 3-5% of the HGP budget was dedicated by the US Department of Energy (DOE) and National Institute of Health (NIH) towards studying the ethical, legal, and social issues (ELSI) surrounding the accessibility of genomic information. At the time, it was the largest existing bioethics program in the world and became a model for ELSI programs to follow.

One of the shortcomings of the HGP is that it only collected and analyzed White, European genetic information when genetic variations exist across the world. The Human Pangenome Project is working to reduce any biases that this may cause by sequencing and distributing the genomes of over 300 people from a variety of backgrounds.

The Human Genome Project has inspired many other databases, such as the Human Proteome Project and Cancer Genome Atlas. Such databases are hallmarks of international scientific cooperation that enable researchers from around the world to advance our understanding of molecular genetics.

Personal and Medical Gene Sequencing

Advances in both sequencing technologies and our understanding of gene linkage have allowed for the widespread use of recreational gene sequencing technologies in the public market. Companies like 23andMe and Ancestry use DNA analyses to build "genetic profiles" for consumers. One common use for this analysis is a geographic "ancestry report" that matches variations in an individual's DNA to variations common to different regions of the world. These

analyses often also include reports on some of an individual's predicted traits and their genetic risk for a wide array of health conditions. The popularity of such reports is enormous; AncestryDNA has sequenced the DNA of over 25 million users worldwide [12].

Sequencing technologies are also vital in the healthcare industry, where doctors use them to screen patients for certain genetic diseases and predict risk factors for medical conditions. This information allows for a more personalized approach to medicine, an incredibly important tool in diseases that may have many different genetic causes, such as a cancerous tumor that is unbothered by some treatments and responsive to others.

23andMe uses DNA sequencing technology to analyze the genomes of customers. The company uses this information to build a geographic ancestry report as well as an individual's genetic predisposition for certain conditions or traits, such as breast cancer or fear of public speaking [13, 14].

Transgenic Organisms

Transgenic organisms, also known as **genetically modified organisms** (or GMOs) are one of the most significant consequences of modern gene-editing techniques. Through these processes, scientists can modify the DNA of a specific organism to change aspects of its function or behavior. Transgenic organisms have a variety of purposes, but one of the most significant is the modification of bacteria to produce specific proteins at an industrial scale in pharmaceutical and manufacturing settings [15].

One example of this protein production is insulin, a hormone that manages blood sugar levels. Without functional insulin, patients develop diabetes, which is often deadly if not properly managed. To obtain insulin, pharmaceutical companies of the 20th century had to extract the molecule from animal pancreases, often in vast amounts–it took 23,500 animal pancreases to

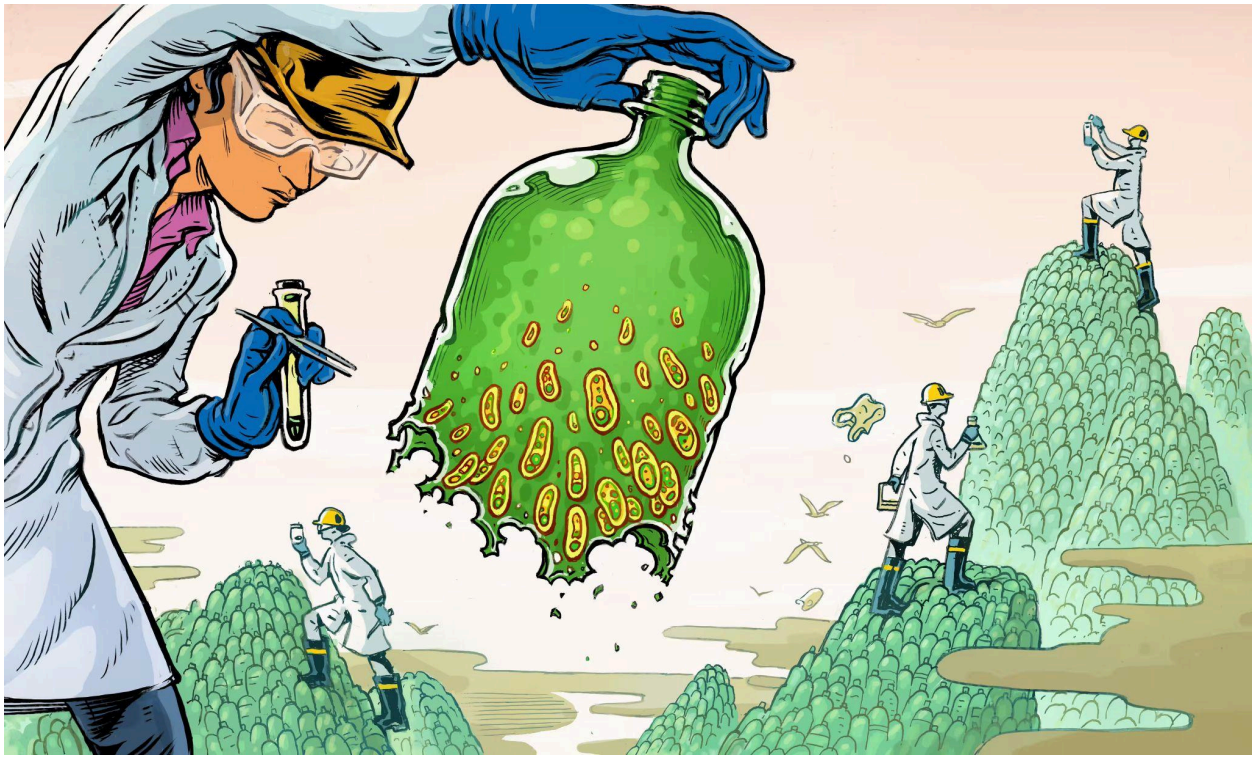
make a single pound of insulin. In 1978, however, a tiny start-up called Genentech made the breakthrough step of producing human insulin in bacterial cells through the use of recombinant DNA. By 1983, this human insulin–"humulin"–was FDA-approved, mass-produced and on the market, helping millions of people worldwide manage their diabetes [16]. Protein production from engineered cell lines continues to be a central focus of biotechnology; other proteins, such as clotting factors for hemophilia and industrial enzymes, are also produced at large scales as drug products and manufacturing materials.

The left and right mice are examples of transgenic animals; their DNA has been genetically modified so that they produce a specific protein that glows green under blue light [15].

Transgenic organisms are also vital for our food industries. Animals like cattle and pigs are being genetically modified to better regulate their own body temperature through shorter hair and metabolic changes, reducing the negative effects of heat stress. Crops can be genetically modified to increase nutrients and shelf life, bolster disease resistance, reduce allergens, and increase tolerance to drought and different herbicides. The vast amount of changes that scientists can make to such foodstuffs can lower costs and make production more manageable [17].

Such modifications go hand-in-hand with biotechnology's power to fight climate change and protect the environment. By using crops with increased herbicide tolerance, farmers can use less pesticides to maintain their fields. Some researchers currently focus on the science of phytoremediation, in which genetically engineered plants can be used to detoxify air, water, and soil pollutants [18]. Critically, scientists have recently discovered an assortment of different bacteria that use plastic-digesting enzymes to consume plastic waste. The mass production and refinement of such organisms could be utilized as a tool to navigate the ever-growing plastic pollution crisis [19]. Many microorganisms are also being used to produce more environmentally friendly alternatives to common building materials, like concrete grown with natural bacterial

binding chemicals. Finally, the modification of different bacteria and algae to increase biomass and ethanol conversion is a critical aspect of biofuel research. These biofuels act as promising, low-carbon alternatives to diesel fuels.



Several labs worldwide are working on developing microorganisms that could eat plastic at an industrial level, offering a potential solution to our global pollution crisis [19].

Gene-Editing in Human Cells

Gene-editing technologies hold enormous potential to treat several debilitating genetic diseases in humans, including sickle-cell anemia, cystic fibrosis, hemophilia, and various forms of cancer. The science of **gene therapy** uses the genetic modification of human cells to prevent or treat various disorders by replacing or eliminating defective genes [20]. Although the "replacement" DNA is often inserted into human cells via viruses, CRISPR technology has significantly increased the efficiency of gene therapy. One recent example of gene therapy is CAR T-cell therapy, which involves the genetic modification of immune cells to make them hypervigilant toward specific forms of cancerous tumors.

While extensive gene-editing innovations have already occurred in human **somatic** (non-reproductive) cells, less research has been done in human **germline** (sperm and egg) cells. As germline cells are involved in reproduction, modifications to the DNA of these cells would carry over to future generations of humans. We will discuss some of the ramifications of this technology in "Ethical Concerns".

Significant Issues

Biosecurity

Both **biowarfare** and **bioterrorism** involve the intentional release of biological weapons. **Bioweapons** are biological agents used to kill, harm, or incapacitate populations as an act of war or terror. Humans have been practicing biowarfare for centuries, but the 21st century's biotechnological advances have dramatically expanded the field of possibilities for bioweapon production. While the 1972 Biological Weapons Convention has strictly prohibited the development, storage, and use of bioweapons, the increasing accessibility and affordability of genetic-engineering technologies will make it easier for non-state actors to obtain such weapons in the coming decades [21]. These malicious agents may gain the capabilities to develop genetically-modified organisms that can disrupt nations; one example may be the production of a "superbug" that can deliver lethal toxins or diseases through highly infectious insects and microorganisms. The capacity to create such weapons currently requires an immense amount of funding and technological infrastructure, but as the field of molecular genetics advances, the likelihood of an intentional bioattack rises.

The deliberate release of hazardous genetically modified organisms is unlikely in the near future. The unintentional "**lab leak**" of such life, however, poses an alarming risk for both human and environmental health, especially as research on these technologies increases [22]. Improper containment in research facilities could cause a wide variety of consequences. Agricultural GMOs may become invasive species that outcompete native wildlife and decimate ecosystems. Bacteria designed to consume materials and decrease pollution can damage city infrastructure. Genetic research on infectious agents can cause major disease events. One significant concern is the growing number of "**gain-of-function**" experiments worldwide. These projects often involve mutating and enhancing the natural capabilities of bacteria and viruses in order to better prepare for pandemics and understand infection development. In 2012, researchers at the University of Wisconsin published a "gain of function" project that modified the bird flu virus to make it transmissible via coughing and sneezing. While the study gave insight as to how viruses may become airborne in humans, it also triggered widespread alarm, resulting in the temporary halting of U.S. funding toward such projects. Gain of function studies are gradually being approved around the world, especially as biotechnological advances enable scientists to modify organisms in new ways.

This committee should consider developing strategies to prepare for, prevent, and respond to the release of dangerous genetically modified organisms, whether intentional or unintentional. Similar concerns regarding biosecurity have been raised in the past; our section about the Asilomar Conference below details how scientists of the 1970s reckoned with biosecurity risks in the early development of recombinant DNA.

A Center for Disease Control and Prevention worker extracts avian flu viruses for research. (Image from James Gathany/CDC)

Should restrictions, monitoring systems, and containment plans be placed on any (or all) biotechnological experiments to ensure safety for both humans and the environment? How do you balance research innovation and accessibility with biosecurity? How can the U.N. prepare for and manage the threats of intentional bioweapons and lab leaks?

Privacy

The mass storage of personal genetic data generates inherent privacy concerns. Many genetic databases allow users to contact other customers who may be their distant relatives based on DNA similarities. In October 2023, hackers were able to use this feature to access 23andMe accounts and create a list of 999,999 users with apparent Ashkenazi Jewish ancestry, complete with their full names, dates of birth, and sex. This list was posted on multiple dark web forums with the intent of selling the data online [13]. As scientists understand more of the human genome, individual genetic data will become increasingly more sensitive. Data leaks risk leaving these individuals vulnerable to **genetic discrimination**, especially in the context of **eugenics**, an issue we will discuss in detail below. Such issues make the secure storage of personal genetic data a priority.

How can we ensure that genetic sequencing data is safely stored and protected?

Ethical Concerns

The practice of modifying life itself is bound to generate a host of ethical concerns. Two which we aim to highlight are the importance of **informed patient consent** in research and treatment as well as the societal implications of human genetic technologies.

Informed Consent in Research and Treatment

Informed patient consent is a core tenet of modern scientific research on humans. In order to participate in a study, experiment, or procedure, an individual should be fully educated about potential risks, benefits, and alternatives to their current plan of action and make a voluntary agreement to participate [23]. The two famous case studies discussed below exhibit the need for informed consent when scientists conduct investigations, especially as personal genetic data becomes increasingly accessible.

Case Study: Birth Control Clinical Trials

John C. Rock and Gregory G. Pincus, professors at Harvard University, together pioneered the hormonal birth control pill meant to prevent accidental pregnancy. This medical innovation is famed to have brought about the "sexual revolution" where sex became less risky for women, yet the pill's formulation relied on concerns regarding invasive tests and questionable consent.

Testing for the pill first began on animals, namely rabbits and rats. Each day, in five-day periods, researchers pumped the reproductive hormones estrogen and progesterone into immature rabbits. On the final day of each period, the rabbits were allowed to copulate and then examined for signs of egg fertilization; this process continued on for years.

Case Study: HeLa Cells

Henrietta Lacks was a Black woman and mother of 5 who was diagnosed with a rare type of cervical cancer known as adenocarcinoma. She received treatment for it at the Johns Hopkins Hospital, one of the few places that allowed Black patients at the time. A portion of her biopsy was given to Dr. George Otto Gay who cultured her cells and established the HeLa cell line without notifying Lacks or her family, continuing to cultivate them in a laboratory setting. HeLa cells are often labeled as "immortal," with an ability to double in number every 24 hours. Despite Lacks passing away a year after her diagnosis, her cells continued to fuel research behind the Polio vaccine, Human Papillomavirus (HPV) vaccine, & chemotherapy and appeared in over 100,000 research papers [24].

There are a variety of ethical concerns that surround HeLa cells, even besides their acquisition without Lacks's permission. While biotechnology companies profited extensively from the value that HeLa cells provided, the Lacks family faced extreme levels of poverty and were financially disadvantaged. Only in 2023, was the family able to win a lawsuit against Thermo-Fisher Scientific that gave them access to a fraction of the monetary benefits associated with their family member's genetic information.

From a medical privacy standpoint, Lars Steinmetz, a geneticist at Stanford University, published a paper in 2013 that contained the entire genome of HeLa cells. This exposed biological information of Lacks's family members, some of whom are still alive, which was viewed as a violation of their privacy. The Lacks family reached out to the National Institutes of Health to

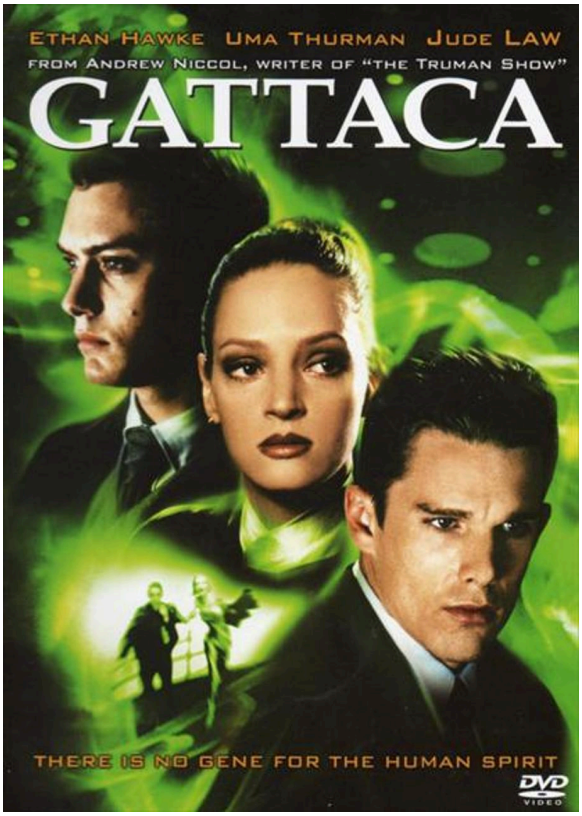
resolve this issue, and ensure that there was still a level of privacy associated with access to the cells.

Henrietta Lacks [24].

Ethical Implications of DNA-Sequencing and Gene-Editing Technologies in Humans

Eugenics is an ideology that aims to "genetically enhance" future generations of humans; the movement promotes the idea that individuals with "desirable" genes should reproduce and continue providing their DNA to the human gene pool, while individuals with "undesirable" genes should not reproduce or *be kept from reproducing* [25]. Eugenics has historically been strongly associated with various radical racist movements, reaching its most influential and horrific culmination with the rise of the Nazi party in the early 20th century.

The fundamental issue with eugenics arises from its attempt to distinguish between "good" and "bad" genes. Genetic variations are *simply natural variations*, and while some may provide different types of functionality than others, it is illogical and highly dangerous to define the majority of variations as "good" or "bad". The widespread use of gene sequencing provides a more dangerous opportunity for eugenics to spread than ever before, as genetic data may be used to increase discrimination between groups with different DNA variants. Thus, this committee should be prepared to deal with the ethical issue of "selecting" certain genotypes as sequencing technologies advance.



As genetic sequencing technologies advanced in the late 20th century, public concerns about genetic discrimination grew. The 1997 film Gattaca *follows a world in which most humans are genetically selected using advanced DNA sequencing technology, and questions the ethics of a world based on such biotechnological eugenics. (Image from Columbia Pictures, 1997)*

Gene-editing technologies, especially in germline cells, also hold immense power in the hands of eugenicists. Germline cells (the sperm and egg cells) are involved in reproduction, so edits in these cells carry on to future generations of humans. While germline editing could potentially be used to eliminate hereditary genetic diseases in an individual's descendants, scientists could also use germline editing to generate "designer babies", or babies with genomes edited for non-health reasons. Such non-therapeutic editing both revokes autonomy from future generations and risks promoting the eugenics movement, especially if certain genetic edits are made to advance the biases of supremacist groups. In addition, the human genome contains around 19,900 genes, and thus the side effects of editing a human gene in germline cells are poorly understood. As such, germline editing is prohibited by law in over 70 countries, including the U.S., China, and the Council of Europe. These rules have been occasionally violated, however: in 2018, a Chinese scientist announced the birth of twin girls whose genomes had been CRISPR-edited as embryos [26]. The news was met with universal condemnation, and he was sentenced to three years in prison. The United Nations does not currently have prohibitory policies regarding germline editing.

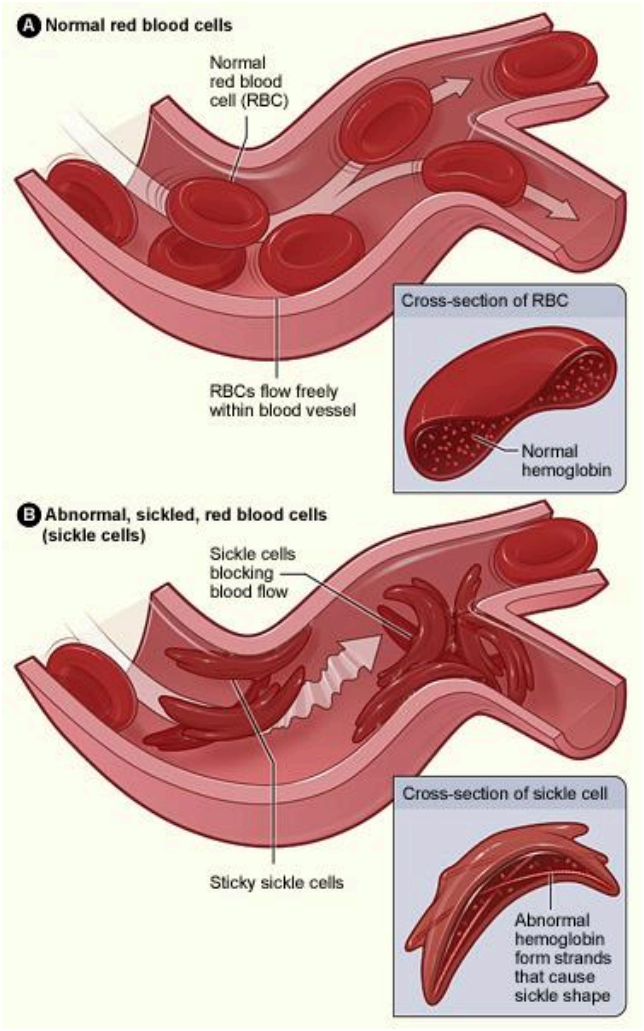
How can we ensure that research is performed ethically to promote principles of informed consent and autonomy? Should we set an international convention of ethical boundaries or guidelines, particularly for human germline gene-editing?

Equitable Access

Although biotechnological innovation may currently be in a revolutionary era, the geographic scope of such research is fairly limited. The high costs, infrastructure, and training required to build the industry causes significant differences in accessibility to biotechnology around the world. In addition, medical devices for patients can possess inherently skewed results based on biased calibration data. The following two case studies illustrate how accessibility to both the biotechnology industry as a whole and medical devices promote unjust disparities.

Case Study: Sickle-Cell Anemia

Sickle-cell anemia is a genetic disease that originates from the mutation of the human gene for hemoglobin, a protein responsible for carrying oxygen in red blood cells. The faulty hemoglobin protein causes the disc-shaped red blood cells to become sickled in nature, interfering with their ability to deliver oxygen throughout the body and causing immense pain. As of 2021, the total mortality burden of the disease was estimated to be 376,000 deaths worldwide [27].



A hemoglobin gene mutation causes sickle-cell patients to produce dysfunctional red blood cells.

Using breakthrough CRISPR technology, researchers have been working on gene therapy techniques that edit cells to add functional hemoglobin genes and return red blood cell activity. Such research reached a pivotal point when the US Food and Drug Administration approved its first CRISPR-based gene therapy in December 2023, a sickle-cell treatment named Casgevy. Unfortunately, the single course of Casgevy treatment costs $2.2 million, a prohibitively expensive price for the 100,000 Americans with the disease, who on average spent $1.7 million in lifetime medical costs associated with sickle-cell. Even more significant is the worldwide distribution of the disease; sickle-cell anemia affects *20 million people globally*, especially in sub-Saharan Africa and South Asia. As the majority of sickle-cell patients are in low- and middle-income countries without large biotechnology industries, treatments like Casgevy will continue to be largely inaccessible both due to costs and technology constraints [28].

The genetic treatment of sickle-cell anemia illustrates a wider issue of how biotechnological treatments are incredibly inaccessible for the majority of the human population, and highlights the narrow geographical range of biotechnological innovation. Delegates should expect to discuss whether the biotechnology industry should be supported in developing nations, and detail potential strategies for how to disseminate technologies and treatment around the world in an accessible manner.

Sickle-cell anemia is most prevalent in South Asia and Sub-Saharan Africa. While innovative CRISPR-based treatments are currently being pioneered at biotechnology institutions like Berkeley, many of these treatments are far too expensive or inaccessible for the 20 million affected individuals worldwide [29].

Case Study: Pulse Oximetry

Recent findings have uncovered varying accuracies between pulse oximetry measurements in Black and White patients in intensive care and critically ill patients with a record of weak respiratory systems. These discoveries reveal that Black patients meeting the above criteria have higher prevalence of occult hypoxemia when compared to their non-Black counterparts. This mismeasurement of pulse oximetry has dire consequences such as a greater likelihood for organ failure and even death, considering the vital role that oxygen movement plays in normal, healthy functioning. To put the importance of incredibly precise pulse oximetry measurements into

perspective, drops of only 2% in levels, especially in high-performance athletes or patients with significantly impaired respiratory abilities and sleep apnea, requires immediate external oxygen supply and hospitalization [30].

Occult hypoxemia can be defined as a low arterial oxygen saturation with SaO2 levels below 88% alongside a normal simultaneous pulse oximetry measurement with SpO2 levels greater than or equal to 92%. SaO2 represents the percentage of binding sites on the hemoglobin currently carrying the oxygen; this value increases with the partial pressure of oxygen since this means that more O2 molecules are available to bind with the hemoglobin. SpO2 represents how many of these binding sites are currently mixed with oxygen to be able to calculate the amount of oxygen available in tissues; this is the value that pulse oximetry calculates. Pulse oximeters measure arterial oxygen saturation by measuring the absorption of red and infrared light, which is affected directly by the levels of hemoglobin. Melanin is a primary light absorber in the skin, so an increased presence of it in the body absorbs more of the red/infrared lights meant to be absorbed by the deoxyhemoglobin which is what pulse oximetry measures. This is why patients with darker skin, therefore higher melanin levels, have increased error in their measurement, because it increasingly hampers the detection of how much light was actually absorbed by the deoxyhemoglobin in the blood [31].

Pulse oximetry systems are often calibrated toward lighter skin tones, causing inflated oximetry readings for darker skin colors. These disparities risk a lower treatment quality for dark-skinned patients with respiratory concerns. (Photo from Madison Grosvenor/The Michigan Daily)

The impact of skin pigmentation on the accuracy of pulse oximetry measurements was studied in various experiments to determine the role of melanin in measuring SpO2 levels. First, very light and dark skin colors were tested to determine statistical significance between inaccuracies of measurements between the two extremes. This uncovered a higher likelihood of dark skin colors to have an incorrect reading when compared to lighter skin. Further, a range of skin colors were studied and it was found that the chance for a wrong pulse oximetry calculation gradually increased as the skin color got darker. This reveals some sort of proportional relationship between skin colors and miscalculated SpO2 levels, likely caused by the varying levels of melanin, as that is the only factor changing across the varied skin types studied. Racism plays into this example because races with predominantly darker skin tones, for example, Black patients, are put at a higher risk for occult hypoxemia and further respiratory damage simply because technology is unable to accurately determine their blood oxygen levels. To quantify the extent of this discrepancy, when compared with White patients, the prevalence of occult hypoxemia was 71% greater among Black or African American patients; so many patients are in need of respiratory assistance but this is not realized due to the inaccuracies presented in their pulse oximetry readings. This slight miscalculation presents grave consequences and its direct relation to skin color puts certain races at an inherent disadvantage for being able to realize and/or receive the respiratory care that they may need [32].

Pulse oximeters are currently calibrated using light-skinned individuals because it had not been previously found that skin pigmentation can alter results. However, given this recently discovered information, pulse oximeters can come in different variations that tailor them towards individuals with varying skin colors to more accurately calculate their SpO2 levels. If medical professionals choose to continue using existing technology, a correction factor can also be weighed depending on a patient's skin tone to attempt a more accurate measurement [33].

Should this committee work to make biotechnology less biased and more accessible for all countries through education, infrastructure, or financial aid? How can the 6th Legal Committee balance equitable access with proper security and management as mentioned above?

Previous Legislation

As you continue your research, consider investigating previous attempts to regulate biotechnology throughout history. Together, these various diplomatic efforts exhibit common themes, triumphs, and struggles when discussing such an incredibly unpredictable field.

The Asilomar Conference

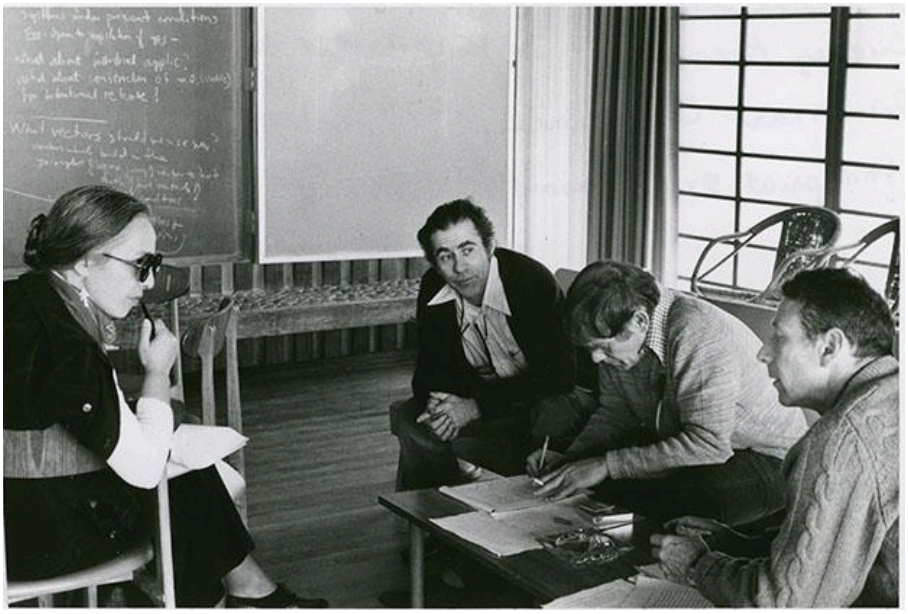
The 1960s and 70s were a revolutionary era within biotechnology; Throughout the period, several key advances enabled scientists to gain a better understanding of molecular and cell biology than ever before. The utilization of DNA "cutting and pasting" enzymes enabled scientists to combine genes from different species into one organism, creating recombinant "hybrid" DNA. The discovery of numerous antibiotic-resistance genes in bacteria allowed for the selection of these "hybrids" based on their unique resistances, thus permitting the mass cloning of recombinant DNA in an industrial setting. Finally, new methods of DNA sequencing were

developed to read the precise genetic codes that corresponded to specific proteins. Together, the technologies of gene sequencing and gene cloning became powerful tools to understand how to study the structure and function of genes throughout the biological world. [5]

With such dramatic shifts came dramatic panic. Cognizant of the biosafety risks present in the creation of certain genetic hybrids (i.e, introducing toxin- or cancer-causing viral genes into human intestinal bacteria), many leading biologists began to call for a moratorium on the most hazardous forms of recombinant DNA research. These sentiments came to a head at the 1975 Asilomar Conference in Monterey, California, in which scientists, lawyers, journalists, and writers from around the world came to discuss the future of recombinant DNA. Although tensions between scientists ran high (especially when debating the moratorium), the conference was able to produce a document detailing containment procedures for experiments based on biohazard risk, as well as several other measures to decrease the risk of lab leaks.

Asilomar was groundbreaking for several reasons; not only was it a rare instance of scientists choosing to moderate their own research (as opposed to external political forces), but its incorporation of the media and public figures enabled an open conversation that allowed the general public to engage in the regulatory discussion. It showed that scientists had the autonomy to regulate themselves while simultaneously increasing public trust in science as a whole [5].

Still, only so much could be done at a single conference–notably, the discussions at Asilomar focused heavily on biosafety issues of recombinant DNA in bacteria while glossing over multiple major issues, including the future potential of human gene editing and any ethical quandaries of modifying life itself. Such issues continue to be vital elements of discussion today, and ones that we expect to discuss in committee.



Asilomar brought together leading molecular and cellular biologists, physicians, lawyers, journalists, and other scientific and public figures to develop a reasonable response to the rapid development of recombinant DNA research. (Image from the National Academy of Sciences)

The United Nations

The United Nations has made several efforts to create international standards for biotechnological innovation and management. Some of the most notable of these agreements include:

1. The 1972 Biological Weapons Convention, which prohibits the development, production, and use of bioweapons [21],
2. The Convention on Biological Diversity, which encourages countries to equitably advance global participation in biotechnology research activities [34],
3. The establishment of the Biosafety Information Network and Advisory Service to help developing countries build national biosafety protocols and risk assessments [35],
4. The United Nations Declaration on Human Cloning, a *nonbinding* statement against all forms of human cloning [36],
5. Part XI, Section 2 of the UN Convention on the Law of the Sea, detailing appropriate forms of research, technology usage, and "transfer of scientific knowledge" across nations specifically for marine environments, as well as Part XII detailing environmental protection during research [37],
6. Sections II–IV of **Agenda 21,** the United Nations' plan for sustainable development, which outlines appropriate management of biotechnology [38],
7. The **UNESCO Universal Declaration on Bioethics and Human Rights**, a framework upholding various international standards and ethical principles that should be prioritized in biological research [39].

We encourage you to explore these sources; as you read the documents, consider the distinction that these agreements make between "ideals" and concrete plans to meet said ideals. Note that the majority of these agreements were made *before the rapid biotechnological breakthroughs of the 21st century*, like CRISPR-technology and massively parallel gene sequencing.

As delegates, will you seek to advance previous legislation proposed by the international community, or will your policies take industry management in new directions? We can't wait to see how you respond to the sweeping advances in biotechnology, advances that dare to change our very conception of life itself. Good luck!

Questions to Consider

1. **Biosecurity:** Should restrictions, monitoring systems, and containment plans be placed on any (or all) biotechnological experiments to ensure safety for both humans and the environment? How do you balance research innovation and accessibility with biosecurity? How can the U.N. prepare for and manage the threat of intentional bioweapons and lab leaks?
2. **Privacy:** How can we ensure that genetic sequencing data is safely stored and protected?
3. **Ethical Concerns:** How can we ensure that research is performed ethically to promote principles of informed consent and autonomy? Should we set an international convention of ethical boundaries or guidelines, particularly for human germline gene-editing?
4. **Equitable Access:** Should this committee work to make biotechnology less biased and more accessible for all countries through education, infrastructure, or financial aid? How can the 6th Legal Committee balance equitable access with proper security and management as mentioned above?
5. Finally, who should be making and managing decisions regarding the regulation of biotechnology? Scientists? Governments? The public? Biotechnology companies? The United Nations?

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