Bioethics and Policy:

Examining possible methods of oversight and regulation

of a new, exciting yet contentious industry

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Introduction

Bioethics is both a new area of study and one that has been on the fringe of the public psyche for many, many years. Different films, novels and television shows have explored the consequences of science that has gone awry, from the bleak to the grotesque. The problems of advanced biotechnology and genetic manipulation have usually been largely relegated to the genre of science fiction due to the real technological limitations preventing these topics from appearing outside of a future setting. As a result, most people are aware of the possible benefits and drawbacks of advances in biotechnology, but they do not consider it a tangible problem that needs to be addressed in the near future. Furthermore, it is an area that is evolving rapidly and where regulations and policies have been lacking.

However, recent scientific advances have made it so that this is not a subject that can be put in the bin of "speculative fiction" any longer. Some of these advances have become very real and even more will be developed within the next decade. Consider that the time to sequence a person's genome may soon be cut drastically down to minutes thanks to nanopore sequencing technology, and costs only a few dollars, when it used to take months and over a million dollars for one genome in as recent as 2007.[1] With micro-encapsulation and viral manipulation technologies[2], whole genes are likely to be able to be inserted into a person's DNA, compensating for pre-existing deficient genes or otherwise

[1] "DNA Sequence Time Could Be Cut by New Technology," London Press Service Mar. 30, 2011 Accessed via http://www.londonpressservice.org.uk/lps/sciencetechnology/item/128853.html.
[2] Kay, Glorioso & Naldini, "Viral Vectors for Gene Therapy: the Art of Turning Infectious Agents into Vehicles of Therapeutics" Nature Medicine Vol. 7, pp. 33-40, 2001.

unwanted ones, providing cures for a wide-range of diseases such as diabetes, sickle-cell anemia, fetal neurological disorders and even lactose intolerance. Diagnostic and imaging technologies are getting more and more effective at diagnosing illness while becoming less and less intrusive.

In addition, it is now possible to manipulate the code of deoxyribonucleic acid (DNA) to create bacteria or algae that will spontaneously produce certain substances given certain inputs. This method would be able to produce these things much more cheaply than the current methods of production. Petroleum and related long-chain organic compounds are the number one target for this method of synthesis;[3] similarly, some bacteria have highly exploitable electrical characteristics, creating what is known as a microbial fuel cell.[4] Ammonia and nitrates for fertilizer production would also be very commercially lucrative.[5] Another popular idea would be to manipulate bacteria and/or algae to produce more Ribulose-1,5-Bisphosphate Carboxylase (RuBisCO), the enzyme that allows photosynthesis to occur, for carbon capturing and sugar or food production purposes.[6]

Some have proposed that these advances in science should somehow be curtailed and monitored.[7] There are many ethical and scientific concerns about this, the least of which is that we still are not fully sure about the full social and medical impacts of procedures such as manipulating DNA. It is also not difficult to imagine this technology

[3] Ayres, Chris, "Scientists Find Bugs That Eat Waste and Excrete Petrol," London Times June 14, 2008.
[4] Rabaey, Korneel, "A Microbial Fuel Cell Capable of Converting Glucose to Electricity at High Rate and Efficiency," Biotechnology Letters Vol. 25 No. 18, pg. 1531-1535, 2003.
[5] Zeikus, JG, "Chemical and Fuel Production by Anaeobic Bacteria," Annual Review of Microbiology Vol. 34 pg.423-464 Oct 1980.

[6] Spreitzer & Salvucci, "RuBisCO: Structure, Regulatory Interactions, and Possibilities for a Better Enzyme," Annual Review of Plant Biology Vol. 53 pp. 449-475 June 2002.
[7] Doyle & Persley, Enabling the Safe Use of Biotechnology: Principles and Practice World Bank Publication 1996.

being misused, whether for social, economic, military or authoritarian reasons. This bioethics debate necessitates answering extremely debatable and subjective questions such as the nature of life and our own identity. There is little question that eventually scientists will be able to create entirely new species and forms of life by manipulating the DNA or ribonucleic acid (RNA) of organisms. Would the introduction of artificial species be considered ethical, since these new species would almost certainly be produced for the sole reason of being put to use to serve humans? In addition, genetic science can solve a very wide range of medical problems, but this may come at a cost to an individual's autonomy, since various aspects of a person's appearance, constitution and perhaps even personality can eventually be customized to someone's or society's whim.

And yet, this field has the potential to create a vast number of treatments for many diseases that plague our society, in addition to providing the ability to circumvent some of the biological limitations that have been placed on the human body or on the amount of resources available to us on the planet. Attempting to stop or slow down these scientific processes could prolong the suffering of millions of people with otherwise incurable diseases.

There are conceivable pros and cons for using different means to establish a biological code of ethics and to create an institution that could hear scientific debates over the morality of future research. By instituting an international convention or treaty, limits will be imposed on every country that becomes a signatory, and would ensure that every nation complied with uniform standards and policies. Allowing individual nations to dictate their own laws would be beneficial since each nation and each culture would have vastly

differing views on the nature of life and how far biological science should be allowed to progress. Finally, allowing the industry itself or a separate private institution to set limits would be beneficial since either would be more able to understand the progress and limits of technology, it would be more able to keep up with each new scientific breakthrough than a legislative body would, and it would better understand all aspects of the issues at hand.

The inspiration for this project was the realization that there are whole agencies to deal with nuclear power and weapons such as the International Atomic Energy Administration (IAEA), just as many scientific and regulatory agents over toxic chemicals, but far fewer official bodies outside of state governments to oversee advances in biological science, which is just as broad and just as potentially dangerous. This project will look to see why this is the case, the viability of a broad international oversight agency, other possible methods of regulation, and whether it would be a good idea to create such a system at all.

This is not to say that there cannot be some sort of combination, or that one solution will stay in place forever. My analysis leads me to conclude that a range of responses will be necessary as not one single strategy would be sufficient to completely and effectively oversee this field while taking into account the various cultural and ideological sensitivities that are inherent to this discussion. In fact, it might be best if some sort of a more stringent legal code is implemented only after the anticipated boom in technology development starts to taper off and the direction of the market and viability of technologies become clearer. However, that will only happen in the future, and until then, it will be difficult to justify having strict policies in place for long, with the possibility of cures for difficult, chronic diseases and the potential profitability of biotech pushing against it. So,

perhaps the best result might be a mix of soft guidelines that can easily change with the field, but still have some sort of an impact. Eventually, once much more information has been discovered, a harder, codified set of laws would become more acceptable.

Context

Numerous moral and ethical questions concerning the appropriate uses of biotechnology surface as part of this discussion. Attempts to judge and litigate what should be standard ethical procedure for biological experiments would likely face many challenges. The main problem is that on these types of issues, there is considerable moral grey area that depends entirely on someone's world view, and therefore any attempt to pass legislation or pass judgment on these issues would necessarily draw ire from the opposing side. Nevertheless, there are other issues that are rather clear cut, and so an attempt to provide guidance would probably be the best solution. There are also many unique legal questions that are outside the realm of ethics that would pop up under the course of research and commercialization of products that would also need to be addressed.

One of the main fears about advances in biotechnology is that they could be used to create advanced capabilities that could have a range of positive and negative effects. Combining genomes from different pathogens could create entirely new diseases that could be much more virulent and deadly than any current disease. Increased understanding of genomes and differences between races and ethnicities could mean that certain diseases could be tailor-made to target specific people. This contingency has already been covered

with the Biological and Toxin Weapons Convention, which bans the use, development and stockpiling of biological weapons, yet allows legitimate research on the manipulation and development of pathogens for the purposes of protection, prevention and prophylaxis of pandemics.[8] While the convention lacks an effective enforcement mechanism outside of information sharing, and not every country in the world has signed on to it, it is generally regarded as a success, since many countries have abandoned programs or dismantled arsenals since its passage, and no state program has used biological weapons in warfare or combat since, either.

One major area with many different ethical and procedural questions is the field of organ donation. The idea of taking a dead person's organs and using them to replace damaged or defective ones in living humans is still considered taboo in some cultures. This is compounded by the fact that organs are usually harvested as close to the moment of death as possible in order to ensure their viability, which involves the medical and spiritual question of when exactly life ends.[9] In addition, while the idea of using donated organs from a person who gave consent while he was still alive may be considered acceptable, the idea of providing financial incentives for unrelated, healthy persons to donate organs or directly having people sell organs to people on the organ transplant list has much less support.[10]

[8] United Nations Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, 1974, Accessed via http://www.unog.ch/80256EE600585943/%28httpPages%29/04FBBDD6315AC720C1257180004B1B2F?OpenDocument.

[9] Volk, Warren, et al, "Attitudes of the American Public toward Organ Donation after Uncontrolled (Sudden) Cardiac Death," American Journal of Transplantation Vol. 10, pp. 675-680; 2010.

[10] Carrillo, Karise, "Examining Attitudes on Organ Donation for Transplant: Amenability to Financial Incentives and Donor Benefits," McNair Scholars Research Journal, University of Nebraska-Lincoln Publication, 2010.

Mental imaging technology is another area with possible ethical concerns.[11] Mental scanners such as magnetic resonance imaging machines (MRIs) are being used more and more to determine just how the brain is wired and what signals the brain makes under certain circumstances. As a result, it is theoretically possible to read people's emotions. This has many applications for handicapped individuals who cannot talk and can be used to provide key insights into mental illness. However, there is concern that these could be used by law enforcement or other groups for lie detection and to obtain a confession. This could be construed as a violation of a person's rights since it would be a violation of the Fifth Amendment.[12]

Perhaps the most sensitive topic would be the potential genetic modification of humans, with many philosophical and ethical issues attached to the subject. Many different forms of media, such as books, films, television shows and video games have commented on the subject and the possible ramifications of modified humans. Brave New World, one of the most famous of these stories, explored how these modifications could be used by authoritarian governments to create entire class systems by modifying the intelligence and physical characteristics of its populace (although the book was published before genetics became mainstream, so the science is not correct).[13]

Even with safe laboratory procedures and approved, ethical experiments, one of the greatest fears about greater biological technological capacity is the threat of either human error or human ignorance. A main purpose in biological research experiments involves

[11] Farah and Wolpe, "Monitoring and Manipulating Brain Function: New Neuroscience Technologies and Their Ethical Implications," Hastings Center Report Vol. 34, 2004.
[12] Stoller and Wolpe, "Emerging Neurotechnologies for Lie Detection and the Fifth Amendment," American Journal of Law and Medicine Vol. 33, 2007, pp.359-375.
[13] Huxley, Aldous Brave New World Chatto and Windus Publishing, London, UK, 1932.

realizing the function of various genes and proteins, and so if a scientist turns on the expression of a particular gene without knowing the full ramifications, there could be a potential for a major incident.

One documented incident involved a scientist manipulating the genes for the Mousepox virus.[14] In essence, researchers in Australia activated a gene for the protein interleukin-4 on the Mousepox Virus. The modified virus was supposed to act as a contraceptive to help keep down rodent populations, but instead it produced a virus that destroyed the mouse immune system, in effect turning a disease the equivalent of the common cold into a vicious, lethal infection. The Mousepox virus only affects mice, but the fear that such an incident could occur with a virus that attacks humans with the same potentially lethal effects.

Another possibility could be that the experiment does have the desired effect, but the scale of the outcome is much different than anticipated. An organism that was thought to have the proper limiters in place turns out to have modified itself or mutated so that the limiters had no effect, and the organism once in nature undergoes a population explosion. Similarly, if a modified organism is released into the wild, and thrives better than the local population, or breeds with the local population to modify the whole bunch, it could cause quite a lot of ecological problems. A good example of such an incident was the release of Africanized killer bees in South America, which was created due to manipulating strains of

[14] Nowak, Rachel, "Killer Virus," New Scientist Jan 10, 2001.

African bees and European bees, and has since established a population throughout the Americas.[15]

One of the greatest fears over human genome manipulation is the artificial, market-driven creation of a significant class genomic distinction between the rich, who can afford enhancements to appearance, intelligence and strength, and the poor, who cannot. The main fear is that these genetic alterations will be inherited by their children, which extends this difference to future generations. These children will be placed in these disparate roles before they are even born. Biologists worry that these enhancements could eventually become large enough to create entirely different species of humans, which creates its own complete set of ethical questions.[16]

As pertains to children and fetuses in the womb, who obviously have no say in the matter, there are many different views as to what the guiding principle should be. The three main opinions are that an infant has the right to be born 'naturally,' the right to be born without crippling disease, and finally, that the parents have the right to determine what their children will be like:[17]

An *Infant has right to be born 'naturally'*: Any attempt to customize infants will take away some of their presumed independence, individuality and personality. Following this line of thought are slippery slope arguments about designer babies and possible future class and discrimination issues between modified and non-modified people due to possible disparity in intelligence, appearance or personality.

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[15] Winston, Mark, Killer Bees: The Africanized Honey Bee in the Americas Harvard University Press, Sept 1993.
[16] Silver, Lee, Remaking Eden: How Genetic Engineering and Cloning will Transform the American Family.
[17] Resnik, David B., and Daniel B. Vorhaus. "Genetic modification and genetic determinism." Philosophy, Ethics, and Humanities in Medicine (2006): 1-11.

An Infant has right to be born without crippling disease: Generally, there is little to no disagreement with the idea of using gene therapy to cure fatal genetic diseases such as sickle-cell anemia or Tay-Sachs. It starts to get more complicated when people talk about non-fatal diseases as the definition of disease can be different for different people. Down Syndrome may be one thing, but what if homosexuality could be prevented? What may be considered a devastating disease to some, such as deafness or blindness, may be considered as just another way of life to others, one that is not necessarily bad.[18]

The Parents have the right to change their unborn children: Parents have the right to choose what constitutes a "disease" and they have some rights over what their child should be like. If the parents feel that some undesirable characteristic, such as a predisposition to obesity, myopia or stuttering, would have a significant impact on that child's self-esteem and mental state, then the parents are completely justified in allowing for corrections for these conditions in the fetal stage, despite the fact that these conditions are usually nowhere near life-threatening or debilitating in developed countries.

One final problem that has already emerged to be a significant issue is the question of intellectual property rights over procedures involving genetic manipulation.[19] This issue is intrinsic to the discussion of biological science since any manipulated genomes for any animal, plant or bacteria can spread to wild populations after a certain amount of time due to general reproduction. In this sense, copyrighted seed stocks that have been genetically modified have been documented to spread their genomes via pollinating insects to the

[18] Sandel, MJ, The Case against Perfection: Ethics in the Age of Genetic Engineering 2007.
[19] Gadgil & Devasia, "Intellectual Property Rights and Biological Resources: Specifying Geographical Origins and Prior Knowledge of Uses," Current Science Vol. 69 No. 8 Oct 25, 1995.

crops of farmers who are not using the patented seed stock[20]. This means that they are unintentionally and unknowingly using the copyrighted materials without permission.[21] It would be extremely difficult, if not infeasible and counterproductive, to isolate agricultural products to the point that insects cannot cross-pollinate them.

The question of intellectual property rights has already reached the courts with the Canadian Supreme Court case, *Schmeiser v Monsanto.*[22] The court heard the case of Percy Schmeiser, who found that over 60% of his crop had been Monsanto patented "Round-up Ready" canola, which is resistant to the herbicide Round-Up. Schmeiser did not purchase the seeds from Monsanto; he used seeds from his own farm's seed stock. The court sided with Monsanto, finding that growing genetically modified crops constitutes a violation of Monsanto's intellectual property rights despite the fact that Schmeiser was unknowingly and unintentionally using these crops. This has sparked a lot of discussion, and the implications for future genetic techniques in other capacities will become important. If human genetic modification was patented, as an example, and the modifications were inheritable, would people have to pay a biotech company every time they wanted to have children?

Other attempts to solve this issue, such as India's Protection of Plant Varieties and Farmers Rights Act[23], have tried to solve the issue by allowing patents for the methods and

[20] Weaver & Morris, "Risks Associated with Genetic Manipulation – An Annotated Bibliography of Peer Reviewed Natural Science Publications," Journal of Agricultural and Environmental Ethics Vol. 18, No. 2, pp.157-189. Section 3.3.
[21] Oguamanam, Chidi, "Intellectual Property Rights in Plant Genetic Resources: Farmers' Rights and Food Security of Indigenous Communities," Drake Journal of Agricultural Law Vol. 11, 2006, pp 273-289.
[22] Case brief accessed via http://scc.lexum.org/en/2004/2004scc34/2004scc34.html.
[23] http://www.wipo.int/wipolex/en/details.jsp?id=2401.

processes of creating the seeds, but not for the seeds themselves.[24] This has created more problems since, while the farmers are not liable anymore, other biotech companies can now easily get around this law by taking the seeds produced and have them reverse engineered through their own processes, and can, therefore, legally sell the same seeds that another company produced.

Keep in mind that these are only a subset of the current issues and foreseeable problems that have been contemplated. Once the technology becomes more fully developed, and a better picture of which treatments and techniques work better than others is developed, many other questions that are likely to arise and will need to be addressed. Any entity that seeks to monitor the course of science would need to be very flexible in its interpretations in order to account for this.

Developing a Code of Ethics

There are many potential problems that would be inherent with any decreed list of ethical practices or would be problematic for any monitoring body that would be involved in this area. Most of these problems are typical of any attempt to pass policy measures in either national or international legal forums, but some are unique to science or biological science based on how the field is structured. Ideally, an institution should be set up that establishes a standard code of ethics that all companies must follow. The institution should also include some sort of body that could monitor and approve research, provide a form of

[24] Brahmi, Saxena & Dhillon, "The Protection of Plant Varieties and Farmers' Rights Act of India," Current Science Vol. 86, No. 3, Feb. 10, 2004.

punishment and to hear cases that are ambiguous or border-line and render some sort of judgment or recommended course of action on that particular issue. The institution should be extremely flexible, since the industry will be constantly changing.

There will also be differences in the outcome depending on what level of rigidity and involvement is set up within the framework. A framework could be created using laws, statutes, civil codes or recommendations, with varying degrees of enforcement capability, flexibility and effectiveness. Given the potential difficulties associated with getting even scientists within one company to agree on an ethics policy, never mind scientists from across the world, it would be a good idea to have a framework that is flexible and open to debate. Enforcement of a code of ethics would likely be one of the major sticking points of any agreement. This is also one issue that cannot be addressed by one country alone since scientists all across the world are doing these experiments. There would be have to be something backing up the framework in order for companies and private individuals to have the incentive to obey and follow it.

One of the major criticisms involves the belief that there is an inherent right to pursue knowledge for the good of all humanity, and any attempt to regulate science and learning is infringing on that right. The counterargument to this would be that this technology does pose significant risks when used improperly, or with malicious intent. This paradigm is similar to many other security versus freedom debates, however biological science is different in that, more than any other scientific field, biology creates huge emotional responses from normal citizens due to the significant implications for the meaning of life and the possibility of an afterlife. As a result, there would be more reason

for caution and greater restrictions on this field than other fields, as long as the restrictions are justified and within reason. What constitutes "within reason" may be entirely debatable, however.

It is interesting to note that the Biological and Toxins Weapons Convention, a weapons ban treaty, has extremely limited enforcement mechanisms in place, which is strange for a large, international weapons ban on a major class of highly destructive weapons.[25] Why are biological weapons treated this way, while nuclear and chemical weapons treaties come complete with enforcement mechanisms? This has usually been explained as the fact that biological materials are much more common than fissile materials or nerve gases, and they require much less sophisticated and specialized machinery to process and store. As a result, it is much harder to monitor groups engaging in biological research, as it is significantly easier to hide biological facilities than nuclear or conventional ones. Any method of enforcement that would go beyond that to monitor more biological experiments than merely those with a questionable purpose needs to keep this in mind for it to have any chance of being effective.

Another major question would be the source of funding for such a venture. While the formulation of an ethics code would not in and of itself have any large or lasting operating costs, if the measure includes any form of enforcement, arbitration or interpretative body, these require a constant source of funding for such a measure to have any effect. In addition, it would not be a good idea to have the funding come directly from the companies involved via some sort of fee schedule since it would have a very good

[25]Biological & Toxin Weapon Convention

chance of creating a direct conflict of interest. However, the budgetary situations of many countries at the moment are rather poor, so the idea of adding yet another expenditure to these already strapped budgets would not go over well.

Another issue in attempting to regulate any medical treatment is the trade-off between drug effectiveness and speed to market. Spending a considerable amount of time testing for the safety of drugs and procedures does have the pernicious side effect of slowing down the process, preventing sick people from getting the treatment that they need. This has the result of people indirectly suffering and perhaps dying from otherwise treatable conditions because the treatment has not been put out to the market yet. Adding another layer of protection and regulation to an already arduous process could exacerbate this phenomenon.

The biotech industry itself could try to interfere with anything that would impose regulations and restrictions on their business. However, a measure such as this would add a definite layer of credibility and assumed safety to any products that have been genetically modified, which is definitely a concern with this technology, so perhaps the companies would support this effort. Most consumers at this stage of development are not at all trusting of new biotechnological products, as evidenced by the huge debate over genetically modified foods.[26]

The largest debate comes from the idea that genetically modified foods should be labeled so that the consumer can make a choice. The main argument by companies such as Monsanto is that the modifications have been approved by the Food and Drug

[26] Hossain, Onyango et al, "Product Attributes, Consumer Benefits and Public Approval of Genetically Modified Foods," International Journal of Consumer Studies Vol. 27, No. 5, pp. 353-365, Nov 2003.

Administration, and have been demonstrated to have no effect on humans, so it is not necessary to let the consumers know about the genetic makeup of the food. It is interesting to compare the results of the legislations of the U.S. and the European Union (EU) since the EU requires labeling of genetically modified, and the U.S. does not. It is also interesting to note that while the main reason for resisting the labeling of genetically modified foods is more likely economic due to the perceived widespread negative customer reactions to having their foods altered, major studies have shown that consumers, even in the EU, do not particularly alter their buying habits in response to GM Foods when given a choice.[27]

Another general criticism of attempting to regulate science is that it would be impossible to know exactly what to include in an ethics code since we do not know beforehand which technologies would end up panning out, becoming widespread and commercially viable. So, it could be the case that any moral code imposed now could possibly have little or no effect if the industry shifts in a completely different direction than what was theorized from the beginning. Also, since the information available would naturally be imperfect, it is argued that imposing restrictions now would only have the effect of needlessly strangling possible new research and the resultant cures and products that may end up being ethical and effective.

A response to that point would note that restrictions do not necessarily have to be rigidly binding, at least for the time being, and restrictions could be couched in terms of guidelines and recommendations as opposed to hard rules that would not be subject to change. Finally, if you wait until the field has been fully and completely developed to

[27] Do European Consumers Buy GM Foods? European Commission Study and Publication, Oct. 14, 2008, Accessed via http://www.whybiotech.com/resources/tps/DoConsumersBuyGMFoods.pdf.

regulate, it may be too late to be able regulate or control key aspects, either due to undesirable techniques becoming too ingrained and ubiquitous to effectively regulate, or because a possible great incident had occurred.

Finally, there could be criticism that such a measure would not have any real impact and would only be a measure of show in order to quell the concerns of excited citizens. Making certain practices illegal would be fine if they were universally agreed upon to have negative consequences, but on issues that are more contentious, an agency would most likely only be able to provide guidance. If the main method of enforcement of these decisions would be restricting governmental grant funds, it would only affect those institutions that receive public funding. There would be almost no ability or reason to effectively monitor every private experiment conducted, and any experiments that would be ethically suspect would be sure to fly under the radar anyway. However, even then, taking some sort of action would still have the effect of creating an international norm, or strengthen already existing ethical norms, in the field of biological science that could do more to prevent a tragic incident than some sort of legislative or procedural step.

National Laws and Regulations

Another possible method of enacting such legislation would be through national laws. While an international treaty would most likely have its implementation through laws passed at the national level, this method is differentiated by individual nations passing their own legislations on their own schedule, without an international mandate from an

organization such as the United Nations. This would give each country the ability to tailor each of its laws to its own national cultural preferences, and would appeal to those who are more sensitive to sovereignty rights.

The negative aspects of this would be that there would be disparities between the countries, which would not allow for integrated policies, and would create a situation where biotech companies could engage in political arbitrage. This might be acceptable for a country that decides to ban genetic modification completely on moral grounds.

An obstacle to this would be making the case to legislative bodies that the existing regulations over drugs and medications are insufficient to cover the new procedures and techniques that will be developed. Many public health and safety organizations exist in different countries such as the U.S.'s Food and Drug Administration, the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) and the Japanese Pharmaceutical and Food Safety Bureau. These usually take into account safety measures and the ethical treatment of human patients, but do not make judgments or decisions about the ethicality of the research itself.

Another major obstacle is that, unfortunately, biological issues do not tend to respect the borders between different countries. Already, this is a significant problem with genetically-modified foods since these plants will spread their pollen and seeds into the air, and intermingle with native plants. These plants would then cross-pollinate with plants, spreading the new genome. As a result, it would be extremely difficult for countries that wish to abstain from biotechnology to fully negate its effects on its ecosystem, or to have complete control over many policies in this area.

Similarly, the fact that different countries would likely create different standards, while positive for allowing and respecting cultural differences and sovereignty concerns, would create a dilemma in that the different standards would create a situation where biotech companies could simply move to the country that had the most favorable regulations.[28]

As for gene therapy for humans, citizens that travel across borders to a country where it is acceptable and obtaining their medical assistance there instead is a distinct possibility, with the major impacts being wasted economic opportunities for local doctors, and significant political issues arising from the increased migration and travel flows. The idea of "medical migrants" has already become well-known with persons travelling to places such as India and Thailand to obtain elective surgeries,[29] and, significantly, has been documented in areas with different abortion laws such as within the different United States and Europe[30],[31]. It would therefore not be a stretch to imagine people travelling to obtain gene therapy to cure whatever genetically-related sickness that they have, which would impair the ability of national laws to effectively regulate these practices.

A particular idiosyncrasy to national level legislation is the large influence of domestic politics. One of its effects is the potential of giving the local population a lot of input into how things are set up. This can end up as a very good thing for establishing

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[28] West, Darrell, "Globalization of Innovation," Biotechnology Policy across National Boundaries: The Science-Industrial Complex Ch. 1, pp.1-14, Palgrave Macmillan, New York, NY; 2007.
[29] Ramirez de Arellano, "Patients without Borders: The Emergence of Medical Tourism," International Journal of Health Services Vol. 37, No. 1, pp. 193-198; 2007.
[30] "United States: Percentage of Legal Abortions Obtained by Out-of-State Residents," Kaiser Foundation Publication, 2006. Accessed via http://www.statehealthfacts.kff.org/profileind.jsp?rgn=1&cat=10&ind=467.
[31] Best, Alyssa, "Abortion Rights along the Irish-English Border and the Liminality of Women's Experiences," Dialectical Anthropology Vol. 29, No. 3-4, pp. 423-437; 2005.

transparency and legitimacy of the process, and input from people will help to ease the use of biotech products and procedures into common use, and to allow people who are concerned about the effects of biotech to eventually acclimate themselves. It also leaves the input open to manipulation by pithy slogans rather than actual facts, distorting the debate and possibly resulting in poor decisions.

A good model for how a system would be set up in this way would be the system set up by the Indian Department of Biotechnology and the Genetic Engineering and Appraisal Committee (GEAC) in the Indian Ministry of Environment and Forests[32,33]. This committee has the task of regulating the activities involving handling, manufacture, storage, testing, and release of genetically modified materials within the country of India. The committee also has the ability to create statutes to enforce any major, broad decisions that the committee deems necessary[34]. The GEAC also sets up Institutional Biosafety Committees (IBSC), which are local boards that implement the guidelines set forth by the GEAC. All research projects, field trials or production activities that involve genetics are required to notify the local IBSC, and obtain approval for environmental and ecosystem impact, good procedure, and competent authority.

The GEAC also sets out three categories that detail the magnitude of potential impact, including pollution or endangerment of the environment, the ecosystem and local humans and animals. These categories detail the required level of investigation and oversight by the local IBSC. Category I experiments, mainly routine laboratory procedures,

[32] Department of Biotechnology Website: http://dbtindia.nic.in/index.asp.
[33] GEAC Website: http://moef.nic.in/divisions/csurv/geac/notification.html.
[34] Dubey, Rajkumar, "India: Biotechnology Laws in India," Mondaq- Pharmaceutical, Healthcare and Life Sciences Publication, May 17, 2004.

need only fill out cursory paperwork, but Category II and III experiments require involvement from entities known as Review Committees on Genetic Manipulations (RCGM), which must review and approve the experiments and then grant permits. Any sufficiently large scale or controversial research must be approved by the GEAC itself.

However, the GEAC system itself focuses on human safety and environmental impact, and it does not appear to involve ethics in its decisions. The GEAC has also faced numerous criticisms, mainly due to its perceived "arbitrary nature and non-transparent procedures."[35] The GEAC is currently undergoing a major upheaval due to the resignation of board member Anand Kumar on April 4, 2011, over questions regarding his conflict of interest over a recent decision regarding the status of approving Bt Brinjal; several other board members are expected to resign alongside him.[36]

In the United States, any experiments that involve human test subjects are subject to review based on the National Research Act of 1974.[37] This act set up institutions known as institutional review boards which are required to approve of any trials or experiments that are funded by the government and have human test subjects, with a few exceptions, and determine whether the research is ethical, whether the researchers have put into place sufficient safeguards to protect the volunteers, and whether informed consent is sufficient for the level of possible distress placed on volunteers. These boards are set up and monitored under the Department for Health and Human Services (DHHS). This act was passed mainly in response to the infamous incident at the Tuskegee Institute where African-

[35] "Farm Bodies Cry Foul over Bt Cotton," Financial Express April 27, 2005.
[36] Mukherjee & Menon, "GEAC Member Quits over Conflict of Interest," Business Standard April 05, 2011.
[37] Office of Human Subjects Research- Regulations and Ethical Guidelines- Accessed via http://ohsr.od.nih.gov/guidelines/belmont.html.

American participants were deliberately injected with syphilis in order to perform experiments and study the progression of the disease, and were then not provided with a cure.[38]

The United States also has the Food and Drug Administration (FDA). This administration has as its mandate the protection of citizens from the harmful effects of contaminated foods and possibly fatal medications.[39] For this topic, the FDA is primarily concerned with the safety and medical side effects of medical treatments performed on humans. The FDA has little to do with ethics as long as the treatment is safe, and the FDA does not deal with general biological experiments that have no impact on humans or do not involve a finished product or treatment, such as manipulating bacterial or viral DNA/RNA. Nevertheless, the FDA will have a large impact in this area once the industry starts producing things that can be sold to the general market.

The United States has recently implemented a commission to study bioethics, entitled the Presidential Commission for the Study of Bioethical Issues[40], which was established on Nov. 24, 2009. The purpose of this commission is mainly to focus on policy issues and provide recommendations and explanations to politicians over certain issues, mainly playing an advisory role for the president and keeping him up to date in the latest advances and controversies within the field.

This commission is the latest in a long line of different presidential commissions that have been created with the express purpose of analyzing various questions involving

[38] Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research US Department of Health, Education and Welfare Publication, 1979.
[39] Official FDA Website- Laws and Regulations- Accessed via http://www.fda.gov/RegulatoryInformation/Legislation/default.htm.
[40] Official Website of the Presidential Commission on Bioethics: http://www.bioethics.gov/.

medicine and biological science. The previous commission was entitled the President's Council on Bioethics; this commission was created by President George W. Bush in 2001, expired in 2009, and provided policy papers on a wide variety of subjects including different medical definitions of death, the nature and practicality of cloning animals and humans, advances made and controversies over stem cell research, and methods of ethical care-giving and possible abuses by caretakers and nursing homes.

Of note, one of the commission's main recent findings was that the field known as synthetic biology, which involves the creation of new organisms designed to perform specified tasks similar to a machine, has not yet progressed to the point where detailed and strict regulation should be warranted.[41] However, the commission does detail how such regulations could be necessary in the future, recognizing that advances in this technology could lead to disastrous consequences due to human error or potential use by terrorists. It also points out how the field could be seen as humans "creating new life" and the hazards involved in such an undertaking. One of its main recommendations was that any and all researchers in this new field should be required to take an ethics course. However, there was little said about what details should be included in this ethics course, or any specifics or guiding principles on where the line should be drawn in certain circumstances.

The Presidential Commission had issued as the core of its philosophy the statement:

"[we think] it imprudent either to declare a moratorium on synthetic biology until all risks can be determined and mitigated, or to simply 'let science rip,' regardless of the likely risks. The Commission instead proposes a middle ground — an ongoing system of prudent

[41] Pollack, Andrew, "US Bioethics Commission Gives Green Light to Synthetic Biology," New York Times Dec. 16, 2010.

vigilance that carefully monitors, identifies and mitigates potential and realized harms over time."[42]

It is admirable to promote such a strategy, but the fact remains that an approach supporting the middle ground needs to be able to address ambiguities and determine where on this continuum the line should be drawn, or if any line should be drawn at all. The commission argues for greater cooperation between different branches of the government that handle different aspects of this technology, namely the FDA, the DHHS and the congressional committees that oversee science and technology.

The U.S. Biological Weapons Anti-Terrorism Act of 1989,[43] dealing with prohibitions on possessing "any biological agent, toxin, or delivery system of a type or in a quantity that, under circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose," is the United States' main implementing legislation for the Biological and Toxin Weapons Convention. This act defines what biological weapons are for the purposes of U.S. Law and sets out procedures for seizing and punishing offenders.

The European Union has the Clinical Trials Directive, which was passed in April 2001. This directive is very similar to the U.S.'s Research Act in that it sets up the proper mechanisms and oversight of clinical experiments and trials involving human test subjects. The Clinical Trials Directive sets up the Ethics Committees, which are the EU equivalent of the Institutional Review Boards, to approve of these experiments. Each EU member has their own FDA equivalent that monitors medical procedures, but each of these national

[42] Pollack, "US Bioethics Commission Gives Green Light" 2010.
[43] Text of the Act Accessed Via http://www.sunshine-project.org/bwintro/uscode.html.

institutions is bound by Eudralex[44], the compilation of EU law that sets down guidelines for medical products and procedures.

In developing countries, such as Kenya and South Africa, biotechnological capabilities are mainly involved with agricultural production, in order to help alleviate poverty and malnutrition.[45] Most research is conducted with the purpose of counteracting things such as inadequate rainfall or poor soil nutrition, and is not particularly concerned with other uses of genetic technology.

International Treaty or Agency

The main institution to have an international treaty on this subject would be the United Nations (UN). The UN is a large, already existing, international network. UN resolutions typically are top down, with the individual countries passing their own implementation legislation, which is the main avenue for compliance. A UN convention would be formulated and debated with input from members all around the world, and so it would include many different perspectives.

A major benefit to creating a UN convention on the issue would be that the convention would create a broad set of ground rules that every signatory country agrees to, avoiding having differences between each country. This would have the benefit of providing a stable, uniform code that most of the countries of the world would hold in common.

[44] Text Accessed Via the Official EU Website http://ec.europa.eu/health/documents/eudralex/index_en.htm.
[45] Ndiritu, Cyrus, "Kenya: Biotechnology in Africa: Why the Controversy?," Agricultural Biotechnology and the Poor 1999.

The UN mainly achieves its power through its creation of international norms. In other words, biotech companies that do business in a country that has not signed onto this convention would be regarded with suspicion if they did not have other means to establish their own legitimacy, whereas this would not be the case with a country in a signatory state. In addition, countries that have already signed onto a convention have an incentive to help recruit other countries who have not signed, since the signatory countries have voluntarily limited their sovereignty in the hopes that other countries agree and sign on as well.

Once again, a very good model for how a biological agency could be structured would be the International Atomic Energy Agency (IAEA). This agency's mandate is the promotion of peaceful use of nuclear technology for energy while simultaneously monitoring nuclear disarmament and preventing technology from being diverted for weapons production. A biological agency could be similarly constructed, with the agency's mandate for promotion of ethical genetic and biological medical practices while overseeing the industry and making sure that it does not get out of control. The UN already oversees the execution of the Biological and Toxin Weapons Convention, but as stated before, the Convention is not enforced beyond a set of confidence-building measures that are voluntarily given by the member states. If some sort of bioethics convention were to come from the UN, it could be the case that it would take the form of a corollary or amendment to this already existing convention.

The analogy has a few key differences, however. First, the equipment required to process and perform experiments on biological material is much smaller, less expensive and is much more prevalent that the equivalent technology for other possible weapon

categories such as nuclear. Also, biological agents themselves are naturally occurring and are technically renewable resources that can reproduce, and it is very hard to detect someone collecting them from the environment, since theoretically someone could obtain the required bacteria or virus from soil in their own backyard, however unlikely that may be.

Another criticism of this model could be a comparison to the Biological and Toxin Weapons Convention, which lacks a real, functional surveillance system. The argument would go that since something as vital as a weapons ban does not have a mechanism for surveillance besides trust-building measures, how can a more inclusive system have any chance of allowing such a mechanism?

Another problem is that countries themselves need to sign on to treaties in order for them to take effect. Any venture would need to address questions of sovereignty; mainly that the need for such a delicate subject to be delegated to another authority would have to be articulated. This would be the biggest obstacle to overcome, since it means that each government would need to voluntarily decide to enter under and be bound by any agreement. This means that it would be rather difficult to get delinquent nations to sign on to this if they do not want to.

Even if it were to include substantial surveillance and executive procedures, the idea of funding would be important. If it were to come from the UN, it could be paid for by UN member dues. The IAEA is mainly funded by mandatory, UN-determined dues from all member countries, and also from voluntary payments from governments in addition to the dues. However, this again would require cooperation from all interested states, and

considering the recent global economic downturn, countries may be unwilling to make payments for a new program that would not have immediate benefits.

As for already existing international organizations, the World Health Organization (WHO) already takes a large role in how medical techniques and priorities are developed and spread across the world. The WHO would certainly be able to take an active role in researching and compiling data about emerging biotechnologies, and to disseminate that information to interested parties across the world. The WHO itself has a department of Ethics, Equity, Trade and Human Rights, which monitors WHO programs and examines potential problems with WHO activities. [46] With the words equity and human rights in the title, one can imagine that most of this department's activities involve moral questions arising from disparity in health care treatment both within and between countries, and the implication of an unequal value of these lives arising from such disparities.

Another part of the WHO's portfolio involves the oversight of the UN Inter-Agency Committee on Bioethics, founded in 2003, which involves promoting and distributing some knowledge about bioethics topics throughout the member countries. [47] The topics on which the committee has issued reports focused mainly on topics that have impacts that cross national boundaries or have some other international scope. An example would be the possibilities of sharing medication and treatment facilities across borders in the event of a

[46] Official WHO Department of Ethics, Equity, Trade and Human Rights Website: http://www.who.int/ethics/about/en/.
[47] Official Website of the UN Inter-Agency Committee on Bioethics: http://www.who.int/ethics/about/unintercomm/en/index.html.

major pandemic.[48] The committee has also published on the possible legal and ethical implications of public health techniques that help stop the spread of infectious diseases but usually result in the detention of the patient in question for a period of time until he or she has become entirely healthy, whether when the patient is crossing a border through customs[49], or when the patient is merely being monitored by a government agency.[50]

This UN Committee, however, is rather small in size and importance. In addition, as stated, it focuses its efforts on ethical issues regarding government policy, international relations, UN and WHO actions and programs, and possible human rights abuses of those policies. It does not give out recommendations to scientists and researchers, and does not delve too deeply into the implications about the nature of life that research seeks to answer. However, it does provide a possible stepping stone for the creation of a UN committee that would have a more active and broader agenda.

For the most part, the main international treaties and/or legislation that has involved monitoring of scientific experiments have come from treaties and bans on the development of major weaponry. The particular one for this discussion would be the Biological and Toxin Weapons Convention, which completely bans the use, development and stockpiling of biological weapons. This would include the manipulation of microbes to become more lethal and virulent if the research is not being conducted for a protective, peaceful or prophylactic reason. However, this only covers usage for the development and

[48] "Ethical Considerations in Developing a Public Health Response to Pandemic Influenza," World Health Organization Publication, 2007, Accessed via http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf.
[49] "Ethical Considerations," pp. 9-16.
[50] "Ethical Issues to be Considered in Second Generation Surveillance of HIV/AIDS," World Health Organization Publication, April 2004, Accessed via http://www.who.int/ethics/topics/ethics_2nd_gen_surveillance_en_2004.pdf.

stockpiling of weaponry. This treaty could be expanded and amended to cover research under the guise of monitoring for possible illegal or dangerous experiments, and indeed, could be the most appealing and legitimate first step in monitoring biological experiments.

Private Institutions

Another aspect could be the creation of a major private review board run either by a prestigious scientific agency, some sort of non-governmental organization (NGO), a bioethics consulting firm that could review potential experiments and provide recommendations, or an entity created and set-up by industry companies and players themselves to monitor and review experiments. This board would set up a standard code of ethics that all companies and research entities would agree to be bound by for the purpose of safe and ethical science. In addition, if it was a highly-regarded scientific organization that was in charge, this would lend a lot more credence and prestige to the efforts to regulate this area.

For this purpose, the board would serve as an arbitration body to determine how well laboratories and experimenters are abiding by the code that was set up and to monitor complaints and render judgments. Since it would be a private entity, the judgments would not likely be legally binding, unless contracts were involved, so it would most likely end up having an advisory purpose only, settling questions about the interpretation of the code.

A private solution may have less problems with having companies cooperate since it would not be seen as government meddling and interference in an area that can be seen as

completely and inherently subjective. Companies would more or less voluntarily seek out the guidance and/or approval of the organization, as opposed to having a legal mandate preventing the companies from carrying out their research.

A private organization would also be able to work across national borders, and due to its origins as a private institution, would be much less likely to incur anger and protestations from other countries about questions of national sovereignty. Since it is not a governmental body that is providing the service, this would be less likely to cause problems with countries seeing this as meddling in domestic affairs.

However, a private institution would probably be more likely to be susceptible to moral hazards depending on how the organization was set up. If the organization is funded by application fees then it would create a strong situation for the organization to simply "rubberstamp" the applications. A private organization would also have much less ability and opportunities for oversight, so a lot of questions about legitimacy and conflicts of interest could arise. This would not be solely a problem with private institutions, as seen by the controversy in India mentioned above.

Alternatively, a solution could be to have the biotechnological companies set their own ethical standards and procedures, subject to internal policing and discipline. A company theoretically would have more capacity for oversight over its own employees, and could administer punishments to offenders ranging from fines to furloughs or even termination. This would come with the attendant loss of status or a mark on an employee's record about their past ethics violations. This is assuming the company is willing to

administer more than just an obligatory punishment for egregious violations, and that the company has competent record keeping and oversight over its own operations.

The largest problem faced by a private institution again would be one of enforcement. Since it would be a private, not a public, body, it would have no legal power to enforce its decisions, unless there were contracts involved that gave the body authority to arbitrate decisions. It would only be able to provide opinions and recommendations, and there would be limited punishments available to reprimand wrongdoers. As a result, a private body would likely not be a permanent solution due to this issue.

Another aspect to consider is the fact that some aspects of bioethics go beyond ethics and enter into legal or human rights territory, which would be outside the purview of any private entity. As mentioned above, intellectual property is likely to be a contentious issue. Discussions of human rights with human testing, disparities in medical care between income brackets, and possible disease and pandemic prevention practices, would also need to be taken into consideration. Private entities would not have the legal jurisdiction to make any claims or recommendations for these areas unless they refer the specific case to a relevant judicial authority.

Governmental solutions, whether through individual legislation or a major international treaty or convention, would have a higher impact than a private organization, and it would have a greater sense of authority and capacity for enforcement. However, it is still very early in the development in many of these technologies, so a more flexible and adaptable approach could be preferred until the technological path and procedures become more tangible, at which point a more codified solution would become more desirable. Since

governmental solutions tend to be more “sticky” and resistant to change, this would favor a private entity until a much clearer picture of where the industry is going has been formed. However, this is a broad generalization, and it does not mean that an effective government program would not be necessarily slow.

Conclusion

The field of biological science has made many great strides in recent years. Done correctly, it could open up an entirely new realm of possibilities. However, it is generally agreed upon that there are many, many dangerous aspects to this technology, and so it would be the wiser choice to proceed with extreme caution as we continue to develop this technology to the best of our potential. We can have many different ways to go about setting boundaries, and there are certainly many questions about the efficacy of such an undertaking, but the most important result could be merely the establishment of a certain key set of norms that could prevent a worldwide disaster.

It is imperative that we realize just how much biological technology has progressed in recent years, and even if an international regulatory body does not end up being realized, we must still work to bring these subjects out into open public discourse and put these topics onto the political agenda. Also, considering how long it takes to do anything of note, either in domestic politics or international politics, it would be better to begin now so that some semblance or general outline has been established once it actually starts becoming very relevant. These problems are only going to stay hypothetical for so long.