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BIOTECHNOLOGY: AN ESSAY ON THE ACADEMY, CULTURAL ATTITUDES AND PUBLIC POLICY

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Biotechnology is the latest historical example of a scientific discipline creating enormous cultural, social, and public policy controversies. By comparing biotechnology to these past controversies, and by comparing biotechnology to present-day computer technology, Professor Kershen argues that acceptance or rejection of biotechnology will ultimately occur as a result of ideological and political beliefs and pressures. He argues that the debate about biotechnology will not be resolved primarily based on expanded knowledge and understanding of biotechnology as a science.

Key words: biotechnology; computer technology; cultural values; public policy; precautionary principle; technology assessment; product regulation; European Union; United States.

Biotechnology In Historical Context

When the half-millennium arrived on January 1, 1501, educated Europeans most assuredly held the view that the Earth was round. They also assuredly held the view that the Earth was the center of the astronomical universe. Forty-three years later the latter view began to shatter when Nicolaus Copernicus (1473-1543) published his On the Revolutions of the Celestial Spheres. Copernicus' theory (that the Earth is a planetary body in the solar system – now established beyond scientific doubt) set in motion further discoveries by Galileo Galilei (1564-1642) and Isaac Newton (1643-1727) in mathematics and mechanics. The work of these three scientists shook the foundations of astronomy and cosmology and, more broadly, shook the foundations of European culture. As important for our understanding today, their work generated tremendous debate and bitter controversies.

If the sixteenth and seventeenth centuries were centuries shaken by the scientific ideas coming from astronomy and mathematics, the eighteenth and nineteenth centuries can be characterized as centuries shaken by the scientific ideas based in physics. Isaac Newton was the bridge between these four centuries with his pioneering work in physics. When we think of the impact of physics upon society, we likely think of machines – the steam engine, the steam boat, the railroad, and the mechanical reaper. The machines of physics created the Industrial Revolution of factories and urban society with its technological progress and its political manifestos.

Before society had fully assimilated the changes caused by the science of physics, the twentieth century faced the science of chemistry. No better expression of the twentieth century can be found than the

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advice delivered in the American movie The Graduate, "Plastics. ... The future is plastics." Even though we laughed at this statement, the twentieth century has indeed been the century of plastics – and polymers, resins, medicines, foods, fuels, pesticides, insecticides, fungicides, and poisonous gases – made by modern chemistry. "Better living through chemistry" has been both an advertising slogan and a guiding principle of the twentieth century. Of course, whether chemistry did bring better living has been the catalyst of bitter and continuing controversies about humankind's use and abuse of one another and the environment.

As we enter the twenty-first century, any short-sighted futurist or uninspired prophet (that is, the author) can comfortably predict that the coming century will be the century of the science of biology. Before the new century even dawns, scientists and society are rabidly discussing genetics, cloning, immune systems, gene therapies, genome mapping projects, and modern biotechnology. Discoveries from the science of biology will fundamentally change society and human self-perception in the twenty-first century. The preceding sentence can be posited as a fact to be proven or disproved as true, probably long after the author's death. Just as comfortably, we can predict tremendous debate and bitter controversies about biological science, just as there were tremendous debates and bitter controversies about astronomy, cosmology, physics, and chemistry in the preceding centuries.

What conclusions can be drawn from this superficial history of past centuries and their related scientific discoveries?

- It is to be expected that scientific discoveries will generate debate and controversy. However, the fact that debate and controversy occur does not mean that science and knowledge are evil.

- Human beings express themselves by creating science and knowledge as tools of our ingenuity. Hence, human beings will expand the boundaries of science and knowledge despite the existence of debates and controversies about scientific discoveries.

- Human beings make choices about how to use science and knowledge. These choices, not science or knowledge, *per se*, are good or evil. Past history shows that human beings will likely choose both good and evil – that is, human beings will use science and knowledge to do good and to do evil. However, the fact that human beings can use science and knowledge to do evil should not dissuade us from seeking to use science and knowledge for doing good.

- To the best of our abilities, our obligation as human beings in civil society (and more particularly in the academy) is three-fold: to promote human ingenuity; to discern the good flowing from our ingenuity; and to promote good choices through sound public policy and laws.

We can not conclude that the task will be easy. We can not conclude that good will triumph over evil. We can not conclude that we will agree upon what is good or evil about a particular scientific theory, discovery, or technology. Each of us realizes that we cannot control how our research and teaching will be used. Assuredly, we will be dismayed and depressed when others use our work in ways and for ends of which we do not approve. Sadly, at times, we will be ashamed when others use our work for evil. Yet these risks of how others will use our work should not dissuade us from our obligation to promote human ingenuity, to discern the good, and to promote good choices. More often we will be amazed and proud when others creatively use our work for good.

Moreover, we can not conclude that the science and technology are inevitably destined to be triumphant in the future. I am a supporter of biotechnology and hold the conviction that the good that biotechnology can bring to humanity and the world will outweigh the evils that might arise from biotechnology. Still, it is society that will inevitably accept biotechnology. Those who support biotechnology should recall that nuclear energy was touted as the wave of the future in the 1950s. However, beginning in the 1970s, those who opposed nuclear energy and nuclear technologies succeeded in many countries in blocking additional nuclear power plants, in shutting existing nuclear power plants, and in drying up demand for nuclear engineers and nuclear programs at universities. Society may ultimately treat biotechnology more like nuclear energy than like telephones.

Computer Technology, Biotechnology And Cultural Values

When we predict that the twenty-first century will be the century of biology, others are likely to reject that prediction. Many others may sensibly conclude that computer technology will be the dominant science in the twenty-first century. One can concede the incredible impact of computer technology upon human beings and society. Indeed, it is instructive to compare these two emerging technologies – computer technology and biotechnology – at the end of the twentieth century.

Computer technology began to impact everyday life in the early 1980s as businesses adopted computer technology in their operations, and as personal computers appeared on the desks of ordinary citizens. Since the early 1980s, nobody can deny the fundamental impact computers have had upon the structure of society and human relationships. Factories use computerized robots; people use the Internet. Despite these phenomenal changes, people have accepted computers with relatively minimal debate and controversy. People have accepted computers even in the face of apocalyptic claims that the modern world will end in a cataclysmic Y2K error-message. As important, from this author's perspective as a lawyer, people have accepted computer technology with a minimum of regulatory oversight and governmental control.

Biotechnology also began to emerge from scientific expertise into general knowledge in the early 1980s. In 1980, we first heard of *in vitro* tissue, cell culture, monoclonal antibodies, and recombinant deoxyribonucleic acid (rDNA) techniques. The pharmaceutical industry used these techniques to develop, among others, self-administered pregnancy tests for women (monoclonal antibodies) and human insulin analog (rDNA). At the same time, agricultural companies developed biotechnological products, among others, the Flavr-Savr™ tomato and Posilac® (recombinant bovine somatotropin (rBST)). Both agricultural products used rDNA technology.

While the pharmaceutical use of biotechnology has had some debate, agricultural biotechnology has been met with unceasing, acrimonious controversy from the start. An often quoted phrase is that ninety percent of the commercialized biotechnology has been in pharmaceuticals but 90 percent of the controversy has been about agriculture. Moreover, the controversy about biotechnology, particularly agricultural biotechnology, has raged even though the United States government has exercised regulatory oversight regarding safety, efficacy, and environmental impacts since biotechnologys earliest stages.[1]

The contrast between computer technology and biotechnology with respect to controversy and regulatory oversight is very striking. Why has society so readily accepted unregulated computer technology and its profound changes, while at the same time struggling contentiously over regulated biotechnology and its profound changes? Three reasons deserve special emphasis, although these three reasons are by no means the only reasons for the contentious debate.

- <u>It is not wise to trick Mother Nature</u>.[2] Our identification with living things (plants, animals, and fellow human beings) is much greater than our identification with inert matter. By the end of the twentieth century, we are quite comfortable with the manipulation of inert matter through physics and chemistry. Even though one must trick Mother Nature for human beings to fly from St. Louis to Columbia, Mother Nature brags about her human offspring when they create flying machines. We are comfortable with the technological tricks that let us fly. However, the appeal to Mother Nature has not lost its punch when the appeal involves living nature. Many feel that Mother Nature frowns upon her human offspring tinkering with biology. We are not comfortable with the technological tricks that let us create living matter.

- Mankind is the destroyer of nature. Until relatively recently, Western societies considered advances in science and technology to be signs of human progress. Western societies believed that science and technology contributed to the betterment of the human condition. While the idea of human progress in the moral realm has been questioned for centuries, the idea of human progress through the human ingenuity expressed in science and technology was well received. Beginning about 1962 – the publication year of Rachel Carson's Silent Spring – modern societies and classes began to doubt the idea that science and technology constituted progress or contributed to human betterment. Since 1962, there have been numerous instances where opinion leaders in society have urged the abandonment of science and technology in preference for the natural, the holistic, the sustainable, and the organic. Far from being helpful to human betterment, many in modern societies or classes view science and technology as destructive of the good and the beauty found in nature and the natural. Indeed, the emergence of the discipline of ecology as a competing science to physics, chemistry, and biology is intimately connected to these now widely-held views that human betterment does not emerge from scientific and technological progress.

- The world is a world of limited resources; therefore, population growth is the most serious threat to the future of the world. Although not identical to the idea of human progress through science and technology, until recently, Western societies believed that the world offered limitless resources for exploration and development. Societies viewed the world as a cornucopia of bounty. Furthermore, although Thomas Malthus (1798) had published his book on population in 1798, population growth was widely viewed as an engine of progress and development. Society after society wanted greater populations with improved education, larger production capacities, and greater consumer desires. By contrast, modern societies and classes are no longer confidant that the world is limitless. Rather, we worry about the limited resources of oil, waste disposal sites, species, and geographic space -- just to name four modern concerns. Moreover, many modern opinion leaders, such as Ehrlich (1968) and Brown (1974) are thorough Malthusians. The computer, telecommunications, and investment billionaires can also be considered Malthusians, through donations to their respective foundations. Warren Buffett, Bill Gates, Ted Turner, and David Packard have all pledged billions of dollars for human population control ("Culture section," 1999). Bill and Melinda Gates recently gave $1.7 million to the United Nations Population Fund. All these opinion leaders worry that unless population is controlled and curtailed the world has no future, except one that involves a poverty ridden, devastated environment.

Proponents of biotechnology tout biotechnology as providing additional food, fiber, and medicines for human populations. Proponents envision biotechnology as providing these additional food, fiber, and medical resources without increasing, and possibly decreasing, human demands upon land and plant-fauna habitats. Opponents of biotechnology hold the opposite vision of biotechnology. Opponents believe that biotechnology will increase the already excessive demands upon the world's resources by increasing human populations and consumer demands for foods, clothes, and other materialistic goods. Proponents view human populations and human demands as opportunities for the good of biotechnology. Opponents view human populations and human demands as siren calls to extinction through biotechnology.

I would assert, without knowing any empirical data to support the assertion,[3] that if you took a survey of people's attitudes on the three points mentioned above, a correlation would exist between the attitudes on those three points and the attitude towards biotechnology. The following correlations can be hypothesized:

- If the person surveyed agreed, or tended to agree, that the three statements mentioned above were factually true, the person would be inclined to oppose biotechnology.
- The more strongly the person agreed with the three statements as being factually true, the more strongly the person would oppose biotechnology.
- If the person surveyed disagreed, or tended to disagree, that the three statements were factually true, the person would be inclined to support biotechnology.
- The more strongly the person disagreed with the factual validity of the three statements, the more strongly the person would support biotechnology.

One can further hypothesize that a person's attitude towards the three statements is a better predictor of a person's attitude towards biotechnology than class, education, ethnic heritage, gender, geography, nationality, occupation, religious affiliation, or religious beliefs. Finally, one can predict that no correlation exists between being a supporter (opponent) of computer technology and being a supporter (opponent) of biotechnology. In the late twentieth century, computer technology and biotechnology century have simply come to occupy distinct intellectual universes even though both technologies appear to have enormous, irreversible impacts on, and potential catastrophic risks for, human beings and human society.

Biotechnology And Public Policy

Elsewhere, I have discussed ten public policy disputes about biotechnology. These public policy issues were debated during negotiations concerning an international biosafety protocol held in Cartagena, Colombia in February 1999 (see Kershen, 1999). Here, just one public policy dispute involving biotechnology – that is, the precautionary principle[4] – is discussed. To my mind, the debate about the precautionary principle embodies the historical and cultural currents discussed in the two preceding sections of this paper.

Proponents of biotechnology view biotechnology as an extension of previously well-established scientific principles and disciplines. Particularly in the agricultural sector, proponents of biotechnology consider the techniques of the genetic modification of plants and animals to be no different, in kind, from traditional breeding techniques that farmers and plant breeders have used for centuries. Consequently, to proponents of biotechnology, the products of biotechnology (such as genetically modified corn, genetically modified milk, genetically modified dairy cattle) are substantially equivalent to corn, milk, and dairy cattle that have been produced by farmers and scientific breeders through conventional techniques of genetic manipulation for a long, long time.

If one adopts the view of the proponents of biotechnology, regulatory policy should focus, therefore, on the product, not the process. In other words, regulatory policy should check the genetically modified plant or animal for its effects on human health, the environment, and nutrition. The process by which the product is produced, however, should be outside the regulatory policy because the process is just human ingenuity using good science to produce a product more safely, more consistently, and more efficiently.

To a significant degree, the United States has focused its biotechnological regulatory policy on the product and not the process. The United States does not have a special, separate regulatory scheme for biotechnology as a process. Rather, the United States uses its usual laws or regulations to test biotechnological products for their impacts on the environment, human health, and food safety.[5] As a consequence, the United States has approved biotechnological products for the pharmaceutical, medical, industrial, and agricultural sectors relatively rapidly; with confidence that biotechnological products are relatively benign for the environment, safe for health and consumption, and are efficacious.

Opponents of biotechnology view biotechnology as different in kind from all previous human and scientific manipulation of genetic material. Particularly in the agricultural sector, opponents view biotechnology as having the potential to change fundamentally the ecology of the world and, through the food products of genetically modified plants and animals, the health risks of human beings. To opponents of biotechnology, each new genetically modified plant or animals is the introduction of an alien species into the web of life, with completely unknown, unpredictable consequences and risks. This introduction is done due to the arrogance of humans.

If one adopts the view of the opponents of biotechnology, regulatory policy should focus on the process first and foremost and, if the process is ever approved,[6] the products only thereafter. Furthermore, in light of the unknown and unpredictable consequences and risks of biotechnology, opponents argue that regulatory policy should approach biotechnology from the stance of the precautionary principle. With the precautionary principle as the default mode of regulation, regulatory policy should evaluate biotechnology for its human health, animal health, environmental, social, economic, cultural, ethical, and communitarian impacts ("Draft negotiating text," 1998). In other words, opponents of biotechnology insist that the regulation of biotechnology be a technology assessment, not a product regulation.

To a significant degree, the European Union has focused its biotechnological regulatory policy on the process, not the product,[7] through its stance of adhering to the precautionary principle. Under European Union laws and regulations, biotechnology has special, separate regulatory schemes.[8] As a consequence, the European Union has been slow to approve biotechnological products, particularly in agricultural biotechnology. Moreover, several European countries (Austria (European Commission (EC), 1997, May 14), Denmark ("One year," 1998), Italy and Luxembourg (EC, 1997, September 10)) have instituted bans on genetically modified crops. It is fair to say that the European Union has been much more cautious, hesitant, and suspicious of biotechnology overall, and of agricultural biotechnology in particular.

As for the international arena, proponents and opponents of biotechnology are still contesting the appropriate public policy regarding the concept of precaution. The Biosafety Working Group (BSWG) of the Convention on Biological Diversity (CBD) did adopt a Biosafety Protocol in Cartagena in February 1999 (Protocol on biosafety, 1999). In this BSWG Biosafety Protocol, the term "precautionary principle" is never used. Rather, the BSWG attempted to find a middle ground between the proponents (the United States) and the opponents (the European Union) by using the term "precautionary approach." The BSWG Biosafety Protocol reaffirms the precautionary approach (contained in Principle 15 of the Rio Declaration on Environment and Development) in the Preamble and in Article 1, Objective. Moreover, the BSWG uses the precautionary approach (though not the term) in Article 8, Decision Procedure for Advance Informed Agreement. However, proponents and opponents of biotechnology may not be willing to accept the compromise represented by the term "precautionary approach."[9]

Conclusions

Biotechnology has become the contested battleground between contending historical forces and cultural values. I am firmly committed to educating the public as broadly and thoroughly as possible about biotechnology as a science and as a technology. I believe in the necessity for a scientifically educated populace in a democracy. And yet, while information is important, and while understanding is important, I would argue that the acceptance or rejection of biotechnology will not be based on information and understanding. Biotechnology will stand or fall based on the ideological beliefs and the cultural values adopted by individual human beings who, in turn, will shape societal beliefs and values.

In this swirl of controversy about biotechnology, I agree with Kalaitzandonakes (1999) who recently wrote:

> Clearly, the burden of social responsibility should not be placed on the knowledge system alone. Relevant supporting institutions must also play their intended roles in filtering new knowledge to achieve desirable social, economic and environmental outcomes. If existing antitrust and environmental regulation, agricultural policies and common law are not up to the task within the new economic and scientific realities, they should be appropriately adjusted. Social engineering of new knowledge is probably a poor substitute for an appropriate institutional framework.

Biotechnology is part and parcel of the human condition and the human dilemmas of the dawn of the coming millennium.

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Endnotes

[1]The National Institute for Health (NIH) issued guidelines for rDNA research in 1976, 41 Fed. Reg. 27,902, 1976 (proposed NIH guidelines). In 1983, the NIH created an rDNA Advisory Committee and reissued guidelines for research in biotechnology, 48 Fed. Reg. 24,556, 1983. United States federal regulatory policy regarding biotechnology took definite shape in 1984 with the issuance of a coordinated framework document (Office of Science and Technology (OST), 1984).

[2]The phrase Mother Nature is used deliberately. The phrase Mother Nature was chosen rather than the

comparable, "If God had wanted us to fly, He would have given us wings."

[3] Making fun of myself, that is, making assertions without empirical evidence is my typical approach. This technique allows me to form my beliefs without having to account for difficult data. Moreover, this technique allows me to harden my beliefs before data arrives so that I can ignore any contrary or contradictory data. I call this technique the Kuhnian (Kuhn, 1962) approach to knowledge.

[4]The precautionary principle has four components: taking precaution in the face of scientific uncertainty; exploring alternatives to harmful actions; placing the burden of proof on proponents of an activity or product rather than on victims or potential victims of the activity; and using democratic processes to carry out and enforce the principle, including the public right to informed consent.

Others argue that the precautionary principle must be strengthened by adding four additional components: precaution must be the default mode of all technological decision making; past technological decisions must be re-examined and reformed, if needed; precaution demands that the mode of regulation fit the scope of the threat; and society must identify, and accommodate itself to broad patterns in ecological processes. These components and proposed components of the precautionary principle can be found in (BNA, 1999).

[5]The three major United States regulatory agencies for biotechnology are the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture. The four major United States laws affecting biotechnology are as follows: Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301 et seq.; Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 et seq.; Federal Plant Pest Act, 7 U.S.C. §§ 150 et seq.; Plant Quarantine Act, 7 U.S.C. §§ 151 et seq.

[6]For example, during the Biosafety Working Group Sixth Session (BSWG-6) in Cartagena, Colombia, forty-nine environmental and social activist organizations signed an appeal for a worldwide moratorium on commercial releases of genetically modified organisms and products thereof ("Appeal to," 1999).

[7] I acknowledge that the distinction between process and product is not a clearly defined or clearly articulated distinction. Yet the distinction between regulatory focus on process versus product is a common way of contrasting the regulatory systems of the United States and the European Union.

Furthermore, several readers of an earlier draft of this paper reminded me that one must distinguish between a regulatory system that focuses on the production process (i.e., the manufacturing technique such as biotechnology), and a regulatory system that focuses on an evaluation process (i.e., standards for production regardless of the specific technique of production). For example, the International Standards Organization (ISO) has promulgated ISO 14001 Certification for Environmental Management Systems that uses an evaluation process.

The statement that the European Union focuses its regulations on the biotechnology process, not biotechnology products, means that the European Union is focusing on the production process – that is, the technique of biotechnology itself. In contrast to the European Union approach, read the discussions of evaluation processes for biotechnology found in Redick, Reavey, and Michels (1997) and Carrato (1999).

[8]The primary European Union laws and regulations are the following – Council Directive 90/220/EEC (marketing of GMO products as raw materials); Regulation No. 258/97 (novel foods); and Commission Directive 97/35/EC (labeling). See also Stewart and Johanson (in press) for a more

general discussion.

[9]I must emphasize that the Conference of the Parties to the CBD refused to endorse the BSWG Biosafety Protocol at a separate meeting also in Cartagena in February, 1999.

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