Biotechnology Policy across National Boundaries

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The Science-Industrial Complex

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To Karin, who knows how to cross national borders

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Preface

Scientists now have the ability to produce genetically modified foods and organisms. They can clone living tissue and have discovered ways to use stem cells to regenerate tissue and fight human diseases. In vitro fertilization allows people to overcome fertility problems. Cells from humans and rabbits can be used to create new, cross-species organisms known as chimeras. Yet despite the prevalence of these advances, little is understood about the role of the state in promulgating biotechnology policy. Who decides what biotechnologies to encourage? How are new initiatives funded and regulated? What role do large multinational pharmaceutical companies play? Whose ethical standards are used to judge these plans?

This book seeks to increase our understanding of biotechnology policy by analyzing how new advances are financed, regulated, and spread. I argue that a "science-industrial complex" based on universities, businesses, and nongovernment organizations has emerged that fuels biotechnological innovation. Much of this innovation is global in nature and independent of state control. As scientists collaborate across national borders, a new kind of globalization has emerged that is quite different from the traditional, economy-based globalization.

Economic globalization centers primarily on financial transactions and liberalization of cross-border trade. Many of the debates surrounding this type of globalization are concerned with how global trade affects the material conditions of nations, industries, and workers. Biotech globalization, by contrast, involves plant, animal, and human regeneration and the effect of boundary lowering on the sanctity of life. This new form of globalization is controversial because it raises ethical dilemmas related to basic human values.

In this research, I analyze the role of the public, private, and nonprofit sectors in promulgating new biotechnologies. I examine five cases (stem cell research, cloning, chimeras, genetically modified food, and in vitro fertilization) in a number of different countries (mainly the United States, Great Britain, France, Germany, India, China, Korea, and Japan) to see what role the state plays in promoting biotechnology. Through an analysis of ethics, finance, regulation, and decision making, I study biotech globalization as a cross-national process.

I focus on these particular cases because they are at the forefront of controversies over biotechnology. Ever since Louise Brown was created as the world's first test-tube baby in 1978, in vitro fertilization has become a common technique for overcoming fertility problems in many countries. The production of Dolly as the first cloned sheep in 1997 placed that topic squarely in the middle of public discussion. The use of genetically modified foods and chimeras over the past decade has sparked very different reactions in various countries. And most recently, stem cell research has emerged as a hot-button issue for scientists, business people, and public officials around the world.

Of the five cases, in vitro fertilization is the one that has generated the least controversy and the most limited state oversight. Genetically modified foods, in contrast, have been the object of intense oversight in some countries but not others. Cloning (especially that involving humans) has been regulated in most, but not all, nations. Stem cell research is controversial nearly everywhere, is the object of considerable public debate, and faces stringent state oversight around the world. Chimeras have attracted surprisingly little public or government attention despite the potentially far-reaching nature of the research.

The focus of scholarly research on biotechnology has thus far been too narrow. Most projects have been limited to individual country studies or comparative studies of small scope that focus on Western players and virtually ignore Far Eastern nations. The former approach lacks the virtue of comparative study. The advantage of examining more than one country is that it allows one to see variation and understand why different places react to the same technology in distinctive ways. The latter approach, a comparative study limited to nations such as the United States, Great Britain, Germany, or France, meanwhile is incomplete. It ignores the significance of biotech innovation in Asia. Since many Western countries have placed more restrictions on biotech than some Asian nations, it behooves scholars to investigate places such as China, India, and Korea to see how their approach to biotech contrasts with that of Western nations. In some respects, these Asian countries are following a different path and it is crucial to understand how they are handling these issues.

In hopes of better understanding biotech decision making, I adopt a cross-national approach to see how different countries deal with biotechnology. A broad comparison allows researchers to look at decision-making structures, group demands, industry composition, religion, and political culture to see why different countries have developed varying approaches to biotech policy. In addition, focusing on a variety of nations helps to see larger patterns in biotechnology such as what I term "country-shopping"

by scientists and businesses, and how biotech innovators play countries off against each other in order to gain autonomy for their research.

The globalization of innovation has produced the most massive spurt in biotechnology in world history, yet it raises a host of questions regarding its long-term significance. If cross-national partnerships have challenged the primacy of the state in setting biotechnology policy and if innovation has undermined the ability of governments to regulate scientific activities, have we created a policy area that is beyond the control of political leaders? If so, this poses a number of interesting social, political, and ethical issues for scientists, politicians, and the general public.

In chapter 1, I discuss how science and technology have become a global enterprise and the role of the state in shaping biotechnology policy. Universities and corporations collaborate across national boundaries and technology transfers are commonplace. The result has been dramatic increases in scientific publications and patents and the diffusion of new technology. I look at the global infrastructure of this "science-industrial complex," and the risks this raises for globalization. Biotech globalization poses a number of problems for the international system, and it is important to understand how it differs from the economic globalization that has dominated the discussion to date.

In chapter 2, I examine the collaboration between science and private business on biotech research. Close collaboration between these sectors is common in many countries. There are a number of features that have brought industry and science close together into a science-industrial complex. Deregulation in the public sector has weakened state capacity to oversee private interests. Corporate partnerships with higher education have made scientists more dependent on industry financing for research support. The emergence of country-shopping and scientist-buying allows researchers and businesses to play nations off against each other and thereby gain considerable autonomy for themselves. Finally, the prevalence of contraband technology in global trade means that even when governments seek to regulate the science-industrial complex, such efforts are not always very successful.

Chapter 3 presents a case study of in vitro fertilization. Fertility treatments and test-tube pregnancies represent some of the earliest applications in the contemporary period. Reproductive technologies are an area that has seen the least public sector regulation in the biotech sphere. Many approaches to in vitro fertilization remain private decisions between medical professionals and patients. Most governments around the world have few restrictions in place and the result has been a rapid proliferation and acceptance of this life-generating technology.

In chapter 4, I take a look at the biotechnology of genetically modified foods that has attracted stringent public sector regulation in some countries,

but not others. For example, the United States has adopted a laissez-faire approach to genetic modifications that has defined new foods as valuable commodities for commerce and trade. Agribusinesses have invested large amounts of money in research and lobbied public officials for nonregulation. In contrast, a number of European and Asian nations have expressed greater alarm over this area and have enacted strict regulations concerning research on and use of genetically modified foods. The cross-national comparison of this area shows how political, economic, and social factors explain the different regulatory reactions on this topic.

Chapter 5 presents a case study of a cloning biotechnology that has seen more serious oversight by most countries. Governments have devoted serious effort to restrict and regulate research on human cloning and even some types of cloning involving other organisms. Concerns raised by religious authorities or ethicists have led to controls on what can and cannot be undertaken. However, this effort has not been entirely successful. Scientists have migrated to locales with fewer restrictions in order to undertake research forbidden in their own homelands. These responses have limited the ability of the state to regulate this biotechnology.

In chapter 6, I investigate stem cell research, which is the biotech field with the strongest and most consistent regulation around the world. Because stem cell research has been defined as life altering, it has generated the most controversy. Many governments have placed sharp restrictions or outright bans on work in this area. This is especially the case in regard to embryonic stem cell research. For this endeavor, biotechnology has become extremely contentious and has moved from a relatively invisible concern of experts to a public issue that engages citizens and groups at large. The expansion of controversy to the public sphere has made this the most contentious biotech of all.

Chapter 7 looks at chimeras, which are genetic hybrids that are created across two or more species. Most cross-species fusions are not controversial. Indeed, crossbreeding is a centuries-old practice, both in terms of plants and animals. However, when new technologies yield organisms with the cells of human beings, the ethical challenges increase dramatically. Ethicists ask what proportion of an organism's genetic material has to be human for the organism to be considered a person? Despite the fundamental nature of this question, most governments have few rules regulating research in this area. This is problematic given the possible long-term dangers of this biotechnology.

Chapter 8 investigates the role of large multinational pharmaceutical companies in biotechnology. I review the funding of biotech, industry policies to facilitate innovation, patent and intellectual property issues in biotechnology, and ramifications for consumers and patients in the health

care area. Basically, I argue that biotech offers considerable advantages to the science-industrial complex, but poses some risks to consumers.

Chapter 9 examines ethical controversies associated with biotech globalization. I contrast nations governed by "international political economy," which tend to adopt permissive biotech policies, with those influenced by "religious political economy," whose policies generally are more restrictive. I discuss whose ethics should play a role in biotechnology decisions and who should act as decision-makers: companies, scientists, universities, public regulators, elected officials, international bodies, or the general public?

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