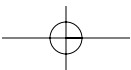
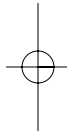
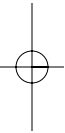


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Biotechnology Policy across National Boundaries



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Biotechnology Policy across National Boundaries

The Science-Industrial Complex

Darrell M. West

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BIOTECHNOLOGY POLICY ACROSS NATIONAL BOUNDARIES

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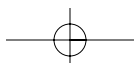
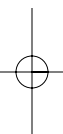
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To Karin, who knows how to cross national borders

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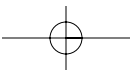
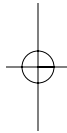
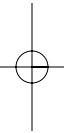
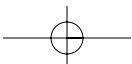
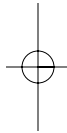
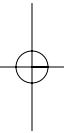


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Preface

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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.

x PREFACE

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

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

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

36 In hopes of better understanding biotech decision making, I adopt a
37 cross-national approach to see how different countries deal with biotech-
38 nology. A broad comparison allows researchers to look at decision-making
39 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"

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

3 The globalization of innovation has produced the most massive spurt
4 in biotechnology in world history, yet it raises a host of questions regard-
5 ing its long-term significance. If cross-national partnerships have chal-
6 lenged the primacy of the state in setting biotechnology policy and if inno-
7 vation has undermined the ability of governments to regulate scientific
8 activities, have we created a policy area that is beyond the control of polit-
9 ical leaders? If so, this poses a number of interesting social, political, and
10 ethical issues for scientists, politicians, and the general public.

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

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

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

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

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

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

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

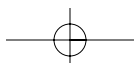
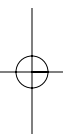
29 Chapter 7 looks at chimeras, which are genetic hybrids that are created
30 across two or more species. Most cross-species fusions are not controver-
31 sial. Indeed, crossbreeding is a centuries-old practice, both in terms of
32 plants and animals. However, when new technologies yield organisms with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

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

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

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

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