

Contents

<i>Series Preface</i>	vii
<i>Preface</i>	ix
<i>Acknowledgments</i>	xiii
<i>Author</i>	xv

SECTION I Bioethics of Biotechnology

1 A Bioethics of Biotechnology	3
Introductory comment	3
The biotechnology of history	6
The nature of science and biotechnology	15
What then is the bioethics of biotechnology?	18
End notes	24

SECTION II Bioethics and Genomics

2 Biotechnology and Bioethics	29
Introductory comment	29
Autonomy	30
Confidentiality and privacy	34
Informed consent	43
Genetic stigmatization and essentialism	50
End notes	57
3 Direct-to-Consumer Genetic Testing	63
An introductory comment	63
DTC genetic tests: Dialectic analysis-implications for personalized medicine	66
Preliminary conclusion	83
End notes	84

SECTION III Regulatory Policy, Law and Biotechnology

4 The Global Regulatory Pathways of Biologics	91
An introductory comment	91
The emergence and development of biologics regulatory pathways in the United States	92
The emergence of biologics regulatory pathways	93

Features of biologics and biotechnology research	95
The prospects of biosimilars	98
The biotechnology landscape in Canada	107
Patent, data, and market exclusivities of biologics	111
Bioethics and some regulatory hurdles	111
End notes	118
5 Biotechnology in the Court of Law	121
Association for molecular pathology versus myriad genetics	121
End notes	130
SECTION IV Gene Modifications and Bioethics	
6 Bioengineering and the Idea of Precision Medicine	135
What is gene editing?	135
Characteristics of gene editing tools	136
Types of gene modification biotechnologies	137
Classifications and applications of gene editing biotechnologies	138
Some ethical quagmires of gene modifications	140
End notes	149
7 Policy, Bioethics, and Bioengineering	153
Precautionary approach	154
Moratoria approach	158
Noninterventionist or proactionary approach	161
End notes	165
8 Some Perspectives and Conclusion	169
End notes	170
Index	171