

TABLE OF CONTENTS

PREFACE TO THE FIFTH EDITION.....	V
ACKNOWLEDGMENTS	VII
PHOTO ACKNOWLEDGMENTS	XV
TABLE OF CASES	XXXIII

PART I. HISTORICAL AND SCIENTIFIC OVERVIEW

Chapter 1. History of Genetic Science	3
Eric S. Lander, Scientific Commentary: The Scientific Foundations and Medical and Social Prospects of the Human Genome Project.....	3
I. Altering DNA.....	5
Paul Berg et al., Letter	7
Notes and Questions	9
II. The Human Genome Project.....	10
National Human Genome Research Institute, NIH, Understanding Our Genetic Inheritance: The U.S. Human Genome Project the First Five Years: Fiscal Years 1991–1995	10
Remarks by the President, Prime Minister Tony Blair of England, Dr. Francis Collins, Director of the National Human Genome Research Institute, & Dr. Craig Venter, President and Chief Officer, Celera Genomics Corporation, on the Completion of the First Survey of the Entire Human Genome Project.....	11
Notes and Questions	14
National Human Genome Research Institute, International HapMap Project Overview.....	16
Notes and Questions	17
Chapter 2. Eugenics.....	19
Allen Buchanan et al., From Chance to Choice: Genetics and Justice.....	19
Philip R. Reilly, Eugenics, Ethics, Sterilization Laws, In 1 Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology.....	20
Buck v. Bell.....	23
Paul A. Lombardo, Three Generations, No Imbeciles: New Light on Buck v. Bell	25
Notes and Questions	29
Skinner v. Oklahoma	35
Notes and Questions	41
Taylor v. Kurapati.....	42
Notes	45
Maxwell J. Mehlman, Modern Eugenics and the Law, in A Century of Eugenics: From the Indiana Experiment to the Human Genome Era ...	47

Notes and Questions	52
Chapter 3. Genetics and Race	55
I. Genetic Basis for Race	55
Osagie K. Obasogie, Playing the Gene Card? A Report on Race and Human Biotechnology	55
Michael J. Malinowski, Dealing With the Realities of Race and Ethnicity: A Bioethics-Centered Argument in Favor of Race- Based Genetics Research	56
II. Sickle Cell Screening.....	58
Lori Andrews et al., Assessing Genetic Risks: Implications for Health and Social Policy	58
Notes and Questions	60
III. Race-Based Drugs	60
Food and Drug Administration, FDA Approves BiDil Heart Failure Drug for Black Patients	60
Rene Bowser, Race as a Proxy for Drug Response: The Dangers and Challenges of Ethnic Drugs	61
Notes and Questions	65
IV. The ELSI Program	67
Chapter 4. New Developments	71
I. Precision Medicine	71
II. More Efficient and Less Costly Gene Editing Techniques	73
III. Human Germline Gene Editing	73
IV. Direct-to-Consumer Genetic Testing	73
V. DNA for Forensic Identification	74
VI. Do-It-Yourself Gene Editing	74
VII. Epigenetics.....	75

PART II. GENETIC SCREENING AND TESTING IN MEDICINE AND RESEARCH

Chapter 5. Genetics Research and the Regulation of Genetic Testing and Marketing	81
I. Genetic Testing Technology.....	81
II. Biobanks and Genetic Research	83
National Bioethics Advisory Commission (NBAC), Research Involving Human Biological Materials: Ethical Issues and Policy Guidance	83
Heather L. Harrell and Mark A. Rothstein, Biobanking Research and Privacy Laws in the United States.....	84
Department of Health and Human Services, Protection of Human Subjects, 45 CFR Part 46, Subpart A: Basic HHS Policy for Protection of Human Subjects Research	93

	Holly Fernandez Lynch, Leslie E. Wolf, and Mark Barnes, Implementing Regulatory Broad Consent Under the Revised Common Rule: Clarifying Key Points and the Need for Evidence	97
	Notes and Questions	100
III.	Government Marketing Regulations for Test Products and Laboratories.....	101
	A. Regulation of Test Products.....	101
	B. Regulation of Laboratories.....	102
	C. Regulation of Direct-to-Consumer Testing	103
	Maxwell J. Mehlman, Direct-to-Consumer Genetic Testing	104
	Note	110
	Chapter 6. Genetic Counseling and Genetic Testing for Susceptibility to Disease.....	111
I.	Genetic Counseling	112
	Anne L. Matthews, Genetic Counseling, in Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology	113
	Notes and Questions	114
II.	Genetic Testing for Susceptibility to Disease.....	116
	Notes and Questions	118
	Tamar Lewin, Boom in Genetic Testing Raises Questions on Sharing Results.....	122
	Notes and Questions	125
III.	Liability Issues	125
	Pate v. Threlkel	125
	Safer v. Pack.....	128
	Notes and Questions	133
	Chapter 7. Genomic Analysis, Cancer Genomics, and Genetic Testing of Children and Adolescents.....	139
I.	Genomic Analysis and Incidental Findings.....	139
	Sonia M. Suter, Genomic Medicine—New Norms Regarding Genetic Information	139
	Presidential Commission for the Study of Bioethical Issues, Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to- Consumer Contexts	140
	ACMG Policy Statement: Updated Recommendations Regarding Analysis and Reporting of Secondary Findings in Clinical Genome-Scale Sequencing	142
	Notes and Questions	144
II.	Cancer Genomics.....	149
	Levi A. Garraway, Genomics Driven Oncology: Framework for an Emerging Paradigm	149
	Bert Vogelstein et al., Cancer Genome Landscapes	150
	Note and Questions	151

III. Genetic Testing of Children and Adolescents.....	152
American Society of Human Genetics, Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents	152
Notes and Questions	157
Chapter 8. Reproductive Genetic Testing.....	159
I. Prenatal Diagnosis and Screening.....	160
Lori B. Andrews, Future Perfect: Confronting Decisions About Genetics.....	160
Ruth M. Farrell, Women and Prenatal Genetic Testing in the 21st Century	162
Notes and Questions	164
II. Preimplantation Genetic Testing.....	170
Notes and Questions	170
III. Liability for Malpractice in Reproductive Testing.....	172
Cailin Harris, Statutory Prohibitions on Wrongful Birth Claims & Their Dangerous Effects on Parents	172
A. Wrongful Birth.....	173
Keel v. Banach.....	173
Notes and Questions	177
B. Wrongful Life.....	182
Curlender v. Bio-Science Laboratories.....	182
Notes and Questions	186
IV. Carrier Testing and Screening.....	187
A. Carrier Testing and Screening Generally.....	187
Notes and Questions	189
B. Assisted Reproductive Technologies and Carrier Screening.....	189
Minimum Genetic Testing for Gamete and Embryo Donors, Approved by the Board of Directors of the American Society for Reproductive Medicine	190
Notes and Questions	192
Chapter 9. Using Reproductive Genetic Technologies for Non- Medical Purposes.....	197
I. Sex and Trait Selection.....	197
Lori B. Andrews, The Clone Age: Adventures in the New World of Reproductive Technology	197
The American Society for Reproductive Medicine's Position on Sex Selection	198
Notes and Questions	201
Sonia M. Suter, The Tyranny of Choice: Reproductive Selection in the Future	202
Notes and Questions	203

II.	Selecting for Disability.....	205
	Kalena R. Kettering, Note, “Is Down Always Out?": The Right of Icelandic Parents to Use Preimplantation Genetic Diagnosis to Select for a Disability	205
	Notes and Questions	207
III.	Conceiving a Sibling to Be a Donor.....	209
	Notes and Questions	210
Chapter 10. Newborn Screening Programs		213
I.	The History and Rationale for Newborn Screening Programs.....	213
	American Academy of Pediatrics, Report of the Task Force on Newborn Screening, Published as a Call for a National Agenda on State Newborn Screening Programs	213
	Sonia M. Suter, Did You Give the Government Your Baby’s DNA? Rethinking Consent in Newborn Screening	215
	Notes and Questions	219
II.	Parental Consent.....	225
	Sonia M. Suter, Did You Give the Government Your Baby’s DNA? Rethinking Consent in Newborn Screening	225
	Ruth R. Faden et al., Parental Rights, Child Welfare, and Public Health: The Case of PKU Screening	226
	Norman Fost, Genetic Diagnosis and Treatment: Ethical Considerations	227
	Notes and Questions	229
	Douglas County v. Anaya	230
	Notes and Questions	235
III.	Research on Newborn Blood Spots.....	236
	Sonia M. Suter, Did You Give the Government Your Baby’s DNA? Rethinking Consent in Newborn Screening	236
	American Academy of Pediatrics, Report of the Task Force on Newborn Screening, Published as a Call for a National Agenda on State Newborn Screening Programs	237
	Notes and Questions	237

PART III. GENE THERAPY

Chapter 11. Regulation of Gene Therapy Research		245
	Department of Health and Human Services, Recombinant DNA Research: Request for Public Comment on “Points to Consider in the Design and Submission of Human Somatic-Cell Gene Therapy Protocols”.....	247
	Notes and Questions	252
	Food and Drug Administration, Statement of Policy for Regulating Biotechnology Products.....	254
	Notes and Questions	260
	U.S. Dept. of Health and Human Services, Office of Protection From Research Risks (OPRR) Protecting Human Research Subjects: Institutional Review Board Guidebook.....	266

Note: State Regulation of Research	270
Larry R. Churchill et al., Genetic Research as Therapy: Implications of “Gene Therapy” for Informed Consent.....	271
Notes and Questions	274
Chapter 12. History of Gene Therapy.....	277
Chapter 13. Germline Therapy.....	285
Christopher Gyngell, Hilaru Bowman-Smart, and Julian Savulescu, Moral Reasons to Edit the Human Genome: Picking Up from the Nuffield Report	290
Genetically Modified Humans? Seven Reasons to Say “No”	299
Notes and Questions	301
Chapter 14. Pharmacogenomics	303
Food and Drug Administration, Guidance for Industry: Pharmacogenomic Data Submissions.....	303
Notes and Questions	308
Mark A. Rothstein & Phyllis Griffin Epps, Ethical and Legal Implications of Pharmacogenomics.....	311
Notes and Questions	318
Chapter 15. Genetic Enhancement	321
Michael Sandel, The Case Against Perfection: What’s Wrong With Designer Children, Bionic Athletes, and Genetic Engineering.....	323
Maxwell J. Mehlman, The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field	326
Notes and Questions	329
PART IV. COMMERCIALIZATION OF GENETIC RESEARCH: PROPERTY, PATENTS, AND CONFLICTS OF INTEREST	
Chapter 16. The Patent System.....	333
I. Requirements for a Patent.....	333
Lori Andrews, The “Progress Clause”: An Empirical Analysis Based on the Constitutional Foundation of Patent Law	333
II. Statutory Authority.....	335
Patent Code	335
III. Policy Arguments Related to Patenting of Genetic Materials	335
Lila Feisee, Are Biotechnology Patents Important? Yes!	335
U.S. Department of Energy Office of Science, Office of Biological and Environmental Research, Human Genome Program.....	336
Notes and Questions	337
IV. Case Law on Patentable Subject Matter	338
Association for Molecular Pathology v. Myriad Genetics, Inc.....	340
Notes and Questions	345

V.	Technology Transfer Laws and Commercialization.....	349
	James V. Lacy et al., Technology Transfer Laws Governing Federally Funded Research and Development.....	349
	Sheldon Krimsky, The Profit of Scientific Discovery and Its Normative Implications	351
	Lori Andrews & Dorothy Nelkin, Body Bazaar: The Market for Human Tissue in the Biotechnology Age	353
	Rebecca Goulding et al., Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research.....	354
	Jacob S. Sherkow & Jorge L. Contreras, Intellectual Property, Surrogate Licensing, and Precision Medicine	356
	Notes and Questions	358

Chapter 17. Patients: The Sources of Genes and Cell Lines 359

	Moore v. Regents of the University of California.....	359
	Greenberg v. Miami Children’s Hospital Research Institute, Inc.	368
	American Medical Association, Council on Ethical and Judicial Affairs, Code of Medical Ethics: Current Opinions With Annotations, 2012– 2013 ed.	374
	Notes and Questions	375

PART V. NON-MEDICAL USES OF GENETICS

Chapter 18. Forensics: DNA Evidence in Criminal Cases 387

I.	The Science of Forensic Testing	388
	The National Commission on the Future of DNA Evidence, the Future of Forensic DNA Testing: Predictions of the Research and Development Working Group.....	389
	Notes and Questions	391
	Emerging Technologies: YSTR, Low Copy Numbers, SNPs, and Massive Parallel Sequencing.....	392
	Notes and Questions	394
II.	The Legal Standards for Admissibility	395
	National Research Council (NRC), The Evaluation of Forensic DNA Evidence	395
III.	Assessing the Reliability of DNA Evidence	396
	Notes and Questions	397
IV.	Obtaining DNA Samples for a Match	403
	Edward Imwinkelried & D. H. Kaye, DNA Typing: Emerging or Neglected Issues	403
	Notes and Questions	406

Chapter 19. Constitutionality of Forensic DNA Databases 413

	Jones v. Murray.....	413
	Maryland v. King	419
	Notes and Questions	423

Chapter 20. Uses of Forensic DNA Databases	429
I. Regulation of DNA Databases	429
Seth Axelrad, Use of Forensic DNA Database Information for Medical or Genetic Research	429
Stephen Mercer & Jessica Gabel, Shadow Dwellers: The Underregulated World of State and Local DNA Databases	430
Notes and Questions	433
II. DNA Familial Searches	438
Sonia M. Suter, All in the Family: Privacy and DNA Familial Searching	438
Erin Murphy, Law and Policy Oversight of Familial Searches in Recreational Genealogy Databases	439
Notes and Questions	443
Chapter 21. Post-Conviction DNA Testing	449
Seth Axelrad & Juliana Russo, Survey of Post-Conviction DNA Testing Statutes	449
Notes and Questions	451
Chapter 22. Mental and Behavioral Genetics in Criminal Law	455
Troy Duster, Behavioral Genetics and Explanations of the Link Between Crime, Violence, and Race in Wrestling With Behavioral Genetics: Science, Ethics, and Public Conversation	455
Mark A. Rothstein, Applications of Behavioural Genetics: Outpacing the Science?	456
Lori B. Andrews, Predicting and Punishing Antisocial Acts: How the Criminal Justice System Might Use Behavioral Genetics, in Behavioral Genetics: The Clash of Culture and Biology	458
Stephen J. Morse, Genetics and Criminal Responsibility	460
Millard v. Maryland	461
Notes and Questions	464
Chapter 23. Environmental and Occupational Regulation and Personal Injury Cases	469
I. Introduction	469
II. Regulation	470
A. Environmental	470
National Research Council, Applications of Toxicogenomic Technologies to Predictive Toxicology and Risk Assessment	470
Gary E. Marchant, Toxicogenomics and Environmental Regulation, in Genomics and Environmental Regulation: Science, Ethics, and Law	472
Notes and Questions	474
Mark A. Rothstein, Yu Cai & Gary E. Marchant, Ethical Implications of Epigenetics Research	475
Notes and Questions	476

B.	Occupational	477
	Mark A. Rothstein, Occupational Health and Discrimination Issues Raised by Toxicogenomics in the Workplace in Genomics and Environmental Regulation: Science, Ethics, and Law	477
	Notes and Questions	479
	Mark A. Rothstein, Genetics and the Work Force of the Next Hundred Years.....	480
	Notes and Questions	481
	Genetic Testing for Susceptibility to Carpal Tunnel Syndrome ...	481
III.	Litigation	483
A.	Injury.....	484
	Bryson v. Pillsbury Co.....	484
	Notes and Questions	487
B.	Causation	488
	Wintz v. Northrop Corp.....	488
	Notes and Questions	491
C.	Damages.....	492
	Mark A. Rothstein, Preventing the Discovery of Plaintiff Genetic Profiles by Defendants Seeking to Limit Damages in Personal Injury Litigation.....	492
	Notes and Questions	493

PART VI. PRIVACY AND CONFIDENTIALITY

	Ellen Wright Clayton et al., The law of genetic privacy: applications, implications, and limitations	495
	Notes and Questions	496
	Chapter 24. Genetic Privacy and Confidentiality	499
I.	Healthcare	499
	Amy L. McGuire et al., Confidentiality, Privacy, and Security of Genetic and Genomic Test Information in Electronic Health Records: Points to Consider	499
	Notes and Questions	500
II.	Compelled Disclosures	501
	Mark A. Rothstein & Meghan K. Talbott, Compelled Disclosures of Health Records: Updated Estimates	501
	Chapter 25. Legal Protections for Medical and Genetic Privacy	503
I.	Constitutional Law.....	503
	NASA v. Nelson	503
	Notes and Questions	507
II.	Legislation	509
A.	State Legislation.....	509
	New Mexico Genetic Information Privacy Act.....	509
	Notes and Questions	511

B.	Federal Legislation.....	512
	Health Insurance Portability and Accountability Act (HIPAA)	512
	Office for Civil Rights, Department of Health and Human Services, Summary of the HIPAA Privacy Rule	512
III.	Common Law	516
	Mark A. Rothstein, Genetic Stalking and Voyeurism: A New Challenge to Privacy	516
	Notes and Questions	518
IV.	Data Privacy Legislation	518
	Mark A. Rothstein & Stacey A. Tovino, California Takes the Lead on Data Privacy	518
	Notes and Questions	520

PART VII. INSURANCE

Chapter 26. Health Insurance	523	
I.	Background.....	523
II.	State Laws	524
	Kan. Stat. Ann. § 40–2259.....	525
	Notes and Questions	526
III.	Federal Laws	526
	Health Insurance Portability and Accountability Act	526
	Notes	528
	Genetic Information Nondiscrimination Act (GINA).....	529
	Mark A. Rothstein, GINA At Ten and The Future of Genetic Nondiscrimination Law.....	531
	Affordable Care Act of 2010.....	532
	Notes and Questions	536
Chapter 27. Life Insurance.....	537	
	Mark A. Rothstein, Time to End the Use of Genetic Test Results in Life Insurance Underwriting	537
	Vermont. Stat. Ann. Tit. 18, Ch. 217	538
	Notes and Questions	540
	Chabner v. United of Omaha Life Insurance Co.....	541
	Notes and Questions	547
Chapter 28. Disability Insurance.....	549	
	Susan M. Wolf & Jeffrey P. Kahn, Genetic Testing and the Future of Disability Insurance: Ethics, Law, and Policy	550
	Notes and Questions	551
Chapter 29. Long-Term Care Insurance	553	
	Mark A. Rothstein, Predictive Genetic Testing for Alzheimer’s Disease in Long-Term Care Insurance.....	553
	Cathleen D. Zick et al., Genetic Testing for Alzheimer’s Disease and Its Impact on Insurance Purchasing Behavior	555

Notes and Questions	557
---------------------------	-----

PART VIII. EMPLOYMENT DISCRIMINATION

Chapter 30. Introduction	561
I. What Is Genetic Discrimination?	563
Mark A. Rothstein & Mary R. Anderlik, What Is Genetic Discrimination and When and How Can It Be Prevented?	563
Notes and Questions	565
II. Employer Access to Genetic Information.....	566
Note on Employer Access to Employee Health Information	566
Chapter 31. Genetic Discrimination Under the Americans with Disabilities Act (ADA).....	569
I. Coverage.....	569
II. Medical Examinations	570
Americans With Disabilities Act	570
Notes and Questions	572
Other Laws Applicable to Genetic Discrimination in Employment.....	573
Chapter 32. Genetic Nondiscrimination Laws	575
I. State Laws	575
II. Federal Laws	575
Overview of the Genetic Information Nondiscrimination Act of 2008 (GINA)	575
Genetic Information Nondiscrimination Act of 2008 (GINA).....	576
Jessica L. Roberts, Preempting Discrimination: Lessons From the Genetic Information Nondiscrimination Act	582
Notes and Questions	583
Mark A. Rothstein, GINA, The ADA, and Genetic Discrimination in Employment.....	583
Notes and Questions	585
Lowe v. Atlas Logistics Group Retail Services (Atlanta), LLC	585
Notes and Questions	590
Mark A. Rothstein, GINA at Ten and The Future of Genetic Nondiscrimination Law.....	591
INDEX.....	593