Bioethics and Law in a Nutshell

Robert Schwartz
University of New Mexico - School of Law, schwartz@law.unm.edu

Sandra H. Johnson

Follow this and additional works at: https://digitalrepository.unm.edu/law_facbookdisplay

Part of the Law Commons

Recommended Citation
WEST’S LAW SCHOOL ADVISORY BOARD

JESSE H. CHOPER
Professor of Law and Dean Emeritus,
University of California, Berkeley

JOSHUA DRESSLER
Professor of Law, Michael E. Moritz College of Law,
The Ohio State University

YALE KAMISAR
Professor of Law, University of San Diego
Professor of Law Emeritus, University of Michigan

MARY KAY KANE
Professor of Law, Chancellor and Dean Emeritus,
University of California,
Hastings College of the Law

LARRY D. KRAMER
Dean and Professor of Law, Stanford Law School

JONATHAN R. MACEY
Professor of Law, Yale Law School

ARTHUR R. MILLER
University Professor, New York University
Professor of Law Emeritus, Harvard University

GRANT S. NELSON
Professor of Law, Pepperdine University
Professor of Law Emeritus, University of California, Los Angeles

A. BENJAMIN SPENCER
Associate Professor of Law,
Washington & Lee University School of Law

JAMES J. WHITE
Professor of Law, University of Michigan

BIOETHICS AND LAW IN A NUTSHELL

By

SANDRA H. JOHNSON
Professor Emerita of Law and Health Care Ethics
Saint Louis University School of Law

ROBERT L. SCHWARTZ
Henry Weihofen Professor of Law
and Professor of Pediatrics
University of New Mexico School of Law

WEST®
A Thomson Reuters business
To the memory of those of our parents who have completed their life journeys, Mary and Clarence (“Tacky”) Hanneken and Jerome Schwartz S.H.J. and R.L.S.

Thomson Reuters created this publication to provide you with accurate and authoritative information concerning the subject matter covered. However, this publication was not necessarily prepared by persons licensed to practice law in a particular jurisdiction. Thomson Reuters does not render legal or other professional advice, and this publication is not a substitute for the advice of an attorney. If you require legal or other expert advice, you should seek the services of a competent attorney or other professional.

Nutshell Series, In a Nutshell and the Nutshell Logo are trademarks registered in the U.S. Patent and Trademark Office.

© 2009 Thomson Reuters
610 Opperman Drive
St. Paul, MN 55123
1-800-313-9378
Printed in the United States of America
PREFACE

For more than twenty years, we have been co-authors, with Barry Furrow, Tim Greaney, and Tim Jost, of Health Law: Cases, Materials and Problems, which is now in its Sixth Edition. The Health Law casebook has always included substantial coverage of bioethics issues, and the bioethics chapters have also been published, with additional material, as Bioethics: Health Care Law and Ethics. As those familiar with the casebooks will recognize, a few parts of this Nutshell are taken directly from one or the other of those casebooks. This Nutshell grows out of our experiences in writing these casebooks and in teaching our students over the years.

Our aim in this Nutshell is to provide students with a brief and accessible introductory overview of the central legal issues in bioethics. This volume is not meant to be, and is not, comprehensive. Our readers certainly will be able to list issues that we have not included.

Our concern is to provide a foundation for legal analysis of the most durable bioethics issues that have consistently found themselves at the center of the public debate over the last quarter of a century,
PREFACE

not to address all of the issues that have made an appearance in that debate. Our focus is on the legal issues, and these materials primarily address issues that have found their way into the courts, legislatures, and administrative agencies in the United States. We have included only a brief chapter to provide a precis of the more influential ethical theories at play in bioethics discussions. This Nutshell provides the overview—the forest, if you will; you will have to go elsewhere to study the individual trees in more detail.

We have enjoyed writing this book, but mostly we have enjoyed collaborating for more than two decades now. One of the things we enjoy is that we do not agree with each other on several quite significant issues, and you may even notice this tension in the text. We have tried to be evenhanded, and we hope that we have explained how reasonable people can hold very different views on the propriety of applying law to almost every issue in bioethics.

As always, we are grateful to the students who assisted us in the preparation of this text: Cara Jackson and Kathryn Krieger of Saint Louis University School of Law and Katey Cortese of University of California, Hastings College of the Law. We are grateful as well to the decades of students who have made us think and express ourselves more clearly. We also thank our deans, Jeffrey Lewis and Kevin Washburn for their continuing support. Finally, we thank our families, far and wide, for their constant love.

September 2009

SANDRA H. JOHNSON
ROBERT L. SCHWARTZ
Chapter 1. Introduction to Ethics

I. Ethical Theories
   A. Utilitarianism
   B. Deontological Theories
      1. Kantianism
      2. Natural Law

II. Applied Ethics
    A. Principlism
    B. Feminist Bioethics
    C. Critical Race Theory and Bioethics
    D. Religious Perspectives in Bioethics
    E. Virtue Ethics
    F. Methodological Approaches
       1. Casuistry
       2. Pragmatism
       3. Narrative Bioethics

III. Distributive Justice

IV. The Relationship of Law and Ethics
    A. Generally
    B. Conflicts of Conscience and Law
# OUTLINE

## Chapter 2. Human Reproduction

<table>
<thead>
<tr>
<th>Outline</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Defining a Human Being—Ethics and Law</td>
<td>23</td>
</tr>
<tr>
<td>A. Introduction</td>
<td>23</td>
</tr>
<tr>
<td>B. Legal Recognition of Human Life</td>
<td>26</td>
</tr>
<tr>
<td>II. Abortion</td>
<td>29</td>
</tr>
<tr>
<td>A. Introduction</td>
<td>29</td>
</tr>
<tr>
<td>B. Roe v. Wade</td>
<td>31</td>
</tr>
<tr>
<td>C. Planned Parenthood of Southeastern Pennsylvania v. Casey</td>
<td>34</td>
</tr>
<tr>
<td>D. Gonzales v. Carhart</td>
<td>37</td>
</tr>
<tr>
<td>E. The Future of Abortion</td>
<td>39</td>
</tr>
<tr>
<td>III. Potential Fetal–Maternal Conflict</td>
<td>41</td>
</tr>
<tr>
<td>IV. Assisted Reproductive Technologies (ART) and Their Legal Consequences</td>
<td>49</td>
</tr>
<tr>
<td>A. Introduction: The Process of Reproduction</td>
<td>49</td>
</tr>
<tr>
<td>B. The Legal Questions</td>
<td>53</td>
</tr>
<tr>
<td>1. Artificial Insemination, In Vitro Fertilization, and the Question of Parentage</td>
<td>55</td>
</tr>
<tr>
<td>2. The Question of the Status of “Extra” Fertilized Ova</td>
<td>63</td>
</tr>
<tr>
<td>3. Surrogacy</td>
<td>67</td>
</tr>
<tr>
<td>4. ART and the Law of Marriage</td>
<td>75</td>
</tr>
<tr>
<td>C. Cloning</td>
<td>77</td>
</tr>
</tbody>
</table>

## Chapter 3. Genetics

<table>
<thead>
<tr>
<th>Outline</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Introduction</td>
<td>82</td>
</tr>
<tr>
<td>A. The Nature of Genetic Information</td>
<td>82</td>
</tr>
<tr>
<td>B. Legal History of Genetics</td>
<td>85</td>
</tr>
<tr>
<td>II. Definitional Issues</td>
<td>86</td>
</tr>
<tr>
<td>A. Genetics and Illness</td>
<td>86</td>
</tr>
<tr>
<td>B. Statutory Definitions of Genetic Information</td>
<td>88</td>
</tr>
<tr>
<td>III. Legal Claims Relating to Confidentiality, Privacy, and Discrimination</td>
<td>89</td>
</tr>
<tr>
<td>A. Confidentiality and Privacy</td>
<td>89</td>
</tr>
<tr>
<td>1. Confidentiality</td>
<td>89</td>
</tr>
<tr>
<td>2. Privacy</td>
<td>91</td>
</tr>
<tr>
<td>B. Discrimination</td>
<td>92</td>
</tr>
<tr>
<td>1. Discrimination in Insurance</td>
<td>92</td>
</tr>
<tr>
<td>2. Discrimination in Employment</td>
<td>93</td>
</tr>
<tr>
<td>IV. Mandatory Newborn Genetic Screening</td>
<td>94</td>
</tr>
<tr>
<td>A. Background</td>
<td>94</td>
</tr>
<tr>
<td>B. State Authority</td>
<td>95</td>
</tr>
<tr>
<td>C. Parental Consent</td>
<td>96</td>
</tr>
<tr>
<td>D. Benefits and Risks</td>
<td>96</td>
</tr>
<tr>
<td>E. Retention of Samples</td>
<td>97</td>
</tr>
<tr>
<td>V. Genetic Research</td>
<td>98</td>
</tr>
<tr>
<td>A. Biobanks</td>
<td>98</td>
</tr>
<tr>
<td>1. Consent</td>
<td>98</td>
</tr>
<tr>
<td>2. Risk–Benefit Analysis</td>
<td>99</td>
</tr>
<tr>
<td>3. Property Claims</td>
<td>100</td>
</tr>
<tr>
<td>B. Clinical Genetic Research</td>
<td>101</td>
</tr>
</tbody>
</table>

## Chapter 4. Legal Standards for the Determination of Death

<table>
<thead>
<tr>
<th>Outline</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Introduction</td>
<td>103</td>
</tr>
<tr>
<td>II. Current Legal Standards</td>
<td>104</td>
</tr>
<tr>
<td>A. Irreversible Cessation of Cardiopulmonary Function</td>
<td>105</td>
</tr>
<tr>
<td>B. Functions of the Entire Brain</td>
<td>106</td>
</tr>
<tr>
<td>C. Accommodation of Individual Beliefs</td>
<td>107</td>
</tr>
</tbody>
</table>
Chapter 5. Decisions Regarding Life-Sustaining Treatment

I. The U.S. Constitution and the “Right to Die”: The Cruzan Case

II. Competent Patients
   A. The General Rule: The Patient Decides
   B. Countervailing State Interests
      1. Preservation of Life
      2. Protection of Innocent Third Parties
      3. Prevention of Suicide
      4. Maintenance of the Ethical Integrity of the Medical Profession
      5. Special Circumstances
   III. Determining Competency
      A. Generally
      B. President's Commission Standards
   IV. Incompetent Patients
      A. Introduction and General Principles: Substituted Judgment and Best Interests
      B. Advance Directives and Family Consent Laws
         1. The Rise of Living Wills

Chapter 6. Physician-Assisted Death

I. Introduction—and a Word on Terminology

II. Constitutional Background

III. State Legislative Developments and the Public Debate

IV. The International Debate

Chapter 7. Organ Transplantation

I. Introduction

II. The Supply of Human Organs for Transplantation
   A. The Uniform Anatomical Gift Act (UAGA)
OUTLINE

II. The Supply of Human Organs for Transplantation—Continued
   1. Structure of the UAGA .................................. 194
   2. Pre-mortem Document of Gift .............................. 195
   3. Post-mortem Donation ...................................... 196
   4. Immunity .................................................. 196
   5. Designated Donation ....................................... 197
B. Presumed Consent ............................................. 198
   1. Statutory Provisions ....................................... 198
   2. Constitutional Challenges to Presumed Consent ......... 199
C. Payment for Organs ........................................... 200
   1. Statutory Restrictions ..................................... 200
   2. Proposals to Allow Payments for Organs ................ 201
D. Living Donors ................................................ 203
   1. Competent Donors ......................................... 203
   2. Incompetent Donors ....................................... 204
E. Determination of Death ....................................... 204
III. Distribution of Organs for Transplantation ................. 205
   A. Federal Law on Organ Distribution and UNOS .......... 206
   B. Listing Patients .......................................... 207
   C. Geographic Distribution of Organs ...................... 208
   D. Organ Matching ........................................... 209
   E. Designated Donees ......................................... 210
      1. Campaigning for Organs ................................. 210
      2. Paired Donations ....................................... 211
      3. LifeSharers .............................................. 211

Chapter 8. Regulation of Research With Human Subjects ....... 213

I. Introduction .................................................. 213
II. Sources of Legal Standards Governing Research .......... 216
   A. State Legislation ......................................... 216
   B. Common Law ................................................ 217
   C. Private Organizations .................................... 218
   D. International Standards .................................. 219
III. The Federal Regulations ..................................... 220
   A. The Common Rule .......................................... 220
   B. Coverage .................................................. 220
      1. Covered Entities ........................................ 220
      2. Definition of Research ................................ 221
         a. Clinical Innovation .................................. 222
         b. Quality Improvement Studies ....................... 223
      3. Human Subjects ......................................... 224
         a. Definition ............................................ 224
         b. Human Tissue and Medical Records ............... 224
   C. Institutional Review Boards ................................ 225
      1. IRB Composition ........................................ 225
      2. IRB Duties and Authority .............................. 226
   D. Governmental Oversight ................................... 227
IV. Substantive Federal Standards ............................... 228
   A. Risk and Safety .......................................... 229
   B. Consent ................................................... 230
      1. Coercion and Undue Influence ......................... 231
      2. No Consent and Proxy Consent ......................... 233
   C. Selection of Subjects .................................... 234
      1. Children ............................................... 234
      2. Mentally Incapacitated Adults ....................... 238
      3. Prisoners .............................................. 239
OUTLINE

V. Commercial Interests in Research 240
   A. Industry Sponsorship of Research 242
      1. Industry Payment Practices in Research 243
      2. Industry Research, Marketing, and Phase IV Trials 244
   B. Ownership of the Results of Research 245
      1. Researcher Ownership Interests 245
      2. Research Subjects' Claims of Ownership Interests 247
   C. Regulation of Financial Interests of Researchers 249

VI. International Research 250

VII. Stem Cell Research 253
   A. Mechanisms 253
   B. Social and Ethical Issues 255
   C. Legal Issues 256
   D. Federal Funding of Stem Cell Research 258
   E. State Regulation 259

INDEX 261

TABLE OF CASES

References are to Pages

Abdullahi v. Pfizer, Inc., 562 F.3d 163 (2nd Cir.2009), 252
Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695 (D.C.Cir.2007), 231

Buck v. Bell, 274 U.S. 200, 47 S.Ct. 584, 71 L.Ed. 1000 (1927), 85
Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990), 114

Douglas County v. Anaya, 269 Neb. 552, 694 N.W.2d 601 (Neb. 2005), 96

Grimes v. Kennedy-Krieger Institute, Inc., 366 Md. 29, 782 A.2d 807 (Md.2001), 217

Guardianship of (see name of party)

In re (see name of party)

Katskee v. Blue Cross/Blue Shield of Nebraska, 245 Neb. 808, 515 N.W.2d 645 (Neb.1994), 87
<table>
<thead>
<tr>
<th>Case</th>
<th>Volume, Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lawrence v. Texas</td>
<td>539 U.S. 558, 123 S.Ct. 2472, 156 L.Ed.2d 508 (2003), 33</td>
</tr>
<tr>
<td>Miller v. HCA, Inc.</td>
<td>118 S.W.3d 758 (Tex.2003), 165</td>
</tr>
<tr>
<td>Moore v. Regents of University of California</td>
<td>271 Cal.Rptr. 146, 793 P.2d 479 (Cal.1990), 247</td>
</tr>
<tr>
<td>Newman v. Sathyavaglswaran</td>
<td>287 F.3d 786 (9th Cir.2002), 199</td>
</tr>
<tr>
<td>Norman-Bloodsaw v. Lawrence Berkeley Laboratory</td>
<td>135 F.3d 1260 (9th Cir.1998), 94</td>
</tr>
<tr>
<td>Pate v. Threlkel</td>
<td>661 So.2d 278 (Fla.1995), 90</td>
</tr>
<tr>
<td>Planned Parenthood of Southeastern Pennsylvania v. Casey</td>
<td>505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992), 30</td>
</tr>
<tr>
<td>Roe v. Wade</td>
<td>410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), 29</td>
</tr>
<tr>
<td>Schiavo, In re Guardianship of</td>
<td>916 So.2d 814 (Fla.App. 2 Dist. 2005), 146</td>
</tr>
<tr>
<td>Schloendorff v. Society of New York Hospital</td>
<td>211 N.Y. 125, 105 N.E. 92 (N.Y.1914), 118</td>
</tr>
<tr>
<td>T.A.C.P., In re</td>
<td>609 So.2d 588 (Fla.1992), 112</td>
</tr>
<tr>
<td>Washington University v. Catalona</td>
<td>490 F.3d 667 (8th Cir.2007), 248</td>
</tr>
</tbody>
</table>