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# THE VISIBLE BRAIN: CONFIDENTIALITY AND PRIVACY IMPLICATIONS OF FUNCTIONAL MAGNETIC RESONANCE IMAGING

by Stacey A. Tovino, J.D.

Dissertation
Presented to the Faculty of The University of Texas Graduate School of
Biomedical Sciences at Galveston
in Partial Fulfillment of the Requirements
for the Degree of

Doctor of Philosophy

Approved by the Supervisory Committee

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May 2006 Galveston, Texas

Key words: neuroethics, neuro exceptionalism, law

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# THE VISIBLE BRAIN: CONFIDENTIALITY AND PRIVACY IMPLICATIONS OF FUNCTIONAL MAGNETIC RESONANCE IMAGING

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To
Eric, for everything, and
Dr. Winslade, for being a model scholar, teacher, and mentor

# THE VISIBLE BRAIN: CONFIDENTIALITY AND PRIVACY IMPLICATIONS OF FUNCTIONAL MAGNETIC RESONANCE IMAGING

| Publication | No. |
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Stacey A. Tovino, J.D., Ph.D.
The University of Texas Graduate School of Biomedical Sciences at Galveston, 2006

Supervisor: William J. Winslade

Functional magnetic resonance imaging (fMRI) has built on a number of technologies, including electroencephalography, magnetoencephalography, positron emission tomography, and single-photon emission computed tomography, to become one of the decade's most powerful tools for mapping sensory, motor, and cognitive function. Scientists also are using fMRI to study the neural correlates of a range of conditions, characteristics, and social behaviors, including severe brain injury, major depression, schizophrenia, dyslexia, cocaine addiction, compulsive gambling, pedophilia, racial evaluation, deception, cooperation, altruism, and even sexual preferences. Poised to move outside the research context, fMRI and its ability to detect correlations between brain activations and sensitive and potentially stigmatizing conditions and behaviors raise a number of confidentiality and privacy issues.

My analysis of these issues begins with the history of the localization of brain function, including phrenology. This nineteenth-century pseudoscience was believed to be capable of revealing character information, including information that individuals may have preferred to keep private. The ability of x-ray, computed tomography, and structural magnetic resonance imaging to peer inside the body intensified privacy concerns, especially as the forensic value of these technologies became known. Today, the media, bioethicists, and other stakeholders are speculating that fMRI may have value in the clinical, employment, insurance, education, evidentiary, criminal justice, and other private and government contexts.

I respond to these reports by examining the confidentiality and privacy issues raised by fMRI under ancient and modern codes of medical and research ethics; federal and state health information confidentiality laws and regulations; federal regulations governing human subjects research; the First, Fourth, and Fifth Amendments to the United States Constitution; the federal Americans with Disabilities Act; the federal Employee Polygraph Protection Act; federal and state rules of evidence; and other applicable ethical and legal authorities. My thesis is that existing ethical and legal authorities create a general framework upon which functional neuroimaging-specific principles and legislation can be built. In the absence of political support for my "neuro exceptional" proposals, physicians, scientists, and others who create, use, and disclose

| neuroimaging information can establish and adhere to internal policies and procedures that will minimize confidentiality and privacy concerns. |
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# LIST OF ABBREVIATIONS

AAA American Anthropological Association

ACR American College of Radiology
ACLU American Civil Liberties Union
ADA Americans with Disabilities Act
AMA American Medical Association
ANZ Australian and New Zealand

APA American Psychological Association
BOLD Blood-oxygenation-level dependent
CAT Computerized axial tomography

CCLE Center for Cognitive Liberty and Ethics

CIA Central Intelligence Agency

CIOMS Council for International Organizations of Medical Sciences

CMS Centers for Medicare and Medicaid Services

CT Computed tomography

DARPA Defense Advanced Research Projects Agency

EEG Electroencephalography

EEOC Equal Employment Opportunity Commission
EMBO European Molecular Biology Organization

EPPA Employee Polygraph Protection Act
FAA Federal Aviation Administration
FDA Food and Drug Administration

FERPA Family Educational Rights and Privacy Act fMRI Functional magnetic resonance imaging

fMRIDC fMRI Data Center

HEW Department of Health, Education, and Welfare HHS Department of Health and Human Services

HIPAA The Health Insurance Portability and Accountability Act of 1996

IRB Institutional review board
MEG Magnetoencephalography
MCS Minimally conscious state
MRI Magnetic resonance imaging

NBAC National Bioethics Advisory Commission

NIH National Institutes of Health OCR Office for Civil Rights

OHRP Office for Human Research Protections

PET Positron emission tomography
PHI Protected health information
PVS Persistent vegetative state

SPECT Single-photon emission computed tomography

# LIST OF LEGAL ABBREVIATIONS

Legal references that are located in the footnotes and bibliography are cited in accordance with the *Chicago Manual of Style*, 15<sup>th</sup> ed. (Chicago: University of Chicago Press, 2005), and the *Bluebook: A Uniform System of Citation*, 18<sup>th</sup> ed. (Boston: Harvard Law Review, 2005). Legal sources may be located in hard copy at any law library, or electronically through the Westlaw or LexisNexis databases to which most libraries have access. To obtain electronic access to a legal source such as "*Palko v. Connecticut*, 302 U.S. 319 (1937)," simply insert the numeric portion of the citation without the year (302 U.S. 319) into the "Find" feature of Westlaw or the "Get a Case" feature of LexisNexis. Abbreviations used in legal references have the following meanings:

Ala. Alabama

Ala. Crim. App. Alabama Court of Criminal Appeals

Amend. Amendment
Ariz. Arizona
Art. Article

A.2d Atlantic Reporter, Second Series

Cal. California

C.F.R. Code of Federal Regulations

Co. Company
Comm. Commission
Cong. Congress
Const. Constitution

Ct. Court

D.C. Cir. United States Court of Appeals for the District of Columbia

Dist. District Educ. Education

F. Federal Reporter

Fla. Florida

F. Supp. Federal Supplement

F. Supp.2d Federal Supplement, Second Series F.2d Federal Reporter, Second Series F.3d Federal Reporter, Third Series

Hosp. Hospital
Ind. Indiana
Ins. Insurance
J. Justice
Kan. Kansas
Mich. Michigan
Mont. Montana

NAACP National Association for the Advancement of Colored People

N.E. Northeastern Reporter

N.E.2d Northeastern Reporter, Second Series

N.M. New Mexico

N.W. Northwestern Reporter

Occ. Occupations

Pub. L. No. Public Law Number

P.2d Pacific Reporter, Second Series

S. Senate Bill S.C. South Carolina

S.C. Ct. App. South Carolina Court of Appeals

Sch. School

S.E. Southeastern Reporter

S.E.2d Southeastern Reporter, Second Series

Sess. Session

So.2d Southern Reporter, Second Series Stat. United States Statutes at Large

Tex. Texas

U.S. United States Reports
U.S.C. United States Code
Va. Cir. Virginia Circuit
Wash. Washington
WL Westlaw

2<sup>nd</sup> Cir.
 3<sup>rd</sup> Cir.
 4<sup>th</sup> Cir.
 5<sup>th</sup> Cir.
 9<sup>th</sup> Cir.
 United States Court of Appeals for the Third Circuit
 United States Court of Appeals for the Fourth Circuit
 United States Court of Appeals for the Fifth Circuit
 United States Court of Appeals for the Ninth Circuit

# INTRODUCTION

The field of neuroethics has been described as an amalgamation of two branches of inquiry: the neuroscience of ethics and the ethics of neuroscience.<sup>1</sup> The neuroscience of ethics may be described as a scientific approach to understanding ethical behavior.<sup>2</sup> The ethics of neuroscience is concerned with the ethical principles that should guide brain research and the treatment of neurological disease, as well as the effects that advances in neuroscience have on our social, moral, and philosophical views.<sup>3</sup> This dissertation is a contribution to the ethics (and law) of neuroscience.

No longer new<sup>4</sup> or emerging, the "burgeoning"<sup>5</sup> field of neuroethics has an expanding literature that includes several edited collections,<sup>6</sup> journal symposia,<sup>7</sup> standalone texts,<sup>8</sup> and hundreds of journal and news articles. Based on topics as varied as neurodegenerative disease, functional neuroimaging, incidental neuroimaging findings,

<sup>&</sup>lt;sup>1</sup> Adina Roskies, "A Case Study of Neuroethics: The Nature of Moral Judgment," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 18.

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Arthur L. Caplan, foreword to *Neuroethics: Defining the Issues in Theory, Practice, and Policy* (Oxford: Oxford University Press, 2006), vii.

<sup>&</sup>lt;sup>5</sup> Colin Blakemore, foreword to *Neuroethics: Defining the Issues in Theory, Practice, and Policy* (Oxford: Oxford University Press, 2006), v.

<sup>&</sup>lt;sup>6</sup> See, e.g., Judy Illes, ed., Neuroethics: Defining the Issues in Theory, Practice, and Policy (Oxford: Oxford University Press, 2006); Brent Garland, ed., Neuroscience and the Law: Brain, Mind, and the Scales of Justice (New York: Dana Press, 2004); Steven J. Marcus, ed., Neuroethics: Mapping the Field (New York: Dana Press, 2002).

<sup>&</sup>lt;sup>7</sup> See, e.g., Journal of Medical Ethics 32, no. 2 (February 1, 2006): 63-113; American Journal of Bioethics 5, no 2. (March-April 2005): 1-63; Brain and Cognition 50, no. 3 (December 2002): 341-519.

<sup>&</sup>lt;sup>8</sup> See, e.g., Laurence Tancredi, Hardwired Behavior: What Neuroscience Reveals about Morality (New York: Cambridge University Press, 2005); Michael S. Gazzaniga, The Ethical Brain (New York: Dana Press, 2005); Steven Rose, The Future of the Brain: The Promise and Perils of Tomorrow's Neuroscience (Oxford: Oxford University Press, 2005); Dai Rees and Steven Rose, The New Brain Sciences: Perils and Prospects (Cambridge: Cambridge University Press, 2004).

transcranial magnetic stimulation, functional neurosurgical interventions, and cognitive enhancement, neuroethics has developed alongside its neuroeconomics<sup>9</sup> and neuropolitics<sup>10</sup> counterparts, and is followed by triple-disciplinary fields such as law and neuroeconomics.<sup>11</sup> Here, I am focusing on one small part of the field of neuroethics: the confidentiality and privacy implications of advances in functional magnetic resonance imaging (fMRI).

Now in its second decade, fMRI identifies localized changes in blood oxygenation that occur in the brain when a patient or research subject performs a mental task. Scientists use fMRI not only to map sensory, motor, and cognitive function, but also to study the neural correlates of a number of conditions, behaviors, and characteristics, including depression, schizophrenia, cocaine addiction, compulsive gambling, pedophilia, racial evaluation, deception, and even sexual preferences. Poised to move outside the research context, fMRI and its ability to detect correlations between brain activation and sensitive and potentially stigmatizing conditions and behaviors raise a number of confidentiality and privacy issues.

The neuroethics literature seems to have been calling for an in-depth analysis of these issues. *Science* editor Donald Kennedy suggested in 2002 that fMRI could

<sup>&</sup>lt;sup>9</sup> Colin Camerer, George Loewenstein, and Drazen Prelec, "Neuroeconomics: How Neuroscience Can Inform Economics," *Journal of Economic Literature* 43, no. 1 (March 2005): 9-64; Colin F. Camerer, George Loewenstein, and Drazen Prelec, "Neuroeconomics: Why Economics Needs Brains," *Scandinavian Journal of Economics* 106, no. 3 (2004): 555-79; Colin F. Camerer, "Strategizing in the Brain," *Science* 300, no. 5626 (June 2003): 1673-75; Kevin McCabe, "Neuroeconomics," in *Encyclopedia of Cognitive Science*, ed. Lynn Nadel (New York: Macmillan Publishing, 2003), 294-98; Kevin McCabe, Daniel Houser, Lee Ryan, Vernon Smith, and Theodore Trouard, "A Functional Imaging Study of Cooperation in Two-Person Reciprocal Exchange," *Proceedings of the National Academy of Sciences* 98, no. 20 (September 25, 2001): 11832-35.

<sup>&</sup>lt;sup>10</sup> William E. Connolly, *Neuropolitics: Thinking, Culture, Speed* (Minneapolis: University of Minnesota Press, 2002); Timothy Leary, *Neuropolitics: The Sociobiology of Human Metamorphosis* (Los Angeles: Starseed/Peace Press, 1977).

<sup>11</sup> Terrence Chorvat, Kevin McCabe, and Vernon Smith, "Law and Neuroeconomics," Supreme Court Economic Review 13 (Spring 2005): 35-62.

jeopardize confidentiality and privacy. 12 Judy Illes, Director of the Program in Neuroethics at the Stanford Center for Biomedical Ethics, requested consideration of the need for additional confidentiality and privacy protections for thought processes in 2003: "Just as the regulations of the new . . . Health Insurance Portability and Accountability Act extend The Belmont Report principles and guidelines for the protection of human participants in research, what will protect the quantitation of human thought in 2010? 13 University of Pennsylvania psychologist Martha Farah expressed similar concerns in 2004: "Our sense of the privacy and confidentiality of our own thought processes may also be threatened by technologies that can reveal neural correlates of our innermost thoughts." 14 In 2005, Harvard criminal law scholar William Stuntz stated his belief that, "brain scanning will put tremendous pressure on the court's understanding of privacy." 15 José van Dijck, Professor of Media and Culture at the University of Amsterdam, inquires more generally, "How does the camera push the limits of privacy...?" 16

Only a handful of publications explore the confidentiality and privacy issues raised by fMRI in any detail. In a 2002 article published in *Brain and Cognition*, attorney Jennifer Kulynych reviewed the federal protection of human subjects regulations as well as an early version of the federal privacy regulations to identify some of the legal

<sup>12 &</sup>quot;The Ethics of Brain Science: Open Your Mind," *Economist* (May 23, 2002), http://www.economist.com/opinion/displayStory.cfm?Storyid=1143317 (accessed February 16, 2006) ("Medical privacy is another area that brain scanning could compromise.").

<sup>&</sup>lt;sup>13</sup> Judy Illes, "Neuroethics in a New Era of Neuroimaging," *American Journal of Neuroradiology* 24, no. 9 (2003): 1740.

<sup>&</sup>lt;sup>14</sup> Martha J. Farah and Paul Root Wolpe, "Monitoring and Manipulating Brain Function: New Neuroscience Technologies and Their Ethical Implications," *Hastings Center Report* 34, no. 3 (May 2004): 36.

<sup>15</sup> Jeffrey Rosen, "Roberts v. The Future," New York Times, August 28, 2005, § 6, 24.

<sup>&</sup>lt;sup>16</sup> José van Dijck, *Transparent Body: A Cultural Analysis of Medical Imaging* (Seattle: University of Washington Press, 2005), 13.

and ethical issues raised by advances in functional neuroimaging.<sup>17</sup> In a 2004 paper commissioned for the Dana Press' *Neuroscience and the Law*, Stanford University law professor Henry Greely introduced a number of confidentiality and privacy issues raised by fMRI.<sup>18</sup> Greely briefly revisited these issues in 2005.<sup>19</sup>

This dissertation builds on the work of Kulynych and Greely. In Chapter 1, I place the confidentiality and privacy issues raised by fMRI in their proper historical context. Phrenology, the nineteenth-century pseudoscience, was believed to be capable of revealing character information, including information that individuals may have preferred to keep private. The discovery of x-ray at the turn of the century led to the development of a number of privacy protections, including "lead underwear" and legislation prohibiting the use of "x-ray glasses." The ability of computed tomography and structural magnetic resonance imaging to peer inside the body intensified privacy concerns, especially as the forensic value of these technologies became known. Old and new methods of brain mapping and neuroimaging thus raise confidentiality and privacy concerns, and history may have a role in informing current policy discussions about fMRI.

Chapter 2 examines the actual and perceived scope of confidentiality and privacy concerns raised by advances in functional neuroimaging. What brain functions does fMRI actually reveal? What can fMRI tell us about an individual's physical or mental health condition, or her social qualities and personal characteristics? Can fMRI reveal whether an individual is racially prejudiced, deceitful, or altruistic? Whether a particular

<sup>&</sup>lt;sup>17</sup> Jennifer Kulynych, "Legal and Ethical Issues in Neuroimaging Research: Human Subjects Protection, Medical Privacy, and the Public Communication of Research Results," *Brain and Cognition* 50, no. 3 (December 2002): 345-57.

<sup>&</sup>lt;sup>18</sup> Henry T. Greely, "Prediction, Litigation, Privacy, and Property: Some Possible Legal and Social Implications of Advances in Neuroscience," in *Neuroscience and the Law: Brain, Mind, and the Scales of Justice*, ed. Brent Garland (New York: Dana Press, 2004), 143-48.

<sup>&</sup>lt;sup>19</sup> Henry T. Greely, "The Societal Effects of Advances in Neuroscience: Legal Problems, Legal Perspectives," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 245-63.

individual is depressed, sexually aroused, or capable of making moral decisions? After reviewing a number of fMRI studies selected due to their popularity in the media and the speculation they have generated regarding their application in non-research contexts, Chapter 2 shows why private and governmental entities are interested in obtaining and creating neuroimaging information, and how the media, with some help from bioethicists and other stakeholders, may have contributed to this interest.

The concepts of confidentiality and privacy -- including their sources and limits, the contexts in which they have been explicated, and how they apply in the context of functional neuroimaging -- are examined next. Chapter 3 explores a range of sources of confidentiality and privacy, including ancient and modern codes of medical and research ethics, constitutional law, property law, tort law, and legislation and regulation, as well as an array of confidentiality and privacy definitions, classifications, and conceptualizations. Chapter 3 proposes definitions of confidentiality and privacy that function in the neuroimaging context and provide a framework for the remaining chapters.

An oft-stated principle is that physicians and scientists have an ethical and legal duty to maintain the confidentiality of medical and study records in their possession. Chapter 4 explores in detail ethical and legal issues of confidentiality raised by various uses and disclosures of functional neuroimaging information. What ethical and legal authorities protect the confidentiality of neuroimaging information? Do these authorities adequately address the unique confidentiality concerns raised by fMRI? Do existing confidentiality protections need to be amended or supplemented in light of advances in functional neuroimaging? Chapter 4 is structured around various legal authorities, including the federal Common Rule, the HIPAA Privacy Rule, state health information confidentiality laws and regulations, Public Health Service provisions providing for certificates of confidentiality, constitutional law, and the common law.

Patients voluntarily disclose some information to health care providers to obtain health care, and human subjects consent to scientists' obtaining some personal information during research studies. But, what if a provider or scientist using fMRI discovers a condition that the patient or subject would have preferred to keep private? What if an employer, insurance company, educational institution, court of law, or governmental agency attempts to obtain neuroimaging information that an individual would prefer to keep to herself? To address these questions, Chapter 5 focuses on privacy, or the interest of individuals in avoiding unwanted intrusions, including the unauthorized or inappropriate gathering of their functional neuroimaging information. Chapter 5 is structured according to the different contexts in which neurological privacy intrusions possibly could occur, including the clinical, research, employment, insurance, education, evidence, government, and private contexts.

Chapter 6 explores the roles and responsibilities of scientists, ethicists, and lawyers in the public and neuroethics arenas, and concludes that existing ethical and legal authorities create a general framework upon which functional neuroimaging-specific principles and legislation can be built. In the absence of political support for my neuro exceptional proposals, individuals who create, use, and disclose neuroimaging information should establish and adhere to internal policies and procedures that will minimize confidentiality and privacy concerns.

# CHAPTER 1: A HISTORY OF THE LOCALIZATION OF BRAIN FUNCTION

The idea that the brain has specialized functional areas is not new.<sup>1</sup> The earliest surviving writing suggesting a correlation between brain structure and function is the *Edwin Smith Surgical Papyrus*, a seventeenth-century B.C. reproduction of an earlier manuscript that described several head wound cases and referred to the effects of such wounds on motor control, including walking.<sup>2</sup> Hippocrates recognized in the fifth century B.C. that a wound to the left side of the head could lead to convulsions on the right side of the body.<sup>3</sup> Galen noted in the second century that hemiplegia could result from a lesion in the opposite side of the brain.<sup>4</sup> Although Vesalius was not particularly receptive to the idea of cerebral localization,<sup>5</sup> medical scholar Johann Schenk Von Grafenberg found in the sixteenth century that many language impairments resulted from injuries to certain parts of the brain, not paralysis of the tongue.<sup>6</sup> Italian anatomist Antonio Maria Valsalva reaffirmed in the early eighteenth century the connection between an injury to one side of the head and paralysis on the contralateral side of the

<sup>&</sup>lt;sup>1</sup> William R. Uttal, *The New Phrenology: The Limits of Localizing Cognitive Processes in the Brain* (Cambridge: MIT Press, 2001), 1.

<sup>&</sup>lt;sup>2</sup> William J. Winslade, Confronting Traumatic Brain Injury: Devastation, Hope, and Healing (New Haven: Yale University Press, 1998), 18; Christine Temple, The Brain: An Introduction to the Psychology of the Human Brain and Behaviour (London: Penguin Books, 1993), 22-23.

<sup>&</sup>lt;sup>3</sup> Hippocrates, "On Injuries of the Head," in *The Genuine Works of Hippocrates*, trans. and ed. Francis Adams (New York: Dover, 1868), 157-58; John C. Marshall and Gereon R. Fink, "Cerebral Localization, Then and Now," *NeuroImage* 20 (November 2003): S2.

<sup>&</sup>lt;sup>4</sup> Walther Riese, A History of Neurology (New York: MD Publications, 1959), 81.

<sup>5</sup> Ibid

<sup>&</sup>lt;sup>6</sup> Arthur L. Benton and Robert J. Joynt, "Early Descriptions of Aphasia," *Archives of Neurology* 3 (August 1960): 209.

body.<sup>7</sup> By the end of the eighteenth century, many thinkers were ready to create functional maps of the brain.

### **PHRENOLOGY**

### In Europe

Franz Josef Gall, an anatomist and physiologist living in Austria, had observed during his education that students who had good memories also had prominent foreheads.<sup>8</sup> Gall hypothesized that the part of the brain responsible for verbal memory must be located behind and slightly above the eyeballs.<sup>9</sup> To test his broader theory that certain parts of the brain were responsible for particular mental faculties, Gall began to examine the indentations and bumps on the heads of prisoners, insane individuals, and other individuals with extreme character traits. Gall summarized his findings in a 1798 letter addressed to a Viennese censorship official that was subsequently reprinted in *Der Neue Teutsche Merkur*, the main literary journal of the Holy Roman Empire.<sup>10</sup> In his letter, Gall stated that moral and intellectual qualities are innate; that the brain is composed of as many organs as there are faculties, tendencies, and feelings; that each organ produced a local protuberance, or bump, on the external surface of the skull; and that the size of each organ, which indicated its power of function, could be increased by exercise.<sup>11</sup> Gall also expressed his desire to "show that it is possible to ascertain different dispositions and inclinations by the elevations and depressions upon the head" and

<sup>&</sup>lt;sup>7</sup> Sven-Göran Fransson and Andrea Rubboli, "Antonio Maria Valsalva," Clinical Cardiology 26 (February 2003): 102.

<sup>&</sup>lt;sup>8</sup> Madeleine B. Stern, *Heads and Headlines: The Phrenological Fowlers* (Norman: University of Oklahoma Press, 1971), x.

<sup>&</sup>lt;sup>9</sup> John D. Davies, *Phrenology: Fad and Science; A 19th-Century American Crusade* (New Haven: Yale University Press, 1955), 6-7.

<sup>10</sup> Franz Josef Gall, "Letter from Dr. F. J. Gall to Joseph Fr[eiherr] von Retzer, upon the Functions of the Brain, in Man and Animals," in David G. Goyder, My Battle for Life: The Autobiography of a Phrenologist (London: Simpkin, Marshall, 1857), 143-52.

<sup>11</sup> Madeleine B. Stern, A Phrenological Dictionary of Nineteenth-Century Americans (Westport, Conn.: Greenwood Press, 1982), x; Riese, A History of Neurology, 92; Stern, Heads and Headlines, xi.

"present in a clear light the most important consequences which result therefrom to medicine, morality, education, and legislation a word, to the science of human nature." 12

Gall's letter lead to his ecclesiastical repression.<sup>13</sup> He was forbidden from publicly lecturing in Austria in 1802 on the grounds that his ideas were subversive of religion and morals.<sup>14</sup> Gall and his pupil, Johann Gaspar Spurzheim, moved to Paris to continue developing and teaching their theories, which later became known as *phrenology*, or the science of the mind.<sup>15</sup> In 1810, Gall published the first volume of his magnum opus, *Anatomie et Physiologie du Système Nerveux en Général et du Cerveau en Particulier*, which ultimately contained four volumes, the first two of which were coauthored by Spurzheim, and an atlas of illustrations.<sup>16</sup> Between 1822 and 1825, Gall published a six-volume, revised edition of *Anatomie* under the title *Sur les Fonctions du Cerveau et Sur Celles de Chacune de ces Parties*.<sup>17</sup> In these works, Gall described 27 different regions, or organs, of the brain, each of which housed an innate, universal faculty such as "Impulse to Propagation" (1), "Murder, carnivorousness" (5), "Larceny, sense of property" (7), "Arithmetic, counting, time" (18), and "Perseverance, firmness"

<sup>12</sup> Gall, "Letter," 152.

<sup>&</sup>lt;sup>13</sup> Andrew E. Norman, introduction to *Phrenology: A Practical Guide to Your Head*, by Orson Squire Fowler and Lorenzo Niles Fowler (New York: Chelsea House Publishers, 1969), vi.

<sup>&</sup>lt;sup>14</sup> Christine Temple, *The Brain: An Introduction to the Psychology of the Human Brain and Behaviour* (London: Penguin Books, 1993), 26; Davies, *Phrenology*, 7; Norman, introduction, vi.

<sup>15</sup> The word phrenology is derived from two Greek words meaning mind and discourse. Johann Gaspar Spurzheim, *Outlines of Phrenology* (Boston: Marsh, Capen and Lyon, 1832), 1 (reprinted in *Significant Contributions to the History of Psychology, 1750-1920*, ed. Daniel N. Robinson (Washington, D.C.: University Publications of America, 1978)).

<sup>16</sup> Franz Josef Gall and Johann Gaspar Spurzheim, Anatomie et Physiologie du Système Nerveux en Général et du Cerveau en Particulier (Paris: F. Schoell, 1810); Franz Josef Gall and Johann Gaspar Spurzheim, Anatomie et Physiologie du Système Nerveux en Général et du Cerveau en Particulier, vol. 2 (Paris: F. Schoell, 1812); Franz Josef Gall, Anatomie et Physiologie du Système Nerveux en Général et du Cerveau en Particulier, vol. 3 (Paris: F. Schoell, 1818); Franz Josef Gall, Anatomie et Physiologie du Système Nerveux en Général et du Cerveau en Particulier, vol. 4 (Paris: F. Schoell, 1819).

<sup>17</sup> Franz Josef Gall, Sur les Fonctions du Cerveau et Sur Celles de Chacune de ces Parties, 6 vols (Paris: J. B. Baillière, 1822-25); Franz Josef Gall, On the Functions of the Brain and of Each of Its Parts, 6 vols., trans. Winslow Lewis, Jr. (Boston: Marsh, Capen and Lyon, 1835).

(27).<sup>18</sup> Those who followed Gall's work may have been concerned for their privacy: Gall believed that his brain maps could be used to explain differences among individuals, advise employers regarding individuals with desirable qualities, and govern the masses.<sup>19</sup>

Despite his grand theories, Gall left some portions of his brain maps blank, presumably because he did not know which faculties resided therein.<sup>20</sup> Unlike some of his successors, Gall used more than one word to describe each organ, perhaps to show that he did not completely understand each organ's function. And, because his early research involved individuals who only had striking head protuberances and extreme character traits, Gall expressed reservation regarding whether character actually could be read from the shape of just any person's head: "I have never pretended to distinguish the influence, which modification of the forms of the cranium slightly marked, may have on the character, or how its corresponding shades may be traced."<sup>21</sup> In light of these and other qualifications and admissions, Gall was regarded as an honest investigator and a scientific pioneer at his death in 1828.

Although Spurzheim had worked with Gall on Anatomie et Physiologie du Système Nerveux, Spurzheim's name did not appear on the title pages of the last two volumes. The omission reportedly occurred because Gall and Spurzheim had a falling out before the last two volumes of Anatomie were published.<sup>22</sup> In any event, Spurzheim moved to England in 1814 and published a formal, English version of his theories, The Physiognomical System of Drs. Gall and Spurzheim, the following year.<sup>23</sup> In subsequent

<sup>&</sup>lt;sup>18</sup> Davies, Phrenology, 8.

<sup>19</sup> Ibid.

<sup>&</sup>lt;sup>20</sup> Ibid.

<sup>&</sup>lt;sup>21</sup> Ibid., 39-40.

<sup>&</sup>lt;sup>22</sup> Ibid., 8.

<sup>&</sup>lt;sup>23</sup> Johann Gaspar Spurzheim, The Physiognomical System of Drs. Gall and Spurzheim: Founded on an Anatomical and Physiological Examination of the Nervous System in General, and of the Brain in Particular, and Indicating the Dispositions and Manifestations of the Mind (London: Baldwin, Cradock, and Joy, 1815).

publications, Spurzheim changed some of Gall's theories, including deleting all faculties that were inherently evil, such as Gall's faculty of "Murder, carnivorousness."<sup>24</sup> Spurzheim also added several organs, changed several of the remaining organs' descriptions, and categorized the organs into propensities, sentiments, and intellect.<sup>25</sup>

The *Edinburgh Review*, a leading scientific journal, heavily criticized Spurzheim's revised system in 1815 on the grounds that it consisted of "a mixture of gross errors, extravagant absurdities, downright misstatements, and unmeaning quotations from Scripture," and that its lead author was ignorant and hypocritical. <sup>26</sup> Spurzheim defended himself by arranging at Edinburgh a brain dissection during which he responded to the journal criticisms one-by-one. <sup>27</sup> Perhaps unaware of the scientific criticism, the Victorian public continued to greet Spurzheim's revised phrenology with enthusiasm. They visited phrenological surgeries and consented to have their heads examined by individual practitioners of phrenology as well as phrenometers --- machines that measured the relative dimension and distribution of head bumps. <sup>28</sup> Queen Victoria had her children's heads read, and George Eliot had her own head shaved and read twice. <sup>29</sup>

## In the United States

Spurzheim and his student, George Combe, brought phrenology to the United States in 1832 through lecture tours and demonstrations.<sup>30</sup> The following year, Amherst College student Henry Ward Beecher was assigned to debate the negative view of phrenology as a science in a college debate that likely was inspired by one of

<sup>&</sup>lt;sup>24</sup> Davies, *Phrenology*, 8.

<sup>&</sup>lt;sup>25</sup> Spurzheim, *Outlines of Phrenology*, 25-72 (identifying thirty-five different faculties).

<sup>&</sup>lt;sup>26</sup> John Gordon, "The Doctrines of Gall and Spurzheim," Edinburgh Review 25 (June 1815): 263.

<sup>&</sup>lt;sup>27</sup> Davies, Phrenology, 10.

<sup>&</sup>lt;sup>28</sup> Temple, Brain, 27.

<sup>&</sup>lt;sup>29</sup> Ibid.

<sup>&</sup>lt;sup>30</sup> Stern. Phrenological Dictionary, x.

Spurzheim's or Combe's lectures.<sup>31</sup> After Beecher won the debate, he told the audience that he actually agreed with the theories he had just argued against and was converting to the science of phrenology.<sup>32</sup> Thereafter, Beecher and his classmate, Orson Squire Fowler, attended phrenology lectures and began lecturing on the subject themselves.<sup>33</sup> Although Beecher eventually returned to his theological studies, phrenology became a life-long passion and profession for Fowler and his younger brother, Lorenzo Niles Fowler. In 1835, the Fowler brothers opened a phrenology practice in New York City and charged one dollar for a head examination, a verbal analysis, and the completion of a head chart in which the faculties were marked in seven degrees (very small, small, moderate, average, full, large, and very large), and three dollars for a complete, handwritten analysis.<sup>34</sup> The Fowler brothers published in 1836 the first edition of their famous text, *Phrenology Proved, Illustrated and Applied*,<sup>35</sup> and launched their monthly *American Phrenological Journal* in 1838. The *Journal* was edited by the Fowler brothers and, eventually, their children until it ceased publication in 1911.<sup>36</sup>

When an individual presented for a head examination, the Fowlers quickly reviewed the individual's features to identify his or her general temperament. Coarse, large features suggested a bilious temperament, in which physical strength predominated over mental attributes.<sup>37</sup> Thin hair, small muscles, and pale skin suggested that the individual favored thought, study, and poetry.<sup>38</sup> The Fowlers then conducted a more

<sup>31</sup> Norman, introduction, vi-vii.; Davies, Phrenology, 31; Stern, Phrenological Dictionary, xiii.

<sup>32</sup> Norman, introduction, vii; Davies, Phrenology, 32.

<sup>33</sup> Norman, introduction, vii.

<sup>&</sup>lt;sup>34</sup> Stern, *Phrenological Dictionary*, xiv; Norman, introduction, vi.

<sup>&</sup>lt;sup>35</sup> Orson Squire Fowler and Lorenzo Niles Fowler, *Phrenology Proved, Illustrated, and Applied, Accompanied by a Chart, Together with a View of the Moral and Theological Bearing of the Science* (Philadelphia: Fowler and Brevoort, 1836).

<sup>&</sup>lt;sup>36</sup> Stern, Phrenological Dictionary, xiii.

<sup>&</sup>lt;sup>37</sup> Ibid.

<sup>38</sup> Ibid.

thorough examination of the individual's skull, using their phrenology charts as a guide. Similar to Gall and Spurzheim's brain maps, the Fowlers' charts were based on the assumption that the distance between the various organs provided information about the magnitude of a trait supported by the underlying brain region.<sup>39</sup> The 37 faculties identified by the Fowlers included Amativeness (Love between the sexes), Parental Love (Regard for offspring), Destructiveness (Executiveness—force), Self-Esteem (Self-respect—dignity), Size (Measuring by the eye), Calculation (Mental arithmetic), and Causality (Applying causes to effect).<sup>40</sup> An optimum level existed for each faculty, and too much or too little of a faculty could be problematic.<sup>41</sup> Too little Size could lead to an inability to judge proportions, and too much Size could lead to an overemphasis of physical views. Similarly, too little Calculation was believed to cause difficulty in assimilating and regulating facts and figures.<sup>42</sup>

The Fowlers also provided directions for cultivating and restraining each of the 37 faculties.<sup>43</sup> To cultivate Parental Love, for example, the Unmotherly should "Play with and make much of children; try to appreciate their loveliness and innocence, and be patient and tender and indulgent toward them; and if you have no own children, adopt some, or provide something to pet and fondle."<sup>44</sup> To restrain Parental Love, the Good Mother should "Set judgment over against affection; rear them intellectually; give yourself less anxiety about them, and if a child dies, by all means turn your mind from that loss by seeking some powerful diversion . . ."<sup>45</sup> Individuals who needed more

<sup>&</sup>lt;sup>39</sup> Ibid; Stern, Heads and Headlines, 17.

<sup>&</sup>lt;sup>40</sup> Norman, introduction, xviii.

<sup>&</sup>lt;sup>41</sup> Christine Temple, *Developmental Cognitive Neuropsychology* (East Sussex, U.K.: Psychology Press, 1997), 255.

<sup>&</sup>lt;sup>42</sup> Ibid.

<sup>43</sup> Norman, introduction, xix.

<sup>&</sup>lt;sup>44</sup> Orson Squire Fowler and Lorenzo Niles Fowler, *Phrenology: A Practical Guide to Your Head* (New York: Chelsea House Publishers, 1969), 85.

<sup>45</sup> Ibid.

Destructiveness were told to "Destroy anything and everything in your way; killing weeds, blasting rocks, felling trees, using edge tools . . . "<sup>46</sup> Individuals who needed to restrain Destructiveness were directed to "never brood over injuries or indulge revengeful thoughts or desires, or aggravate yourself by brooding over wrongs . . . "<sup>47</sup>

The Fowlers' phrenological theories were admired by many of their distinguished contemporaries. Several notable nineteenth-century Americans, including Ralph Waldo Emerson, Oliver Wendell Holmes, Susan B. Anthony, Lizzie Borden, Jenny Lind, Horace Greeley, Brigham Young, Lucretia Mott, Walt Whitman, Horace Mann, and Lola Montez, allowed one of the Fowlers, or another phrenologist, to read their heads.<sup>48</sup> After Lorenzo Niles Fowler read Walt Whitman's head in 1849, Whitman even described the results in two editions of his *Leaves of Grass*: "Leading traits of character appear to be Friendship, Sympathy, Sublimity, and Self-Esteem, and markedly among his combinations the dangerous faults of Indolence . . . and a certain swing of animal will, too unmindful, probably, of the conviction of others."<sup>49</sup>

# Phrenological Findings and Applications

Many phrenological findings, perhaps coincidentally, proved true. Orson Squire Fowler reportedly described a particular subject as having "'No Conscientiousness! [N]ot a bit! No Approbativeness! No Feeling of Shame!'" before learning that the subject had killed a female slave.<sup>50</sup> Before he became known as the father of the American private investigator, Allen Pinkerton was told by a phrenologist that he "'would make a capital detective; he would smell a rogue three miles.'"<sup>51</sup> Before his raid on Harpers Ferry, abolitionist John Brown presented for a phrenological examination

<sup>&</sup>lt;sup>46</sup> Ibid., 101.

<sup>&</sup>lt;sup>47</sup> Ibid.

<sup>48</sup> Stern, Phrenological Dictionary, xiv, xviii, 14-19, 33-39.

<sup>&</sup>lt;sup>49</sup> Davies, *Phrenology*, 123-24; Norman, introduction, x.

<sup>&</sup>lt;sup>50</sup> Stern, Heads and Headlines, 18.

<sup>51</sup> Stern, Phrenological Dictionary, xiv.

during which he was told, "'This man has firmness and energy enough to swim up the Niagara river and tow a 74-gun ship, holding the tow-line in his teeth. He has courage enough to face anything that man may face, if he think it right, and be the last to retreat if advance be impossible."<sup>52</sup> The parents of a very young Clara Barton, the future founder of the American Red Cross, were told by Lorenzo Niles Fowler to "throw responsibility" upon young Clara in an effort to improve upon her shy, hypersensitive, and withdrawn personality.<sup>53</sup> Clara later viewed Fowler's analysis as an important moment in her life: "'Know thyself' became my text and my study. . . . It has enabled me to better comprehend the seeming mysteries about me . . . It has enriched my field of charitable judgment; enlarged my powers of forgiveness . . . "'<sup>54</sup>

Phrenology also "revealed" hidden information about its analysands. Humorist Samuel Langhorne Clemens (whose pen name was Mark Twain) used an assumed name in 1873 when he requested a head examination from Lorenzo Niles Fowler.<sup>55</sup> During this initial, incognito examination, Fowler discovered an indentation in Twain's skull that was interpreted as a "'total absence of the sense of humor."<sup>56</sup> Three months later, Fowler welcomed a second visit from Twain, who announced himself using pen name. During this examination, Fowler discovered a "'Mount Everest' of a 'bump of humor'" on Twain's head.<sup>57</sup> During a third examination conducted in 1901, Fowler's daughter, Jessie revealed a serious, tragic, and reforming side to Twain's character -- a popular view that did not develop until after Twain's death in 1910.<sup>58</sup> Although Twain wrote about his first

<sup>52</sup> Ibid., xv.

<sup>53</sup> Ibid.

<sup>&</sup>lt;sup>54</sup> Ibid.

<sup>55</sup> Ibid., xviii.

<sup>&</sup>lt;sup>56</sup> Ibid.

<sup>&</sup>lt;sup>57</sup> Ibid.

<sup>58</sup> Ibid., xix.

two experiences with phrenology, he never referred to his third examination, perhaps because he had wanted to keep the results of that examination private.<sup>59</sup>

Like Gall and Spurzheim, the Fowlers believed that phrenology could be used as a basis for vocational counseling.60 Lawyers apparently required the "Mental-Vital temperament, to give them intensity of feeling and clearness of intellect; large Eventuality, to recall law cases and decisions; large Comparison, to compare different parts of the law and evidence . . . and large Language, to give freedom of speech."61 Physicians, on the other hand, needed "large Perceptive Faculties, so that they may study and apply a knowledge of Anatomy and Physiology with skill and success . . . [and] full Destructiveness, lest they shrink from inflicting the pain requisite to cure . . . "62 American newspaper editor and politician Horace Greeley was so convinced of the usefulness of phrenology in the employment context that he argued in an 1852 editorial that railroad accidents could be reduced if trainmen were selected "by the aid of phrenology, and not otherwise."63 Some employers apparently agreed with the Fowlers and Greeley: they posted job advertisements that requested both personal references and phrenological analyses.<sup>64</sup> Although some job applicants may have preferred to keep the relative size of their faculties to themselves, "[e]rrand boys and candidates for political office would be appraised by [phrenology's] standards."65

<sup>&</sup>lt;sup>59</sup> Ibid.

<sup>60</sup> Ibid., xi.

<sup>61</sup> Fowler and Fowler, Phrenology, 200; Stern, Phrenological Dictionary, xi.

<sup>62</sup> Ibid.

<sup>63</sup> Norman, introduction, x.

<sup>&</sup>lt;sup>64</sup> Davies, Phrenology, 39; Stern, Phrenological Dictionary, x.

<sup>65</sup> Stern, Heads and Headlines, xiv.

# The Fall of Phrenology

Scientists began to dispute the validity of phrenology as a science well before Orson Squire and Lorenzo Niles Fowler died in 1887 and 1896, respectively.66 Scientists argued that the Fowlers' correlational methods were based on anecdotal descriptions of felonious criminals, the insane, and individuals such as Galileo and Edgar Allen Poe, who had extreme characteristics. Scientists also criticized the Fowlers' lack of documented experiments and statistical validation, as well as their inability to replicate their brain maps across individuals.<sup>67</sup> In 1838, American anatomy professor Thomas Sewall published the first edition of his An Examination of Phrenology, in which he attacked phrenology on several grounds. Among other things, Sewall argued that dissection of the brain did not reveal discrete areas, no exact relationship between the size of the brain and intelligence existed, and impairment did not always result to a faculty when the area in which the faculty allegedly resided was injured or destroyed.<sup>68</sup> Four years later, French physiologist Pierre Flourens published the results of his brain excisions, in which he concluded that brain functions were not localized in discrete areas of the brain and, moreover, that the different areas of the brain appeared to work in concert.<sup>69</sup> Although the phrenologists attempted to respond to Sewall, Flourens, and other opponents by amending their charts to include more faculties, the idea of phrenology as a science had collapsed.<sup>70</sup> By the beginning of the twentieth century, the inductive methods of pure science and medicine and Sigmund Freud's psychoanalysis made phrenology seem like a fad.<sup>71</sup> Today, phrenology is referred to as a pseudoscience<sup>72</sup> or quackery.<sup>73</sup>

<sup>&</sup>lt;sup>66</sup> Scott A. Huettel, Allen W. Song, and Gregory McCarthy, Functional Magnetic Resonance Imaging (Sunderland, Mass.: Sinauer Associates, 2004), 1; Davies, Phrenology, 174.

<sup>67</sup> Davies, Phrenology, 174.

<sup>&</sup>lt;sup>68</sup> Thomas Sewall, *An Examination of Phrenology* (London: James S. Hodson, 1838); Davies, *Phrenology*, 141.

<sup>&</sup>lt;sup>69</sup> Riese, History of Neurology, 96.

<sup>&</sup>lt;sup>70</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 1.

<sup>71</sup> Stern, Phrenological Dictionary, xix.

### Phrenological Reform

Although phrenology did not become the science of the mind, its principles formed the basis of several nineteenth-century reform movements in the areas of women's rights, education, mental health care, and criminal justice. These reform movements were no accident. The Fowlers repeatedly had expressed their hope and belief that phrenological principles would be used to perfect society: "Phrenologize Our Nation, for thereby it will Reform The World... Mould the Now Forming Character of Our Republic... Perfect our Republic... Reform governmental abuses...."

Women were one focus of the phrenologists. Spurzheim hoped that phrenology would elevate the status of women by giving them equal participation "in the labors of the mind." Orson Squire Fowler was more specific: "Women's Sphere of Industry should . . . be enlarged till it equals that of men. . . . " Fowler further argued that, "Printing, architecture, drawing, engraving, all the arts, all kinds of storekeeping and manufacturing, all departments of literature, telegraphy, law, legislation, public offices and clerkships . . . should be shared and filled equally by both." Other phrenologists were convinced that phrenological tenets required women to be relieved of their binding corsets and, metaphorically, "the 'tight lacing' of their intellectual and moral lives." Referred to as pioneer sex educators, many phrenologists also tried to bring sex out into the open and to encourage its study. 80 Lorenzo Niles Fowler even used phrenology to

<sup>&</sup>lt;sup>72</sup> Donald Simpson, "Phrenology and the Neurosciences: Contributions of F. J. Gall and J. G. Spurzheim," *ANZ Journal of Surgery* 75, no. 6 (June 2005): 475.

<sup>73</sup> Davies, Phrenology, ix.

<sup>&</sup>lt;sup>74</sup> Ibid., 71; Stern, *Phrenological Dictionary*, ix.

<sup>75 &</sup>quot;The American Phrenological Journal for 1849," Phrenological Journal 11 (1849): 12.

<sup>&</sup>lt;sup>76</sup> Stern, Phrenological Dictionary, xi.

<sup>&</sup>lt;sup>77</sup> Stern, Heads and Headlines, 167.

<sup>78</sup> Ibid.

<sup>&</sup>lt;sup>79</sup> Stern, Phrenological Dictionary, xi.

<sup>80</sup> Ibid.

advise clients regarding whom they should marry.<sup>81</sup> For example, individuals who had large Amativeness were advised not to marry individuals who had small Amativeness.<sup>82</sup>

Phrenology impacted more than women, sexual relations, and marriage.

Educational reforms also were a particular emphasis of many of the British and American phrenologists. Because the phrenologists believed that the mind was a collection of different organs, they discouraged methods of learning based solely on memorization, reasoning that memorization only trained the organs of Language and Eventuality.

Students needed to train all of their mental organs by singing, running, and avoiding unhealthy substances such as coffee and tobacco, 83 and by visiting museums, fields, gardens, and shops. 84 Educators also were instructed in the principles of phrenology during "Children, Their Health, Growth, Training & Schooling" lectures, and were told not to severely punish students for misbehaving in school, because "no chastisement can ever be inflicted without the exercise of Combativeness and Destructiveness in the punisher." Summarizing the importance of educational reforms, Lorenzo Niles Fowler stated that, "The training of children is at the very foundation of society. . . . Reformers . . . commence at the beginning." 87

Phrenological principles also were applied to the care and treatment of the insane. Phrenologists believed that insanity was caused by the "'sickness of the Organs of the

<sup>81</sup> Ibid.

<sup>82</sup> Ibid.

<sup>&</sup>lt;sup>83</sup> George Combe, Lectures on Popular Education (Boston: Marsh, Capen and Lyon, 1834); Johann Gaspar Spurzheim, Education, Its Elementary Principles Founded on the Nature of Man (New York: Fowlers and Wells, 1847); Orson Squire Fowler, Education and Self-Improvement (New York: Fowlers and Wells, 1847).

<sup>84</sup> Stern, Phrenological Dictionary, xi.

<sup>85</sup> Stern, Heads and Headlines, 190.

<sup>86</sup> Ibid.

<sup>87</sup> Stern, Phrenological Dictionary, xi.

erring faculties, not by depravity of purpose,"\*88 and that insanity could be cured: "'Phrenology enables us to retain a proper balance between our physical and mental functions, to restore loss equilibrium, and to treat successful the various phases of insanity and other disorders."\*89 Insane asylum superintendents not infrequently adopted these beliefs. A superintendent of two insane asylums located in Maine and Rhode Island, Isaac Ray documented in his famous *Treatise on the Medical Jurisprudence of Insanity* his belief that insanity was a physical disease that involved derangement of brain structures, 90 and argued in the seminal *Mental Hygiene* that insanity should be treated as a disease, not a behavior requiring punishment. 91

Phrenology also was applied to principles of criminal justice. The traditional theory of penology during the eighteenth century -- that severe penalties would deter criminals from repeating their crimes and serve as an example of what might happen to potential criminals -- was based on the assumption that criminals and good citizens had similar minds. Because the phrenologists believed that most criminals acted impulsively and did not have sufficient moral strength to be inhibited by the thought of punishment, they favored a program of moral treatment over severe penalties. Gall perhaps led the call for the more gentle treatment of the insane: "Although we reserve to ourselves the right to prevent these unhappy beings from injuring us, all punishment exercised on them is not less unjust than useless . . . they merit indeed only our

<sup>&</sup>lt;sup>88</sup> Orson Squire Fowler, *Education and Self-Improvement*, vol. 1 (New York: Fowlers and Wells, 1847), 43.

<sup>89</sup> Stern, Phrenological Dictionary, xii.

<sup>&</sup>lt;sup>90</sup> Isaac Ray, A Treatise on the Medical Jurisprudence of Insanity (Boston: Little and Brown, 1838), 17.

<sup>91</sup> Isaac Ray, Mental Hygiene (Boston: Ticknor and Fields, 1863), 43.

<sup>92</sup> Davies, Phrenology, 98.

<sup>93</sup> Ibid., 99.

<sup>94</sup> Ibid.

compassion."<sup>95</sup> The phrenologists' theories regarding penology worked their way down to the level of the state prison. Eliza Farnham, superintendent of the women's ward at Sing Sing, New York's third state prison, believed that the application of phrenological principles contributed to the reform of criminals in her institution.<sup>96</sup>

Although phrenology ultimately failed as a science, it left behind a formalized concept of cerebral localization<sup>97</sup> and the idea that science, perhaps a science not too different from the pseudoscience of phrenology, could be used to investigate the functions of different regions of the brain.<sup>98</sup> To reform society, however, the phrenologists needed to know the relative size of individuals' faculties. Thus, phrenology also raised issues relating to neurological privacy. Although Gall, Spurzheim, and the Fowlers believed that the information gleaned from their brain maps could be used to explain differences among individuals, advise employers regarding individuals with desirable qualities, and govern the masses, the Victorians and the nineteenth-century Americans may have had an interest in keeping their head bumps and dents to themselves. Mark Twain's third phrenological examination, which allegedly revealed a serious and tragic side to Twain's character to which Twain never publicly referred, is an example of the potential of (pseudo)science to reach the private confines of the mind.

#### LESION STUDIES

In the second half of the nineteenth century, scientists focused less on skull bumps and dents and more on changes in brain physiology caused by lesions. Although the subject of some debate, some of the first brain lesion studies may have been conducted in

<sup>95</sup> Gall, "Letter," 311-32.

<sup>96</sup> Davies, Phrenology, 103.

<sup>&</sup>lt;sup>97</sup> Uttal, *The New Phrenology*, 20; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 2.

<sup>98</sup> Stern, Phrenological Dictionary, xii; Stern, Heads and Headlines, 34.

the early 1800s by French physician Marc Dax.<sup>99</sup> Dax reportedly hypothesized in 1811 that speech was more likely to be affected by lesions in the left cerebral hemisphere than lesions in the right hemisphere.<sup>100</sup> Dax confirmed his hypothesis in 1836, when he had collected approximately 80 speech defect cases from the literature and his own practice, many of which involved paralysis on the right side of the body.<sup>101</sup> Dax allegedly prepared a paper for presentation at the University of Montpellier in 1836 identifying the coincidence of hemiplegia of the right side with speech defect (although significant debate as to whether Dax actually read his paper at the conference exists).<sup>102</sup> Dax died the following year without having published his paper.<sup>103</sup>

Dax's son, French physician Gustave Dax, continued his father's studies. After collecting additional cases relating to his and other patients' speech problems, Gustave prepared a paper in 1858 addressing the relationship between the left side of the brain and the speech function. 104 Five years later, Gustave sent copies of his paper, which included his father's 1836 paper, to the French Academy of Sciences and the French Academy of Medicine, which received the papers on March 23 and 24, 1863, respectively. 105 One member of the French Academy of Medicine issued in 1864 a negative publication decision, stating that Gustave was attempting to resurrect phrenology. 106 Rejection notwithstanding, Marc's and Gustave's theory that the ability to produce language was localized in the left hemisphere of the brain was cited in a paper published by Charles

<sup>99</sup> Winslade, Confronting Traumatic Brain Injury, 19.

<sup>100</sup> Stanley Finger and Daniel Roe, "Does Gustave Dax Deserve to Be Forgotten? The Temporal Lobe Theory and Other Contributions of an Overlooked Figure in the History of Language and Cerebral Dominance," *Brain and Language* 69, no. 1 (August 1999): 17.

<sup>&</sup>lt;sup>101</sup> Ibid., 17-18.

<sup>102</sup> Ibid., 18.

<sup>&</sup>lt;sup>103</sup> Ibid.

<sup>&</sup>lt;sup>104</sup> Ibid., 19.

<sup>105</sup> Ibid.

<sup>106</sup> Ibid.

Brouchard in 1864.<sup>107</sup> In addition, Marc's original paper (translated, "Lesions of the Left Half of the Brain Coincident with the Forgetting of the Signs of Thought") and an abridged version of Gustave's paper (translated, "On the Same Subject") were officially, and finally, published on their own on April 28, 1865,<sup>108</sup> although four years after Paul Broca published his famous remarks regarding the localization of speech generation.<sup>109</sup>

The subject of another early, famous lesion study was Phineas Gage, a Vermont railroad worker. Gage was tamping down a charge of gunpowder in 1848 when the charge exploded, sending a three-centimeter-thick iron rod through Gage's left frontal lobe. He fore the accident, Gage had been known for being mild-mannered, responsible, and obedient. Although recent scholarship suggests insufficient evidence regarding Gage's post-injury behavior to support the many claims that have been made about his personality change, the bulk of the literature discussing Gage's story, including the *Boston Medical and Surgical Journal* report authored by Gage's own physician, explains that Gage became irreverent, profane, impatient, obstinate, capricious, and vacillating. A contemporary phrenologist interpreted Gage's injury as

<sup>107</sup> Charles Bouchard, "Aphasie Sans Lésion de la Troisième Circonvolution Frontale Gauche," Comptes Rendus des Séances et Mémoires de la Société de Biologie 16 (1864): 116.

<sup>108</sup> Marc Dax, "Lésions de la Moitié Gauche de l'encé Phale Coincidant avec l'oubli des Signes de la Pensée (lu au Congrés Méridional tenu à Montpellier en 1836)," Gazette Hebdomadaire de Médecine et de Chirurgie 2 (1865): 259-60; Gustave Dax, "Sur le même Sujet," Gazette Hebdomadaire de Médecine et de Chirurgie 2 (1865): 260-62.

<sup>109</sup> See text accompanying notes 120-122 in this chapter.

<sup>110</sup> Winslade, Confronting Traumatic Brain Injury, 20.

<sup>111</sup> Ibid.

<sup>&</sup>lt;sup>112</sup> Ibid.

<sup>113</sup> Malcolm Macmillan, An Odd Kind of Fame: Stories of Phineas Gage (Cambridge: MIT Press, 2000); Malcolm Macmillan, "Restoring Phineas Gage: A 150<sup>th</sup> Retrospective," Journal of the History of the Neurosciences 9, no. 1 (April 2000): 42-62.

<sup>114</sup> John M. Harlow, "Recovery from the Passage of an Iron Bar through the Head," Boston Medical and Surgical Journal 39 (1848): 389-92; Winslade, Confronting Traumatic Brain Injury, 20; Adina Roskies, "A Case Study of Neuroethics: The Nature of Moral Judgment," in Neuroethics: Defining the Issues in Theory, Practice, and Policy, ed. Judy Illes (Oxford: Oxford University Press, 2006), 19; Tom

damaging his organs of Benevolence and Veneration, but a more common interpretation of Gage's personality change is that "the key to responsible and appropriate behavior lay somewhere in the left frontal lobe of the brain . . . "115

A patient named Leborgne who was unable to speak other than to repeat the word "tan" is the subject of a third, famous lesion study. 116 Although the results of French physician Paul Broca's 1861 autopsy of Leborgne are well known, few know the details of Leborgne's lengthy illness. Leborgne had been epileptic since his youth, aphasic at the age of thirty, and weakened on the right side at the age of forty. Leborgne died of cellulitis with gangrene of his paralyzed right leg at fifty-one. 117 Within twenty-four hours of his death in 1861, 118 Broca performed an autopsy and found damage to Leborgne's left frontal lobe. 119 In remarks published that same year (translated, "Remarks on the Seat of the Faculty of Articulate Language, Followed by an Observation of Aphemia"), Broca famously concluded that the ability to produce speech must be at least partially localized in the left frontal operculum. 120 Broca is frequently referred to as

Buller, "Brains, Lies, and Psychological Explanations," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 55; Paul J. Ford and Jaimie M. Henderson, "Functional Neurosurgical Intervention: Neuroethics in the Operating Room," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 218-19; National Institutes of Health, National Institute of Neurological Disorders and Stroke, *Traumatic Brain Injury: Hope through Research* (Bethesda: National Institute of Neurological Disorders and Stroke, 2002), 1-2.

<sup>115</sup> Winslade, Confronting Traumatic Brain Injury, 20.

<sup>116</sup> Huettel, Scott, and McCarthy, Functional Magnetic Resonance Imaging, 4.

<sup>117</sup> Francis Schiller, Paul Broca: Explorer of the Brain (Oxford: Oxford University Press, 1992), 182.

<sup>&</sup>lt;sup>118</sup> Ibid., 177.

<sup>119</sup> Ibid., 186-87; Carl Sagan, *Broca's Brain* (New York: Ballantine Books, 1980), 9; Marcus A. Raichle, "Functional Neuroimaging: A Historical and Physiological Perspective," in *Handbook of Functional Neuroimaging of Cognition*, ed. Roberto Cabeza and Alan Kingstone (Cambridge: MIT Press, 2001), 5; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 160.

<sup>120</sup> Paul Broca, "Perte de la Parole, Ramollissement Chronique et Destruction Partielle du Lobe Antérieur Gauche du Cerveau," *Bulletins de la Societe d'Anthropologie* 2 (1861): 235-38; Paul Broca, "Remarques sur le Siège de la Faculté du Langage Articulé," *Bulletin de la Societe Anatomique de Paris* 6 (1861): 330-57; Paul Broca, "Nouvelle Observation Aphémie Produite Par un Lésion de la Moité posté

having "discovered" the localization of the speech function, <sup>121</sup> although many historians emphasize that Broca's remarks were published twenty-five years after Marc Dax reportedly presented similar findings at the University of Montpellier. <sup>122</sup>

Fifteen years after Broca published his famous remarks, German neurologist and psychiatrist Carl Wernicke published his own findings<sup>123</sup> showing that patients who struggled to understand language had lesions in another part of the brain, which became known as Wernicke's area. Wernicke's observations led to the modern notion of "component process localization," according to which complex mental functions, such as language, are believed to result from the combined processing of a number of subcomponent processes in different areas of the brain.

Although the observations of Dax, Broca, and Wernicke contributed significantly to the understanding of the speech and language functions, lesion studies have certain limitations. A particular brain function may be supported by more than one brain region, and a particular brain region may support more than one brain function.<sup>124</sup> Thus, damage to one region of the brain that results in a particular behavioral impairment means that that region of the brain is necessary for the behavior, but it does not specify the timing of that region's activity or the specific function it serves.<sup>125</sup> Time also may change the effect of a brain lesion.<sup>126</sup> An injured part of the brain might regain over time its ability

Rieure des Deuxiè me et Troisiè me Circonvolutions Frontales," Bulletins de la Societe Anatomique de Paris 6 (1861): 398-407.

<sup>&</sup>lt;sup>121</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 4; Sagan, Broca's Brain, 9-10.

<sup>122</sup> Riese, History of Neurology, 100.

<sup>123</sup> Carl Wernicke, Der Aphasische Symptomenkomplex (Breslau, Ger.: Cohn and Weigert, 1874).

<sup>124</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 4.

<sup>125</sup> David N. Levine and Eric Sweet, "Localization of Lesion's in Broca's Motor Aphasia," in Localization in Neuropsychology, ed. Andrew Kertesz (New York: Academic Press, 1983), 190; Huettel, Functional Magnetic Resonance Imaging, 4.

<sup>126</sup> Andrew Kertesz, "Issues in Localization," in *Localization in Neuropsychology*, ed. Andrew Kertesz (New York: Academic Press, 1983), 7-8.

to control behavior, such as when an individual re-learns how to walk after a traumatic brain injury. Other parts of the brain also may take on new functions to compensate for injury to the other parts of the brain.<sup>127</sup> Thus, lesion studies require the careful evaluation of the effects of numerous lesions over time.<sup>128</sup> In addition, many types of brain lesions result from traumatic brain injury and stroke, which cause diffuse damage and limit the ability of scientists to study the effect of a particular lesion on a particular brain function.<sup>129</sup> Some types of brain lesions occur infrequently, which may result in an insufficient number of lesions from which scientific conclusions may be drawn.

Although scientists can create a lesion in a particular region of an animal's brain, scientists generally do not have the same option with humans (outside of the context of transcranial magnetic stimulation, which scientists can use to temporarily interrupt a particular human brain function).<sup>130</sup> As a result of these and other factors, lesion studies are inadequate for studying all aspects of human cognition.<sup>131</sup>

# ELECTROENCEPHALOGRAPHY AND MAGNETOENCEPHALOGRAPHY

Two additional methods of understanding brain function include recording electrical activity and magnetic fields in the brain.<sup>132</sup> Recording electrical activity in humans and animals dates back to the late eighteenth century, when Italian physiologist Luigi Galvani found that the muscles in frogs' legs were excitable tissues.<sup>133</sup> In the midnineteenth century, German physiologist Du Bois-Reymond found that an electrical

<sup>127</sup> Ibid., 4; Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 4.

<sup>128</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 5.

<sup>129</sup> Ibid., 5.

<sup>130</sup> Ibid.

<sup>131</sup> Ibid.

<sup>132</sup> Riese, *History of Neurology*, 95; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 4.

<sup>133</sup> Elena M. Kouri and Scott E. Lukas, "Electroencephalography, Topographic Mapping, and Event-Related Potentials in Substance Abuse Research," in *Brain Imaging in Substance Abuse: Research, Clinical, and Forensic Applications*, ed. Marc J. Kaufman (Totowa, N.J.: Human Press, 2001), 1.

signal occurred at the same time as nerve impulses, thus showing recognition that the electrical activity of living tissue could be used as a sign of its function.<sup>134</sup> Du Bois-Reymond's finding is believed to have prompted English physician Richard Caton to detect the presence of electrical currents in animals' brains in 1875,<sup>135</sup> and German neurologist Hans Berger to record the presence of electrical currents in human brains in 1924 or 1925.<sup>136</sup> Berger's radio equipment, which amplified the human brain's electrical activity and recorded it on graph paper, is sometimes referred to as the first human electroencephalogram (EEG).<sup>137</sup> Not all scientists accepted Berger's finding until 1934, when British scientists Edgar Adrian and B. Matthews replicated Berger's homemade EEG.<sup>138</sup>

Today's modern EEG has a number of clinical uses, including localizing tumors and lesions and determining whether individuals are asleep, anesthetized, brain dead, or suffering from an epileptic attack.<sup>139</sup> EEG also is used in a number of different brain mapping studies to reflect neuronal activity in the top layers of the cerebral cortex.<sup>140</sup> EEG's temporal resolution -- which can be measured in milliseconds from the underlying neuronal activity<sup>141</sup> -- allows scientists to accurately measure the timing of brain

<sup>134</sup> Ibid.

<sup>135</sup> Uttal, New Phrenology, 10-11.

<sup>&</sup>lt;sup>136</sup> L. F. Haas, "Neurological Stamp: Hans Berger (1873-1941), Richard Caton (1842-1926) and Electroencephalography," *Journal of Neurology, Neurosurgery, and Neuropsychology* 74, no. 1 (2003): 9; Uttal, *New Phrenology*, 50.

<sup>137</sup> Haas, "Neurological Stamp," 9; Judy Illes and Eric Racine, "Imaging or Imagining? A Neuroethics Challenge Informed by Genetics," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 6.

<sup>138</sup> Kouri and Lukas, "Electroencephalography," 1-2.

<sup>139</sup> Arthur W. Toga and John C. Mazziotta, "Introduction to Cartography of the Brain," in *Brain Mapping: The Methods*, ed. Arthur W. Toga and John C. Mazziotta (San Diego: Academic Press, 1996), 18; Uttal, *New Phrenology*, 52.

<sup>140</sup> Toga and Mazziotta, "Introduction," 18.

<sup>&</sup>lt;sup>141</sup> Ibid.

processes.<sup>142</sup> EEG does not, however, provide completely accurate correlations of brain functions and localizations with psychological states in part because of the diffuse nature of the responses and the lack of tight linkage to definable stimuli.<sup>143</sup>

Magnetoencephalography (MEG) is based on the knowledge that the brain's electrical fields also generate a measurable magnetic field. Hans Christian Oersted discovered in the early nineteenth century that electric currents generated a magnetic field. The first recording of biomagnetic signals (from the human heart) occurred in the early 1960s, and the first successful measurements of magnetic fields generated by intracranial currents occurred in 1972. Like EEG, today's modern MEG also has an excellent temporal resolution. However, extracranial MEG (and EEG) do not allow scientists to identify the exact location of a neural activity and thus do not provide detailed information about the relationship between brain structure and function. Although scientists can use intracranial electrodes to directly measure neuronal activity in animal studies, the implantation of electrodes in human subjects is highly controversial and currently limited to treatment of patients with certain types of epilepsy<sup>149</sup> and

<sup>142</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 5.

<sup>143</sup> Uttal, New Phrenology, 52.

<sup>144</sup> Toga and Mazziotta, "Introduction," 18.

<sup>145</sup> James W. Wheeless et al., "Magnetoencephalography (MEG) and Magnetic Source Imaging (MSI)," *Neurologist* 10, no. 3 (May 2004): 138.

<sup>146</sup> Gerhard M. Baule and Richard McFee, "Detection of the Magnetic Field of the Heart," *American Heart Journal* 66 (1963): 95; Gerhard M. Baule and Richard McFee, "Theory of Magnetic Detection of the Heart's Electrical Activity," *Journal of Applied Physics* 36, no. 6 (June 1965): 2066-73.

<sup>147</sup> David Cohen, "Magnetoencephalography: Detection of the Brain's Electrical Activity with a Super Conducting Magnetometer," *Science* 175, no. 4022 (February 11, 1972): 664-66.

<sup>148</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 5-6.

<sup>&</sup>lt;sup>149</sup> Mark S. George et al., "Vagus Nerve Stimulation: A New Tool for Brain Research and Therapy," *Biological Psychiatry* 47 (2000): 287-95.

Parkinson's disease, 150 and to research involving patients with treatment-resistant depression. 151

## X-RAY

A brief overview of the history, structural power, and functional limitations of x-ray and computed tomography must precede a discussion of modern functional neuroimaging techniques. On November 8, 1895, German physicist Wilhelm Conrad Röntgen was working with a device known as the "Crookes vacuum discharge tube" when he accidentally discovered a faint light shimmering on a nearby bench.<sup>152</sup> Röntgen found that the source of the light was a barium platinocyanide-coated screen that was lying on the bench.<sup>153</sup> After conducting several additional experiments, Röntgen found that the shimmering light, which he inferred were rays, could actually penetrate glass, air, and a variety of metals, but not a thin sheet of lead.<sup>154</sup> In the process of playing with the rays, Röntgen made an image of two of his fingers on the barium platinocyanide-coated screen and, over the next several weeks, made several other images using a photographic plate.<sup>155</sup> On December 28, 1895, Röntgen summarized his findings in a manuscript submitted to the *Proceedings of the Physical Medical Society of Würzburg*. Entitled "Uber eine Neue Art von Strahlen" (translated, "On a New Kind of Rays"), Röntgen's

<sup>150</sup> Maria C. Rodriguez-Oroz et al., "Bilateral Deep Brain Stimulation in Parkinson's Disease: A Multicentre Study with 4 Years Follow-Up," *Brain* 128, no. 10 (October 2005): 2240-49; U.S. Department of Health and Human Services, Food and Drug Administration, "FDA Approves Implanted Brain Stimulator to Control Tremors," *HHS News* (August 4, 1997), http://www.fda.gov/bbs/topics/NEWS/NEW00580.html (accessed February 16, 2006).

<sup>151</sup> Helen S. Mayberg et al., "Deep Brain Stimulation for Treatment-Resistant Depression," *Neuron* 45, no. 5 (March 3, 2005): 651-60.

<sup>152</sup> Richard I. Frankel, "Centennial of Röntgen's Discovery of X-rays," Western Journal of Medicine 164, no. 6 (June 1996): 498; Bettyann Holtzmann Kevles, Naked to the Bone: Medical Imaging in the Twentieth Century (New Brunswick, N.J.: Rutgers University Press, 1997), 2.

<sup>153</sup> Frankel, "Centennial," 498.

<sup>154</sup> Ibid.

<sup>155</sup> Ibid.

manuscript introduced the world to x-rays. Röntgen's findings, which included a now famous x-ray image of his wife's fingers with a rather substantial wedding ring, were first published in Vienna's popular journal *Die Presse* on January 5, 1896. The *Die Presse* piece noted the importance of Röntgen's rays to the future of medicine and surgery: "The surgeon could then determine the extent of a complicated bone fracture . . . he could find the position of a foreign body such as a bullet or a piece of shell much more easily than has been possible heretofore . . . "158

Röntgen's rays also raised privacy issues. In the six months following Röntgen's discovery, the fact that x-ray could "peer" inside the human body was made the subject of theatrical plays, and a London dry goods company began offering for sale x-ray-proof lead panties. One cartoon, showing three attractive women frolicking on the beach in swimsuits that looked like skeletons, carried the caption: "Cameramen see through the Bathing Beauties at Malibou Beach." Cartoons in which tax authorities and highway robbers used x-rays to find hidden moneys and full pockets were published, and a New Jersey legislator reportedly introduced a bill that would prohibit the use of x-ray opera glasses. The fact that x-ray could see the "unseen," including unseen spirits, also became a topic of interest within the spiritualist community. Manufacturers of x-ray machines even incorporated privacy themes into their marketing materials. One manufacturer's advertising pamphlets, published in 1896, came with red-tinted glasses.

<sup>156</sup> Ibid.

<sup>157</sup> Andrzej Stasiak, "Broken Symmetry," EMBO Reports 2, no. 7 (2001): 562.

<sup>158</sup> Frankel, "Centennial," 498.

<sup>159</sup> Kevles, *Naked to the Bone*, 27; Arne Hessenbruch, "A Brief History of X-Rays," *Endeavour* 26, no. 4 (December 1, 2002): 137.

<sup>160</sup> Lisa Cartwright, Screening the Body: Tracing Medicine's Visual Culture (Minneapolis: University of Minnesota Press, 1995), 122.

<sup>&</sup>lt;sup>161</sup> Hessenbruch, "A Brief History," 137.

<sup>162</sup> Kevles, Naked to the Bone, 27.

<sup>163</sup> Hessenbruch, "A Brief History," 137.

When the demurely dressed cover girl was viewed through the glasses, only her skeleton could be seen. A second x-ray machine advertisement, entitled "Naked Truth," featured two naked women. Emily Culverhouse even wrote a poem in 1897 about the loss of privacy resulting from Röntgen's rays:

An Englishman's body belongs to himself, But surely that proverb was made Before Dr. Roentgen's impertinent rays, With furtive, adumbrate, and mystical ways, Our structures began to invade.

'T is an "habeas corpus" of uncanny source, A forerunner of agencies evil, A gruesome, weird, and mysterious force, (But clothed in a garb of science of course) A league between man and the devil.

For a steady gaze thrown on the sensitive plate. With a one-ness of theme and conception. And fixing our minds in a uniform strain. Will picture the image begot by our brain. And reveal our most inmost perception.

Who among us is safe if this can be done, Who can bear such a scrutinization? Scant courtesy, too, our friends would afford. When they find that our actions are often a fraud. And our words but mis representation.<sup>166</sup>

The privacy concerns raised by Röntgen's rays were not just theoretical. French physician Charles Bourchard made his female servant the subject of an x-ray demonstration and exposed her breastbone to his colleagues in 1896, a time when

<sup>164</sup> Keyles, Naked to the Bone, 27.

<sup>165</sup> Ibid., 29; Cartwright, Screening the Body, 122.

<sup>166</sup> Kevles, Naked to the Bone, 28.

women's bodies were still considered somewhat a mystery.<sup>167</sup> Women became the most frequent subjects of early x-ray research – research that was conducted primarily by men.<sup>168</sup> *Highlights and Shadows*, a 1937 film by filmmaker-radiographer James Sibley Watson, contains several sequences featuring an attractive woman in a bathing suit, accompanied by narration that x-rays have made the woman vulnerable.<sup>169</sup>

X-rays were first used for forensic purposes two months after Röntgen's discovery. <sup>170</sup> In 1895, Canadian George Holder shot fellow countryman Tolman Cunnings in the leg during a barroom brawl. Although health care providers at Montreal General Hospital were able to stabilize Cunnings following the shooting, they could not find the bullet, and Cunnings continued to suffer great pain even after his hospital discharge. By the time the criminal case against Holder had reached the Court of Queen's Bench in Montreal in 1896, Cunning's lawyer had heard of Röntgen's discovery and requested a McGill University physics professor to use x-ray to locate the bullet inside Cunning's leg. The x-ray image was used to guide the surgical removal of the bullet, and then both the bullet and the image were admitted and considered key evidence in Holder's subsequent conviction and fourteen-year prison sentence. <sup>171</sup>

The first American case to admit an x-ray as evidence was tried in Denver, Colorado, in 1896.<sup>172</sup> Although judges in several prior American cases had refused to Röntgen's rays as evidence on the grounds that "'there is no proof that such a thing is possible," and defense counsel in the Denver case argued against the admission of the

<sup>&</sup>lt;sup>167</sup> Ibid., 30.

<sup>168</sup> Cartwright, Screening the Body, 154.

<sup>169</sup> Ibid., 155.

<sup>170</sup> Kevles, Naked to the Bone, 30-31.

<sup>171</sup> Ibid.

<sup>&</sup>lt;sup>172</sup> Ibid., 31.

<sup>173</sup> Ibid., 32n17.

proffered impacted femur fracture x-ray for three straight hours, Judge Owen E. Le Fevre decided to admit the x-ray into evidence:

We have been presented with a photograph taken by means of a new scientific discovery. . . . It knocks at the temple of learning; what shall we do or say? Close fast the doors or open wide the portal? Rather let the courts throw open the doors to all well considered scientific discoveries. Modern science has made it possible to look beneath the tissues of the human body and has aided surgery in telling of the hidden mysteries. We believe it to be our duty in this case to be the first, if you please to so consider it, in admitting in evidence the process known and acknowledged as a determinate science. The exhibits will be admitted in evidence.<sup>174</sup>

Today, we know that x-ray images (sometimes called radiographs) are produced by high-energy electrons that are thermally emitted from a negatively charged and heated filament (the cathode).<sup>175</sup> The negatively charged electrons are attracted to a positively charged metal electrode (the anode), which is also contained within the same evacuated tube as the cathode.<sup>176</sup> The voltage difference between the anode and the cathode accelerates the negatively charged electrons and thus increases their kinetic energy.<sup>177</sup> When the negative charge on the accelerated electrons interacts with the charged components of the nuclei of the atoms of the metal in the anode, the electrons change direction.<sup>178</sup> This change of direction is the primary source of x-rays.<sup>179</sup>

Although x-ray is not invasive and can show the detailed structure of the skull, as well as any fractures or tumors involving the bones of the skull, x-ray generally cannot detect the brain's soft tissues, including the gray and white matter of the brain, or

<sup>174</sup> Ibid., 32n18.

<sup>175</sup> Uttal, New Phrenology, 57.

<sup>176</sup> Ibid.

<sup>177</sup> Ibid.

<sup>&</sup>lt;sup>178</sup> Ibid.

<sup>&</sup>lt;sup>179</sup> Ibid.

distinguish between them.<sup>180</sup> X-ray has several other limitations, including the fact that it exposes its subjects to radiation and provides only two-dimensional pictures of the three-dimensional brain.<sup>181</sup> X-ray also is not capable of providing information about how the brain functions.<sup>182</sup>

#### **COMPUTED TOMOGRAPHY**

Computed tomography (CT), also referred to as computerized axial tomography (CAT), improves on x-ray by providing detailed, three-dimensional structural pictures of the brain. CT scanning was invented in 1972 through the independent efforts of British engineer Godfrey Hounsfield (Sir Godfrey, after his Knighthood) of Electrical and Musical Industries Limited Laboratories, in England, and by South African-born physicist Allan Cormack at Tufts University. Unlike conventional radiography, which sends a single x-ray through the body, CT scanning sends several x-rays through the body from several different angles and measures their strength after they have passed through the body. Beams that have passed through dense tissue, such as the bones of the skull, are weaker than beams that have passed through less dense tissue, such as the gray and white matter of the brain. A computer processes this information, determines the relative density of the tissues examined, and displays the results as a two-dimensional image on a computer monitor. Modern CT scanners reconstruct the two-dimensional computer images to produce three-dimensional images of the brain that can be used, for example, to help surgeons assess surgical risk and plan surgical routes. 184

Because it can distinguish among soft tissues in the brain, CT scanning has improved physicians' ability to assess brain damage and diagnose neurological diseases.

<sup>&</sup>lt;sup>180</sup> Ibid., 61.

<sup>&</sup>lt;sup>181</sup> Ibid., 68.

<sup>182</sup> Ibid.

<sup>183</sup> Ibid., 62.

<sup>184</sup> Ibid.

After John Hinckley shot President Ronald Reagan, James Brady, a police officer, and a secret service agent, George Washington Medical Center (GWMC) neurosurgeon Arthur Kobrine ordered a CT scan to determine the severity of damage to Brady's head, which had been hit by one of the bullets. After GWMC neuroradiologist David Davis showed Kobrine the CT, which revealed a huge blood clot, Kobrine used the information to surgically pop the clot and save Brady's life. In an interesting twist, Hinckley subsequently attempted to use a CT scan of his own brain as evidence to show the jury in his criminal trial that his brain was "shrunken" and had "enlarged sulci." Hinckley was attempting to prove that he was mentally diseased and therefore not criminally responsible for the shootings. Hinckley's CT was the first CT to be admitted as evidence in an American court. 187

Although CT scanning is not invasive and modern CT scanners acquire images quite rapidly, <sup>188</sup> CT scanning does have several limitations. <sup>189</sup> The technology exposes its subjects to radiation, <sup>190</sup> requires very expensive computers to process the three-dimensional images, and has a spatial resolution that is considered inferior to magnetic resonance imaging. <sup>191</sup> CT also is incapable of providing information about how the brain functions. <sup>192</sup>

<sup>185</sup> Kevles, Naked to the Bone, 146.

<sup>186</sup> Lincoln Caplan, *The Insanity Defense and the Trial of John W. Hinckley, Jr.* (Boston: D. R. Godine, 1984), 85; Kevles, *Naked to the Bone*, 169.

<sup>187</sup> Kevles, Naked to the Bone, 169.

<sup>188</sup> Toga and Mazziotta, "Introduction," 17.

<sup>189</sup> Uttal, New Phrenology, 68.

<sup>&</sup>lt;sup>190</sup> Ibid.

<sup>&</sup>lt;sup>191</sup> Toga and Mazziotta, "Introduction," 17.

<sup>192</sup> Uttal, New Phrenology, 68.

# POSITRON EMISSION TOMOGRAPHY AND SINGLE-PHOTON EMISSION COMPUTED TOMOGRAPHY

Although x-ray and CT scanning only provide structural information about the brain, positron emission tomography (PET) and single-photon emission computed tomography (SPECT) can provide information about how the brain actually functions.<sup>193</sup> The history of PET dates back to the 1940s, when Hungarian George de Hevesy discovered that a radioactive isotope of a molecule could be used in place of the molecule because it is chemically indistinguishable, and that the radioactivity of the isotope could be tracked.<sup>194</sup> PET involves the use of a cyclotron, which produces positron-emitting isotopes of carbon, oxygen, nitrogen, or fluorine.<sup>195</sup> Atoms from these positron-emitting isotopes are used to "tag" molecules of a compound of interest, which are then injected intravenously into the subject's body.<sup>196</sup> These compounds are referred to as biological tracers or probes because they are used to trace or probe biological processes.<sup>197</sup> The atoms of the isotopes, which are attached to the biological probe, have very short half-lives and emit a positively charged electron, or a positron, in the process of decay.<sup>198</sup> When this positron collides with an electron, the two particles annihilate each other and

<sup>&</sup>lt;sup>193</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 3; Uttal, New Phrenology, 69.

<sup>&</sup>lt;sup>194</sup> Joseph Dumit, *Picturing Personhood: Brain Scans and Biomedical Identity* (Princeton, N.J.: Princeton University Press, 2004), 27-28.

<sup>195</sup> Simon R. Cherry and Michael E. Phelps, "Imaging Brain Function with Positron Emission Tomography," in *Brain Mapping: The Methods*, ed. Arthur W. Toga and John C. Mazziotta (San Diego: Academic Press, 1996), 192; D. Frank Benson et al., "Positron-Computed Tomography in Neurobehavioral Problems," in *Localization in Neuropsychology*, ed. Andrew Kertesz (New York: Academic Press, 1983), 123.

<sup>196</sup> Cherry and Phelps, "Imaging Brain Function," 192; Randy L. Buckner and Jessica M. Logan, "Functional Neuroimaging Methods: PET and fMRI," in *Handbook of Functional Neuroimaging of Cognition*, ed. Roberto Cabeza and Alan Kingstone (Cambridge: MIT Press, 2001), 28.

<sup>197</sup> Cherry and Phelps, "Imaging Brain Function," 192.

<sup>198</sup> Per E. Roland, Brain Activation (New York: Wiley-Liss, 1993), 427.

the result is the emission of two gamma rays in opposite directions, 180 degrees apart. A PET scanner contains circular, and thus oppositely-placed, gamma ray-detectors that detect the gamma rays as they simultaneously leave the patient's body. This information is fed into a computer, which determines the line, called a coincidence line, along which the annihilation took place. By combining coincidence lines from many different angles over time, PET makes it possible to determine the rate of biological processes in which the probe is involved. 202

In 1973, Michael Phelps, Edward Hoffman, and Michael Ter-Pogossian at Washington University in St. Louis built the first PET scanner, which collected 12 coincidence lines of response between detectors.<sup>203</sup> Phelps eventually moved to UCLA and moved PET technology into the mainstream of medical imaging.<sup>204</sup> Today, PET is known for its ability to measure local neuronal activity, neurochemistry, and pharmacology in the human brain.<sup>205</sup> Current clinical uses of PET include, but certainly are not limited to, determining heart tissue viability, diagnosing head trauma, and locating cancer in the brain, breast, lung, lower gastrointestinal tract, and other sites. PET also allows research scientists to see in three-dimension the areas of the brain that are metabolically correlated with certain mental functions, such as seeing faces, reading

<sup>199</sup> E. Jeffrey Metter and Wayne R. Hanson, "Use of Positron Emission Tomography to Study Aphasia," in *Localization and Neuroimaging in Neuropsychiatry*, ed. Andrew Kertesz (San Diego: Academic Press, 1994), 124; Roland, *Brain Activation*, 428; Cherry and Phelps, "Imaging Brain Function," 192.

<sup>&</sup>lt;sup>200</sup> Roland, Brain Activation, 428-29.

<sup>201</sup> Benson et al., "Positron-Computed Tomography," 123-24.

<sup>&</sup>lt;sup>202</sup> Cherry and Phelps, "Imaging Brain Function," 192.

<sup>&</sup>lt;sup>203</sup> Michael E. Phelps, Edward J. Hoffman, and Nizar A. Mullani, "Application of Annihilation Coincidence Detection to Transaxial Reconstruction Tomography," *Journal of Nuclear Medicine* 16 (1975): 210-33; Dumit, *Picturing Personhood*, 27, 29.

<sup>&</sup>lt;sup>204</sup> Cherry and Phelps, "Imaging Brain Function," 197-98.

<sup>&</sup>lt;sup>205</sup> Robert T. Malison, "Positron Emission Tomography and Single-Photon Emission Computed Tomography," in *Brain Imaging in Substance Abuse: Research, Clinical, and Forensic Applications*, ed. Marc J. Kaufman (Totowa, N.J.: Humana Press, 2001), 29.

sentences, and touching or moving a part of the body.<sup>206</sup> Research using PET has contributed to the understanding of oxygen utilization and the metabolic changes that accompany disease, including Alzheimer's disease, Parkinson's disease, epilepsy, and coronary artery disease, and drug and alcohol abuse. Psychiatrists also have used PET to conduct extensive studies of schizophrenia, bipolar disorder, and depression.<sup>207</sup>

Like x-ray and CT, PET has been put to forensic use. Most of the referrals to the PET Laboratory at the University of California at Irvine during the mid-1990s came from defense attorneys requesting PET scans of the brains of their clients, who had been convicted of felonies and were waiting sentencing.<sup>208</sup> However, concerns regarding the use of PET for forensic purposes have been raised. Some scientists argue that predicting behavior using PET is not sufficiently accurate for forensic settings,<sup>209</sup> while others are concerned that courtroom juries will view PET more objectively than those physicians and scientists who interpret it.<sup>210</sup>

Compared to CT and magnetic resonance imaging, PET is extremely sensitive, as determined by its ability to quantitatively determine and display tracer concentrations in the nanopolar range. However, PET is not without its limitations. PET requires the injection of a radioactive material into the patient or research subject and, thus, is invasive.<sup>211</sup> Creating radioactive isotopes in a cyclotron is expensive, and PET acquires images relatively slowly.<sup>212</sup> Finally, the value of PET images continues to be debated,

<sup>&</sup>lt;sup>206</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 3-4.

<sup>&</sup>lt;sup>207</sup> Dumit, Picturing Personhood, 27.

<sup>&</sup>lt;sup>208</sup> Kevles, Naked to the Bone, 215.

<sup>&</sup>lt;sup>209</sup> John C. Mazziotta, "The Use of Positron-Emission Tomography (PET) in Medical-Legal Cases: The Position Against Its Use," in *Controversies in Neurology*, American Academy of Neurology Syllabus, Course No.147 (1997).

<sup>&</sup>lt;sup>210</sup> Dumit, Picturing Personhood.

<sup>&</sup>lt;sup>211</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 4.

<sup>&</sup>lt;sup>212</sup> Ibid.

especially because of the wide variation in results among individuals and groups scanned.<sup>213</sup>

Single-photon emission computed tomography (SPECT) also measures local neuronal activity, neurochemistry, and pharmacology in the human brain, but in a slightly different way than PET. Whereas PET infers the site of an annihilation event from the coincidence detection of photons, SPECT infers photon paths from their ability to pass through a collimator that has certain long and narrow holes.<sup>214</sup> Whereas PET employs a circular ring of radiation detectors, SPECT usually collects data through several rotating detector heads.<sup>215</sup> SPECT is more simple and less expensive than PET, although frequently noted for its lower resolution. Today, SPECT frequently is used in brain perfusion imaging and to study dementia, stroke, trauma, seizures, schizophrenia, and several other neurodegenerative processes.<sup>216</sup>

### MAGNETIC RESONANCE IMAGING

Like PET and SPECT, functional magnetic resonance imaging (fMRI) can provide detailed information about how the brain actually functions. Before discussing the extraordinary powers and current limitations of fMRI, an understanding of magnetic resonance imaging is necessary.

## The First Report of Nuclear Magnetic Resonance

The notion that atomic nuclei have magnetic properties that can be manipulated in an experiment developed in the 1920s.<sup>217</sup> In 1924, Austrian physicist Wolfgang Pauli hypothesized that atomic nuclei could spin at some frequencies, but not other frequencies,

<sup>&</sup>lt;sup>213</sup> Dumit, Picturing Personhood, 24.

<sup>&</sup>lt;sup>214</sup> Malison, "Positron Emission Tomography," 31-32.

<sup>&</sup>lt;sup>215</sup> Ibid., 33.

<sup>&</sup>lt;sup>216</sup> Tuberous Sclerosis Alliance, *Images of the Living Brain* (Silver Spring, Md.: Tuberous Sclerosis Alliance, 2004), 2.

<sup>&</sup>lt;sup>217</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 11.

and that atomic nuclei could exert particular magnetic forces, but not other magnetic forces.<sup>218</sup> To test this hypothesis, Otto Stern and Walter Gerlach developed a technique that involved passing a gaseous beam of a single element through a strong, static magnetic field before hitting a detector plate.<sup>219</sup> If the magnetic field split the beam into a number of smaller beams, that meant that different atomic nuclei spin at discrete frequencies.<sup>220</sup> On the other hand, if the detector showed a continuous distribution of intensity, that meant that the spin frequencies could take a continuous range of possible values.<sup>221</sup> Stern and Gerlach found that their technique split the beam into a number of small beams, which meant that different atomic nuclei spin at discrete frequencies.<sup>222</sup>

Scientists still did not know, however, what the different atomic nuclei's frequencies were. In 1937, Dutch physicist Cornelis Gorter shared with American physicist Isidor Rabi Gorter's recent experiments involving oscillating magnetic fields.<sup>223</sup> Inspired by his meeting with Gorter, Rabi hypothesized that an atomic nucleus might absorb energy from a magnetic field if the frequency of the oscillating magnetic field matched the spin frequency of the atomic nucleus.<sup>224</sup> Rabi confirmed his hypothesis in an experiment and published the results in a 1938 letter to the editor ("A New Method of Measuring Nuclear Magnetic Moment") of *Physical Review*.<sup>225</sup> Rabi won the Nobel

<sup>&</sup>lt;sup>218</sup> Ibid.

<sup>&</sup>lt;sup>219</sup> Ibid., 14.

<sup>&</sup>lt;sup>220</sup> Ibid.

<sup>&</sup>lt;sup>221</sup> Ibid.

<sup>&</sup>lt;sup>222</sup> Ibid.

<sup>&</sup>lt;sup>223</sup> Ibid.

<sup>&</sup>lt;sup>224</sup> Ibid.

<sup>&</sup>lt;sup>225</sup> Isidor I. Rabi et al., "A New Method of Measuring Nuclear Magnetic Moment," *Physical Review* 53, no. 4 (February 15, 1938): 318.

Prize in Physics in 1944 for this work, which is considered the first report of nuclear magnetic resonance.<sup>226</sup>

# Magnetic Resonance in Bulk Matter; Practical Applications

The first reports of nuclear magnetic resonance relied on experiments that involved gaseous beams, not bulk matter.<sup>227</sup> For practical applications to be developed, magnetic resonance also would need to be demonstrated in bulk matter.<sup>228</sup> Physicist Edward Purcell and his colleagues at Harvard and MIT first investigated the magnetic resonance of bulk matter in December 1945.<sup>229</sup> In their first experiment, they inserted paraffin wax into the center of a strong magnetic field for a short period of time, reasoning that the wax would absorb energy if they matched its resonance frequency to the oscillating magnetic field. The scientists then could determine whether the wax actually absorbed any energy by using a circuit to detect the wax's changed electrical conductance.<sup>230</sup> The scientists found no resonance in the wax from this first experiment, and no resonance in the wax from a second experiment in which the wax was placed in the magnetic field for a longer period of time.<sup>231</sup> In a third experiment, in which the scientists gradually increased the magnetic current to the highest level and then brought it back down to the lowest level, they found a clear resonance effect at a high magnetic current.<sup>232</sup> Apparently, they had simply misjudged in the first two experiments the

<sup>&</sup>lt;sup>226</sup> Perry F. Renshaw, Blaise Frederick, and Luis C. Maas, "Fundamentals of Magnetic Resonance," in *Brain Imaging in Substance Abuse: Research, Clinical, and Forensic Applications*, ed. Marc J. Kaufman (Totowa, N.J.: Humana Press, 2001), 48.

<sup>&</sup>lt;sup>227</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 16.

<sup>&</sup>lt;sup>228</sup> Ibid.

<sup>&</sup>lt;sup>229</sup> P. T. Narasimhan and Russell E. Jacobs, "Neuroanatomical Micromagnetic Resonance Imaging," in *Brain Mapping: The Methods*, ed. Arthur W. Toga and John C. Mazziotta (San Diego: Academic Press, 1996), 147; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 16; Raichle, "Functional Neuroimaging," 11.

<sup>&</sup>lt;sup>230</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 16.

<sup>&</sup>lt;sup>231</sup> Ibid.

<sup>&</sup>lt;sup>232</sup> Ibid.

amount of current that was necessary to generate the appropriate magnetic field.<sup>233</sup> Purcell and his colleagues' third experiment, which demonstrated magnetic resonance effects in paraffin wax, was published in a letter to the editor ("Resonance Absorption by Nuclear Magnetic Moments in a Solid") of *Physical Review* dated December 24, 1945.<sup>234</sup>

While Purcell and his colleagues were demonstrating the magnetic resonance effects in paraffin wax at MIT's Radiation Laboratory in Cambridge, Felix Bloch and his colleagues at Stanford also were trying to demonstrate magnetic resonance effects in water.<sup>235</sup> Bloch and his colleagues conducted an experiment in which they placed water in a brass box in a magnetic field that they could manipulate.<sup>236</sup> Then, the scientists used a transmitter coil to send electromagnetic energy into the water and a detector coil to measure the energy absorbed by the water.<sup>237</sup> Bloch and his colleagues published their findings, which demonstrated magnetic resonance effects in water, in a letter to the editor ("Nuclear Induction") of *Physical Review* dated January 29, 1946.<sup>238</sup> The scientists concluded their letter with a nod to the promise of their findings: "We have thought of various investigations in which this effect can be used fruitfully. A detailed account will be published in the near future."<sup>239</sup> In 1952, Purcell and Bloch received a joint Nobel Prize in Physics for their discovery of nuclear induction, also called nuclear magnetic resonance.<sup>240</sup> The fundamentals of the design that Bloch and his colleagues used in their

<sup>&</sup>lt;sup>233</sup> Ibid.

<sup>&</sup>lt;sup>234</sup> Edward M. Purcell, Henry C. Torrey, and Robert V. Pound, "Resonance Absorption by Nuclear Moments in a Solid," *Physical Review* 69, no. 1-2 (January 1, 1946): 37-38.

<sup>&</sup>lt;sup>235</sup> Raichle, "Functional Neuroimaging," 11; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 17.

<sup>&</sup>lt;sup>236</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 17.

<sup>&</sup>lt;sup>237</sup> Ibid.

<sup>&</sup>lt;sup>238</sup> Felix Bloch, William W. Hansen, and Martin Packard, "Nuclear Induction," *Physical Review* 69, no. 3-4 (February 1, 1946): 127.

<sup>&</sup>lt;sup>239</sup> Ibid.

<sup>&</sup>lt;sup>240</sup> Huettel, Functional Magnetic Resonance Imaging, 17.

experiment -- the static magnetic field, transmitter coil, and detector coil -- are used in today's magnetic resonance imaging scanners.<sup>241</sup>

In the late 1960s and early 1970s, early detection of cancer remained difficult because of the high permeability of cancer tumors to X rays.<sup>242</sup> In the early 1970s, an American physician named Raymond Damadian hypothesized that nuclear magnetic resonance might help this problem by distinguishing between cancerous and noncancerous cells.<sup>243</sup> Damadian investigated his hypothesis by analyzing tissue samples taken from rats that had been infected with Walker sarcoma and Novikoff hepatoma.<sup>244</sup> Damadian's findings -- that nuclear magnetic resonance made it possible to detect the presence of Walker sarcoma or Novikoff hepatoma in the tissue of rats -- were published in *Science* on March 19, 1971.<sup>245</sup>

# **Magnetic Resonance Imaging and Commercial Scanners**

Damadian's cancer experiment measured the total amount of energy absorbed and emitted by the different rat tissue samples, but it did not involve the creation of any images.<sup>246</sup> After reviewing Damadian's experiments, an American physicist named Paul Lauterbur realized that nuclear magnetic resonance might also have the potential to create images.<sup>247</sup> Lauterbur hypothesized in 1972 that if the strength of the magnetic field varied over space, the resonant frequencies of protons at different field locations also would vary.<sup>248</sup> If one could measure how much energy was emitted at each different

<sup>&</sup>lt;sup>241</sup> Ibid.

<sup>&</sup>lt;sup>242</sup> Raymond Damadian, "Tumor Detection by Nuclear Magnetic Resonance," *Science* 171, no. 3796 (March 19, 1971): 1151.

<sup>&</sup>lt;sup>243</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 17.

<sup>&</sup>lt;sup>244</sup> Damadian, "Tumor Detection," 1152.

<sup>&</sup>lt;sup>245</sup> Ibid.

<sup>&</sup>lt;sup>246</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 18.

<sup>&</sup>lt;sup>247</sup> Ibid.

<sup>&</sup>lt;sup>248</sup> Ibid.

frequency, then one could identify the size of the object at each location in space.<sup>249</sup> Known as the induction of spatial gradients in the magnetic field, Lauterbur's idea formed the foundation of modern magnetic resonance imaging.<sup>250</sup> Lauterbur also realized that he could create a two-dimensional image by acquiring a succession of one-dimensional projections.<sup>251</sup> Lauterbur used this latter technique to create and publish in *Nature* in 1973 the first magnetic resonance image, which happened to be an image of a pair of water-filled test tubes.<sup>252</sup>

Although Lauterbur's technique formed the foundation of modern magnetic resonance imaging, the number of acquisitions required made the technique very slow.<sup>253</sup> In 1976, British physicist Peter Mansfield proposed a more efficient technique known as echo-planar imaging.<sup>254</sup> In echo-planar imaging, data is collected from an entire image slice at one time by sending one electromagnetic pulse from a transmitter coil and then introducing rapidly changing magnetic field gradients while recording the magnetic resonance signal.<sup>255</sup> Because it reduced the amount of time needed to collect a single image from minutes to seconds, Mansfield's technique contributed to the feasibility of both structural imaging in the clinical setting as well as functional imaging, the latter of which requires very fast imaging to measure changes in brain function.<sup>256</sup> Lauterbur and

<sup>&</sup>lt;sup>249</sup> Ibid.

<sup>&</sup>lt;sup>250</sup> Narasimhan and Jacobs, "Neuroanatomical Micromagnetic Resonance Imaging," 148; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 18.

<sup>&</sup>lt;sup>251</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 18.

<sup>&</sup>lt;sup>252</sup> Paul C. Lauterbur, "Image Formation by Induced Local Interactions: Examples Employing Nuclear Magnetic Resonance," *Nature* 242 (1973): 190-91.

<sup>&</sup>lt;sup>253</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 18-19.

<sup>&</sup>lt;sup>254</sup> Narasimhan and Jacobs, "Neuroanatomical Micromagnetic Resonance Imaging," 148.

<sup>&</sup>lt;sup>255</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 19.

<sup>&</sup>lt;sup>256</sup> Jeffrey R. Binder and Stephen M. Rao, "Human Brain Mapping with Functional Magnetic Resonance Imaging," in *Localization and Neuroimaging in Neuropsychology*, ed. Andrew Kertesz (San Diego: Academic Press, 1994), 186-87.

Mansfield jointly received the 2003 Nobel Prize in Physiology or Medicine for their use of magnetic resonance in image formation.<sup>257</sup>

Despite the developments in magnetic resonance imaging theory, commercial scanners big enough to scan humans had yet to be engineered.<sup>258</sup> In 1977, Damadian's FONAR Corporation built the first human nuclear magnetic resonance scanner, which they nicknamed the "Indomitable."<sup>259</sup> On July 3 of that year, Larry Minkoff, a postdoctoral fellow in Damadian's laboratory, was the first human subject from whom data was recorded by a nuclear magnetic resonance scanner.<sup>260</sup> The resulting image, which showed a slice of Minkoff's chest including his heart, lungs, and surrounding muscles, took almost four hours to complete.<sup>261</sup> By 1979, Damadian and other researchers had used nuclear magnetic resonance imaging technology to create images of individuals' abdomens, upper torsos, heads, and brains, the latter of which had been especially difficult to obtain using x-ray.<sup>262</sup> Around the same time, the adjective nuclear was dropped from the technology due to the negative health connotations of the word and the fact that nuclear magnetic resonance does not use ionizing radiation.<sup>263</sup> By the early 1980s, nuclear magnetic resonance became known as magnetic resonance imaging (MRI).<sup>264</sup>

By the early 1980s, several companies had developed industrial MRI scanners with magnetic fields of 0.1 to 1.0 Tesla.<sup>265</sup> General Electric was the first company to

<sup>&</sup>lt;sup>257</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 19.

<sup>&</sup>lt;sup>258</sup> Ibid.

<sup>&</sup>lt;sup>259</sup> Ibid.

<sup>&</sup>lt;sup>260</sup> Ibid., 20.

<sup>&</sup>lt;sup>261</sup> Ibid.

<sup>&</sup>lt;sup>262</sup> Ibid.

<sup>&</sup>lt;sup>263</sup> Ibid.

<sup>&</sup>lt;sup>264</sup> Ibid., 21.

<sup>&</sup>lt;sup>265</sup> Ibid., 2.

create a commercial, human-body scanner with a relatively strong (1.5-Tesla) magnetic field in 1982, and hospitals began installing the scanners, which became the standard scanner for clinical imaging for the next twenty years, a short time later.<sup>266</sup> In 1985, the Food and Drug Administration approved MRI technology for clinical use, which allowed health care providers to order MRI scans and bill them to health insurance companies.<sup>267</sup> By the mid-1990s, thousands of MRI scanners were installed in hospitals and imaging centers across North America, and structural MRI had become one of the most common diagnostic imaging procedures.<sup>268</sup>

Today, MRI is considered one of the most powerful and efficient methods of imaging the human brain.<sup>269</sup> Because it is not invasive, MRI is superior to PET and SPECT, which require the injection of radioactive material into the patient or research subject.<sup>270</sup> MRI does not use any radiation, as does x-ray and CT scanning.<sup>271</sup> MRI also can provide more detail than CT, PET, and SPECT scanning because of its unique contrast characteristics.<sup>272</sup> Because of these qualities, MRI is considered to provide the best *in vivo* structural images of the human brain.<sup>273</sup>

Like x-ray and CT scans, MRI scans also were put to use in the courtroom. An MRI of Rodney King's head, which was beaten by four white policemen in Los Angeles in 1991, was admitted as evidence in King's civil trial. The MRI showed the jury "where cerebral spinal fluid had leaked through multiple skull fractures . . . into King's right maxillary sinus," and is considered key evidence leading to King's \$3.8 million

<sup>&</sup>lt;sup>266</sup> Ibid., 21.

<sup>&</sup>lt;sup>267</sup> Ibid.

<sup>&</sup>lt;sup>268</sup> Ibid.

<sup>&</sup>lt;sup>269</sup> Narasimhan and Jacobs, "Neuroanatomical Micromagnetic Resonance Imaging," 148.

<sup>&</sup>lt;sup>270</sup> Ibid.

<sup>&</sup>lt;sup>271</sup> Ibid.

<sup>&</sup>lt;sup>272</sup> Ibid.

<sup>&</sup>lt;sup>273</sup> Toga and Mazziotta, "Introduction," 17.

compensatory damage award.<sup>274</sup> MRI scans of infants' heads also have been used in "shaken baby" cases, both as incriminating and exculpatory evidence in cases involving parents and other caretakers.<sup>275</sup>

## The Physiological Basis of BOLD fMRI

Although MRI is capable of measuring structural differences between tissues, it does not measure brain function, as does functional magnetic resonance imaging (fMRI). Very generally, fMRI measures localized changes in blood oxygenation that occur in the brain when a patient or research subject performs a particular mental task.<sup>276</sup> A brief history of the physiological basis of fMRI is necessary to understand the fMRI studies discussed in Chapter 2.

In 1881, Italian physiologist Angelo Mosso recorded the pulsation of the human cortex in post-neurosurgery patients with skull defects.<sup>277</sup> Mosso found that the pulsations increased regionally during mental activity and concluded that brain circulation must change with neuronal activity.<sup>278</sup> In his seminal *Principles of Psychology* (1890), William James referred to Mosso's work when stating that blood flow in the brain changes during mental activities.<sup>279</sup> In 1936, an American chemist and Nobel Prize winner named Linus Pauling and one of his students, Charles Coryell, discovered that deoxygenated blood has approximately one-fifth more magnetic susceptibility than fully oxygenated blood. Pauling and Coryell predicted that certain magnetic resonance pulse sequences would show more magnetic resonance signal when blood is highly oxygenated and less magnetic resonance signal where blood is highly

<sup>&</sup>lt;sup>274</sup> Kevles, Naked to the Bone, 175.

<sup>&</sup>lt;sup>275</sup> Ibid., 194.

<sup>&</sup>lt;sup>276</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 23.

<sup>277</sup> Raichle, "Functional Neuroimaging," 5.

<sup>&</sup>lt;sup>278</sup> Ibid.

<sup>&</sup>lt;sup>279</sup> William James, *Principles of Psychology*, vol. 1 (New York: Holt, 1890), 97.

deoxygenated.<sup>280</sup> This prediction, which was verified in the early 1980s by Keith Thulborn and his colleagues, provided a theoretical basis for measuring blood oxygenation changes using MRI.<sup>281</sup>

The possibility of using MRI to study brain physiology was first explored by Seiji Ogawa, a Bell Laboratories research scientist, in the late 1980s.<sup>282</sup> Ogawa and his colleagues hypothesized that blood flow could serve as an indirect measure of metabolism that could be measured by MRI.<sup>283</sup> More specifically, their theory was that changes in blood flow would be accompanied by changes in oxygen consumption, which would lead to measurable changes in the amount of oxygen remaining in blood vessels at the site of brain activation.<sup>284</sup> Ogawa and his colleagues tested their hypothesis by using an MRI scanner with a very strong (7-Tesla) magnetic field to image the brains of anesthetized rats while they breathed air with different amounts of oxygen. Ogawa and his colleagues found that the presence of deoxygenated hemoglobin in blood vessels caused magnetic susceptibility effects that could be imaged.<sup>285</sup> The scientists verified their findings, which were referred to as blood-oxygenation-level dependent (BOLD) contrast, in a second experiment in which they used an MRI scanner to image tubes filled with oxygenated and deoxygenated blood. The second experiment confirmed the scientists' earlier conclusion that the presence of deoxygenated blood reduces the

<sup>&</sup>lt;sup>280</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 159.

<sup>&</sup>lt;sup>281</sup> Keith R. Thulborn et al., "Oxygenation Dependence of the Transverse Relaxation Time of Water Protons in Whole Blood at High Field," *Biochimica et Biophysica Acta* 714, no. 2 (February 2, 1982): 265-70.

<sup>&</sup>lt;sup>282</sup> Raichle, "Functional Neuroimaging," 3; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 160.

<sup>&</sup>lt;sup>283</sup> Ibid.

<sup>&</sup>lt;sup>284</sup> Raichle, "Functional Neuroimaging," 1.

<sup>&</sup>lt;sup>285</sup> Seiji Ogawa et al., "Oxygenation-Sensitive Contrast in Magnetic Resonance Image of Rodent Brain at High Magnetic Fields," *Magnetic Resonance Imaging* 14, no. 1 (1990): 68-78.

magnetic resonance signal relative to the presence of oxygenated blood.<sup>286</sup> In a third experiment, the scientists attempted to verify that BOLD contrast resulted from the metabolic demand for oxygen by changing the gases inhaled by anesthetized rats while measuring BOLD contrast at a high magnetic field. The scientists found that BOLD contrast depends on the metabolic demand for oxygen.<sup>287</sup>

Although Ogawa and his colleagues found in their three initial experiments that MRI could be used to measure changes in blood oxygenation, scientists still needed to demonstrate that MRI could be used to identify the parts of the human brain that were responsible for different functions.<sup>288</sup> Three groups of scientists published BOLD fMRI studies involving human subjects in 1992. In the first study, Kenneth Kwong and his colleagues used a 1.5-Tesla magnetic field to scan the brains of individuals as they alternated between watching a flashing pattern and watching nothing. The scientists found significant activity in the subjects' visual cortex that lasted while the pattern flashed, but that receded when nothing was shown.<sup>289</sup> In the second study, Ogawa and his colleagues replicated the findings of Kwong and his colleagues using a much higher (4-Tesla) magnetic field.<sup>290</sup> In a third study, Peter Bandettini and his colleagues scanned the brains of their research subjects using a 1.5-Tesla magnetic field while the subjects repeatedly touched their fingers to their thumbs. The scientists found significant activity

<sup>&</sup>lt;sup>286</sup> Seiji Ogawa and Tso-Ming Lee, "Magnetic Resonance Imaging of Blood Vessels at High Fields: In Vivo and in Vitro Measurements and Image Simulation," *Magnetic Resonance Imaging* 16, no. 1 (October 1990): 9-18.

<sup>&</sup>lt;sup>287</sup> Seiji Ogawa et al., "Brain Magnetic Resonance Imaging with Contrast Dependent on Blood Oxygenation," *Proceedings of the National Academy of Sciences* 87, no. 24 (December 15, 1990): 9868-72.

<sup>&</sup>lt;sup>288</sup> Huettel, Song, and McCarthy, Functional Magnetic Resonance Imaging, 171.

<sup>&</sup>lt;sup>289</sup> Kenneth K. Kwong et al., "Dynamic Magnetic Resonance Imaging of Human Brain Activity during Primary Sensory Stimulation," *Proceedings of the National Academy of Sciences* 89, no. 12 (June 15, 1992): 5675-79.

<sup>&</sup>lt;sup>290</sup> Seiji Ogawa et al., "Intrinsic Signal Changes Accompanying Sensory Stimulation: Functional Brain Mapping with Magnetic Resonance Imaging," *Proceedings of the National Academy of Sciences* 89, no. 13 (July 1, 1992): 5951-55.

in the subjects' primary motor cortex.<sup>291</sup> Although the identification of the parts of the brain responsible for visual and sensorimotor functions had been known since the end of the nineteenth century, the studies of Kwong, Ogawa, and Bandettini replicated these findings, thus validating the use of fMRI to study other brain functions.

Today, fMRI is considered a powerful and efficient method of imaging human brain function. In a typical fMRI experiment, subjects are assigned one or more control and experimental tasks, and their brains are scanned during the performance of such tasks.<sup>292</sup> By subtracting the control images from the experimental images, scientists can create maps of the brain showing the areas to which a surplus of oxygenated blood flowed in response to performance of the experimental task.<sup>293</sup>

#### Criticisms of fMRI

A number of popular fMRI studies are introduced in Chapter 2; however, these studies have been criticized on a number of grounds. As an indirect measurement of brain activity based on hemodynamics, aspects of fMRI are incompletely understood, in part because the hemodynamic response lasts longer than the underlying neuronal activity.<sup>294</sup> Experts thus debate what aspects of neural function fMRI actually measures.<sup>295</sup> Some believe that fMRI signals are better correlated with the neurons' receiving input and processing activity compared to their spiking, or output, activity.<sup>296</sup> Others emphasize that fMRI measures very small changes in blood flow, which may not

<sup>&</sup>lt;sup>291</sup> Peter A. Bandettini, "Time Course EPI of Human Brain Function during Task Activation," *Magnetic Resonance Imaging* 25, no. 2 (June 1992): 390-97.

<sup>&</sup>lt;sup>292</sup> Illes and Racine, "Imaging or Imagining?" 7.

<sup>&</sup>lt;sup>293</sup> Ibid.; Binder and Rao, "Human Brain Mapping," 193; Donald Kennedy, "Neuroimaging: Revolutionary Research Tool of a Post-Modern Phrenology?" *American Journal of Bioethics* 5, no. 2 (March-April 2005): 19.

<sup>&</sup>lt;sup>294</sup> Buckner and Logan, "Functional Neuroimaging Methods," 27-29.

<sup>&</sup>lt;sup>295</sup> Rachel Jones, "Neuroimaging: A Bold Step Forward," *Nature Reviews Neuroscience* 2, no. 8 (August 2001): 531.

<sup>&</sup>lt;sup>296</sup> Sandie Cleland, "What Does fMRI Actually Measure?" *Psychologist* 17, no. 7 (July 1, 2004): 388; Jones, "Neuroimaging," 531.

be significant.<sup>297</sup> Still others point to the difficulties associated with identifying the activity or occurrence that triggered the increased blood flow. A particular brain response could be due to the fact that a particular image is shown to the subject; or, it may be due to the brightness of the image, the task of identifying the image, the subject's fear of the fMRI, or her current emotional state.<sup>298</sup>

Reading fMRI scans also is considered a highly interpretive practice:

"Sometimes, the difference between seeing higher activity in the parietal lobe compared to the occipital lobe is akin to deciding whether Van Gogh or Matisse is the more colorful artist." Stated another way, "What constitutes a 'significantly greater' activation is, in a way, in the eye of the beholder." Based on these concerns, some believe that fMRI offers nothing more than "pretty pictures that simply show where activity occurs in the brain." Those who recognize the ability of fMRI to show regional activations argue that, "[just] knowing where something happens does not reveal how it happens." Still others question the reliability of many of the popular fMRI research studies, especially those involving low numbers of research subjects: "The signals they get are highly massaged. It means they clean up their data to make it look good, like applying makeup, for a general audience." 303

Functional MRI research also poses a number of practical issues. Research subjects must lie completely still for a period of time within an MRI scanner, which can

<sup>&</sup>lt;sup>297</sup> Dennis O'Brien, "Mind Readers Scanning Technology Promises to Map the Brain's Pathways, But Some Fear Its Ability to Expose a Patient's Secrets and Lies," *Baltimore Sun*, December 10, 2004, 1E.

<sup>&</sup>lt;sup>298</sup> Ibid.; Kennedy, "Neuroimaging," 19.

<sup>&</sup>lt;sup>299</sup> Sam Jaffee, "Fake Method for Research Impartiality," Scientist 18, no. 14 (July 19, 2004): 64.

<sup>&</sup>lt;sup>300</sup> Turhan Canli and Amin Zenab, "Neuroimaging of Emotion and Personality: Scientific Evidence and Ethical Considerations," *Brain and Cognition* 50, no. 3 (December 2002): 425.

<sup>&</sup>lt;sup>301</sup> David I. Donaldson, "Parsing Brain Activity with fMRI and Mixed Designs: What Kind of a State Is Neuroimaging in?" *Trends in Neurosciences* 27, no. 8 (August 1, 2004): 442.

<sup>&</sup>lt;sup>302</sup> Sandra Blakeslee, "Just What's Going On Inside that Head of Yours?" *New York Times*, March 14, 2000, F6.

<sup>&</sup>lt;sup>303</sup> Ibid.

be loud and claustrophobic.<sup>304</sup> Brain motion resulting from the subject's movement or, even, the subject's respiratory and cardiac cycles, can interfere with data acquisition.<sup>305</sup> Finally, the validity of the test results depends on the willingness and ability of the subject to carry out the assigned mental task.<sup>306</sup> It remains to be seen whether fMRI can be used to examine brain function in criminals and other individuals who may have little incentive to complete an assigned task. Because of these theoretical and practical limitations, the use of fMRI outside the research context has been described by some as "frivolous," a "gimmick," "pseudoscience," and "snake oil."<sup>307</sup>

### **SUMMARY**

Although the idea of localized brain function dates back to prehistoric times, more recent efforts to assign mental functions to different parts of the brain have involved phrenology, lesion studies, EEG, MEG, PET, SPECT, and fMRI. Each new brain mapping method suggests a desire for greater transparency of the brain. Now two centuries old, phrenology and its underlying assumptions have been laid to rest, but analogies can be drawn between the phrenologists' head charts and the brain maps produced by today's cognitive neuropsychologists. The phrenologists believed in discrete organs associated with arithmetical and numerical processes, including the faculties of Size and Calculation -- beliefs that are somewhat analogous to contemporary cognitive neuropsychologists' modular subsystems.<sup>308</sup> Like the phrenologists, current

<sup>&</sup>lt;sup>304</sup> Joan Hamilton, "Journey to the Center of the Mind: 'Functional' MRI Is Yielding a Clearer Picture of What Thoughts Look Like," *Business Week*, April 19, 2004, 78; Huettel, Song, and McCarthy, *Functional Magnetic Resonance Imaging*, 14.

<sup>305</sup> Buckner and Logan, "Functional Neuroimaging Methods," 30-31.

<sup>&</sup>lt;sup>306</sup> Ibid., 30; Martha J. Farah, "Emerging Ethical Issues in Neuroscience," *Nature Reviews Neuroscience* 5, no. 11 (November 2002): 1126.

<sup>307</sup> Emily Eakin, "Looking for that Brain Wave Called Love; Humanities Experts Use M.R.I.'s to Scan the Mind for the Locus of the Finer Feelings," *New York Times*, October 28, 2000, B11; Paul Raeburn, "The Therapeutic Mind Scan," *New York Times*, February 20, 2005, § 6, 20.

<sup>&</sup>lt;sup>308</sup> Temple, Developmental Cognitive Neuropsychology, 255.

cognitive neuropsychologists also recognize that perception, thought, and intellectual processing are dissociable into different brain components.<sup>309</sup> Although phrenology has been discredited as a science, its concept of localized brain function remains, along with new techniques for identifying and measuring such function.

The phrenologists believed that their head charts were the key to self-improvement, self-perfection, and societal reforms, and Chapter 2 shows that fMRI is the subject of similar claims. Along with the hope for medical and scientific advances, fMRI also carries with it modern notions of perfectibility and modifiability.<sup>310</sup> But to perfect and, perhaps, modify or enhance the brain, physicians and scientists first need to know how our brains function. A major premise of this dissertation is that fMRI's ability to localize brain function raises issues relating to confidentiality and privacy,<sup>311</sup> but this chapter shows that these issues are not new. Phrenology, probably by coincidence, revealed character information about individuals that they may have preferred to keep private. X-ray's ability to produce "naked" skeletal images led to privacy protections, including lead panties and anti-x-ray legislation. The ability of CT and MRI to "peer" inside the body opened the door for the forensic use of medical imaging technology. And, as will be explored in the next chapter, modern scientists are using fMRI to map the regions of the brain that correlate to deception, love, sexuality, and morality – things that many of us prefer to keep private.<sup>312</sup>

<sup>&</sup>lt;sup>309</sup> Ibid.

<sup>&</sup>lt;sup>310</sup> Jose van Dijck, *Transparent Body: A Cultural Analysis of Medical Imaging* (Seattle: University of Washington Press, 2005), 3-4.

<sup>311</sup> Illes and Racine, "Imaging or Imagining," 11.

<sup>312</sup> Dumit, Picturing Personhood, 23.

# CHAPTER 2: FMRI IN NON-RESEARCH CONTEXTS: SCIENCE OR SPECULATION?

Functional MRI thus has built on several predecessor technologies, including EEG, MEG, PET, and SPECT, to become one of the most powerful functional neuroimaging tools in modern science. But, what brain functions does fMRI actually reveal? What can fMRI tell us about an individual's physical or mental health condition, or her social qualities and personal characteristics? Can fMRI reveal whether an individual is racially prejudiced, deceitful, or altruistic? Whether a particular individual is depressed, sexually aroused, or capable of making moral decisions? To answer these questions, this chapter analyzes a handful of fMRI studies selected due to their popularity in the media and the speculation they have generated regarding their application in clinical, employment, insurance, education, marketing, evidentiary, criminal justice, and government contexts. Within each category of research, the study authors' published conclusions are presented alongside any related media reports. The purpose of this chapter is to show why private and governmental entities might have an interest in creating or obtaining neuroimaging information, and how the media – with some help from bioethicists and other stakeholders – may have contributed to that interest.

## **NEUROSURGICAL APPLICATIONS**

Several different brain-mapping techniques have been used in an attempt to preserve brain function during neurosurgery, and fMRI has been identified as one technique that may help in this regard. Among other efforts, Joy Hirsch and her colleagues at Columbia University decided to build on these brain mapping techniques in 2000 by evaluating an integrated battery of preoperative fMRI tasks in an attempt to

<sup>&</sup>lt;sup>1</sup> Joy Hirsch et al., "An Integrated Functional Magnetic Resonance Imaging Procedure for Preoperative Mapping of Cortical Areas Associated with Tactile, Motor, Language, and Visual Functions," *Neurosurgery* 47, no. 3 (2000): 711-22.

identify the regions of the brain that are associated with tactile, motor, language, and visual functions.<sup>2</sup> The authors concluded that the cortical maps they developed could help neurosurgeons assess surgical risk, plan surgical routes, and direct intraoperative electrophysiological procedures, so that "a greater range of structural and functional relationships is brought to bear in the service of optimal outcomes for neurosurgery."<sup>3</sup>

The brain mapping efforts of Hirsch and her colleagues seem to have caught on. As just one among many possible examples, a research team based out of Washington University in St. Louis used fMRI in 2003 to help them pinpoint the unusual location of language centers in a patient with a long history of severe epileptic seizures. Knowledge of the precise location of the language centers ultimately was critical to the patient's successful surgical outcome.<sup>4</sup> Scientists continue to study how fMRI can be used to improve neurosurgery,<sup>5</sup> and medical center press releases not infrequently advertise the ways in which fMRI can help to map functional areas of the brain and preserve brain function.<sup>6</sup> Although some exaggerate fMRI's brain mapping capabilities — "At this rate, it seems that neuroscientists will soon pinpoint the regions in the brain where mediocre poetry is generated, where high school grudges are lodged, where sarcasm blooms like a

<sup>&</sup>lt;sup>2</sup> Ibid., 712.

<sup>&</sup>lt;sup>3</sup> Ibid., 711, 718-720.

<sup>&</sup>lt;sup>4</sup> Monica V. Baciu et al., "Functional MRI Reveals an Interhemispheric Dissociation of Frontal and Temporal Language Regions in a Patient with Focal Epilepsy," *Epilepsy and Behavior* 4, no. 6 (December 2003): 776-80.

<sup>&</sup>lt;sup>5</sup> Paul E. Kim and Manbir Singh, "Functional Magnetic Resonance Imaging for Brain Mapping in Neurosurgery," *Neurosurgical Focus* 15, no. 1 (July 2003): 1-7.

<sup>&</sup>lt;sup>6</sup> Gerry Everding, "Better Brain Imaging Helps Surgeons Avoid Damage to Language Functions," Washington University in St. Louis News and Information (November 4, 2003), http://mednews.wustl.edu/tips/page/normal/494.html (accessed February 16, 2006); "Functional MRI Used In Brain Activity Mapping for Surgical Planning," University of Iowa Department of Radiology News Archives (June 20, 2001), http://www.radiology.uiowa.edu/news/mri-surg.html (accessed February 16, 2006).

red rose"<sup>7</sup> – others believe that fMRI has yet to impress: "[fMRI] has told us nothing more than what a neurologist of the mid-20th century could have told you about brain functions and where they're localized."<sup>8</sup>

Notwithstanding fMRI's clinical potential, some caution against the leap from functional imaging to functional neurosurgery. One concern is that reports of functional neurosurgery may lead to patient demand and performance by surgeons with inadequate functional neurosurgical training or expertise. Additional ethical concerns relate to surgical candidacy and patient selection, conflicts of interest raised by neurosurgeons who are simultaneously engaging in neurological research, awake neurosurgeries (and the possibility that a patient may discontinue her consent in the middle of the procedure due to anxiety or other reasons), the potential for neurosurgery to alter a patient's understanding of the world, the expense of functional neurosurgery and related distributive justice and resource allocation issues, and safety issues raised by cosmetic neurology. Functional MRI thus has the potential to enhance neurosurgery, but also raises a variety of ethical issues relating to informed consent, cost, and medical necessity.

<sup>&</sup>lt;sup>7</sup> Benedict Carey, "Searching for the Person in the Brain," *New York Times*, February 5, 2006, 41, http://www.nytimes.com/2006/02/05/weekinreview/05carey.html?ex=1296795600&en=bbc8fede11af6a48 &ei=5090&partner=rssuserland&emc=rss (accessed February 14, 2006).

<sup>&</sup>lt;sup>8</sup> Ibid.

<sup>&</sup>lt;sup>9</sup> Paul J. Ford and Jaime M. Henderson, "Neuroethics in the Operating Room: Functional Neurosurgical Interventions," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 213-28; Paul J. Ford and Cynthia S. Kubu, "Caution in Leaping from Functional Imaging to Functional Neurosurgery," *American Journal of Bioethics*, 5, no. 2 (2005): 23-25.

<sup>&</sup>lt;sup>10</sup> Ford and Kubu, "Caution in Leaping," 24.

<sup>11</sup> Ford and Henderson, "Functional Neurosurgical Intervention," 220-26; Paul J. Ford and Cynthia S. Kubu, "Stimulating Debate: Ethics in a Multidisciplinary Functional Neurosurgery Committee," *Journal of Medical Ethics* 32, no. 2 (February 1, 2006): 106; Anjan Chatterjee, "The Promise and Predicament of Cosmetic Neurology," *Journal of Medical Ethics* 32, no. 2 (February 1, 2006): 110.

## UNDERSTANDING SEVERE BRAIN INJURY

In the past, patients who suffered catastrophic brain injuries due to trauma, anoxia, or hypoxia were viewed as relatively hopeless from a clinical perspective, <sup>12</sup> and few attempts were made to understand the amount of cerebral function that remained or to improve their functional capacities. <sup>13</sup> Nicholas Schiff and his colleagues responded to this dearth in the neuroscientific literature in 2002 by using PET, MRI, and MEG to study five patients in a persistent vegetative state (PVS), a condition characterized by lack of awareness of self and the environment despite the preservation of certain brainstem functions and sleep/wake functions. <sup>14</sup> Schiff unexpectedly found that certain regions of the brain "retain anatomical integrity and remain active in modular fashion that can support isolated but defined behavioural events." <sup>15</sup> Schiff concluded more generally that certain cerebral regions can retain partial function despite catastrophic injuries. <sup>16</sup>

Unlike patients in the PVS, patients in the minimally conscious state (MCS) demonstrate unequivocal, but intermittent, behavioral evidence of awareness of self or their environment.<sup>17</sup> Hirsch, Schiff, and their colleagues conducted a second study in 2005 to test their hypothesis that patients in the MCS retain active cerebral networks that underlie cognitive function notwithstanding their inconsistent ability to follow commands and communicate.<sup>18</sup> The study, which included seven healthy volunteers and two

<sup>&</sup>lt;sup>12</sup> Nicholas D. Schiff et al., "Residual Cerebral Activity and Behavioural Fragments Can Remain in the Persistently Vegetative Brain," *Brain* 125, no. 6 (June 2002): 1211.

<sup>13</sup> Ibid.

<sup>&</sup>lt;sup>14</sup> Bryan Jennett and Fred Plum, "Persistent Vegetative State after Brain Damage: A Syndrome in Search of a Name," *Lancet* 1, no. 7753 (April 1, 1972): 734.

<sup>&</sup>lt;sup>15</sup> Schiff et al., "Residual Cerebral Activity," 1228.

<sup>&</sup>lt;sup>16</sup> Ibid., 1230.

<sup>&</sup>lt;sup>17</sup> Nicholas D. Schiff et al., "fMRI Reveals Large-Scale Network Activation in Minimally Conscious Patients," *Neurology* 64, no. 3 (February 8, 2005): 515; Joseph T. Giacino et al., "The Minimally Conscious State: Definition and Diagnostic Criteria," *Neurology* 58, no. 3 (February 12, 2002): 349.

<sup>18</sup> Schiff et al., "fMRI Reveals Large-Scale Network Activation," 514-23.

patients in the MCS, produced the first fMRI maps of brain activity correlated with three tasks: tactile stimulation (lightly touching both hands of the subject), the playing of an audio narrative about shared experiences by a relative or loved one, and the playing of the same narrative backwards (so that the narrative was recognizable for speech but absent for content). During the tactile stimulation and passive listening tasks, the MCS patients "showed remarkably similar brain activity to that evoked in healthy control subjects." According to the authors' February 8, 2005, published study, their findings suggest that, "some MCS patients may retain widely distributed cortical systems with potential for cognitive and sensory function despite their inability to follow simple instructions or communicate reliably." Scientists continue to use fMRI examine the neural activity of PVS and MCS patients.<sup>21</sup>

On the same day that Schiff and Hirsch published their study, their colleague Joseph Fins was quoted as stating, "'This study gave me goose bumps, because it shows this possibility of this profound isolation, that these people are there, that they've been there all along, even though we've been treating them as if they're not."<sup>22</sup> Fins also suggested that his colleagues' research would have clinical implications: "A better understanding of brain patterns in minimally conscious patients should also help cut down on misdiagnosis by doctors."<sup>23</sup> Also on the same day, Hirsch was quoted as stating that the MCS patients in the study are "'more human than we imagined in the past, and it is unconscionable not to aggressively pursue research efforts to evaluate them and

<sup>&</sup>lt;sup>19</sup> Ibid.

<sup>&</sup>lt;sup>20</sup> Ibid.

<sup>&</sup>lt;sup>21</sup> Adrian M. Owen et al., "Residual Auditory Function in Persistent Vegetative State: A Combined PET and fMRI Study," *Neuropsychological Rehabilitation* 15, no. 3-4 (July-September 2005): 290-306; Steven Laureys, Adrian M. Owen, and Nicholas Schiff, "Brain Function in Coma, Vegetative State, and Related Disorders," *Lancet Neurology* 3, no. 9 (September 2004): 537-46; Steven Laureys et al., "Cerebral Processing in the Minimally Conscious State," *Neurology* 63, no. 5 (September 14, 2004): 916-18

<sup>&</sup>lt;sup>22</sup> Benedict Carey, "Study Finds Awareness in Comatose," Daily Breeze, February 8, 2005, A10.

<sup>&</sup>lt;sup>23</sup> Ibid.

develop therapeutic techniques.""<sup>24</sup> The reporter who covered the front-page story for the *New York Times* concluded that, "The findings, if repeated in follow-up experiments, could have sweeping implications for how to care best for these patients . . . and consequences for legal cases in which parties dispute the mental state of an unresponsive patient."<sup>25</sup>

Shortly thereafter, Hirsch began receiving e-mails from family members of minimally conscious patients who stated that they now knew, based on Hirsch's study and related newspaper stories, that their touching of and talking to their minimally conscious loved ones "had meant something."<sup>26</sup> Others requested Hirsch to help their loved ones -- who had been diagnosed as vegetative -- to regain consciousness.<sup>27</sup> Perhaps to clarify any misunderstandings regarding the meaning of their research, Hirsch published an editorial in May 2005 explaining that current neuroimaging methods could not distinguish between PVS and MCS conditions, and that patients such as Terri Schiavo would not have benefited from current treatment options. Hirsch did, however, reemphasize her belief that a large population of MCS patients could "directly benefit from accelerated research, improved treatment options, and dialogue regarding the medical, therapeutic, ethical, and legal issues that surround care and treatment objectives for patients with disorders of consciousness."<sup>28</sup>

<sup>&</sup>lt;sup>24</sup> Benedict Carey, "New Signs of Awareness Seen in Some Brain-Injured Patients," *New York Times*, February 8, 2005, A1.

<sup>&</sup>lt;sup>25</sup> Ibid.

<sup>&</sup>lt;sup>26</sup> Douglas Steinberg, "Revelations from the Unconsciousness," *Scientist* 19, no. 17 (September 12, 2005): 17.

<sup>&</sup>lt;sup>27</sup> Ibid.

<sup>&</sup>lt;sup>28</sup> Joy Hirsch, "Raising Consciousness," *Journal of Clinical Investigation* 115, no. 5 (May 2005): 1103.

## UNDERSTANDING RACIAL EVALUATION

Research over the last several decades has showed that self-reports of prejudicial attitudes towards individuals of other racial groups have declined,<sup>29</sup> and that fewer White Americans express negative attitudes towards Black Americans now than 40 years ago.<sup>30</sup> Notwithstanding these findings, scientists continue to observe negative evaluations of individuals of different racial groups in studies that bypass access to conscious awareness and control.<sup>31</sup> One of the goals of the field of social cognition is to understand the nature of these unconscious evaluations, and scientists believe that fMRI may be helpful in this regard.<sup>32</sup>

The response of the amygdala – a small, almond-shaped structure in the medial temporal lobe that is best known for its role in emotional learning and memory – to computer images of individuals of different racial groups was first studied by Allen Hart and his colleagues at Amherst College, Massachusetts General Hospital, and other institutions in 2000.<sup>33</sup> The study authors used fMRI to acquire images while eight healthy subjects between 20 and 35 years of age who had identified themselves as Black or White were presented with 60 grayscale photographs of Black and White faces.<sup>34</sup> During the later stimulus presentations, the authors observed significantly greater BOLD signal in the amygdala in response to outgroup (individuals of a different race) versus ingroup (individuals of their own race) faces.<sup>35</sup> The authors concluded that amygdala

<sup>&</sup>lt;sup>29</sup> Elizabeth A. Phelps et al., "Performance on Indirect Measures of Race Evaluation Predicts Amygdala Activation," *Journal of Cognitive Neuroscience* 12, no. 5 (September 2000): 729.

<sup>&</sup>lt;sup>30</sup> Elizabeth A. Phelps and Laura A. Thomas, "Race, Behavior, and the Brain: The Role of Neuroimaging in Understanding Complex Social Behaviors," *Political Psychology* 24, no. 4 (2003): 751.

<sup>31</sup> Ibid.

<sup>&</sup>lt;sup>32</sup> Ibid.

<sup>&</sup>lt;sup>33</sup> Allen J. Hart et al., "Differential Response in the Human Amygdala to Racial Outgroup vs. Ingroup Face Stimuli," *NeuroReport* 11, no. 11 (August 3, 2000): 2351-55.

<sup>&</sup>lt;sup>34</sup> Ibid., 2352.

<sup>&</sup>lt;sup>35</sup> Ibid., 2352-53.

responses to human face stimuli must be affected by the relationship between the perceived race of the stimulus face and that of the subject.<sup>36</sup> Although their data "provide a foundation for future related studies in the neuroscience of social cognition and race," the authors cautioned against drawing premature conclusions, emphasizing the lack of BOLD signal difference observed during initial (as opposed to later) stimulus presentations.<sup>37</sup>

Elizabeth Phelps and her colleagues at New York University, Yale University, and Massachusetts Institute of Technology conducted a second study in 2000 that used fMRI to explore the neural substrates involved in the unconscious evaluation of Black and White social groups.<sup>38</sup> In their first experiment, the study authors used fMRI to acquire images while presenting White American subjects with pictures of unfamiliar Black and White male faces with neutral facial expressions. In their second experiment, the authors presented pictures of famous and positively regarded Black and White individuals, including Martin Luther King, Jr., Michael Jordan, and Will Smith.<sup>39</sup> In both experiments, the authors also measured conscious and unconscious evaluations of racial groups. The data from the first experiment led the authors to their now famous conclusion that:

representations of social groups that differ in race evoke differential amygdala activity and that such activation is related to unconscious social evaluation. Notably, variability in amygdala activation among White subjects is correlated with negative indirect responses to Black compared to White faces on behavioral measures.<sup>40</sup>

<sup>&</sup>lt;sup>36</sup> Ibid., 2354.

<sup>&</sup>lt;sup>37</sup> Ibid.

<sup>&</sup>lt;sup>38</sup> Phelps et al., "Performance on Indirect Measures of Race Evaluation," 729-38.

<sup>&</sup>lt;sup>39</sup> Ibid., 730.

<sup>&</sup>lt;sup>40</sup> Ibid., 733.

The authors found the significant activity in the left-superior amygdala interesting in light of findings that that region is activated when fearful (versus neutral) facial expressions are presented.<sup>41</sup>

The authors also had hypothesized that any amygdala activity that was observed during the first experiment would disappear if they showed their subjects "exemplars of Black Americans who are as familiar and well liked as White Americans." Indeed, in their second experiment, the authors observed no consistent pattern of amygdala activity. The results of both experiments suggested to the authors that the amygdala may be specifically involved in indirect or nonconscious responses to racial groups and that amygdala response is a function of culturally acquired information about social groups, modified by individual knowledge and experience. The authors concluded by noting that they had, for the first time, related indirect behavioral measures of social evaluation to neuronal activity. Scientists continue to build on the initial work of Hart, Phelps, and their colleagues by examining the neural correlates of social and racial evaluation.

Following the publication of Phelps' research, some speculated that advances in functional neuroimaging technology could be used to reveal individuals' racial prejudices

<sup>&</sup>lt;sup>41</sup> Ibid.

<sup>&</sup>lt;sup>42</sup> Ibid.

<sup>&</sup>lt;sup>43</sup> Ibid.

<sup>44</sup> Ibid., 734.

<sup>45</sup> Ibid.

<sup>46</sup> Matthew D. Lieberman et al., "An fMRI Investigation of Race-Related Amygdala Activity in African-American and Caucasian-American Individuals," *Nature Reviews Neuroscience* 8, no 6. (June 2005): 720-22; Mary E. Wheeler and Susan T. Fiske, "Controlling Racial Prejudice: Social-Cognitive Goals Affect Amygdala and Stereotype Activation," *Psychological Science* 16, no. 1 (January 2005): 56-63; William A. Cunningham et al., "Separable Neural Components in the Processing of Black and White Faces," *Psychological Science* 15, no. 12 (December 2004): 806-13; Elizabeth A. Phelps, Christopher J. Cannistraci, and William A. Cunningham, "Intact Performance on an Indirect Measure of Race Bias Following Amygdala Damage," *Neuropsychologia* 41, no. 2 (2003): 203-8; Jennifer L. Eberhardt, "Imaging Race," *American Psychologist* 60, no. 2 (February/March 2005): 181-190 (reviewing the literature in the neuroscientific study of race).

and preferences: "studies show[] that the brain reacts differently at first sight when seeing a person of the same or a different skin colour. That does not necessarily mean that everyone is a racist, but refinement of such methods could unveil personal prejudices or preferences." Other radio and news reports carried headlines such as, "Racial Bias on the Brain," Inside the Mind of a Racist: Scans May Reveal Brain's Hidden Centres of Prejudice," and "Hiding Racial Bias Can Tax Brain." Perhaps in response to headlines such as these, Phelps issued a statement expressly warning against such use: "The measures used in this research should not and cannot be assumed to be a battery of tests that can be used to reveal an individual's hidden racism. It would be improper to use them in any selection or diagnostic context." 51

Phelps and a colleague also wrote a review article in 2003 in which they argued that brain science should not yet be used to guide social and political choices.<sup>52</sup> The authors recognized that, "a good understanding of the potential contributions of brain imaging can help us discover the structure and organization of a behavior"; however, they cautioned that, "a poor understanding can lead us to conclusions that are inappropriate and possibly hurtful."<sup>53</sup> The authors also explained that simply showing a behavior "in

<sup>&</sup>lt;sup>47</sup> Holger Breithaupt and Katrin Weigmann, "Manipulating Your Mind: What Will Science Discover About Our Brains, and How Are We Going to Deal with It?" *EMBO Reports*, 5, no. 3 (2004): 232.

<sup>&</sup>lt;sup>48</sup> Natasha Mitchell, "Racial Bias on the Brain," *Radio National*, November 30, 2003, http://www.abc.net.au/rn/science/mind/s997984.htm (accessed February 14, 2006).

<sup>&</sup>lt;sup>49</sup> David Adam, "Inside the Mind of a Racist: Scans May Reveal Brain's Hidden Centres of Prejudice," *Guardian*, November 17, 2003, http://www.guardian.co.uk/uk\_news/story/0,3604,1086737,00.html (accessed January 16, 2006).

<sup>&</sup>lt;sup>50</sup> Amanda Gardner, "Hiding Racial Bias Can Tax Brain," *HealthDay*, November 26, 2003, http://www.hon.ch/News/HSN/516175.html (accessed February 16, 2006).

<sup>&</sup>lt;sup>51</sup> "NYU/Yale Research Team Explores Neural Basis of Racial Evaluation," *NYU Press Releases*, September 18, 2000, http://www.nyu.edu/publicaffairs/newsreleases/b\_amygdala.shtml (accessed February 16, 2005).

<sup>&</sup>lt;sup>52</sup> Phelps and Thomas, "Race, Behavior, and the Brain," 748.

<sup>&</sup>lt;sup>53</sup> Ibid., 754.

the brain" does not mean that the behavior is "hardwired" or "unchangeable." For example, if we visit a new restaurant and enjoy the experience, a neural signature underlying the preference may be observed in our brains. However, if our next visit to the same restaurant is disappointing, the neural representation may change too. The authors careful distinction between the imaging of behavior and hardwired behavior can be contrasted with recent news and radio reports and other publications that suggest that certain individuals brains may be wired for particular skills or negative behaviors. Phelps and her colleague concluded by arguing that, "we should not label someone racist' because of the pattern of his or her brain response," and calling for cautious and reasonable interpretation of fMRI study results:

[t]here is a disturbing trend developing in the interpretation of brain imaging research in the general public, as well as among some scientists. This trend is rooted in the assumption that a biological understanding of a behavior is more informative or reliable than a psychological understanding of a behavior. Although brain science can inform our understanding of complex human behaviors, it cannot help us predict human behavior with any more certainty than can be derived from examining behavior itself. . . . For neuroscientists, it is an exciting time to try to unravel the complex circuits that tie together the brain and behavior. However, we need to be reasonable in our interpretation of this research and use it to enhance, not subtract from, other means of investigation. These advances in neuroscience should not negate nor substitute for advances in the psychological understanding of behavior.<sup>58</sup>

<sup>&</sup>lt;sup>54</sup> Ibid.

<sup>&</sup>lt;sup>55</sup> Ibid., 755.

<sup>&</sup>lt;sup>56</sup> Richard Knox, "Music Appreciation 'Hard Wired' in Brain, Research Shows," *National Public Radio*, December 28, 2002, http://www.npr.org/templates/story/story.php?storyId=893948 (accessed February 16, 2006); Laurence Tancredi, *Hardwired Behavior: What Neuroscience Reveals about Morality* (New York: Cambridge Press, 2005).

<sup>&</sup>lt;sup>57</sup> Phelps and Thomas, "Race, Behavior, and the Brain," 755.

<sup>&</sup>lt;sup>58</sup> Ibid., 748, 756. Phelps stated more recently that, "'I don't think we've gotten to the point where we can say anything about how people will act in the future, but I think we will—it's a matter of time." Steve Olson, "Brain Scans Raise Privacy Concerns," *Science* 307, no. 5715 (March 11, 2005): 1549.

## **DETECTING DECEPTION**

According to the federal Office of Technology Assessment, polygraph – which relies on skin conductance, heart rate, and respiration – currently is the most widely used method for detection of deception, or lying.<sup>59</sup> Because of the difficulty associated with admitting polygraph results into courtroom evidence due to the technology's unreliability,<sup>60</sup> the search has been on for a new and better method of lie detection. In 2001, Sean Spence and his colleagues at the University of Sheffield used fMRI to scan the brains of 10 male subjects as they answered 36 questions including, "Have you made your bed today?" and "Have you taken a tablet today?" Finding that reaction times were significantly longer when the subjects were lying and that "there was reliable activation within specific regions of prefrontal cortex," the study authors concluded that, "by using a highly constrained behavioural protocol we may begin to delineate the cognitive components of deception in human subjects. fMRI may provide a feasible method for investigating their neural correlates."

Daniel Langleben and his colleagues at the University of Pennsylvania also used fMRI to examine the neural correlates of deception in 2001.<sup>64</sup> In their oft-cited study, the authors' subjects held a 5 of Clubs playing card in their pocket and were told to deny that they held the card while their brains were being scanned.<sup>65</sup> The authors concluded from the scans that, "there is a neurophysiological difference between deception and truth at the brain activation level that can be detected with fMRI" and that "refinements of the

<sup>&</sup>lt;sup>59</sup> Daniel D. Langleben et al., "Brain Activity during Simulated Deception: An Event-Related Functional Magnetic Resonance Study," *NeuroImage* 15, no. 3 (March 2002): 727.

<sup>&</sup>lt;sup>60</sup> Chapter 5 discusses the evidentiary rules that prohibit the admission of unreliable evidence.

<sup>&</sup>lt;sup>61</sup> Sean A. Spence et al., "Behavioural and Functional Anatomical Correlates in Humans," *NeuroReport* 12, no. 13 (September 17, 2001): 2849-50.

<sup>&</sup>lt;sup>62</sup> Ibid., 2851.

<sup>63</sup> Ibid., 2852.

<sup>&</sup>lt;sup>64</sup> Langleben et al., "Brain Activity during Simulated Deception," 727-32.

<sup>65</sup> Ibid., 729.

paradigm design and image analysis methodology could . . . establish an activation pattern predictive of deception on an individual level."66

In a third study conducted in 2001, Tatia Lee and her colleagues at the University of Hong Kong hypothesized that the pattern of brain activation in malingerers — individuals who intentionally and falsely or fraudulently simulate or exaggerate physical or mental disease — would provide unique markers for the detection of deception.<sup>67</sup> The authors thus used fMRI to image the brain activations of six healthy male volunteers while they performed forced-choice memory tasks involving simulated malingering and under normal control conditions.<sup>68</sup> The authors concluded that their findings provided "some initial evidence for the existence and involvement of a prefrontal-parietal-sub-cortical circuit in feigned memory impairment" and that, "this suggests that our work may have identified some extremely significant preliminary markers that have the promise to enhance the development of valid and sensitive methods for the detection of malingering."<sup>69</sup> The authors further concluded that, "Potentially significant applications of our findings for future investigations include research aiming at distinguishing different types of liars and different types of lying with or without meta-cognitive calculations."<sup>70</sup>

Following the initial work of Spence, Langleben, Lee, and their colleagues, other scientists have used fMRI to examine the neural correlates of different types of deception.<sup>71</sup> In one among several recent studies, Christos Davatzikos and his colleagues

<sup>&</sup>lt;sup>66</sup> Ibid., 731.

<sup>&</sup>lt;sup>67</sup> Tatia M. C. Lee et al., "Lie Detection by Functional Magnetic Resonance Imaging," *Human Brain Mapping* 15, no. 3 (March 2002): 157-64.

<sup>&</sup>lt;sup>68</sup> Ibid., 158.

<sup>&</sup>lt;sup>69</sup> Ibid., 163.

<sup>70</sup> Ibid.

<sup>71</sup> G. Ganis et al., "Neural Correlates of Different Types of Deception: An fMRI Investigation," Cerebral Cortex 13, no. 8 (August 2003): 830-36; Frank Andrew Kozel et al., "A Pilot Study of Functional Magnetic Resonance Imaging Brain Correlates of Deception in Healthy Young Men," Journal of Neuropsychiatry and Clinical Neurosciences 16, no. 3 (July 1, 2004): 295-305; Frank Andrew Kozel,

used fMRI to correctly identify 99% of true and false responses, leading to their conclusion that, "accurate clinical tests could be based on measurements of brain function with fMRI." In a second recent study, Daniel Langleben and his colleagues concluded that, "fMRI, in conjunction with a carefully controlled query procedure, could be used to detect deception in individual subjects."

After these studies were published, the media issued dozens of reports both stating that fMRI is, and suggesting that fMRI will be, capable of accurate lie detection. BBC News' headline – "Brain Scanner Is a Lie Detector" – was perhaps the most convincing. Others were strongly suggestive: "Don't Even Think About Lying: How Brain Scans Are Reinventing the Science of Lie Detection" and "Are They Lying? Functional MRI Holds the Answer, Scientists Say." Other reports that are perhaps more accurate hedge by using words such as "may," "might," and "yet": "Brain Scans May Beat Polygraphs at Lie Detection" and "Lying Makes the Brain Work More, But Brain Scans Can't Spot Liars -- Yet."

Tamara M. Padgett, and Mark S. George, "A Replication Study of the Neural Correlates of Deception," *Behavioral Neuroscience* 118, no. 4 (August 2004): 852-56; C. Davatzikos et al., "Classifying Spatial Patterns of Brain Activity with Machine Learning Methods: Application to Lie Detection," *NeuroImage* 28, no. 3 (November 15, 2005): 663-68; Daniel D. Langleben et al., "Telling Truth from Lie in Individual Subjects with Fast Event-Related fMRI," *Human Brain Mapping* 26, no. 4 (December 2005): 262-72.

<sup>&</sup>lt;sup>72</sup> Davatzikos et al., "Classifying Spatial Patterns of Brain Activity," 663.

<sup>&</sup>lt;sup>73</sup> Langleben et al., "Telling Truth from Lie in Individual Subjects," 262.

<sup>&</sup>lt;sup>74</sup> "Brain Scanner Is a Lie Detector," *BBC News*, November 30, 2004, http://news.bbc.co.uk/2/hi/health/4051211.stm (accessed February 13, 2006).

<sup>&</sup>lt;sup>75</sup> Steve Silberman, "Don't Even Think About Lying: How Brain Scans Are Reinventing the Science of Lie Detection," *Wired*, January 2006, http://www.wired.com/wired/archive/14.01/lying\_pr.html (accessed February 16, 2006).

<sup>&</sup>lt;sup>76</sup> Office of Public Affairs, University of Texas Health Science Center at San Antonio, "Are They Lying? Functional MRI Holds the Answer, Scientists Say," *News* 35, no. 16 (April 19, 2002), http://www.uthscsa.edu/opa/issues/new35-16/fMRI.html (accessed February 16, 2006).

<sup>&</sup>lt;sup>77</sup> "Brain Scans May Beat Polygraphs at Lie Detection," *Forbes.com* (January 31, 2006), http://www.forbes.com/health/feeds/hscout/2006/01/31/hscout530651.htm (accessed February 13, 2006).

<sup>&</sup>lt;sup>78</sup> Miranda Hitti, "Lying Makes the Brain Work More, But Brain Scans Can't Spot Liars – Yet," *WebMD Medical News*, February 2, 2006, http://www.webmd.com/content/article/118/112923?printing=true (accessed February 15, 2006).

Fueled by reports that the Department of Homeland Security granted \$3.5 million to Lockheed Martin and Rutgers University to develop a lie detector, 79 that the Department of Defense Polygraph Institute requested funding proposals investigating lie detection,<sup>80</sup> and that the Department of Defense Advanced Research Projects Agency is developing a "head web," a helmet that conducts non-invasive brain monitoring to measure brain waves while soldiers are in combat,81 reporters also have speculated that fMRI will be used by government and criminal justice officials to determine whether criminal suspects and terrorists are engaging in deception: "Brain Imaging Ready to Detect Terrorists, Say Neuroscientists,"82 and "You might be able to tell, with a great deal of accuracy, whether suspected terrorists are lying or telling the truth."83 Bioethicists, lawyers, and physicians have contributed to the speculation. Lawyer and bioethicist O. Carder Snead believes that, ""Officials who are examining the suspects could hook them up to an f.M.R.I. device, show them pictures of the battlefield in Afghanistan, and [ask them] if they've been in that particular place before." 84 Psychiatrist and lawyer Laurence Tancredi believes that, "With the refinement of liedetecting techniques, it is likely that they will be used extensively not only by law enforcement agencies, but possibly even schools and the health care system."85

<sup>&</sup>lt;sup>79</sup> Amy Ellis Nutt, "What Makes a Terrorist? Science Is Finding Out," *Newhouse News*, http://www.newshousenews.com/archive/nutt122305.html (accessed February 15, 2006).

<sup>80</sup> Silberman, "Don't Even Think About Lying."

<sup>&</sup>lt;sup>81</sup> Morgan Ratcliffe, "Author Shares Insight on Link between Neuroscience, Government," *Daily Utah Chronicle*, January 24, 2006,

http://www.dailyutahchronicle.com/media/paper 244/news/2006/01/24/News/Author. Shares. In sight. On. Link. Between. Neuroscience. Government-

<sup>1502635.</sup>shtml?norewrite&sourcedomain=www.dailyutahchronicle.com (accessed February 15, 2006).

<sup>&</sup>lt;sup>82</sup> Jennifer Wild, "Brain Imaging Ready to Detect Terrorists, Say Neuroscientists," *Nature* 437, no. 7058 (September 21, 2005): 457.

<sup>83</sup> Beth W. Orenstein, "Guilty? Investigating fMRI's Future as a Lie Detector," *Radiology Today* 6, no. 10 (2005): 30.

<sup>84</sup> Jeffrey Rosen, "Roberts v. The Future," New York Times, August 28, 2005, § 6, 24.

<sup>85</sup> Tancredi, Hardwired Behavior, 122.

Drawing the line between fact and fiction, or science and speculation, is difficult in the context of functional neuroimaging, especially since two companies – No Lie MRI and Cephos – have reported that they will bring fMRI's ability to detect deception to market by summer 2006.86 No Lie MRI plans to market its services to law enforcement agencies, immigration agencies, the military, counterintelligence groups, and foreign governments, as well as private companies that want to peer into the brains of potential high-level executives.<sup>87</sup> Some believe that the services developed by companies such as No Lie MRI will change the entire judicial system by exonerating the innocent and aiding the prosecution of the guilty.88 Robert Shapiro, who is best known for defending O.J. Simpson in his double-murder case (and who has a financial interest in Cephos), says that he would "'use it tomorrow in virtually every criminal and civil case on my desk' to check the truthfulness of clients."89 Perhaps in response to reports such as these, Daniel Langleben and two of his colleagues at the University of Pennsylvania expressed their opinion in mid-2005 that, "Premature application of these technologies outside of research settings should be resisted, and the social conversation about the appropriate parameters of its civil, forensic, and security use should begin."90

<sup>86</sup> Silberman, "Don't Even Think About Lying."

<sup>87</sup> Ibid.

<sup>88</sup> Ibid.

<sup>&</sup>lt;sup>89</sup> Malcolm Ritter, "Brain Scans as Lie Detectors? A Lying Thief Checks it Out," *NCTimes.com*, January 28, 2006, http://www.nctimes.com/articles/2006/01/29/science/17\_00\_211\_28\_06.txt (accessed February 16, 2006).

<sup>&</sup>lt;sup>90</sup> Paul Root Wolpe, Kenneth R. Foster, and Daniel D. Langleben, "Emerging Neurotechnologies for Lie-Detection: Promises and Perils," *American Journal of Bioethics*, 5, no. 2 (March-April 2005): 39-49. See generally Ruth L. Fischbach and Gerald D. Fischbach, "The Brain Doesn't Lie," *American Journal of Bioethics*, 5, no. 2 (March-April 2005): 55 ("We are not ready to turn away from the skin and the heart to rely on still mysterious central mechanisms that correlate with a lie."); Tom Buller, "Can We Can for Truth in a Society of Liars?" *American Journal of Bioethics* 5, no. 2 (March-April 2005): 58.

## UNDERSTANDING SOCIAL COOPERATION AND ALTRUISM

For many years, evolutionary biologists, behaviorists, economists, and even political scientists have attempted to understand why cooperation (the act of working together to achieve a common aim) or altruism (the belief that acting for the benefit of others is right and good) exist, even though these acts and beliefs frequently do not result in any direct or immediate reward to the cooperative or altruistic individual.<sup>91</sup> During the last decade, scientists have used fMRI in an attempt to better understand cooperative and altruistic behavior.

In one study involving two separate experiments conducted in 2002, James Rilling and his colleagues at Emory University scanned the brains of 36 women as they played the Prisoner's Dilemma, a game in which two players independently choose whether to cooperate with each other or betray each other for immediate gain.<sup>92</sup> The study authors concluded that mutual cooperation was associated with consistent activation in regions of the brain linked to reward processing, including the nucleus accumbens, the caudate nucleus, the ventromedial frontal/orbitofrontal cortex, and the rostral anterior cingulated cortex.<sup>93</sup> The authors proposed that the pattern of neural activation positively reinforces reciprocal altruism, thereby motivating subjects to resist the temptation to act in their immediate self-interest and defect, rather than cooperate.<sup>94</sup>

In a second study conducted in 2004, Rilling and his colleagues hypothesized that reciprocated cooperation would increase the firing frequency of midbrain dopamine neurons, but that unreciprocated cooperation would decrease the firing frequency.<sup>95</sup> The

<sup>&</sup>lt;sup>91</sup> James K. Rilling et al., "A Neural Basis for Social Cooperation," *Neuron* 35, no. 2 (July 18, 2002): 395.

<sup>92</sup> Ibid.

<sup>93</sup> Ibid., 403.

<sup>94</sup> Ibid.

<sup>&</sup>lt;sup>95</sup> See, e.g., James K. Rilling et al., "Opposing BOLD Responses to Reciprocated and Unreciprocated Altruism in Putative Reward Pathways," *NeuroReport* 15, no. 16 (November 15, 2004): 2539.

purpose of the study was to better understand the neural mechanism that allows individuals to learn who is a good social partner and who is not, thereby protecting individuals from partnering with cheaters. The study authors scanned the brains of 19 subjects while they played a series of single-shot Prisoner's Dilemma games and found that reciprocated cooperation was associated with an increased BOLD response and that an unreciprocated cooperation was associated with a decreased BOLD response. The authors believe that the difference in BOLD response may teach individuals to partner with other individuals who reciprocate and to avoid individuals who do not reciprocate.

Following the publication of Rilling's first study in 2002, a *New York Times* reporter quoted one of Rilling's colleagues as stating, "'If we put some C.E.O.'s in [an fMRI scanner], I'd like to see how they respond. Maybe they wouldn't find a positive social interaction rewarding at all."" Perhaps prominent bioethicist Jonathan Moreno read the *Times* article; he speculated in 2003 that employers might want to use fMRI to recruit applicants for employment who experience more or less pleasure from cooperation, depending on the requirements of the job. 100

## UNDERSTANDING SEXUAL AROUSAL AND LOVE

Functional MRI also has been used to study the neural correlates of sexual arousal and maternal and romantic love. Notwithstanding the common understanding of the brain as the "master organ" that governs sexual function, little has been known about the neural correlates of sexual arousal.<sup>101</sup> In an attempt to better understand this relationship

<sup>96</sup> Ibid.

<sup>&</sup>lt;sup>97</sup> Ibid., 2543.

<sup>98</sup> Ibid.

<sup>&</sup>lt;sup>99</sup> Natalie Angier, "Why We're So Nice: We're Wired to Cooperate," New York Times, July 23, 2002, F1.

<sup>100</sup> Jonathan D. Moreno, "Neuroethics: An Agenda for Neuroscience and Society," *Nature Reviews Neuroscience* 4, no. 2 (February 1, 2003): 152.

<sup>&</sup>lt;sup>101</sup> Bruce A. Arnow et al., "Brain Activation and Sexual Arousal in Healthy, Heterosexual Males," *Brain* 125, no. 5 (May 2002): 1014.

between brain activation and sexual response, Bruce Arnow and his colleagues at Stanford University conducted a study in 2000 that used fMRI to examine the brains of 14 heterosexual males aged 18 to 30 years as they watched erotic, relaxing, and sports video material. The erotic segments involved four types of sexual activities, including rear entry intercourse, intercourse with the female in the superior position, and fellatio and sexual intercourse with the male in the superior position. A custom-built pneumatic pressure cuff was used to measure the subjects' penile turgidity while their brains were being scanned. The study authors observed strong brain activations associated with penile turgidity in the right subinsular regions of the subjects' brains and smaller, but still significant, activations in the subjects' right hypothalamuses. Although they clarified that they could not draw any causal conclusions regarding brain-behavior relationships from their study, the authors did state that their findings suggest which regions of the brain, if damaged, might produce changes in sexual function. The authors hinted that future studies involving brain-damaged subjects might provide more information about the precise role of the activated regions in sexual arousal.

Although romantic and maternal love are regarded as highly rewarding experiences and are linked to the maintenance and perpetuation of the species, very little has been known about their neural correlates. In an attempt to better understand the neural correlates of romantic love, Andreas Bartels and Semir Zeki in 2000 used fMRI to image the brains of 11 female and 6 male volunteers who claimed to be truly, deeply, and madly in love while they viewed images of the objects of their affections. The study

<sup>&</sup>lt;sup>102</sup> Ibid., 1015.

<sup>&</sup>lt;sup>103</sup> Ibid., 1016.

<sup>&</sup>lt;sup>104</sup> Ibid.

<sup>&</sup>lt;sup>105</sup> Ibid., 1019-21.

<sup>106</sup> Ibid., 1021-22.

<sup>&</sup>lt;sup>107</sup> Ibid., 1022.

<sup>&</sup>lt;sup>108</sup> Andreas Bartels and Semir Zeki, "The Neural Correlates of Maternal and Romantic Love," *NeuroImage* 21, no. 3 (March 2004): 1155.

authors compared this brain activity to the activity that resulted when the volunteers viewed control images of three other individuals (non-love interests) of the same sex and age.<sup>109</sup> The authors found significant activations in the foci in the medial insula and the anterior cingulated cortex and, subcortically, in the caudate nucleus and the putamen, all bilaterally, and concluded that a unique network of areas are associated with romantic love.<sup>110</sup>

In an attempt to better understand the neural correlates of maternal love, Bartels and Zeki conducted a second study in 2003 that used fMRI to measure brain activity in 20 mothers aged 27 to 49 while they viewed pictures of their own children as well as control images of other children.<sup>111</sup> The authors then compared the maternal brain activations to those associated with romantic love from their 2000 study, finding that both types of attachment activated areas of the brain specific to each, as well as overlapping areas in the brain's reward system that coincide with areas rich in oxytocin and vasopressin receptors.<sup>112</sup> The authors also found that both romantic and maternal love deactivated a common set of regions associated with negative emotions, social judgment, and the assessment of other people's intentions and emotions.<sup>113</sup> The authors concluded that human attachment bonds individuals through a "push-pull" mechanism that deactivates networks used for critical social assessment and negative emotions and triggers mechanisms involved in reward.<sup>114</sup> Picking up on both the romantic and

<sup>&</sup>lt;sup>109</sup> Andreas Bartels and Semir Zeki, "The Neural Basis of Romantic Love," *NeuroReport* 11, no. 17 (November 27, 2000): 3829.

<sup>&</sup>lt;sup>110</sup> Ibid., 3831.

<sup>111</sup> Bartels and Zeiki, "The Neural Correlates of Maternal and Romantic Love," 1155.

<sup>&</sup>lt;sup>112</sup> Ibid., 1161-62.

<sup>113</sup> Ibid.

<sup>&</sup>lt;sup>114</sup> Ibid., 1162-64.

maternal love studies, the media has reported that, "Science Unlocks Secrets of the Elixir of Love," and "Love Makes You Light Up—Even in Your Brain, Researchers Say." 116

Scientists continue to study the neural correlates of love and sexual arousal, <sup>117</sup> and even facial recognition in individuals who have different sexual preferences. In a study published in January 2006, Felicitas Kranz and Alumit Ishai of the University of Zurich hypothesized that heterosexual and homosexual subjects would exhibit a greater response in the amygdala and the reward circuitry to faces deemed sexually preferable. <sup>118</sup> To test their hypothesis, the study authors used fMRI to scan the brains of 40 subjects, including 10 heterosexual women, 10 heterosexual men, 10 homosexual women, and 10 homosexual men classified based on self-report, as they viewed faces of individuals of different genders. <sup>119</sup> Consistent with their hypothesis, the authors found that the gender of a viewed individual, when the sexual preference of the subject was taken into account, did make a difference in the reactions seen in the thalamus and the orbitofrontal cortex, a region of the brain's reward circuitry. <sup>120</sup> Heterosexual women and homosexual men exhibited a significantly greater response to male faces, whereas heterosexual men and

<sup>115</sup> Chris Ayres, "Science Unlocks Secrets of the Elixir of Love," *The Times*, March 13, 2004, http://www.sensualism.com/love/elixir.html http://www.sensualism.com/love/elixir.html (accessed February 14, 2006).

<sup>116 &</sup>quot;Love Makes You Light Up—Even in Your Brain, Researchers Say," *CNN.com*, http://archives.cnn.com/2000/HEALTH/11/08/love.in.lights.ap/index.html (accessed February 14, 2006).

Arousal in Premenopausal and Menopausal Women by Using BOLD-Based Functional MRI," *Journal of Sexual Medicine* 2, no. 5 (September 2005): 645-61; Arthur Aron et al., "Reward, Motivation and Emotion Systems Associated with Early-Stage Intense Romantic Love," *Journal of Neurophysiology* 94 (July 2005): 327-37; Ivanka Savic, Hans Berglund, and Per Lindström, "Brain Response to Putative Pheromones in Homosexual Men," *Proceedings of the National Academy of Sciences* 102, no. 20 (May 17, 2005): 7356-61; Helen Fisher, *Why We Love: The Nature and Chemistry of Romantic Love* (New York: Henry Holt, 2004).

<sup>&</sup>lt;sup>118</sup> Felicitas Kranz and Alumit Ishai, "Face Perception is Modulated by Sexual Preference," *Current Biology* 16, no. 1 (January 10, 2006): 63-68.

<sup>&</sup>lt;sup>119</sup> Ibid., 66-67.

<sup>&</sup>lt;sup>120</sup> Ibid., 63.

homosexual women responded significantly more to female faces.<sup>121</sup> The authors concluded that the brain's response to faces in the reward circuitry is modulated by sexual preference and that their study provides neural evidence for the role of face processing in mating.<sup>122</sup> Following publication of Kranz and Ishai's study, news magazines and blogs reported that, "Gays Read Faces Differently than Straights," and "Gay Brains Respond Differently to Faces Than Straight Brains." These headlines add to prior speculation that the government and other organizations might want to use fMRI to test soldiers and members for homosexuality or unconscious sexual impulses, and discharge such individuals based upon "positive" test results.<sup>125</sup>

## UNDERSTANDING ETHICAL DECISION MAKING

Functional MRI also has been used to study the neural correlates of ethical decision making, including the decisions required by the classic, two-scenario trolley problem. In the trolley problem, a runaway train is approaching five people on a track. 126 In the first scenario, all five people on the track will die unless an individual pulls a lever that will move the train onto a second track, on which a sole railman is working. If the individual pulls the lever and diverts the train onto the second track, the railman will be killed but the other five people will be saved. The question is, what should the individual

<sup>&</sup>lt;sup>121</sup> Ibid.

<sup>122</sup> Ibid., 66.

<sup>123</sup> Bob Roehr, "Gays Read Faces Differently Than Straights," *In Health*, January 11, 2006, http://www.innewsweekly.com/innews/?class\_code=He&article\_code=1120 (accessed February 14, 2006).

<sup>124 &</sup>quot;Gay Brains Respond Differently to Faces than Straight Brains," *Minnesota Queer Blogs*, January 16, 2006, http://www.eleventh-avenue-south.com/archives/000676.html (accessed February 14, 2006).

<sup>125</sup> Austin Cline, "Brain Privacy: Are Your Thoughts Safe? MRIs Revealing More Than Even You Know About Yourself," *About*, http://atheism.about.com/library/FAQs/phil/blphil\_ethbio\_brainpriv.htm (accessed February 14, 2006).

<sup>126</sup> Adina Roskies, "A Case Study of Neuroethics: The Nature of Moral Judgment," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 18.

do and why? Most people would say that the individual ought to pull the lever and save five lives at the expense of one. In the second scenario, the individual is standing on a footbridge overlooking the same track. Right next to the individual on the footbridge is a man who is overweight. If the individual pushes the man onto the track, the individual will stop the train and save five people, although the man who is overweight will be killed. Again, the question is, what should the individual do and why?

Many people believe that it is morally acceptable to pull the lever in the first scenario, but not to push the man who is overweight to his death in the second scenario. Although the logic in both cases is the same, some philosophers have described the difference as the "emotional closeness" of the second action compared to the "relative distancing" of the first.<sup>127</sup> Stated another way, the thought of directly pushing someone to his death may be more "emotionally salient" than the thought of hitting a switch that will cause a trolley to produce similar consequences.<sup>128</sup>

Joshua Greene and his colleagues at Princeton University decided to test this hypothesis using fMRI in 2001.<sup>129</sup> Greene found that, when confronted by the second scenario, his subjects' fMRI scans showed activation in areas associated with the emotions of sadness, fright or general uneasiness, areas were not activated by the first scenario. Although the study authors concluded that the emotional response was the crucial difference between the two scenarios, they emphasized in their published report that their conclusion was descriptive, rather than prescriptive, and that they were not claiming to have shown that any actions or judgments were morally right or wrong.<sup>130</sup> However, several news reports announced Greene's research findings using headlines such as "Cerebral Scans for Right and Wrong" and "Brain Imaging Sheds Light on Moral

<sup>&</sup>lt;sup>127</sup> Joshua D. Greene et al., "An fMRI Investigation of Emotional Engagement in Moral Judgment," *Science* 293, no. 5537 (September 14, 2001): 2105.

<sup>128</sup> Ibid.

<sup>&</sup>lt;sup>129</sup> Ibid., 2105-08.

<sup>130</sup> Ibid., 2107.

Decision Making.<sup>131</sup> Scientists continue to use fMRI to study the areas of the brain that are activated during ethical and moral decision making.<sup>132</sup>

#### **NEUROMARKETING**

Functional MRI also has been used to examine individuals' preferences regarding consumer goods and services, such as automobiles, <sup>133</sup> soft drinks, <sup>134</sup> campaign advertisements, <sup>135</sup> and the content of movie trailers, <sup>136</sup> in part to help manufacturers and marketing companies determine the best way to market certain products and services. In one study sponsored by DaimlerChrysler in 2002, Susanne Erk and her colleagues used fMRI to study the rewarding properties of cars that signaled wealth and social dominance. <sup>137</sup> The study authors hypothesized that sports cars – in contrast to other cars such as small cars and even limousines – would activate the reward circuitry in the brain. <sup>138</sup> To test their hypothesis, the scientists asked 12 healthy male subjects to view different classes of cars while having their brains scanned. The authors observed

<sup>131</sup> Ronald Bailey, "Morality on the Brain: Cerebral Scans for Right and Wrong," *ReasonOnline*, January 27, 2006, http://www.reason.com/rb/rb012706.shtml (accessed February 14, 2006); "Brain Imaging Study Sheds Light on Moral Decision-Making," *Science Daily*, September 14, 2001, http://www.sciencedaily.com/releases/2001/09/010914074303.htm (accessed February 14, 2006).

<sup>132</sup> Michael S. Gazzaniga, *The Ethical Brain* (New York: Dana Press, 2005); Hauke R. Heekeren et al., "An fMRI Study of Simple Ethical Decision-Making," *NeuroReport* 14, no. 9 (July 1, 2003): 1215-19; Antonio Damasio, *Looking for Spinoza: Joy, Sorrow, and the Feeling Brain* (New York: Harcourt, 2003); Jorge Moll et al., "The Neural Correlates of Moral Sensitivity: A Functional Magnetic Resonance Imaging Investigation of Basic and Moral Emotions," *Journal of Neuroscience* 22, no. 7 (April 1, 2002): 2730-76.

<sup>133</sup> Susanne Erk et al., "Cultural Objects Modulate Reward Circuitry," *NeuroReport* 13, no. 18 (December 20, 2002): 2499-2503.

<sup>134</sup> Samuel M. McClure et al., "Neural Correlates of Behavioral Preference for Culturally Familiar Drinks," *Neuron* 44, no. 2 (October 14, 2004): 379-87.

<sup>135</sup> John Tierney, "Using M.R.I.'s to See Politics on the Brain," New York Times, April 20, 2004, A1.

<sup>136 &</sup>quot;Inside the Mind of the Consumer," Economist 371, no. 8379 (June 10, 2004): 12.

<sup>137</sup> Erk et al., "Cultural Objects," 2499.

<sup>138</sup> Ibid.

significantly more activation in the ventral striatum, orbitofrontal cortex, anterior cingulated and occipital regions for sports cars in contrast to other categories of cars, and concluded that "artificial cultural objects associated with wealth and social dominance elicit activation in reward-related brain areas."<sup>139</sup>

In a second neuromarketing study, Samuel McClure and his colleagues at Baylor College of Medicine used fMRI to examine the neural correlates underlying soft-drink preferences and their influence by cultural images. When brain images were acquired during the subjects' blind taste-test of Coke and Pepsi, the study authors found activity in the subjects' ventromedial prefontral cortex, an area of the brain that is implicated in signaling basic appetitive aspects of reward. When brain images were acquired when the subjects were told that they were drinking Coke, the hippocampus, dorsolateral prefrontal cortex, and the midbrain – areas of the brain known to be implicated in modifying behavior based on emotion and affect – were activated. When brain images were acquired when the subjects were told that they were drinking Pepsi, the same activation in these areas was not observed. The authors concluded that brand knowledge of Coke dramatically influenced certain brain activations, perhaps because of Coke's excellent advertising and brand recognition.

In a third neuromarketing study, scientists at UCLA used fMRI in 2004 to study the brain reaction of known Republican and Democrat voters who were shown campaign advertisements that included images of the September 11, 2001, terrorist attacks. The scientists found that the campaign advertisements caused the amygdala – an area of the brain known to be associated with fear and anger – to light up more vividly in Democrats than in Republicans. Although the scientists warned against drawing conclusions

<sup>139</sup> Ibid.

<sup>&</sup>lt;sup>140</sup> McClure et al., "Neural Correlates," 379.

<sup>&</sup>lt;sup>141</sup> Ibid.

<sup>142</sup> Tierney, "Using M.R.I.'s," A17.

<sup>143</sup> Ibid.

about the ability of fMRI to help with political campaigns until they had experimented with a greater number of subjects, news reports relied on the work at UCLA to speculate that fMRI will help candidates rely less on campaign clichés and more on "scientific" advertising.<sup>144</sup> The UCLA scientists used fMRI more recently to study the brains of individuals as they watched advertisements aired during the 2006 Super Bowl. FedEx's "Caveman" advertisement supposedly "fell flat," while the commercials that inspired the most neural engagement, including responses of fear, desire, conflict, and reward, were Disney's "NFL Dreamers," Sierra Mist's "Airport Security," and Bud Light's "Employee Incentive Plan" advertisements.<sup>145</sup>

In addition to automobiles, soft drinks, and campaign and product advertisements, fMRI also has been used to study the marketability of movie trailers and beautiful female faces, <sup>146</sup> and companies on both sides of the Atlantic – the Brighthouse Institute for Thought Sciences in Atlanta and FKF Applied Research in Los Angeles, as well as the UK's Neurosense/Neuromarketing Consultancy – claim that they can use fMRI and the principles of cognitive neurosicence to gain novel and objective insights into consumer thought and behaviour. <sup>147</sup> Not surprisingly, the media has picked up on the neuromarketing potential of fMRI to ask whether the brain has a "buy button," to discuss the "science of shopping" and the "why of buy," and to explore the "inside [of] the mind of the consumer." <sup>148</sup>

<sup>&</sup>lt;sup>144</sup> Ibid.

<sup>145</sup> Stefanie Olsen, "This Is Your Brain On a Super Bowl Ad," *CNETNews.com*, February 7, 2006, http://news.com.com/2100-1024\_3-6036456.html (accessed February 16, 2006); Marco Iacoboni, "Who Really Won the Superbowl? The Story of an Instant-Science Experiment," *Edge*, January 2006, http://www.edge.org/3rd\_culture/iacoboni06\_index.html (accessed February 15, 2006).

<sup>&</sup>lt;sup>146</sup> Sandra Blakeslee, "If You Have a 'Buy Button,' What Pushes It?" *New York Times*, October 19, 2004, F5.

<sup>147</sup> Neurosense, "About Neurosense," http://www.neurosense.com/about.html (accessed January 16, 2006); Iacoboni, "Who Really Won the Superbowl?"

<sup>148</sup> Blakeslee, "If You Have a 'Buy Button," F5; Margo Kelly, "The Science of Shopping," *CBC News*, December 2, 2002, http://www.cbc.ca/consumers/market/files/money/science\_shopping/ (accessed February 14, 2006); Eric Roston, "The Why of Buy: Theory Says We Are Rational about Money, But

## OTHER FMRI STUDIES

This chapter presents a few popular fMRI studies that have generated speculation regarding their application in non-research contexts. Other studies that have generated similar speculation involve Alzheimer's disease, <sup>149</sup> major depression, <sup>150</sup> schizophrenia, <sup>151</sup> bipolar disorder, <sup>152</sup> dyslexia and hyperlexia, <sup>153</sup> attention-deficit/hyperactivity disorder, <sup>154</sup> pedophilia, <sup>155</sup> cocaine addiction, <sup>156</sup> compulsive gambling, <sup>157</sup> expected and unexpected

Brain-Probing Scientists Are Discovering Otherwise," *Time*, March 8, 2004, http://www.time.com/time/insidebiz/article/0,9171,1101040308-596161,00.html (accessed February 16, 2006); "Inside the Mind of the Consumer," 12.

- <sup>149</sup> Alexandra J. Golby et al., "Memory Encoding in Alzheimer's Disease: An fMRI Study of Explicit and Implicit Memory," *Brain* 128, no. 4 (2005): 773-87.
- <sup>150</sup> Avram J. Holmes et al., "Prefrontal Functioning during Context Processing in Schizophrenia and Major Depression: An Event-Related fMRI Study," *Schizophrenia Research* 76, no. 2-3 (2005): 199-206; Mary Duenwald, "Lab Monkeys May Reveal Secrets of Childhood Depression," *New York Times*, December 24, 2002, F5.
- 151 Holmes, "Prefrontal Functioning," 199-206; Cherine Fahim, "Brain Activity during Emotionally Negative Pictures in Schizophrenia with and without Flat Effect: An fMRI Study," *Psychiatry Research: Neuroimaging* 140, no. 1 (October 30, 2005): 1-15; Rachel L. C. Mitchell et al., "Neural Response to Emotional Prosody in Schizophrenia and in Bipolar Affective Disorder," *British Journal of Psychiatry*, 184, no. 3 (March 2004): 223-30.
  - 152 Mitchell et al., "Neural Response to Emotional Prosody," 223-230.
- 153 Serge Ruff et al., "Neural Substrates of Impaired Categorical Perception of Phonemes in Adult Dyslexics: An fMRI Study," *Brain and Cognition*, 53, no. 2 (November 2003): 331-34; Peter E. Turkeltaub et al., "The Neural Basis of Hyperlexic Reading: An fMRI Case Study," *Neuron* 41, no. 1 (January 8, 2004): 11-25; Gina Kolata, "Scientists Track the Process of Reading Through the Brain," *New York Times*, March 3, 1998, F3.
- <sup>154</sup> George Bush, Eve M. Valera, and Larry J. Seidman, "Functional Neuroimaging of Attention-Deficit/Hyperactivity Disorder: A Review and Suggested Future Directions," *Biological Psychiatry* 57, no. 11 (June 1 2005): 1273-84.
- 155 Harald Dressing et al., "Homosexual Pedophilia and Functional Networks—An fMRI Case Report and Literature Review," *Fortschritte der Neurologie-Psychiatrie* 69, no. 11 (2001): 539-44.
- 156 Hans C. Breiter et al., "Acute Effects of Cocaine on Human Brain Activity and Emotion," *Neuron* 19, no. 3 (September 1997): 591-611; "Precise Effects of Cocaine Are Seen in Brain Scans," *New York Times*, September 26, 1997, A18.
- 157 David N. Crockford et al., "Cue-Induced Brain Activity in Pathological Gamblers," *Biological Psychiatry* 58 (2005): 787-95.

pleasure,<sup>158</sup> satiety and obesity,<sup>159</sup> anxiety,<sup>160</sup> neuroticism,<sup>161</sup> extraversion,<sup>162</sup> self-consciousness,<sup>163</sup> physical pain,<sup>164</sup> social rejection,<sup>165</sup> intelligence,<sup>166</sup> humanity,<sup>167</sup> empathy (or lack thereof),<sup>168</sup> trust,<sup>169</sup> humor,<sup>170</sup> recognition of beauty<sup>171</sup> and, even, the differences in the way men's and women's brains function when they are thinking.<sup>172</sup>

<sup>158</sup> Gregory S. Berns et al., "Predictability Modulates Human Brain Response to Reward," Journal of Neuroscience 21 (April 2001): 2793-98; Eric Nagourney, "Brain Likes Thrill of Unknown," New York Times, April 17, 2001, F6.

<sup>159</sup> G. Andrew James, Wei Guo, and Yijun Liu, "Imaging *In Vivo* Brain-Hormone Interaction in the Control of Eating and Obesity," *Diabetes Technology and Therapeutics* 3, no. 4 (December 2001): 617-22.

<sup>&</sup>lt;sup>160</sup> Ahmad R. Hariri et al., "Serotonin Transporter Genetic Variation and the Response of the Human Amygdala," *Science* 297, no. 5580 (July 19, 2002): 400-3; Eric Nagourney, "Fearing More than Fear Itself," *New York Times*, July 30, 2002, F6.

<sup>161</sup> Naomi I. Eisenberger, Matthew D. Lieberman, and Ajay B. Satpute, "Personality from a Controlled Processing Perspective: An fMRI Study of Neuroticism, Extraversion, and Self-Consciousness," Cognitive, Affective, and Behavioral Neuroscience 5, no. 2 (2005): 169-81.

<sup>162</sup> Ibid.

<sup>163</sup> Ibid.

<sup>164</sup> Alexander Ploghaus et al., "Dissociating Pain from Its Anticipation in the Human Brain," Science 284, no. 5422 (June 18, 1999): 1979-81; Holcomb B. Noble, "Pain at Work: Startling Images and New Hope," New York Times, August 10, 1999, F1; "Fear of Pain May Be Worse than Pain Itself," New York Times, June 22, 1999, F14.

<sup>165</sup> Naomi I. Eisenberger, Matthew D. Lieberman, and Kipling D. Williams, "Does Rejection Hurt? An fMRI Study of Social Exclusion," *Science* 302, no. 5643 (October 10, 2003): 290-92.

<sup>166</sup> Jeremy R. Gray and Paul M. Thompson, "Neurobiology of Intelligence: Science and Ethics," *Nature Reviews Neuroscience* 5, no. 6 (June 2004): 471-82; Jeremy R. Gray, Christopher F. Chabris, and Todd S. Braver, "Neural Mechanisms of General Fluid Intelligence," *Nature Reviews Neuroscience* 6, no. 3 (March 2003): 316-22; Erica Goode, "Brain Scans Reflect Problem-Solving Skill," *New York Times*, February 17, 2003, A14.

<sup>&</sup>lt;sup>167</sup> Sandra Blakeslee, "Humanity? Maybe It's in the Wiring," *New York Times*, December 9, 2003, F1.

<sup>168</sup> Tania Singer et al., "Empathic Neural Responses Are Modulated by the Perceived Fairness of Others," *Nature* 439 (January 26, 2006): 466-69; James Gorman, "This Is Your Brain on Schadenfreude. Do You Feel Bad About Feeling Good?" *New York Times*, January 24, 2006, F3.

<sup>169</sup> Brooks King-Casas et al., "Getting to Know You: Reputation and Trust in a Two-Person Economic Exchange," *Science* 308, no. 5718 (April 1, 2005): 78-83; Henry Fountain, "Study of Social Interactions Starts with a Test of Trust," *New York Times*, April 1, 2005, A20.

# **CONCLUSIONS**

In the nineteenth century, the phrenologists attempted to measure the size of various mental faculties labeled "love between the sexes," "parental love," "self-esteem," "murder," and "calculation." Today, scientists are using fMRI to study the neural correlates of very similar conditions and characteristics, including romantic and maternal love, sexual arousal, pedophilia, self-consciousness, and intelligence. Some nineteenthcentury employers required phrenological examination results to be submitted along with employment applications, and the media and others speculate that today's employers also will want to create or obtain functional neuroimaging test results. Like the phrenologists, who hoped that their theories would form the basis of reform movements in mental health care, education, and criminal justice, neuroscientists and those who follow advances in neuroscience hope and speculate that fMRI will be used to help treat mental health conditions such as depression and bipolar disorder, discover new ways of learning for individuals who have dyslexia and attention-deficit/hyperactivity disorder, and identify individuals who have engaged in criminal behavior and exonerate not-guilty criminal suspects. Separated by almost two centuries, phrenology and fMRI share similar topics of study, goals, and reforms.

Phrenology ultimately failed as a science, but fMRI has successfully been applied in the neurosurgical context and has great potential to assist decision making in other clinical contexts. Only time will tell whether, and the extent to which, fMRI will be

<sup>170</sup> Glen Collins, "Scientists Try to Find Out What's So Funny About Humor," *New York Times*, September 28, 2004, F3.

<sup>&</sup>lt;sup>171</sup> Penelope Green, "Mirror, Mirror; Biologically Speaking, Isn't She Beautiful?" *New York Times*, February 28, 1999, § 9, 1.

<sup>172</sup> Bennett A. Shaywitz et al., "Sex Differences in the Functional Organization of the Brain for Language," *Nature* 373, no. 6515 (February 16, 1995): 607-9; Gina Kolata, "Men and Women Use Brain Differently, Study Discovers," *New York Times*, February 16, 1995, http://query.nytimes.com/gst/fullpage.html?sec=health&res=990CE1D8173FF935A25751C0A963958260 (accessed February 16, 2006); Gina Kolata, "Man's World, Woman's World? Brain Studies Point to Differences," *New York Times*, February 28, 1995, C1 (noting that the authors stressed "extreme caution in drawing conclusions from the data...").

actually and accurately used in the employment, insurance, evidence, criminal justice, and other private and governmental contexts. Although the scientists who conduct neuroimaging studies generally use care when publishing their findings – and even caution readers against inappropriate or too eager interpretations and applications – the descriptions of neuroimaging research in the popular media (including physicians', lawyers', and bioethicists' statements to the media) are not as constrained.<sup>173</sup> The public must wade through reports suggesting that fMRI is (or soon will be) capable of completely transforming neurosurgical interventions, distinguishing between PVS and MCS patients, determining which brain-injured patients will emerge from unconsciousness, identifying individuals' racial preferences and prejudices, determining deception on an individual level, selecting socially cooperative or competitive individuals from among a pool of applicants, and recognizing whether an individual is heterosexual or homosexual, capable of making moral and ethical decisions, or prefers a particular product. The public is increasingly confronted with reports that racial evaluation, deception, maternal and romantic love, violence and mental disorders are "hardwired" in the brain, notwithstanding scientists' careful statements that their research simply examines the neural correlates of such conditions and behaviors. 174 Notwithstanding most neuroimaging study authors' attempts to clarify their research findings and identify appropriate and inappropriate uses of their testing methodologies, the public – as well as employers, insurers, educators, marketing companies, judges, criminal justice officials, and government officials – still may be confused regarding what is science and what is speculation.<sup>175</sup>

<sup>&</sup>lt;sup>173</sup> Mark Rothstein, "Applications of Behavioural Genetics: Outpacing the Science?" *Nature Reviews Genetics* 6 (October 2005): 793 (identifying a similar phenomenon in the context of genetics research).

<sup>174</sup> Tancredi, *Hardwired Behavior*, 11; Rothstein, "Applications of Behavioural Genetics," 793 (identifying a similar effect in the field of genetics).

<sup>&</sup>lt;sup>175</sup> Rothstein, "Application of Behavioural Genetics," 793 (finding that the public continues to be confused regarding genetics research).

Individuals and organizations face economic, social, and legal pressures to obtain information, including neuroimaging information, that will help them make accurate decisions. Health care providers, including neurosurgeons, are under pressure to preserve brain function during surgery. Insurers are under pressure to underwrite only the healthiest individuals. Employers are under pressure to hire only the most productive applicants, educational institutions are under pressure to admit only the most qualified students, and marketing companies are under pressure to advertise their clients' products in the most cost-efficient manner. Judges want to convict only those individuals who have actually committed crimes, criminal justice officials want to reduce jail and prison overcrowding by freeing those individuals who will behave appropriately during probation, and government officials want to identify which individuals will commit terrorist acts to prevent another September 11. Viewed in light of these pressures, the extensive speculation regarding fMRI's non-research applications is better understood.

Because of the potential for neuroimaging information to be used in non-research contexts, scientists need to continue the care with which they describe their research findings and the diligence with which they identify appropriate and inappropriate uses of neuroimaging information.<sup>176</sup> Private and governmental organizations that are legally permitted<sup>177</sup> and are considering conducting fMRI tests or obtaining neuroimaging test results should consult with scientists who conduct functional neuroimaging studies to ensure that they understand the limitations of neuroimaging research and the meaning of fMRI test results.<sup>178</sup> And, because functional neuroimaging information can be sensitive and stigmatizing, individuals who create, obtain, or use such information must protect its

<sup>176</sup> Ibid. (advising genetics researchers to make careful public pronouncements regarding their research and to temper their enthusiasm for the potential implications of preliminary research).

<sup>177</sup> Chapters 3, 4 and 5 discuss the legal constraints that apply to the creation, use, and disclosure of neuroimaging information.

<sup>178</sup> Rothstein, "Application of Behavioural Genetics," 797 (arguing that commercial and social institutions need to consult with experts before applying behavioural genetics to avoid limiting opportunities for individuals or stigmatizing them).

confidentiality as well as the privacy of the individuals to whom the information relates.  $^{179}$ 

 $<sup>^{179}</sup>$  Ibid. (arguing that those who hold behavioural genetic information must ensure its confidentiality).

# CHAPTER 3: UNDERSTANDING CONFIDENTIALITY AND PRIVACY

Chapter 2 calls for the confidentiality of functional neuroimaging information and the privacy of neuroimaging subjects. But, what do we mean by privacy and confidentiality? How are privacy and confidentiality different? What are their sources and what are their limits? In what contexts have privacy and confidentiality been explicated, and how do these concepts apply in the context of functional neuroimaging? This chapter answers these questions by examining historical and current perspectives of privacy and confidentiality. Following a discussion of the various sources of privacy and confidentiality -- including ancient and modern codes of medical and research ethics, constitutional law, property law, tort law, and legislation and regulation -- different definitions, classifications, and conceptualizations of privacy and confidentiality are examined. This chapter concludes by proposing definitions of confidentiality and privacy that work in the context of functional neuroimaging and that provide a framework for the remaining chapters.

## CODES OF MEDICAL AND RESEARCH ETHICS

Ancient and modern codes of medical and research ethics are a primary source of rights and duties relating to privacy and confidentiality. Hippocrates stated in the fifth century B.C. that, "What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about." This "promise of silence" requires physicians to maintain the confidentiality of information obtained during the treatment context, as well as information acquired outside the

<sup>&</sup>lt;sup>1</sup> Albert R. Jonsen, Mark Siegler, and William J. Winslade, *Clinical Ethics: A Practical Approach* to Ethical Decisions in Clinical Medicine, 5<sup>th</sup> ed. (New York: McGraw Hill, 2002), 158.

<sup>&</sup>lt;sup>2</sup> Ludwig Edelstein, *The Hippocratic Oath: Text, Translation and Interpretation* (Baltimore: Johns Hopkins Press, 1943), 3.

treatment context.<sup>3</sup> The concern underlying the promise is "the physician's renommée[,] which might suffer if he is a prattler."<sup>4</sup> The promise has been interpreted neither as a right of patients nor a general precaution, but as a duty of physicians, and has been analogized to the Pythagoreans' moral obligation to be silent regarding things that were not supposed to be communicated to others:

They did not tell everything to everybody. They did not indiscriminately impart their knowledge to others. They expected the scientist to be reticent and ready to listen. They observed silence even in daily life. That they were taciturn beyond all other men no less than the fact that they were frugal in their habits made them the object of ridicule in ancient comedy. Certainly if the doctor who promises not to talk about anything that he may see or hear is to be placed in any philosophical school, it must be the Pythagorean.<sup>5</sup>

Modern codes of medical ethics are another source of privacy and confidentiality rights and duties. Based on respect for the autonomy of the patient, the loyalty owed by the health care provider, and the possibility that inappropriate disclosures of medical information may discourage patients from sharing important information with their health care providers, multiple codes of medical ethics are potentially applicable in the functional neuroimaging context. Four illustrative codes are discussed in this chapter.

The American Medical Association's (AMA's) Code of *Medical Ethics* defines confidentiality as "information told in confidence or imparted in secret," and establishes

<sup>&</sup>lt;sup>3</sup> Ibid., 37. The reason for the second clause in the promise ("or even outside of the treatment in regard to the life of men") is the subject of considerable debate. Some commentators believe that utilitarian reasons, not professional considerations, support its existence. Ibid., 37n118, 37n119.

<sup>&</sup>lt;sup>4</sup> Ibid., 37.

<sup>&</sup>lt;sup>5</sup> Ibid.

<sup>&</sup>lt;sup>6</sup> Jonsen, Siegler, and Winslade, Clinical Ethics, 158; Tom L. Beauchamp and James F. Childress, Principles of Biomedical Ethics, 5th ed. (New York: Oxford University Press, 2001), 296; William J. Winslade, "Confidentiality," in Encyclopedia of Bioethics, ed. Warren T. Reich (New York: Free Press, 1978), 195; William J. Winslade and Judith Wilson Ross, "Privacy, Confidentiality, and Autonomy in Psychotherapy," Nebraska Law Review 64, no. 4 (1985): 579.

<sup>&</sup>lt;sup>7</sup> American Medical Association, *Code of Medical Ethics: Current Opinions with Annotations* (Chicago: American Medical Association, 1997), Op. 5.059.

the general ethical principle that, "The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree."8 Underlying the principle is the recognition that full information disclosure is required for effective treatment and that physician secrecy will encourage patients to disclose pertinent information to their physicians.<sup>9</sup> The AMA principle is narrower than Hippocrates' promise, applying by its stated terms only to information disclosed to the physician in the treatment context. Although not expressly stated, the phrasing of the principle seems to focus on the duty of physicians, not the confidentiality rights of patients. In subsequent language, the AMA recognizes that the duty of confidentiality is not absolute. The AMA permits physicians to disclose otherwise confidential information in situations involving "overriding social considerations," such as when the patient gives her express consent to the disclosure, a law requires the physician to make the disclosure, the patient threatens to inflict serious bodily harm to herself or another individual and a reasonable probability that the patient may carry out the threat exists, or the patient presents with a communicable disease or a gun or knife wound that applicable law requires the physician to report.<sup>10</sup>

The AMA also requires physicians to be "mindful of patient privacy, which encompasses information that is concealed from others outside of the patient-physician relationship." As with confidentiality, the AMA Code recognizes that patient privacy is not absolute "and must be balanced with the need for the efficient provision of medical care and the availability of resources." 12

In its most recent *Ethical Principles of Psychologists and Code of Conduct*, the American Psychological Association (APA) refers to confidentiality and privacy both as

<sup>&</sup>lt;sup>8</sup> Ibid., Op. 5.05.

<sup>&</sup>lt;sup>9</sup> Ibid.

<sup>10</sup> Ibid.

<sup>&</sup>lt;sup>11</sup> Ibid., Op. 5.059.

<sup>&</sup>lt;sup>12</sup> Ibid.

rights of persons ("Psychologists respect the dignity and worth of all people, and the rights of individuals to privacy, confidentiality, and self-determination"13) and duties of psychologists ("Psychologists have a primary obligation and take reasonable precautions to protect confidential information . . . ").14 The APA Code requires psychologists to discuss at the outset of a relationship the relevant limits of confidentiality and the foreseeable uses of the information generated through their psychological activities, 15 a requirement that will become relevant in Chapter 4's discussion of whether and how providers and scientists should disclose unanticipated neuroimaging findings. The APA Code also requires psychologists to include in written and oral reports and consultations only information that is germane to the purpose for which the communication is made. 16 The APA Code recognizes that the duty of confidentiality is not absolute, and permits psychologists to disclose otherwise confidential information with the person's consent or without the person's consent when permitted by law for a valid purpose, including providing needed professional services; obtaining appropriate professional consultations; protecting the person, psychologist, or others from harm; or obtaining payment for services.17

The American College of Radiology's (ACR's) *Code of Ethics* states very succinctly a duty of confidentiality for radiologists: "Members may not reveal confidences entrusted to them in the course of medical attendance, or deficiencies they may observe in the character of patients." Exceptions exist for disclosures required by law or situations in which a disclosure is necessary to protect the welfare of the

<sup>&</sup>lt;sup>13</sup> American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct* (Washington, D.C.: American Psychological Association, 2002), Principle E.

<sup>&</sup>lt;sup>14</sup> Ibid., Ethical Standard 4.01

<sup>15</sup> Ibid., Ethical Standard 4.02(a) and (b).

<sup>&</sup>lt;sup>16</sup> Ibid., Ethical Standard 4.04(a).

<sup>&</sup>lt;sup>17</sup> Ibid., Ethical Standard 4.05(a) and (b).

<sup>&</sup>lt;sup>18</sup> American College of Radiology, *Code of Ethics* (Reston, Va.: American College of Radiology, 2003), § 1.

individual or of the community."<sup>19</sup> The "deficiencies they may observe in the character of patients" language is rather interesting and presented by the ACR without further elaboration, and could be implicated in situations in which a radiologist interprets a functional magnetic resonance image to reveal information about a patient's character.

The American Psychiatric Association's *Principles of Medical Ethics* establishes confidentiality and privacy rights and duties: "A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law."<sup>20</sup> The *Principles* further explain that:

Psychiatric records, including even the identification of a person as a patient, must be protected with extreme care. Confidentiality is essential to psychiatric treatment. This is based in part on the special nature of psychiatric therapy as well as on the traditional ethical relationship between physician and patient. Growing concern regarding the civil rights of patients and the possible adverse effects of computerization, duplication equipment, and data banks makes the dissemination of confidential information an increasing hazard. Because of the sensitive and private nature of the information with which the psychiatrist deals, he or she must be circumspect in the information that he or she chooses to disclose to others about a patient. The welfare of the patient must be a continuing consideration.<sup>21</sup>

The American Psychiatric Association's concern regarding the disclosure of confidential information to data banks is relevant in the context of fMRI research, given that at least one neuroscience journal requires its authors to submit their raw fMRI data to a neuroimaging data bank.<sup>22</sup>

<sup>19</sup> Ibid.

<sup>&</sup>lt;sup>20</sup> American Psychiatric Association, *Principles of Medical Ethics, with Annotations Especially Applicable to Psychiatry* (Arlington, Va.: American Psychiatric Association, 2001), § 4.

<sup>&</sup>lt;sup>21</sup> Ibid., § 4 (Annotations).

<sup>&</sup>lt;sup>22</sup> Journal of Cognitive Neuroscience, *Submission Guidelines*, http://mitpress.mit.edu/catalog/item/default.asp?ttype=4&tid=12&xid=6&xcid=0 (accessed February 16, 2006).

Stand-alone codes of research ethics also establish certain rights and duties relating to confidentiality and privacy that apply specifically in the research context.<sup>23</sup> In 1964, the World Medical Association recommended through its Declaration of Helsinki that, "Every precaution should be taken to respect the privacy of the subject . . . "<sup>24</sup> Although confidentiality does not seem to have been a concern of the World Medical Association, it is a focus of the Council for International Organizations of Medical Sciences (CIOMS) in its most recent edition of *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. The *Guidelines* require investigators to "establish secure safeguards of the confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality."<sup>25</sup>

Although codes of medical and research ethics generally do not establish judicially enforceable rights and duties relating to confidentiality and privacy, they do provide statements of social policy relating to moral issues in the practice of medicine and the conduct of research.<sup>26</sup> Conduct that violates applicable ethical principles also can justify disciplinary action such as censure, suspension, or expulsion from medical society membership.<sup>27</sup>

<sup>&</sup>lt;sup>23</sup> Some codes of medical ethics also apply in the conduct of research. The American Psychological Association's Ethics Code applies to "psychologists' activities that are part of their scientific, educational, or professional roles as psychologists. Areas covered include but are not limited to the clinical, counseling, and school practice of psychology; research..." American Psychological Association, *Ethical Principles*, Introduction and Applicability.

<sup>&</sup>lt;sup>24</sup> World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (Helsinki: World Medical Association, 1964), Principle 21.

<sup>&</sup>lt;sup>25</sup> Council for International Organizations of Medical Sciences, *International Ethical Guidelines* for Biomedical Research Involving Human Subjects (Geneva: Council for International Organizations of Medical Sciences, 2002), Guideline 18.

<sup>&</sup>lt;sup>26</sup> American Medical Association, *Code of Medical Ethics*, E-1.01 and E-1.02 (discussing the relationship between law and ethics).

<sup>&</sup>lt;sup>27</sup> Ibid., E-1.01.

## CONSTITUTIONAL LAW

Constitutional law is a rich source of privacy rights and duties. Adopted in 1791, the first ten amendments to the United States Constitution are called the Bill of Rights. Their principal purpose is to protect individuals against various sorts of intrusions, or interference, by the government. Although the word privacy is not located anywhere in the Bill of Rights or the Constitution, the United States Supreme Court (Court) has interpreted five of the ten Bill of Rights and the Fourteenth Amendment to protect certain privacy interests.<sup>28</sup>

#### The First Amendment

The First Amendment to the Constitution provides that, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."<sup>29</sup> Some of the better-known privacy interests protected by the First Amendment include the interest of political groups and social organizations in holding physically private meetings and in maintaining the privacy of their membership lists.<sup>30</sup> A seminal case upholding these interests is *NAACP v. Alabama*,<sup>31</sup> in which the Court held that a state order requiring disclosure of the NAACP's membership list violated the NAACP's and its members' rights under the Constitution. The Court recognized in *NAACP* the "vital relationship between freedom to associate and privacy in one's associations" as well as the "inviolability of privacy in group association."<sup>32</sup> In a later opinion in *Griswold v. Connecticut*, the Court reaffirmed *NAACP* and again recognized the privacy protections

<sup>&</sup>lt;sup>28</sup> Anita Allen-Castellitto, "Origins and Growth of U.S. Privacy Law," *Practising Law Institute* 701 (June 2002): 92.

<sup>&</sup>lt;sup>29</sup> U.S. CONST. amend. I.

<sup>&</sup>lt;sup>30</sup> Allen-Castellitto, "Origins and Growth," 92.

<sup>31</sup> NAACP v. Alabama, 357 U.S. 449 (1958).

<sup>&</sup>lt;sup>32</sup> Ibid., 462.

provided by the First Amendment: "the First Amendment has a penumbra where privacy is protected from governmental intrusion."33

The First Amendment also protects the interest of individuals in reading books and watching movies in their homes, regardless of the content of such books or films. Scholars have categorized this right as "freedom of thought and solitude in the home" or, more generally, "privacy of thought."34 In Stanley v. Georgia, 35 a seminal "privacy of thought" case, the Court reviewed whether a state could make an adult's possession of obscene material in his own home criminal. Justice Marshall answered the question in the negative, balancing the state's weak interest in controlling private possession of obscenity and the individual's strong interest in not being prohibited its private usage: "For also fundamental is the right to be free, except in very limited circumstances, from unwanted governmental intrusions into one's privacy."<sup>36</sup> Justice Marshall then issued his famous statement that, "If the First Amendment means anything, it means that a State has no business telling a man, sitting alone in his own house, what books he may read or what films he may watch. Our whole constitutional heritage rebels at the thought of giving government the power to control men's minds."37 Using the language of privacy for the second time, Justice Marshall further explained that, "Whatever the power of the state to control public dissemination of ideas inimical to the public morality, it cannot constitutionally premise legislation on the desirability of controlling a persons private thoughts."38

<sup>&</sup>lt;sup>33</sup> Griswold v. Connecticut, 381 U.S. 479, 483 (1965).

<sup>&</sup>lt;sup>34</sup> Allen-Castellitto, "Origins and Growth," 92.

<sup>&</sup>lt;sup>35</sup> Stanley v. Georgia, 394 U.S. 557 (1969).

<sup>&</sup>lt;sup>36</sup> Ibid., 564.

<sup>&</sup>lt;sup>37</sup> Ibid., 565.

<sup>&</sup>lt;sup>38</sup> Ibid., 566. The right to privacy of thought has its limits, especially in cases involving child pornography. *New York v. Ferber*, 458 U.S. 747, 758 (1982) ("[T]he use of children as subjects of pornographic material is harmful to the physiological, emotional and mental health of the child. That judgment, we think, easily passes muster under the First Amendment.").

Stanley v. Georgia is not the Court's only "privacy of thought" case. A plurality of the Court found in Board of Education v. Pico that the First Amendment is broad enough to encompass additional rights not enumerated in its terms, including a "right to receive information and ideas."39 Several additional First Amendment cases decided over the last century speak to a protected interest in thought. Justice Cardozo stated in 1937 in Palko v. Connecticut that, "freedom of thought . . . is the matrix, the indispensable condition, of nearly every other form of freedom."40 In 1942, the Court stated in West Virginia State Board of Education v. Barnette<sup>41</sup> that the First Amendment gives a constitutional preference for "individual freedom of mind" over "officially disciplined uniformity for which history indicates a disappointing and disastrous end."42 The same year, the Court explained in Jones v. Opelika that, "[f]reedom to think is absolute of its own nature; the most tyrannical government is powerless to control the inward workings of the mind."43 Justice Harlan, concurring in 1971's United States v. Reidel, described the Constitutional right protected in Stanley v. Georgia as "the First Amendment right of the individual to be free from governmental programs of thought control, however such programs might be justified in terms of permissible state objectives," and as the "freedom from governmental manipulation of the content of a man's mind . . . "44 In 1977, the Court stated in Abood v. Detroit Board of Education that "freedom of belief is no incidental or secondary aspect of the First Amendment's protections." The Court explained, "at the heart of the First Amendment, is the notion that an individual should be

<sup>&</sup>lt;sup>39</sup> Board of Educ. v. Pico, 457 U.S. 853, 867 (1982) (plurality opinion).

<sup>&</sup>lt;sup>40</sup> Palko v. Connecticut, 302 U.S. 319, 326-27 (1937).

<sup>41</sup> West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624, 642 (1943).

<sup>&</sup>lt;sup>42</sup> Ibid., 637.

<sup>&</sup>lt;sup>43</sup> Jones v. Opelika, 316 U.S. 584, 618 (1942).

<sup>&</sup>lt;sup>44</sup> U.S. v. Reidel, 402 U.S. 351, 359 (1971) (Harlan, J., concurring).

free to believe as he will, and that in a free society one's beliefs should be shaped by his mind and his conscience rather than coerced by the State."45

The First Amendment thus is an important source of privacy for political groups and social organizations that wish to hold closed meetings and keep from public disclosure their membership lists, as well as a potential source of privacy for individuals who would like to protect their own thoughts, regardless of content. Chapter 5 discusses the extent to which the First Amendment could be implicated by government-ordered functional magnetic resonance images that seek to identify, describe, or measure an individual's thoughts.

#### The Third Amendment

The Third Amendment to the Constitution provides that, "No soldier shall, in time of peace be quartered in any house, without the consent of the Owner, nor in time of war, but in a manner to be prescribed by law." This provision, the least litigated and one of the most dated in the Constitution, prevents the quartering of soldiers in homes without the home owner's consent in times of peace; however, during war time, quartering may occur if in accordance with the law. The intent of the provision was to prevent soldiers from living in citizens' homes as the British soldiers did before the American Revolution. The only case in which a federal court addressed the constitutionality of a law or action under the Third Amendment was *Engblom v. Carey*, decided by the Second Circuit Court of Appeals in 1982. Notwithstanding the lack of case law directly interpreting it, the Third Amendment is known for protecting an individual's interest in the privacy of his or her own home. The Court explained in *Griswold v. Connecticut* that, "The Third Amendment in its prohibition against the quartering of soldiers 'in any house' in time of

<sup>&</sup>lt;sup>45</sup> Abood v. Detroit Board of Education, 431 U.S. 209, 234-35 (1977).

<sup>&</sup>lt;sup>46</sup> U.S. CONST. amend. III.

<sup>&</sup>lt;sup>47</sup> Engblom v. Carey, 677 F.2d 957 (2<sup>nd</sup> Cir. 1982).

<sup>&</sup>lt;sup>48</sup> Allen-Castellitto, "Origins and Growth," 92.

peace without the consent of the owner is another facet of th[e zone of] privacy."<sup>49</sup> The only Amendment not potentially relevant in the context of functional neuroimaging, the Third Amendment is considered one of the six constitutional sources of privacy.

### The Fourth Amendment

The Fourth Amendment to the Constitution provides that, "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized." Aspects of privacy protected by the Fourth Amendment include, but are not limited to, an individuals interest in the privacy of her own home, personal property, papers, correspondence, conversations, and electronic communications.

The Supreme Court first tied the concept of privacy to the Fourth Amendment's guarantee against unreasonable searches and seizures in its 1886 opinion in *Boyd v*. *United States*.<sup>52</sup> Writing for the *Boyd* majority, Justice Bradley relied on the "sanctities of a man's home and the privacies of life" to find unconstitutional the seizure of thirty-five cases of plate glass by federal authorities at the port of New York.<sup>53</sup> Forty-two years after *Boyd*, Justice Brandeis wrote a stirring dissent in *Olmstead v*. *United States*<sup>54</sup> in which he argued that wiretapping of telephone lines by federal officers and the resulting interception of communications constituted an illegal "search and seizure" under the Fourth Amendment. Justice Brandeis disagreed with the five-Justice majority holding that wiretapping constituted neither a "search" (defined as a physical trespass) or

<sup>&</sup>lt;sup>49</sup> Griswold v. Connecticut, 381 U.S. 479, 484 (1965).

<sup>&</sup>lt;sup>50</sup> U.S. CONST. amend. IV.

<sup>&</sup>lt;sup>51</sup> Allen-Castellitto, "Origins and Growth," 92.

<sup>&</sup>lt;sup>52</sup> Ken Gormley, "One Hundred Years of Privacy," Wisconsin Law Review (1992): 1359.

<sup>&</sup>lt;sup>53</sup> Boyd v. United States, 116 U.S. 616, 630 (1886).

<sup>&</sup>lt;sup>54</sup> Olmstead v. United States, 277 U.S. 438 (1928).

"seizure" (of tangible property); instead, Brandeis argued that the Fourth Amendment established a broader "right to be let alone." Using the language of privacy, Brandeis explained that:

Subtler and more far-reaching means of invading privacy have become available to the Government. Discovery and invention have made it possible for the Government, by means far more effective than stretching upon the rack, to obtain disclosure in court of what is whispered in the closet. . . . The protection guaranteed by the [4th and 5th] Amendments is much broader in scope. The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only part of the pain, pleasure and satisfactions of life are to be found in the material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the Government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment. And the use, as evidence in a criminal proceeding, of facts ascertained by such intrusion must be deemed a violation of the Fifth.<sup>56</sup>

It took almost forty years for Brandeis' dissent in Olmstead to be recognized by a majority of the Supreme Court in *Katz v. United States*.<sup>57</sup> Charles Katz was arrested by federal authorities in Los Angeles after an electronic listening device attached to the outside of a telephone booth was used to record Katz' bookmaking conversations. Writing for the majority, Justice Stewart held that the government's use of the electronic listening device violated the Fourth Amendment even though the government had not searched or seized any of Katz' physical property. Justice Stewart reasoned that the Fourth Amendment "protects people, not places" and used the language of privacy in

<sup>55</sup> Ibid., 471-73 (Brandeis, J., dissenting).

<sup>&</sup>lt;sup>56</sup> Ibid., 478-79 (Brandeis, J., dissenting).

<sup>&</sup>lt;sup>57</sup> Katz v. United States, 389 U.S. 347 (1967).

<sup>&</sup>lt;sup>58</sup> Ibid., 351.

his conclusion that, "[W]hat [a person] seeks to preserve as private, even in an area accessible to the public, may be constitutionally protected."59

Justice Harlan's concurring opinion in *Katz*, which has since become more famous than Justice Stewart's majority opinion, would have established a "reasonable expectation of privacy" test.<sup>60</sup> Finally adopted by a majority of the Court in 1968 in *Terry v. Ohio*,<sup>61</sup> Justice Harlan's concurrence in *Katz* recognized the existence of a protected zone of Fourth Amendment privacy if an individual has an "actual" expectation of privacy and that expectation is "reasonable." Since *Terry*, the privacy right secured by the Fourth Amendment has been summarized as the "right to be let alone, with respect to governmental searches and seizures which invade a sphere of individual solitude deemed reasonable by society." <sup>63</sup>

Following *Terry*, the Court has found that a reasonable expectation of privacy exists in cases involving bugging devices, administrative searches of homes and businesses, searches of closed luggage and footlockers, beepers placed by federal agents inside chemical drums, roving border patrols searching for illegal aliens, traffic checkpoints searching for concealed aliens, and random spot-checks for automobiles to inspect drivers' licenses and vehicle registrations.<sup>64</sup> However, the Court also has found that no reasonable expectation of privacy exists in other cases involving bank records, voice and writing exemplars, phone numbers recorded by pen registers, conversations

<sup>&</sup>lt;sup>59</sup> Ibid.

<sup>&</sup>lt;sup>60</sup> Ibid., 360-61 (Harlan, J., concurring).

<sup>61</sup> Terry v. Ohio, 392 U.S. 1, 9 (1968).

<sup>62</sup> Katz, 389 U.S. at 361 (Harlan, J., concurring).

<sup>63</sup> Gormley, "One Hundred Years of Privacy," 1374.

<sup>&</sup>lt;sup>64</sup> Berger v. New York, 388 U.S. 41 (1967); United States v. United States Dist. Ct., 407 U.S. 297 (1972); Camara v. Municipal Ct., 387 U.S. 523 (1967); G.M. Leasing Corp. v. United States, 429 U.S. 338 (1977); Mancusi v. DeForte, 392 U.S. 364 (1968); United States v. Chadwick, 433 U.S. 1 (1977); Arkansas v. Sanders, 442 U.S. 753 (1979); Walter v. United States, 447 U.S. 649 (1980); United States v. Karo, 468 U.S. 705 (1984); United States v. Brignoni-Ponce, 422 U.S. 873 (1975); United States v. Ortiz, 422 U.S. 891 (1975).

recorded by wired informants, and a growing list of cases involving cars, car trunks, glove compartments, and closed containers.<sup>65</sup> Chapter 5 discusses the extent to which a stated-ordered functional magnetic resonance image could constitute a search or seizure under the Fourth Amendment.

### The Fifth Amendment

The Fifth Amendment to the Constitution provides in relevant part that, "nor shall any person . . . be compelled in any criminal case to be a witness against himself . . ."66

The Fifth Amendment's privilege against self-incrimination has been interpreted to protect an individual's interest in the privacy of her body, mind, and beliefs. 67

Although the Supreme Court stated in dicta in *Griswold v. Connecticut* that, "The Fifth Amendment in its Self-Incrimination Clause enables the citizen to create a zone of privacy which government may not force him to surrender to his detriment,"68 the Court has not established absolute Fifth Amendment privacy protections against governmental intrusions. For example, in *Couch v. United States*, 69 the Supreme Court reviewed whether the privilege against self-incrimination could be claimed by a taxpayer who gave various business and tax records to an independent accountant. Justice Powell, writing for the Court, acknowledged that some type of Fifth Amendment privacy interest does exist:

The importance of preserving inviolate the privilege against compulsory self-incrimination has often been stated by this Court and need not be elaborated. . . .

<sup>65</sup> United States v. Miller, 425 U.S. 435 (1976); United States v. Dionisio, 410 U.S. 1 (1973); Smith v. Maryland, 442 U.S. 735 (1979); United States v. White, 401 U.S. 745 (1971); Chambers v. Maroney, 399 U.S. 42 (1970); South Dakota v. Opperman, 428 U.S. 364 (1976); Rakas v. Illinois, 439 U.S. 128 (1978); California v. Carney, 471 U.S. 386 (1985); United States v. Ross, 456 U.S. 798 (1982); and New York v. Belton, 453 U.S. 454 (1981).

<sup>&</sup>lt;sup>66</sup> U.S. CONST. amend. V.

<sup>&</sup>lt;sup>67</sup> Allen-Castellitto, "Origins and Growth," 92; Gormley, "One Hundred Years of Privacy," 1432.

<sup>&</sup>lt;sup>68</sup> Griswold v. Connecticut, 381 U.S. 479, 484 (1965).

<sup>&</sup>lt;sup>69</sup> Couch v. United States, 409 U.S. 322 (1973).

By its very nature, the privilege is an intimate and personal one. It respects a private inner sanctum of individual feeling and thought and proscribes state intrusion to extract self-condemnation.<sup>70</sup>

However, Powell concluded that the taxpayer could not, in the particular case before the Court, "reasonably claim, either for Fourth or Fifth Amendment purposes, an expectation of protected privacy or confidentiality."<sup>71</sup> (Justice Douglas disagreed in a stirring dissent: "the Fourth and Fifth Amendments delineate a 'sphere of privacy' which must be protected against governmental intrusion."<sup>72</sup>). Chapter 5 discusses whether a state-ordered functional magnetic resonance image could violate an individual's Fifth Amendment privilege against self-incrimination.

#### The Ninth Amendment

The Ninth Amendment to the Constitution provides that, "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." The Ninth Amendment reserves unenumerated, traditional rights to the people. The privacy interests protected by the Ninth Amendment include an individual's interest in all forms of physical, informational, decisional, and proprietary privacy that are traditionally respected.<sup>74</sup>

The Ninth Amendment was implicated in *Griswold v. Connecticut*, in which the Supreme Court reviewed the constitutionality of a Connecticut statute that imposed a fine or imprisonment or both on any person who used "any drug, medicinal article, or instrument for the purpose of preventing conception." Six members of the Supreme

<sup>&</sup>lt;sup>70</sup> Ibid., 327.

<sup>&</sup>lt;sup>71</sup> Ibid., 334.

<sup>&</sup>lt;sup>72</sup> Ibid., 339-340.

<sup>73</sup> U.S. CONST. amend. IX.

<sup>&</sup>lt;sup>74</sup> Allen-Castellitto, "Origins and Growth," 92.

<sup>&</sup>lt;sup>75</sup> Griswold v. Connecticut, 381 U.S. 479 (1965).

Court held that the statute violated a fundamental right of "marital privacy" <sup>76</sup> that was embodied somewhere in the Constitution ("The present case, then, concerns a relationship lying within the zone of privacy created by several fundamental constitutional guarantees."). <sup>77</sup> However, the precise location of the fundamental right was the source of splintered opinions. <sup>78</sup> In the opinion of the Court, Justice Douglas explained that the right to privacy could be found drifting among the "penumbras" of the Ninth (as well as the First, Third, Fourth, and Fifth) Amendments. <sup>79</sup> And, a majority of the Court did find a fundamental right of privacy broad enough to protect the ability of married couples to decide what to do in the privacy of their marital bedrooms without intrusion by the State of Connecticut: "We deal with a right of privacy older than the Bill of Rights—older than our political parties, older than our school system. Marriage is a coming together for better or for worse, hopefully enduring, and intimate to the degree of being sacred." <sup>80</sup>

Subsequent decisions of the Court also have recognized the Ninth Amendment as an important source of the right to privacy. As one example, Justice Blackmun stated in *Roe v. Wade* that, "The right of privacy, whether it be founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action, as we feel it

<sup>&</sup>lt;sup>76</sup> Ibid., 485-86 ("Would we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives? The very idea is repulsive to the notions of privacy surrounding the marriage relationship").

<sup>&</sup>lt;sup>77</sup> Ibid., 485.

<sup>&</sup>lt;sup>78</sup> Ibid., 486-86 (Goldberg, J., concurring) ("Although I have not accepted the view that 'due process' as used in the Fourteenth Amendment includes all of the first eight Amendments . . . "); ibid., 499 (Harlan, J., concurring) ("In my view, the proper constitutional inquiry in this case is whether this Connecticut statute infringes the Due Process Clause of the Fourteenth Amendment because the enactment violates basic values 'implicit in the concept of ordered liberty,' . . . For reasons stated at length in my dissenting opinion in Poe v. Ullman, supra, I believe that it does. While the relevant inquiry may be aided by resort to one or more of the provisions of the Bill of Rights, it is not dependent on them or any of their radiations. The Due Process Clause of the Fourteenth Amendment stands, in my opinion, on its own bottom.").

<sup>&</sup>lt;sup>79</sup> Ibid., 484-85.

<sup>80</sup> Ibid., 486.

is, or, as the District Court determined, in the Ninth Amendment's reservation of rights to the people is broad enough to encompass a woman's decision whether or not to terminate her pregnancy."81 Chapter 5 discusses the extent to which a state-ordered functional magnetic resonance images could violate an individual's traditionally respected privacy rights.

### The Fourteenth Amendment

The Fourteenth Amendment to the Constitution provides that, "No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny any person within its jurisdiction the equal protection of the laws." Although the intent of the Fourteenth Amendment was to protect the rights of newly freed slaves, the interests now protected by the Fourteenth Amendment include, but are not limited to, an individual's privacy in decision-making and a very limited interest in non-disclosure of information.83

Privacy in decision-making was central in *Roe v. Wade*, in which the Supreme Court held that the Fourteenth Amendment was a source of a fundamental right to privacy strong enough to strike down a Texas law categorically prohibiting abortion.<sup>84</sup> Because of cases such as *Roe* and *Griswold*, one might think that a constitutionally-protected interest in not having a government gather or release information about an individual exists. Stated another way, one might be inclined to argue that because *Griswold* established a constitutionally-protected privacy interest for married couples to "keep secret" from the government the fact of contraceptive use, a similar protection would apply to other types of information that people generally wish to "keep secret."

<sup>81</sup> Roe v. Wade, 410 U.S. 113, 153 (1973).

<sup>82</sup> U.S. CONST. amend, XIV.

<sup>83</sup> Allen-Castellitto, "Origins and Growth," 92.

<sup>84</sup> Ibid.

Although the Court has recognized that individuals have a limited right to non-disclosure of information, the Court has not given significant weight to that interest. <sup>85</sup> In *Whalen v. Roe*, the Court reviewed a New York statute that required physicians to disclose to the state a copy of every prescription written for drugs with a high potential of abuse. <sup>86</sup> The statute also established security measures for the prescription information once it had been received by the state. <sup>87</sup> Affected patients, physicians, and two physician associations argued that the statute violated their constitutionally protected rights of privacy:

Appellees contend that the statute invades a constitutionally protected "zone of privacy." The cases sometimes characterized as protecting "privacy" have in fact involved at least two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions. Appellees argue that both of these interests are impaired by this statute. The mere existence in readily available form of the information about patients' use of Schedule II drugs creates a genuine concern that the information will become publicly known and that it will adversely affect their reputations. This concern makes some patients reluctant to use, and some doctors reluctant to prescribe, such drugs even when their use is medically indicated. It follows, they argue, that the making of decisions about matters vital to the care of their health is inevitably affected by the statute. Thus, the statute threatens to impair both their interest in the nondisclosure of private information and also their interest in making important decisions independently.<sup>88</sup>

Although the district court agreed with the plaintiffs ("'the doctor-patient relationship intrudes on one of the zones of privacy accorded constitutional protection' and the patient-identification provisions of the [New York statute] invaded this zone with 'a needlessly broad sweep,""),89 the Supreme Court disagreed. Writing for the Court,

<sup>85</sup> Lawrence O. Gostin, "Health Information Privacy," Cornell Law Review 80 (March 1995): 495.

<sup>86</sup> Whalen v. Roe, 429 U.S. 589 (1977).

<sup>87</sup> Ibid., 591.

<sup>88</sup> Ibid., 599-600.

<sup>89</sup> Ibid., 596.

Justice Stevens recognized in dicta "the threat to privacy implicit in the accumulation of vast amounts of personal information in computerized data banks or other massive government files." Justice Stevens further recognized that "in some circumstances" the duty to avoid unwarranted disclosures of information "arguably had its roots in the Constitution." However, Justice Stevens found that any such privacy interest was outweighed by the state's interest in gathering the data, coupled with the state's establishment of "adequate standards and procedures for protecting such information," which included locking computer tapes in cabinets, running computers off-line to avoid access by others, and limiting access to the information to a limited number of state officials. Justice Stevens concluded that:

We are persuaded, however, that the New York program does not, on its face, pose a sufficiently grievous threat to either interest to establish a constitutional violation. Public disclosure of patient information can come about in three ways. Health Department employees may violate the statute by failing, either deliberately or negligently, to maintain proper security. A patient or a doctor may be accused of a violation and the stored data may be offered in evidence in a judicial proceeding. Or, thirdly, a doctor, a pharmacist, or the patient may voluntarily reveal information on a prescription form. The third possibility existed under the prior law and is entirely unrelated to the existence of the computerized data bank. Neither of the other two possibilities provides a proper ground for attacking the statute as invalid on its face. There is no support in the record, or in the experience of the two States that New York has emulated, for an assumption that the security provisions of the statute will be administered improperly. And the remote possibility that judicial supervision of the evidentiary use of particular items of stored information will provide inadequate protection against unwarranted disclosures is surely not a sufficient reason for invalidating the entire patient-identification program.<sup>92</sup>

Although the interest in non-disclosure of information protected by the Fourteenth Amendment is very limited, Chapter 4 discusses the extent to which the Fourteenth

<sup>&</sup>lt;sup>90</sup> Ibid., 605.

<sup>&</sup>lt;sup>91</sup> Ibid., 593-94.

<sup>&</sup>lt;sup>92</sup> Ibid., 600-602.

Amendment could be implicated by a provider or scientist's disclosure of neuroimaging information to a state actor.

### **State Constitutions**

As initially drafted, few state constitutions recognized an express right to privacy, although a few constitutions did contain provisions that implied some type of privacy right, such as "No person shall be disturbed in his private affairs, or his home invaded, without authority of law."93 Like the U.S. Constitution, many state constitutions implicitly recognized rights to privacy by virtue of provisions modeled after the federal Bill of Rights. In addition, many states amended their constitutions in the period after 1970 to include explicit privacy protections.<sup>94</sup> For example, Alabama amended its constitution to provide: "The right of the people to privacy is recognized and shall not be infringed."95 California enacted a similar amendment: "All people are by nature free and independent and have inalienable rights. Among those are enjoying and defending life and liberty, acquiring, possessing and protecting property, and pursuing and obtaining safety, happiness and privacy."<sup>96</sup> Florida, too: "Every natural person has the right to be let alone and free from governmental intrusion into his private life except as otherwise provided herein."97 Some states have interpreted their constitutional provisions to provide stronger protections than those provided by the U.S. Constitution.<sup>98</sup> Like the federal Constitution, most state constitutional provisions only protect individuals against breaches of privacy by the government, not private individuals or organizations.99

<sup>93</sup> WASH. CONST. art. I, § 7; ARIZ. CONST. art. II, § 8.

 <sup>&</sup>lt;sup>94</sup> Gostin, "Health Information Privacy," 498; Gormley, "One Hundred Years of Privacy," 1423 24; Allen-Castellitto, "Origins and Growth," 94-95.

<sup>95</sup> ALA. CONST. art. I, § 22.

<sup>&</sup>lt;sup>96</sup> CAL. CONST. art. I, § 1.

<sup>&</sup>lt;sup>97</sup> FLA. CONST. art. I, § 23.

<sup>98</sup> Allen-Castellitto, "Origins and Growth," 92; Gormley, "One Hundred Years of Privacy," 1424.

<sup>99</sup> Gostin, "Health Information Privacy," 498.

### PROPERTY AND TORT LAW

Before 1890, few American judicial opinions identified a right of privacy distinct from the rights associated with private property.<sup>100</sup> If one individual harmed another individual's reputation by revealing sensitive or stigmatizing information about the second individual, a nineteenth-century court that found for the plaintiff might do so on the theory that the first individual damaged something the second individual owned as property, such as his or her reputation.<sup>101</sup> Nineteenth-century courts generally inferred privacy rights from stronger property rights because the right to private property was treated as "semisacred: a reflection of a natural law, an inalienable right, and an unmitigated, or at least strongly privileged, good."<sup>102</sup> Even today, scholars continue to emphasize and debate the relationship between property and privacy.<sup>103</sup> Some argue that because moral claims to privacy rights can be reduced to other rights, such as property rights, no separate "right to privacy" really exists.<sup>104</sup> Others argue that privacy rights, to the extent they exist at all, are second-order rights: "Privacy, however lofty its pedigree, is the least important tort for a civilized society."<sup>105</sup>

<sup>&</sup>lt;sup>100</sup> Amitai Etzioni, *The Limits of Privacy* (New York: Basic Books, 1999), 189.

<sup>101</sup> Ibid.

<sup>102</sup> Ibid.

<sup>103</sup> Anita Allen-Castellitto, "Coercing Privacy," *William and Mary Law Review* 40 (March 1999): 724 ("The liberal conception of privacy overlaps considerably with the liberal conception of private property").

<sup>104</sup> Judith Jarvis Thomson, "The Right to Privacy," *Philosophy and Public Affairs* 4, no. 4 (Summer 1975): 295; Alan Westin, *Privacy and Freedom* (New York: Atheneum, 1967), 324; Jerry Kang, "Information Privacy in Cyberspace Transactions," *Stanford Law Review* 50 (1998): 1246; Hal R. Varian, "Economic Aspects of Personal Privacy," in *Privacy and Self-Regulation in the Information Age* (Washington: National Telecommunications and Information Administration, 1997), 36; Kenneth C. Laudon, "Extensions to the Theory of Market and Privacy: Mechanics of Pricing Information," in *Privacy and Self-Regulation in the Information Age* (Washington: National Telecommunications and Information Administration, 1997), 43.

<sup>&</sup>lt;sup>105</sup> Richard Epstein, "Privacy, Property Rights and Misrepresentations," *Georgia Law Review* 12 (1978): 463.

However, a few nineteenth-century treatises and judicial opinions did recognize privacy rights independent of any reference to property rights. In his 1880 *Treatise on the Law of Torts*, Judge Thomas Cooley identified a "right of personal immunity," which included a "right to be let alone." The following year, a Michigan court declared in *DeMay v. Roberts*<sup>107</sup> that a woman had a right to privacy during childbirth. The defendant in *DeMay* was a physician who was attending the plaintiff's childbirth and was accompanied by an "unprofessional unmarried man" who had no reason for being at the delivery other than to observe the case. In granting the plaintiff damages for the intrusion of her privacy, the Michigan court reasoned that, "The plaintiff had a legal right to the privacy of her apartment at such a time, and the law secures to her this right by requiring others to observe it, and to abstain from its violation." <sup>108</sup>

Ten years after Cooley published his *Treatise on the Law of Torts*, Samuel Warren and Louis Brandeis published "The Right to Privacy" in the *Harvard Law Review*. 109 "The Right to Privacy" is known as the most famous essay on privacy ever written. 110 Warren and Brandeis recognized that individuals had full protection "in person and in property" under then-current law; however, they argued that the extent of such protection needed to be redefined in light of then-current political, social, and economic changes, including the aggressiveness of the press and the viciousness of the gossip mill:

Of the desirability -- indeed of the necessity -- of some such protection, there can, it is believed, be no doubt. The press is overstepping in every direction the obvious

<sup>106</sup> Thomas M. Cooley, A Treatise on the Law of Torts, or the Wrongs which Arise Independent of Contract (Chicago: Callaghan and Company, 1880), 29.

<sup>107</sup> DeMay v. Roberts, 9 N.W. 146 (Mich. 1881).

<sup>&</sup>lt;sup>108</sup> Ibid., 149, 166.

<sup>109</sup> Samuel Warren and Louis Brandeis, "The Right to Privacy," *Harvard Law Review* (1890), http://www.lawrence.edu/fast/boardmaw/Privacy brand warr2.html (accessed February 16, 2006).

<sup>&</sup>lt;sup>110</sup> Jeffrey Rosen, *The Unwanted Gaze: The Destruction of Privacy in America* (New York: Vintage Books, 2001), 5.

bounds of propriety and of decency. Gossip is no longer the resource of the idle and of the vicious, but has become a trade, which is pursued with industry as well as effrontery. To satisfy a prurient taste the details of sexual relations are spread broadcast in the columns of the daily papers. To occupy the indolent, column upon column is filled with idle gossip, which can only be procured by intrusion upon the domestic circle. The intensity and complexity of life, attendant upon advancing civilization, have rendered necessary some retreat from the world, and man, under the refining influence of culture, has become more sensitive to publicity, so that solitude and privacy have become more essential to the individual; but modern enterprise and invention have, through invasions upon his privacy, subjected him to mental pain and distress, far greater than could be inflicted by mere bodily injury.<sup>111</sup>

Warren and Brandeis thus raised the issue "whether the existing law affords a principle which can properly be invoked to protect the privacy of the individual; and, if it does, what the nature and extent of such protection is." Warren and Brandeis ultimately concluded that individuals have a general "right to be let alone," or a "right to privacy," which they also referred to as the "right to an inviolate personality" and an individual's right to determine "to what extent his thoughts, sentiments, and emotions shall be communicated to others." The primary goal of their new right appeared to be preventing the press from disclosing personal information. 114

Warren and Brandeis did not view their right to privacy as derivative of stronger property rights; instead, they analogized their new right to the rights individuals already had under the common law of slander and libel, although Warren and Brandeis' right would provide a remedy for injury to feelings, whereas the law of slander and libel only provided a remedy for material injuries, such as injury to reputation. Although Warren and Brandeis rejected the notion that their right derived from property rights, they have

<sup>111</sup> Warren and Brandeis, "The Right to Privacy."

<sup>112</sup> Ibid.

<sup>113</sup> Ibid.

<sup>114</sup> Rosen, *The Unwanted Gaze*, 5; Richard S. Murphy, "Property Rights in Personal Information: An Economic Defense of Privacy," *Georgetown Law Journal* 84 (July 1996): 2389.

<sup>115</sup> Warren and Brandeis, "The Right to Privacy."

been criticized for failing to articulate any new legal foundation for privacy,<sup>116</sup> and for failing to identify the types of information their right should protect.<sup>117</sup> For example, would Warren and Brandeis' right to privacy protect information that was especially intimate or offensive, but not other, less sensitive, information?<sup>118</sup>

Although they did not define or discuss in detail the scope of their new right, Warren and Brandeis recognized that the right was not absolute. The right would not prohibit the publication of matter considered to be of public or general interest; would not grant any redress for the invasion of privacy by oral publication in the absence of special damages; and would cease upon the publication of the facts by the individual, or with her consent. Warren and Brandeis concluded by identifying the remedies for invasion of the right to privacy, including a tort action for damages in all cases and an injunction in a limited class of cases. 120

State courts did not immediately adopt Warren and Brandeis' right to privacy. A New York court in 1902 declined to create a right to privacy as a remedy for a woman whose photograph was used without her permission in a product advertisement. The court reasoned that the plaintiff's claim lacked the formal attributes of a property right. However, the New York Legislature amended the New York Civil Rights Act to create a right against commercial appropriation of name or likeness the following year, <sup>123</sup> and the

<sup>116</sup> Etzioni, The Limits of Privacy, 190.

<sup>117</sup> Diane L. Zimmerman, "Requiem for a Heavyweight: A Farewell to Warren and Brandeis's Privacy Tort," *Cornell Law Review* 68 (1983): 295.

<sup>118</sup> Ibid.

<sup>119</sup> Warren and Brandeis, "The Right to Privacy."

<sup>120</sup> thia

<sup>121</sup> Robertson v. Rochester Folding Box Co., 64 N.E. 442 (N.Y. 1902).

<sup>122</sup> Ibid.

<sup>123</sup> New York Civil Rights Act, §§ 50, 51 (1903).

common law invasion of privacy tort was officially born<sup>124</sup> two years later, in the 1905 case of *Pavesich v. New England Life Insurance Company*. The Georgia Supreme Court in *Pavesich* unanimously upheld the right of a man whose photograph was used without his permission in an insurance advertisement to assert a right of privacy:

The right of privacy has its foundation in the instincts of nature. . . . Each individual as instinctively resents any encroachment by the public upon his rights which are of a private nature as he does the withdrawal of those of his rights which are of a public nature. A right of privacy in matters purely private is therefore derived from natural law. 126

The concept of privacy, not confidentiality, received most of the attention in the early twentieth century. However, a Nebraska court upheld a plaintiff's common law breach of confidentiality claim in the medical context in 1920:

The relation of physician and patient is necessarily a highly confidential one. It is often necessary for the patient to give information about himself which would be most embarrassing or harmful to him if given general circulation. This information the physician is bound, not only upon his own professional honor and the ethics of his high profession, to keep secret. . . . A wrongful breach of such confidence, and a betrayal of such trust, would give rise to a civil action for the damages naturally flowing from such wrong. 127

Like Warren and Brandeis' privacy right, the Nebraska court's right to confidentiality in the medical context was not absolute. For example, the right did not apply if a statute required a physician to disclose the information or if disclosure would protect the health and safety of others.<sup>128</sup>

<sup>124</sup> Allen-Castellitto, "Origins and Growth," 92 (referring to *Pavesich* as "the birth of the tort law privacy right").

<sup>125</sup> Pavesich v. New England Life Ins. Co., 50 S.E. 68 (Ga. 1905).

<sup>126</sup> Ibid., 69-70.

<sup>127</sup> Simonsen v. Swenson, 177 N.W. 831, 832 (Neb. 1920).

<sup>128</sup> Ibid.

Today, the common law of torts generally recognizes four basic privacy rights, which were first identified by William Prosser in a seminal 1960 *California Law Review* article<sup>129</sup> and first codified in the mid-1960s in the Restatement (Second) of Torts.<sup>130</sup> These rights include intrusion upon seclusion (intrusion), publication of embarrassing private facts (disclosure), publicly placing a person in false light (false light), and appropriation of name likeness and identity (appropriation).

The intrusion tort generally protects against intrusions into an individual's "personal sphere." A classic intrusion case is *Galella v. Onassis*, in which the Second Circuit Court of Appeals barred a photographer from following Jacqueline Onassis too closely, even when she was in public. The Restatement of Torts and subsequent courts have significantly narrowed the "personal sphere" protected by the intrusion tort to "outrageous" intrusions into a person's solitude or seclusion.

Under the disclosure tort, an individual who gives publicity to a matter concerning the private life of another can be subject to liability for invasion of privacy, but only if the matter publicized is of a kind that would be highly offensive to a reasonable person and the matter is not of legitimate concern to the public.<sup>134</sup> The disclosure tort is difficult for plaintiffs to prove for several reasons. Plaintiffs must prove not only "publication," as is also required for defamation, but also "publicity," which is defined as "widespread dissemination." Even if the "publicity" element has been satisfied, the defendant may be able to invoke the "of legitimate concern to the public"

<sup>129</sup> William L. Prosser, "Privacy," California Law Review 48 (1960): 389-407.

<sup>130</sup> RESTATEMENT (SECOND) OF TORTS, §§ 652A-E (1977).

<sup>131</sup> Richard S. Murphy, "Property Rights in Personal Information: An Economic Defense of Privacy," *Georgetown Law Journal* 84 (July 1996): 2391.

<sup>132</sup> Galella v. Onassis, 487 F.2d 986 (2nd Cir. 1973).

<sup>133</sup> Murphy, "Property Rights," 2391.

<sup>134</sup> RESTATEMENT (SECOND) OF TORTS, § 652D (1977).

<sup>135</sup> Murphy, "Property Rights," 2392.

defense.<sup>136</sup> Finally, the First Amendment frequently thwarts plaintiffs' disclosure claims. For example, the Supreme Court held in *Florida Star v. B.J.F.* that imposing tort remedies against a newspaper that published a rape victim's name violated the First Amendment.<sup>137</sup>

The false light tort is a variation on defamation, sometimes referred to as "implicit defamation." The classic false light tort case involves the publication of an individual's photograph next to an article addressing drug abuse or prostitution even though the individual is not a drug user or prostitute. The false light tort is designed to protect reputation. The final tort, appropriation, exists when a defendant "appropriates to his own use or benefit the name or likeness of another," usually for commercial gain. Classic appropriation cases involve product manufacturers that, without prior permission, include photographs of famous individuals in their product advertisements. Chapter 4 discusses the extent to which the disclosure and false light torts could apply to inappropriate disclosures of functional neuroimaging information, and Chapter 5 discusses how functional neuroimaging could implicate the intrusion and appropriation torts.

In addition to the four privacy torts, the common law also recognizes a breach of confidentiality tort in the medical context. A typical statement of the common law's recognition of the breach of confidentiality cause of action exists in *McCormick v*.

England, in which the South Carolina Court of Appeals stated in 1997 that, "A majority of jurisdictions faced with the issue have recognized a cause of action against a physician

<sup>136</sup> Ibid.

<sup>137</sup> Florida Star v. B.J.F., 491 U.S. 524, 536 (1989).

<sup>138</sup> Murphy, "Property Rights," 2390.

<sup>139</sup> Ibid.

<sup>140</sup> Ibid.

<sup>&</sup>lt;sup>141</sup> Andrew J. McClurg, "A Thousand Words Are Worth a Picture: A Privacy Tort Response to Consumer Data Profiling," *Northwestern University Law Review* 98 (Fall 2003): 69.

<sup>142</sup> Murphy, "Property Rights," 2391.

for the unauthorized disclosure of confidential information unless the disclosure is compelled by law or is in the patient's interest or the public interest." Chapter 4 discusses the extent to which inappropriate disclosures of neuroimaging information implicate individuals' common law rights to confidentiality.

## LEGISLATION AND REGULATION

As referenced above, the New York Legislature in 1903 enacted a statute creating a right against commercial appropriation of name or likeness. The 1903 New York legislation certainly was not the last federal or state statute or regulation that created judicially enforceable rights to privacy and confidentiality. Over the past thirty years, Congress has enacted numerous laws that use the language of privacy in their titles or text including, but not limited to, the Privacy Act of 1974 (protecting certain federal records), the Freedom of Information Act of 1974 (generally opening government records to the public but establishing privacy exceptions for medical, personnel, and similar files), the Family Education Rights and Privacy Act of 1974 (regulating the disclosure of school records by institutions receiving federal funding), the Right to Financial Privacy Act of 1978 (governing certain banking and financial transactions), the Privacy Protection Act of 1980 (establishing certain procedures for government access to newspapers), the Electronic Communications Privacy Act of 1986 (regulating the surveillance and interception of telephone calls placed on phones and other electronic communications means), 1988 amendments to the Public Health Service Act (relating to the privacy of individuals who are research subjects), the Fair Credit Reporting Act of 1988 (limiting the disclosure of consumer credit information), the Employee Polygraph Protection Act of 1988 (limiting the use of polygraphs by certain employers), the Video Privacy Protection Act of 1988 (governing access to records of individual's movie video rentals), the Computer Matching and Privacy Protection Act of 1988 (regulating the

<sup>&</sup>lt;sup>143</sup> McCormick v. England, 494 S.E.2d 431 (S.C. Ct. App. 1997); Biddle v. Warren General Hosp., 715 N.E.2d 518 (Ohio 1999).

practice of sharing and comparing data about identified individuals contained in different government databanks), the Health Insurance Portability and Accountability Act of 1996 (protecting the confidentiality of certain protected health information), the Children's On-Line Privacy Protection Act of 2000 (prohibiting commercial websites from gathering personal information from children under 13 without parental consent), the Financial Services Modernization Act of 2000 (imposing certain privacy requirements on banks, insurance companies, and securities firms); and the USA Patriot Act (enhancing the power of government to intercept communications and hold individuals captive). These statutes and their implementing regulations are additional sources of rights and duties relating to confidentiality and privacy. Those statutes and regulations that are implicated by functional magnetic resonance imaging are discussed in Chapters 4 and 5.

#### SECONDARY SOURCES

In addition to primary sources of privacy and confidentiality, secondary sources offer their own definitions, classifications, and conceptualizations. A brief review of a few secondary source discussions of privacy and confidentiality will lay the foundation for my own definitions of privacy and confidentiality, which provide a framework for the remaining chapters.

The bioethics literature is a rich source of commentary relating to confidentiality and privacy. An article written by William Winslade in the first (1978) edition of the *Encyclopedia of Bioethics* noted that confidentiality has "blurred edges" and that the concepts of confidentiality and privacy are "elastic," "vague," and "easily confused." Although not "concerned with the appropriateness of alternative definitions of privacy and confidentiality," Winslade explained that confidentiality "is essentially linked to

<sup>144</sup> William J. Winslade, "Confidentiality," in *Encyclopedia of Bioethics*, ed. Warren T. Reich (New York: Free Press, 1978), 195-96.

<sup>145</sup> Ibid., 196.

control over the disclosure of and access to certain information."<sup>146</sup> Tom Beauchamp and James Childress' *Principles of Biomedical Ethics* is a foundation text in medical ethics. In its fifth (2001) edition, Beauchamp and Childress attempt the difficult tasking of defining privacy and confidentiality. "Rights of privacy are valid claims against unauthorized access that have their basis in the right to authorize or decline access,"<sup>147</sup> whereas confidentiality is a "branch or subset of informational privacy—it prevents redisclosure of information that was originally disclosed within a confidential relationship."<sup>148</sup> Beauchamp and Childress summarize the differences between privacy and confidentiality as follows:

The basic difference between the concepts is this: An infringement of a person's right to confidentiality only occurs if the person (or institution) to whom the information was disclosed in confidence fails to protect the information or deliberately discloses it to someone without first-party consent. By contrast, a person who without authorization enters a hospital record room or computer databank violates rights of privacy rather than rights of confidentiality. Only the person (or institution) who receives information in a confidential relationship can be charged with violating rights of confidentiality.<sup>149</sup>

Albert Jonsen, Mark Sigler, and William Winslade's *Clinical Ethics* is another foundation medical ethics text. In its fifth (2002) edition, the authors explain that confidentiality protects "sensitive personal information that a patient discloses to a physician," and emphasize that confidentiality is not an absolute concept: "Confidentiality is a stringent but not unlimited, ethical obligation." <sup>151</sup>

<sup>&</sup>lt;sup>146</sup> Ibid., 195.

<sup>147</sup> Beauchamp and Childress, Principles of Biomedical Ethics, 296.

<sup>148</sup> Ibid., 304.

<sup>149</sup> Ibid.

<sup>150</sup> Jonsen, Siegler, and Winslade, Clinical Ethics, 158.

<sup>&</sup>lt;sup>151</sup> Ibid., 159.

The law review literature also is a rich source of scholarship relating to confidentiality and privacy. In a seminal article published in the *Yale Law Journal* in 1980, Ruth Gavison describes privacy as a "limitation of others' access to an individual." Gavison believes that a loss of privacy occurs when information becomes known about an individual (loss of secrecy), when attention is paid to an individual (loss of anonymity), or when others gain physical access to an individual (loss of solitude). Gavison's own concept of privacy would include the collection, storage, and computerization of information; the dissemination of information about individuals; peeping, following watching, and photographing individuals; intruding or entering "private" places; eavesdropping, wiretapping, reading of letters; drawing attention to individuals; required testing of individuals; and forced disclosure of information. Gavison would not include within her concept of privacy an individual's exposure to unpleasant noises, smells, and sights; as well as prohibitions relating to contraception and abortion. 155

In his thorough "100 Years of Privacy," Ken Gormley argued in 1992 that scholars have been unable to agree upon a one-size-fits-all definition of legal privacy because it actually consists of five distinct species: (1) Warren and Brandeis' original privacy tort, or the right to be let alone with respect to the acquisition and dissemination of information concerning the person, particularly through unauthorized publication, photography or other media; (2) Fourth Amendment privacy, or the right to be let alone with respect to governmental searches and seizures that invade a sphere of individual solitude deemed reasonable by society; (3) First Amendment privacy, or the right to be let alone when one individual's freedom of speech threatens to disrupt another citizen's liberty of thought or repose; (4) fundamental-decision privacy, or the right to be let alone

<sup>152</sup> Ruth Gavison, "Privacy and the Limits of the Law," Yale Law Journal 89 (1980): 428.

<sup>153</sup> Ibid., 428-33.

<sup>154</sup> Ibid., 436.

<sup>155</sup> Ibid.

with respect to fundamental (often unanticipated) decisions concerning the individual's own person, which are explicitly or implicitly reserved to the citizen (rather than ceded to the government) by the terms of the social contract; and (5) state constitutional privacy, or the right to be let alone with respect to a variety of private and governmental intrusions under state constitutional provisions.<sup>156</sup>

Perhaps the nation's leading expert on privacy law, Anita Allen-Castellitto has written more than eleven books and articles addressing privacy, in which she identifies four basic types of privacy: Informational privacy, physical privacy, decisional privacy, and proprietary privacy.<sup>157</sup> According to Allen, informational privacy includes issues relating to control over personal information and medical records, employer access to email, on-line anonymity, data encryption, and the executive privilege; physical privacy includes issues relating to spatial seclusion and solitude, governmental searches and seizure, "peeping toms," and "ambush journalism"; decisional privacy includes issues relating to abortion, assisted suicide, and homosexuality; and proprietary privacy includes issues relating to publicity rights, identity, ownership of the body, and control over names and likeness.<sup>158</sup>

Daniel Solove, another leading expert on privacy law, identifies six, slightly different, traditional conceptions of privacy: the right to be let alone, including Warren and Brandeis' right to privacy; limited access to the self; secrecy, including prevention of public disclosure of previously concealed information; control over personal information; personhood, including ideas about individuality, dignity, autonomy, and antitotalitarianism; and intimacy, which recognizes that privacy is not just essential to individual self-creation, but also to human relationships.<sup>159</sup> Solove offers to

<sup>156</sup> Gormley, "One Hundred Years of Privacy," 1407, 1433-34.

<sup>157</sup> Allen-Castellitto, "Origins and Growth," 86; Anita L. Allen, "Coercing Privacy," William and Mary Law Review 40 (March 1999): 723; Richard C. Turkington and Anita Allen, Privacy Law: Cases and Materials, 2nd ed. (St. Paul: West, 2002), 77.

<sup>158</sup> Allen-Castellitto, "Origins and Growth," 89; Allen, "Coercing Privacy," 723-24.

<sup>159</sup> Daniel J. Solove, "Conceptualizing Privacy," California Law Review 90 (2002): 1087.

reconceptualize privacy through a bottom-up approach. Solove's new approach would conceptualize privacy within three contexts: privacy and practices, including social practices, family, body, and home; the value of privacy; and practical applications. <sup>160</sup>

The literature is replete with numerous other definitions of privacy and confidentiality. Alan Westin defines privacy as the claims of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others. Arthur Miller argues that, "the basic attribute of an effective right of privacy is the individual's ability to control the circulation of information relating to him." Radhika Rao recognizes privacy as "a cluster of personal interests that encompasses the right to possess one's own body and exclude others." Richard Murphy defends a right to privacy that includes the right to "control . . . information concerning an individual's person." Joel Reidenberg believes that privacy "encompasses concerns about fair and reasonable information practices as well as confidentiality." The United States Supreme Court has defined privacy as the "control over information concerning his or her person."

Others recognize the difficulty of establishing a definition of privacy. Arthur Miller thinks that privacy is "difficult to define because it is exasperatingly vague and evanescent." Alan Westin notes that, "[f]ew values so fundamental to society as

<sup>160</sup> Ibid., 1129.

<sup>&</sup>lt;sup>161</sup> Alan Westin, *Privacy and Freedom* (New York: Atheneum, 1967), 7.

<sup>162</sup> Arthur Raphael Miller, *The Assault on Privacy: Computers, Data Banks, and Dossiers* (Ann Arbor: University of Michigan Press, 1971), 25.

<sup>&</sup>lt;sup>163</sup> Radhika Rao, "Property, Privacy, and the Human Body," *Boston University Law Review* 80 (April 2000): 389.

<sup>164</sup> Murphy, "Property Rights," 2381.

<sup>&</sup>lt;sup>165</sup> Joel R. Reidenberg, "Privacy in the Information Economy: A Fortress or Frontier for Individual Rights?" Federal Communications Law Journal 44 (1992): 201.

<sup>166</sup> United States Dep't of Justice v. Reporters Comm., 489 U.S. 749, 763 (1989).

<sup>&</sup>lt;sup>167</sup> Solove, "Conceptualizing Privacy," 1088.

privacy have been left so undefined in social theory . . . "168 Jonathan Kahn explains that, "The meaning of privacy . . . has proven elusive . . . "169 According to William Beaney, "even the most strenuous advocate of a right to privacy must confess that there are serious problems of defining the essence and scope of this right." <sup>170</sup>

Beyond definitions, scholars debate the conceptual nature of privacy. For example, Ruth Gavison asks, "[I]s privacy a situation, a right, a claim, a form of control, a value?"<sup>171</sup> Jonathan Kahn examines a number of different privacy conceptions, including a social situation of autonomy, a claim, a psychological state, a physical area, or a form of control.<sup>172</sup> Robert Post has stated that, "Privacy is a value so complex, so entangled in competing and contradictory dimensions, so engorged with various and distinct meanings, that I sometimes despair whether it can be usefully addressed at all."<sup>173</sup> More generally, Ruth Gavison thinks that, "Anyone who studies the law of privacy today may well feel a sense of uneasiness."<sup>174</sup> Julie Inness believes that the legal and philosophical discourse of privacy is "in a state of chaos."<sup>175</sup> Perhaps Judith Jarvis Thomson says it best: "Perhaps the most striking thing about the right to privacy is that nobody seems to have any very clear idea what it is."<sup>176</sup>

<sup>168</sup> Westin, Privacy and Freedom, 7.

<sup>169</sup> Jonathan Kahn, "Privacy as a Legal Principle of Identity Maintenance," Seton Hall Law Review 33 (2003): 371.

<sup>170</sup> William M. Beaney, "The Right to Privacy and American Law," Law and Contemporary Problems 31 (1966): 255.

<sup>171</sup> Gavison, "Privacy and the Limits of the Law," 424.

<sup>172</sup> Kahn, "Privacy as a Legal Principle of Identity Maintenance," 371.

<sup>173</sup> Robert C. Post, "Three Concepts of Privacy," Georgetown Law Journal 89 (2001): 2087.

<sup>174</sup> Gavison, "Privacy and the Limits of the Law," 421.

Julie C. Inness, *Privacy, Intimacy, and Isolation* (New York: Oxford University Press, 1992),3.

<sup>176</sup> Judith Jarvis Thomson, "The Right to Privacy," *Philosophy and Public Affairs* 4, no. 4 (Summer 1975): 295.

Notwithstanding the lack of conceptual clarity, many (but not all) scholars agree that confidentiality and privacy are not absolute.<sup>177</sup> This position is supported by reference to some of the sources of confidentiality and privacy. Although the First Amendment establishes a relatively broad right to speech and press ("Congress shall make no law . . ."),178 the Fourth Amendment expressly permits searches and seizures if they are reasonable ("The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated"),179 the Third Amendment permits quartering during war time if it is done in accordance with law, 180 and the Fourteenth Amendment permits the deprivation of life, liberty, and property with due process.<sup>181</sup> Even Warren and Brandeis' right to privacy would not prohibit the publication of general interest matter and would cease upon the publication of the facts by the individual, or with her consent. Case law addressing confidentiality within the physician-patient relationship clarifies that a physician's duty of confidentiality does not apply if a state statute required the physician to disclose information or if disclosure would protect the health and safety of others. The HIPAA Privacy Rule, as with numerous other state health information confidentiality statutes and regulations, contains exceptions to the general rule of confidentiality for disclosures that are required by law, disclosures necessary for the health of the public, disclosures for health oversight activities, disclosures necessary to report abuse and neglect, disclosures for law enforcement activities, disclosures for research activities, and so on.<sup>182</sup>

<sup>177</sup> Amitai Etzioni, The Limits of Privacy (New York: Basic Books, 1999).

<sup>178</sup> U.S. CONST. amend. I.

<sup>179</sup> Ibid., amend. IV.

<sup>180</sup> Ibid., amend. III.

<sup>181</sup> Ibid., amend XIV.

<sup>&</sup>lt;sup>182</sup> 45 C.F.R. § 164.512 (2005).

### **SUMMARY**

Confidentiality and privacy have a history rich in ethics and law. Ancient and modern codes of medical and research ethics established both rights and duties relating to confidentiality and privacy. Legal rights to privacy in the United States initially derived from property rights, although they began to develop through tort law at the end of the nineteenth century. By the second half of the twentieth century, the common law of most jurisdictions recognized four distinct privacy torts (intrusion, disclosure, false light, and appropriation), as well as a common law right to confidentiality in the medical context. Beginning with the 1886 case of *Boyd v United States*, legal rights to privacy also developed through the Fourth, as well as the First, Third, Fifth, Ninth, and Fourteenth, Amendments to the Constitution, and their state law counterparts. Legal rights to confidentiality and privacy further developed through statutes and regulations, beginning with the New York Legislature's amendment of the New York Civil Rights Act in 1903 to create a right against commercial appropriation of name or likeness. Today, federal and state legislatures and administrative agencies continue to adopt statutes and regulations addressing confidentiality and privacy.

The literature contains no shortage of confidentiality and privacy definitions and conceptualizations. Yet another attempt to reconcile these definitions and conceptualizations would not meaningfully add to this literature. While recognizing the existence and validity of the various definitions and conceptualizations of confidentiality and privacy, my own definitions must represent the ethical and legal sources of confidentiality and privacy, provide meaning in the context of functional neuroimaging, and add organization to the remaining chapters.

I therefore define *confidentiality* relatively narrowly to mean the obligation of an individual or institutional health care provider or scientist to prevent the unauthorized release of appropriately gathered information, including neuroimaging information, relating to a patient or research subject. Confidentiality issues raised by fMRI include, but certainly are not limited to, the appropriateness of various uses and disclosures of

neuroimaging information by radiologists, neurologists, psychiatrists, psychologists, hospitals, academic medical centers, and imaging centers.

I define *privacy* much more broadly to include any individual's interest in avoiding unwanted intrusions including, but certainly not limited to, an individual's interest in avoiding the unwanted collection of neuroimaging information about herself. In the context of functional neuroimaging, privacy issues include an individual's interest in preventing health care providers, scientists, insurance companies, employers, educational institutions, the government, criminal justice officials, courts, litigants, and marketing companies from gathering or obtaining neuroimaging information relating to the individual other than information voluntarily disclosed by the individual.

These definitions structure the remaining chapters. Chapter 4 discusses the confidentiality implications of fMRI. Chapter 5 discusses the privacy implications of fMRI. Chapter 6 examines whether existing ethical and legal rights and duties relating to confidentiality and privacy provide sufficient protections to individuals who consent or are subjected to fMRI, and identifies options for supplementing these rights and duties in the functional neuroimaging context.

# CHAPTER 4: THE CONFIDENTIALITY IMPLICATIONS OF FMRI

Most physicians and scientists know that patients and research subjects expect the confidentiality of their medical and research records to be maintained, and the majority of physicians and scientists probably strive to adhere to their ethical and legal duties of confidentiality. Notwithstanding, Chapter 2 reveals speculation that functional neuroimaging information created by providers and scientists will leak beyond the clinical and research contexts and become available to employers, insurers, and others for use in hiring, firing, underwriting, and similar business decisions. Using the definition of confidentiality offered in Chapter 3 – the obligation of an individual or institutional health care provider or scientist to prevent the unauthorized release of appropriately gathered functional neuroimaging information – this chapter explores in detail ethical and legal issues of confidentiality raised by various uses and disclosures of functional neuroimaging information? What ethical and legal authorities protect the confidentiality of neuroimaging information? Do these authorities adequately address the unique confidentiality concerns raised by fMRI? Do existing confidentiality protections need to be amended or supplemented in light of advances in functional neuroimaging?

The analysis in this chapter is structured around various legal authorities, including the federal Common Rule, the HIPAA Privacy Rule, state health information confidentiality laws and regulations, Public Health Service provisions providing for certificates of confidentiality, Constitutional law, and the common law. Unique confidentiality issues raised by incidental neuroimaging findings and the creation of neuroimaging databanks are discussed under the authorities that are particularly relevant, with the recognition that similar analyses could be made under other authorities. The focus of this chapter is confidentiality, but related privacy issues are discussed when necessary.

## THE COMMON RULE

# Application to Research Involving fMRI

The regulations with which scientists are perhaps most familiar are the Protection of Human Subjects regulations (the Common Rule), the first version of which was published by the federal Department of Health, Education, and Welfare in 1974.<sup>1</sup> Today, the Common Rule regulates all research involving human subjects that receives federal financial support from a signatory federal agency,<sup>2</sup> research conducted in contemplation of a submission to the Food and Drug Administration for approval, and human subjects research conducted by an institution that has signed a "multiple project assurance," which is an institutional promise to comply with the Common Rule in all research, regardless of the funding source.<sup>3</sup> A brief review of the prerequisites to application of the Common Rule is necessary before the Common Rule's confidentiality provisions can be applied in the context of functional magnetic resonance imaging.

The Common Rule only applies to research involving *human subjects*. Human subjects is broadly defined to include living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.<sup>4</sup> The first prong of the definition of human subjects would be implicated when an investigator asks an individual to participate in a prospective study and collects data relating to the individual as a result of her

<sup>&</sup>lt;sup>1</sup> U.S. Department of Health, Education, and Welfare, "Protection of Human Subjects," *Federal Register* 39 (May 30, 1974): 18,914, amended by U.S. Department of Health, Education, and Welfare, "Protection of Human Subjects," *Federal Register* 40 (March 13, 1975): 11,854, amended by U.S. Department of Health and Human Services, "Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects," *Federal Register* 46 (January 26, 1981); 8,366, codified at 45 C.F.R. Part 46.

<sup>&</sup>lt;sup>2</sup> Stacey A. Tovino, "The Use and Disclosure of Protected Health Information for Research under the HIPAA Privacy Rule: Unrealized Patient Autonomy and Burdensome Government Regulation," South Dakota Law Review 49 (2004): 448n8 (listing the federal agencies that are signatories to the Common Rule).

<sup>&</sup>lt;sup>3</sup> 45 C.F.R. § 46.101(a) (2005); Mark Rothstein, "Research Privacy under HIPAA and the Common Rule," *Journal of Law, Medicine and Ethics* 33 (Spring 2005): 155.

<sup>&</sup>lt;sup>4</sup> 45 C.F.R. § 46.102(f)(1) and (2) (2005).

participation in the study. The second prong would be implicated when an investigator accesses identifiable private information about an individual.

Private information is defined to include information about behavior that occurs in a context in which an individual reasonably expects that no observation or recording is taking place, as well as information that an individual has provided for a specific purpose and that the individual reasonably expects will not be made public, such as medical record information.<sup>5</sup> In the functional neuroimaging context, the first prong of the definition of private information could be implicated if an individual's brain was scanned without her knowledge, and the second prong would be implicated if an investigator accessed for retrospective research medical or other research records that contained functional magnetic resonance images or related data sets and reports.

Private information is *identifiable* when "the identity of the subject is or may readily be ascertained by the investigator or associated with the information." The definition of identifiable has been broadly interpreted. If a data custodian removes direct identifiers such as name and social security number and replaces them with codes, research using the information would still constitute human subjects research if the key to the code exists and the identifiers could be re-associated with the data. The Office for Human Research Protections (OHRP) only regards coded data as not relating to human subjects when the key to decipher the code is destroyed before the research begins; the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased; there are IRB-approved written policies and operating procedures for a repository or data

<sup>&</sup>lt;sup>5</sup> Ibid., § 46.102(f).

<sup>&</sup>lt;sup>6</sup> Ibid.

<sup>&</sup>lt;sup>7</sup> U.S. Department of Health and Human Services, Office for Human Research Protections, Division of Human Subject Protections, *Engagement of Institutions in Research* (January 26, 1999), 2; Jennifer Kulynych, "Legal and Ethical Issues in Neuroimaging Research: Human Subjects Protection, Medical Privacy, and the Public Communication of Research Results," *Brain and Cognition* 50, no. 3 (December 2002): 350.

management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.<sup>8</sup>

Applying the Common Rule's definition of human subjects to research involving fMRI leads to several basic conclusions. First, when an investigator asks a patient or a healthy volunteer to participate in a prospective study that uses fMRI to test a research hypothesis, the investigator is engaging in human subjects research that must be reviewed and approved in accordance with the Common Rule.<sup>9</sup> The reason is that the investigator would be obtaining "data through intervention or interaction with the individual." Second, when an investigator requests access to existing fMRIs or related data sets and reports in order to engage in retrospective research, the investigator also would be engaging in human subjects research that must be reviewed and approved in accordance with the Common Rule if the identity of the subject could be ascertained (for example, through labels that contain names, social security numbers, or other similar identifiers) by the investigator when looking at the scans or related records.<sup>10</sup> The reason is that the investigator would be obtaining identifiable private information. However, an investigator who requests access to existing fMRI scans or other related records would not be engaging in human subjects research if, prior to disclosure to the investigator, the data holder strips the scans and records of all identifiers, including codes, or the investigator unequivocally agreed in writing that she would not have access to the code key.11

<sup>&</sup>lt;sup>8</sup> U.S. Department of Health and Human Services, Office for Human Research Protections, Guidance on Research involving Coded Private Information or Biological Specimens (August 10, 2004), 3-4, http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf (accessed February 16, 2006); U.S. Department of Health and Human Services, Engagement of Institutions in Research, 3.

<sup>&</sup>lt;sup>9</sup> Kulynych, "Legal and Ethical Issues," 350.

<sup>10</sup> Ibid.

<sup>11</sup> Ibid.

One question unique to neuroimaging is whether investigators who engage in retrospective research using high-resolution fMRIs that are not labeled with obvious identifiers are still engaging in human subjects research regulated by the Common Rule. The analysis is complicated by the existence of computer software that is capable of generating images of a subject's facial features from images of the surface of the subject's brain and skull.<sup>12</sup> To the extent the identity of the patient or research subject "may be readily ascertainable" or "associated" from the reproduced facial image, research using the underlying neuroimage could constitute human subjects research regulated by the Common Rule.<sup>13</sup> To avoid application of the Common Rule, the data holder must strip or scramble image elements in the scans or datasets that could be reconstructed into cranio-facial features,<sup>14</sup> while preserving the usefulness of the data for retrospective research.

## **Confidentiality Protections**

With this background, the Common Rule's confidentiality protections can now be examined in the context of research involving fMRI. When the Common Rule applies to a particular research protocol, an institutional review board (IRB) must review and approve the protocol in accordance with certain criteria<sup>15</sup> that are designed to safeguard the welfare of human research subjects. One criterion requires the IRB to determine that, "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." An additional provision requires the informed consent documentation signed by the research subject to describe the extent to

<sup>12</sup> Paul Root Wolpe, "Neuroethics" in *Encyclopedia of Bioethics*, 3<sup>rd</sup> ed., vol. 4, ed. Stephen G. Post (New York: Macmillan Reference, 2004), 1897; Arthur W. Toga, "Neuroimage Databases: The Good, the Bad and the Ugly," *Nature Reviews Neuroscience* 3, no. 4 (April 2002): 307.

<sup>&</sup>lt;sup>13</sup> Kulynych, "Legal and Ethical Issues," 353.

<sup>&</sup>lt;sup>14</sup> Ibid., 354; Toga, "Neuroimage Databases," 308.

<sup>15 45</sup> C.F.R. § 46.111 (2005).

<sup>&</sup>lt;sup>16</sup> Rothstein, "Research Privacy under HIPAA and the Common Rule," 155.

<sup>&</sup>lt;sup>17</sup> 45 C.F.R. § 46.111(a)(7) (2005).

which confidentiality of records identifying the subject will be maintained.<sup>18</sup> A third provision permits an IRB to waive the requirement for the investigator to obtain a signed consent form if the IRB finds that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, the subject shall be asked whether she wants documentation linking her with the research, and her wishes shall govern.<sup>19</sup>

These three provisions are the only provisions in the Common Rule that address confidentiality and privacy in human subjects research, and HHS has not provided significant guidance regarding their design, interpretation, and application. HHS has generally interpreted the "adequate provisions" language in the first provision to require investigators to replace names and other identifiers with codes and to store paper and electronic research records securely.<sup>20</sup> HHS commentary published in the *Federal Register* in 1981 further reveals that the confidentiality and privacy requirements were not intended to be absolute ("[i]t is inappropriate to require institutions to give assurances of privacy and confidentiality which they not be able to honor in all circumstances")<sup>21</sup> and that a reasonableness standard should apply in determining the adequacy of the confidentiality provisions provided by investigators:

confidentiality provisions should meet reasonable standards for protection of privacy and comply with applicable laws. Reasonable protection might in some instances include legal protection available upon application (such as the immunity from legal process of certain drug and alcohol abuse and mental health research subject data under [the Public Health Service Act].<sup>22</sup>

<sup>&</sup>lt;sup>18</sup> Ibid., § 46.116(a)(5).

<sup>&</sup>lt;sup>19</sup> Ibid., § 46.117(c)(1).

<sup>&</sup>lt;sup>20</sup> Kulynych, "Legal and Ethical Issues," 353.

<sup>&</sup>lt;sup>21</sup> U.S. Department of Health and Human Services, "Final Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects," *Federal Register* 46 (January 26, 1981): 8386.

<sup>&</sup>lt;sup>22</sup> Ibid. The application for immunity refers to certificates of confidentiality, discussed in the text accompanying notes 125-138 in this chapter.

However, the Common Rule does not provide any additional confidentiality requirements or guidance, identify the types of confidentiality protections that would be acceptable, or even define what it means by confidentiality or privacy.

The question thus becomes whether the Common Rule adequately protects the confidentiality of human subjects' functional neuroimaging information. The Common Rule places the burden on the IRB to determine the adequacy of the investigator's privacy and confidentiality protections and the adequacy of the statement in the informed consent documentation, if not waived, regarding the extent to which confidentiality of records identifying the subject will be maintained. For the IRB to make such a determination, the investigator needs to describe to the IRB the specific confidentiality and privacy policies and procedures that have been established for the study. Relevant policies and procedures could involve replacing names and other identifiers embedded in neuroimages or contained on record labels with codes; storing raw image data and related paper and electronic research records securely during the research study; planning for the long-term storage and use of raw image data and related records; and ensuring that any neuroimages and related data sets and reports that are disclosed to neuroimaging databanks and other third parties are completely stripped of all identifiers, including any image elements that could be reconstructed into cranial-facial features. The IRB is required to review these policies and procedures and determine their adequacy.

Some investigators do not provide sufficient descriptions of their confidentiality policies and procedures to enable the IRB to make such a determination. The OHRP found in October 2005 that IRBs frequently lack information to determine whether a particular research protocol has adequate confidentiality and privacy provisions.<sup>23</sup> According to the OHRP, many IRBs only review minimal information – usually boilerplate informed consent language – regarding the establishment of confidentiality

<sup>&</sup>lt;sup>23</sup> U.S. Department of Health and Human Services, Office for Human Research Protections, Division of Compliance Oversight, *OHRP Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance* (October 12, 2005), 3, http://www.hhs.gov/ohrp/compliance/findings.pdf (accessed February 16, 2006).

and privacy policies and procedures.<sup>24</sup> The OHRP concluded that, "the IRB appears not to consider systematically and rigorously such issues as . . . privacy and confidentiality . . ."<sup>25</sup>

Although primary responsibility for ensuring compliance with the Common Rule rests with the institutional IRB charged with reviewing and approving the research, <sup>26</sup> general oversight of the institution is vested in the OHRP. <sup>27</sup> If an investigator makes an unauthorized disclosure of functional neuroimaging information to a third party, such as an employer or insurer, or functional neuroimaging information in the possession of an investigator was somehow obtained by a third party, the OHRP could take several courses of action, including recommending improvement of the institution's human subject protection policies; requiring the development and implementation of a corrective action plan; increasing, or requiring attendance at, education and training for investigators and IRB members; restricting or attaching conditions to the institution's multiple project assurance; requiring prior OHRP review of some or all research projects conducted under the multiple project assurance; suspending all research conducted under the multiple project assurance; temporarily suspending or permanently removing the institution from participation in certain research projects; requiring the withdrawal of federal funding; or placing a government-wide debarment on the investigators. <sup>28</sup>

While the Common Rule requires IRBs approving research protocols to ensure that investigators have adequate provisions to protect the confidentiality of human subject research data, the Common Rule does not offer any guidance regarding how investigators engaged in functional neuroimaging should protect their neuroimaging data. The

<sup>&</sup>lt;sup>24</sup> Ibid., 3, 9.

<sup>&</sup>lt;sup>25</sup> Ibid., 3.

<sup>&</sup>lt;sup>26</sup> 45 C.F.R. § 46.103 (2005).

<sup>&</sup>lt;sup>27</sup> U.S. Department of Health and Human Services, Office for Human Research Protections, *OHRP's Compliance Oversight Procedures for Evaluating Institutions* (October 19, 2005), http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf (accessed February 16, 2006).

<sup>28</sup> Ibid. Government-wide debarment procedures are codified at 45 C.F.R Part 76.

combination of ethical duties of confidentiality and the threat of OHRP oversight, including government-wide debarment, likely provides incentive for the majority of investigators to establish policies and procedures that provide specific protections for their functional neuroimaging data. The OHRP's finding that some IRBs accept boilerplate assertions regarding the existence of confidentiality provisions shows that the Common Rule does not always result in the creation, and systematic and rigorous review of, relevant confidentiality provisions. The Common Rule does not provide any guidance regarding procedures to be followed in using and disclosing functional neuroimaging data during the research study, eliminating raw facial image elements, storing raw neuroimaging data and related data sets, or planning for long-term storage and use of functional neuroimaging information. In summary, the Common Rule establishes a framework for protecting the confidentiality of most fMRI study data and the privacy of most fMRI research subjects, although it does not offer specific guidance regarding how scientists should protect confidentiality and privacy in the context of functional neuroimaging research.

Because the Common Rule's confidentiality requirements only apply to human subjects research financially supported by one of 17 federal agencies, research conducted in contemplation of a submission to the Food and Drug Administration for approval, and human subjects research conducted by an institution that has signed a multiple project assurance, compliance with the Common Rule is optional for research that is funded by a non-signatory government agency, as well as non-federally funded research, including research conducted by the private sector or lay advocacy organizations. Neuromarketing research studies requested and paid for by product and service manufacturers, examples of which were provided in Chapter 2, are classic examples of research to which the Common Rule might not apply (and that might require supplemental protections).

## The Common Rule and Neuroimaging Databanks

Data sharing has become an important practice in many areas of science, including astrophysics, proteomics, and genomics, and the Human Genome Database is a specific example of how data sharing has been used to benefit science and society.<sup>29</sup> Neuroscience also stands to benefit from data sharing. Experts estimated in 2001 that investigators were conducting approximately 1,500 new brain imaging studies each year, involving 10,000 human subjects and 100 terabytes of neuroimaging data, although published studies revealed only a small portion of the neuroimaging data actually collected.<sup>30</sup> Proponents of neuroimaging databanks believe that databanks make neuroimaging data more accessible for sharing, which facilitates the comparison of neuroimaging findings across laboratories, allows for better assessment of the reliability of methods and reproducibility of results, encourages meta-analyses that explore phenomena that are not apparent in individual data sets, and provides investigators who do not have access to neuroimaging facilities the opportunity to conduct research using existing data.<sup>31</sup>

To that end, the National Science Foundation, the W.M. Keck Foundation, the National Institutes of Mental Health, and the Sun Center of Excellence for Neuroscience have established and funded the fMRI Data Center (fMRIDC), a public repository of peer-reviewed fMRI studies and their underlying data located at Dartmouth College in Hanover, New Hampshire.<sup>32</sup> In addition to the National Institutes of Health (NIH), which

<sup>&</sup>lt;sup>29</sup> Organization for Human Brain Mapping, "Neuroimaging Databases," *Science* 292, no. 5522 (June 1, 2001): 1673; John D. Van Horn and Michael S. Gazzaniga, "Databasing fMRI Studies Towards a 'Discovery Science' of Brain Function," *Nature Reviews Neuroscience* 3, no. 4 (April 2002): 314.

<sup>&</sup>lt;sup>30</sup> Organization for Human Brain Mapping, "Neuroimaging Databases," 1673.

<sup>31</sup> Sylvain Faisan et al., "Unsupervised Learning and Mapping of Active Brain Functional MRI Signals Based on Hidden Semi-Markov Event Sequence Models," *IEEE Transactions on Medical Imaging* 24, no. 2 (February 1, 2005): 263; Joan Hamilton, "Journey to the Center of the Mind: 'Functional' MRI Is Yielding a Clearer Picture of What Thoughts Look Like," *Business Week*, April 19, 2004, 78; Organization for Human Brain Mapping, "Neuroimaging Databases," 1673.

<sup>&</sup>lt;sup>32</sup> fMRI Data Center, "Privacy Guidelines for Authors: The Protection of Human Subjects Data," http://www.fmridc.org/submissions/privacyguidelines.html (accessed January 5, 2006).

requires all investigators who submit applications seeking \$500,000 or more in direct costs in a single year to address data sharing in their applications,<sup>33</sup> the *Journal of Cognitive Neuroscience* requires its authors to submit their complete fMRI study data to the fMRIDC as a condition of publication.<sup>34</sup> At least two other journals strongly encourage submission of complete study data to neuroimaging databanks to support the findings, outcomes, and claims in the journals' published articles, and some scientists encourage the disclosure of neuroimaging information to neuroimaging databanks to speed the understanding of cognitive processes and the neural substrates that underlie them.<sup>35</sup> The question becomes whether and how investigators can disclose neuroimaging data to neuroimaging databanks while maintaining research subject confidentiality and complying with the Common Rule.

If an investigator de-identifies information before submitting it to a databank, the subject's confidentiality concerns should be minimized because the data cannot be traced back to the subject. The Common Rule does not prohibit an IRB from approving or an investigator from obtaining prospective consent for unspecified future uses of information, including information complied in a databank for future research by the submitting investigator or other researchers.<sup>36</sup> However, layered or tiered consents (in which a subject is offered the option of consenting to the current study, as well as the option of consenting to future studies with goals broadly related to the area of the original

<sup>&</sup>lt;sup>33</sup> National Institutes of Health, *Final NIH Statement on Sharing Research Data*, Notice NOT-OD-030032 (February 26, 2003).

<sup>34</sup> Journal of Cognitive Neuroscience, "Submission Guidelines," http://mitpress.mit.edu/catalog/item/default.asp?ttype=4&tid=12&xid=6&xcid=0 (accessed February 16, 2006) ("All papers accepted in JOCN will be required to submit their fMRI data to the FMRI Data Center"); Elliott Marshall, "A Ruckus over Releasing Images of the Human Brain," *Science* 289, no. 5484 (September 1, 2000): 1458.

<sup>&</sup>lt;sup>35</sup> John D. Van Horn et al., "The Functional Magnetic Resonance Imaging Data Center: The Challenges and Rewards of Large-Scale Databasing of Neuroimaging Studies," *Philosophical Transactions of the Royal Society of London: Biological Sciences* 356, no. 1412 (August 29, 2001): 1323-24; Van Horn and Gazzaniga, "Databasing fMRI Studies," 318.

<sup>&</sup>lt;sup>36</sup> 45 C.F.R. § 46.116 (2005).

study, and even the option of consenting to future studies with goals unrelated to the area of the original study) are preferred to blanket consents (in which a subject is asked to consent to the use of her information for all future, unspecified research projects).<sup>37</sup>

As discussed above, the Common Rule requires identifiable private information to be obtained by an investigator for retrospective research to constitute human subjects research. Stated another way, the Common Rule would not apply to a later investigator who obtains non-identifiable information from a neuroimaging databank.<sup>38</sup> The Common Rule defines information as not identifiable if the information "cannot be linked to specific individuals by the investigator(s) either directly or through coding systems."<sup>39</sup> To render information not identifiable under the Common Rule in preparation for submission to a databank, the submitting investigator must remove all direct identifiers from the information, and strip or scramble image elements in the scans or datasets that could be reconstructed into cranio-facial features. The Common Rule thus does not prohibit the submission of de-identified information to neuroimaging databanks.

The fMRIDC has established author guidelines that complement the prerequisites for avoiding application of the Common Rule. The guidelines require authors to remove identifiers such as name, subject initials, social security number, and internal subject identification codes before data is submitted to the fMRIDC.<sup>40</sup> If an author fails to remove one or more identifiers, the fMRIDC will upon receipt of the data remove the

<sup>&</sup>lt;sup>37</sup> Rothstein, "Research Privacy under HIPAA and the Common Rule," 157.

<sup>&</sup>lt;sup>38</sup> National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants* (Bethesda: National Bioethics Advisory Commission, 2001), 39 http://www.georgetown.edu/research/nrcbl/nbac/human/oversumm.html (accessed February 16, 2006) ("Research involving the analysis of existing data that are unidentifiable does not involve human participants.").

<sup>&</sup>lt;sup>39</sup> U.S. Department of Health and Human Services, Office for Human Research Protections, Guidance on Research Involving Coded Private Information or Biological Specimens (August 10, 2004), www.hhs.gov/ohrp/humansubjects/guidance/cdebid.pdf (accessed February 16, 2006).

<sup>&</sup>lt;sup>40</sup> fMRI Data Center, "Privacy Guidelines for Authors: The Protection of Human Subjects Data," § I, http://www.fmridc.org/submissions/privacyguidelines.html (accessed February 16, 2006).

identifiers itself.<sup>41</sup> To eliminate the possibility that high-resolution fMRI images can be reconstructed to reveal the contour of the subjects' faces, the fMRIDC also strips high-resolution images of any remaining facial features.<sup>42</sup> Finally, the fMRIDC recommends that investigators include statements in their informed consent forms identifying the potential for anonymized data collected from study participants to be made publicly available to the fMRIDC.<sup>43</sup> The fMRIDC thus has established internal policies and procedures that support and uphold the prerequisites for nonapplication of the Common Rule. Confidentiality concerns associated with neuroimaging databanks, although potentially significant, will be realized only when an investigator does not de-identify information sufficiently to escape application of the Common Rule prior to databank disclosure *and* if the receiving databank has failed to establish and adhere to internal de-identification policies and procedures like those established by the fMRIDC.

#### THE HIPAA PRIVACY RULE

# Application to Treatment and Research Involving fMRI

Enacted on August 21, 1996, the Health Insurance Portability and Accountability Act (HIPAA) was designed primarily to eliminate "job lock" by allowing employees to keep their health insurance coverage when they changed jobs.<sup>44</sup> A second purpose, added later during the legislative process, was administrative simplification, or the more efficient processing of health claims through standard electronic transactions.<sup>45</sup> Anticipating public concern about the confidentiality and privacy implications of shared electronic health information systems, Congress included another provision in HIPAA

<sup>&</sup>lt;sup>41</sup> Van Horn and Gazzaniga, "Databasing fMRI Studies," 314.

<sup>&</sup>lt;sup>42</sup> Ibid.

<sup>&</sup>lt;sup>43</sup> fMRIDC, "Privacy Guidelines for Authors," § V.

<sup>44 42</sup> U.S.C. § 300gg et seq. (2005).

<sup>&</sup>lt;sup>45</sup> Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, Title II, Subtitle F, §§ 261-264 (August 21, 1996).

directing HHS to adopt health information privacy<sup>46</sup> regulations if Congress failed to enact privacy legislation within three years of HIPAA's date of enactment.<sup>47</sup> When Congress missed its own deadline, HHS became responsible for adopting privacy regulations.<sup>48</sup> HHS responded by issuing proposed privacy regulations on November 3, 1999,<sup>49</sup> final privacy regulations on December 28, 2000,<sup>50</sup> and proposed and final modifications to the final regulations on March 27, 2002,<sup>51</sup> and August 14, 2002,<sup>52</sup> respectively. Today, what is referred to as the HIPAA Privacy Rule (Privacy Rule) is codified in the same title of the Code of Federal Regulations<sup>53</sup> as is the Common Rule.

The Privacy Rule is frequently misunderstood due in part to HHS' failure to allocate resources to provide sufficient outreach and education regarding the Rule.<sup>54</sup> Accordingly, a brief review of the prerequisites to application of the Privacy Rule is necessary before its confidentiality protections can be applied in the context of functional magnetic resonance imaging. The Privacy Rule only applies to individuals and organizations that constitute *covered entities*. Covered entities are defined to include health plans and health care clearinghouses, which are not too relevant in the context of

<sup>&</sup>lt;sup>46</sup> Although Congress directed HHS to adopt *privacy* regulations, the regulations as adopted actually address *confidentiality* because they prohibit health care providers and health insurance companies from using or disclosing patients' protected health information without prior patient authorization unless an exception to the general prohibition applies.

 $<sup>^{47}</sup>$  Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, Title II, Subtitle F,  $\S$  264(c)(1).

<sup>&</sup>lt;sup>48</sup> Ibid.

<sup>&</sup>lt;sup>49</sup> U.S. Department of Health and Human Services, "Standards for Privacy of Individually Identifiable Health Information, Proposed Rule," *Federal Register* 63 (November 3, 1999): 59,918-60,065.

<sup>50</sup> U.S. Department of Health and Human Services, "Standards for Privacy of Individually Identifiable Health Information, Final Rule," Federal Register 65 (December 28, 2000): 82,462-82,829.

<sup>51</sup> U.S Department of Health and Human Services, "Standards for Privacy of Individually Identifiable Health Information, Proposed Rule," Federal Register 67 (March 27, 2002): 14,776-14,815.

<sup>&</sup>lt;sup>52</sup> U.S. Department of Health and Human Services, "Standards for Privacy of Individually Identifiable Health Information, Final Rule," *Federal Register* 67 (August 14, 2002): 53,182-53,273.

<sup>&</sup>lt;sup>53</sup> 45 C.F.R. Parts 160 and 164 (2005).

<sup>54</sup> Rothstein, "Research Privacy under HIPAA and the Common Rule," 154.

functional magnetic resonance imaging, but also health care providers who transmit health information in electronic form in connection with certain standard transactions.<sup>55</sup> Most, but certainly not all, physicians, hospitals, and imaging centers (including those providers that use fMRI for treatment purposes, such as assessing surgical risk or planning surgical routes) transmit health information in electronic form in connection with insurance claims and other standard transactions. Thus, the Privacy Rule applies to most physicians, hospitals, and imaging centers.

The application of the Privacy rule to scientists who use fMRI to test various research hypotheses is less straightforward. If an investigator does not transmit health information in electronic form in connection with a standard transaction conducted in association with the research, the Privacy Rule generally will not regulate the investigator's research activities. On the other hand, if the investigator provides treatment to research subjects as part of a protocol and the investigator (or an academic medical center or billing company on the investigator's behalf) transmits health information in electronic form in connection with an insurance claim or other standard transaction associated with the research, then the investigator (or the academic institution) would constitute a covered entity and the Privacy Rule will apply to the investigator's research activities. <sup>56</sup> Or, if the investigator is a workforce member of an

<sup>55 45</sup> C.F.R. § 164.104(a) (2005). These standard transactions generally include: (1) claims for reimbursement and patient encounter information; (2) payment for health care services and remittance advice; (3) coordination of benefits; (4) health care claim status; (5) enrollment and disenrollment in a health plan; (6) eligibility for a health plan; (7) health plan premium payments; (8) referral certification and authorization; (9) first report of injury; and (10) health claims attachments. Ibid. §§ 162.1101-162.1802.

<sup>&</sup>lt;sup>56</sup> The Department of Health and Human Services clarified the application of the Privacy Rule to researchers in a frequently-asked question:

Ouestion: When is a researcher a covered health care provider under HIPAA?

Answer: A researcher is a covered health care provider if he or she furnishes health care services to individuals, including the subjects of research, and transmits any health information in electronic form in connection with a transaction covered by the Transactions Rule. . . . For example, a researcher who conducts a clinical trial that involves the delivery of routine health care, such as an MRI or liver function test, and transmits health information in electronic form to a third party payer for payment, would be a covered health care provider under the Privacy Rule. Researchers who provide health care to the subjects of research or

organization such as an academic medical center that has both health care (regulated) and academic (not regulated) functions, and the academic medical center fails to designate in writing the investigator as part of its academic component, then the Privacy Rule would regulate the investigator's research activities.<sup>57</sup> The Privacy Rule thus applies to some, but not all, scientists who use fMRI. Because the Privacy Rule only applies to health plans, health care clearinghouses, and certain health care providers, the Privacy Rule does not apply to many of the other individuals and organizations reported to have an interest in obtaining or using neuroimaging information, including employers, life insurance companies, educational institutions, criminal justice officials, government agencies, courts, litigants, and marketing companies.<sup>58</sup>

The Privacy Rule only regulates covered entities' use and disclosure of a certain class of information known as *protected health information*.<sup>59</sup> Protected health information is defined as individually identifiable health information,<sup>60</sup> which generally means information that (1) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual and (2)

other individuals would be covered health care providers even if they do not themselves electronically transmit information in connection with a HIPAA transaction, but have other entities, such as a hospital or billing service, conduct such electronic transactions on their behalf. . . .

U.S. Department of Health and Human Services, *Questions and Answers* (May 19, 2003), http://healthprivacy.answers.hhs.gov/cgibin/hipaa.cfg/php/enduser/std\_adp.php?p\_faqid=314&p\_created=1040406580&p\_sid=pNRkpl\*h&p\_lva=&p\_sp=cF9zcmNoPTEmcF9zb3J0X2J5PWRmbHQmcF9ncmlkc29ydD0mcF9yb3dfY250PTI2JnBfcHJvZHM9JnBfY2F0cz03LDAmcF9wdj0mcF9jdj0xLjc7Mi51MCZwX3NlYXJjaF90eXBlPWFuc3dlcnMuc2VhcmNoX25sJnBfcGFnZT0xJnBfc2VhcmNoX3RleHQ9cmVzZWFyY2hlcg\*\*&p\_li=&p\_topview=1 (accessed February 16, 2006).

<sup>&</sup>lt;sup>57</sup> Ibid.

<sup>&</sup>lt;sup>58</sup> Rothstein, "Research Privacy under HIPAA and the Common Rule," 155.

<sup>&</sup>lt;sup>59</sup> 45 C.F.R. § 164.500(a) (2005).

<sup>&</sup>lt;sup>60</sup> Ibid., § 160.103.

identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.<sup>61</sup>

In the context of neuroimaging, the first prong of the definition of protected health information would be satisfied by an MRI showing diffuse brain damage resulting from traumatic brain injury or stroke, because the MRI would relate to the past and present physical health of the individual. The first prong of the definition also would be satisfied if a scientist interpreted an fMRI as revealing that a subject has schizophrenia or will develop Alzheimer's disease, because the interpretations would relate to the subject's current and future mental health, respectively. But, what about fMRI scans that are taken for purposes of studying many of the social phenomena discussed in Chapter 2? For example, what if fMRI is used to study one-time deception that does not rise to the level of pathological lying ("I do not have the 5 of Clubs card")? What about an fMRI scan that shows amygdala activity interpreted as unconscious social evaluation of a person who belongs to a different racial group? What about an fMRI scan that is interpreted to reveal an individual's preference for a particular soft drink, automobile, campaign advertisement, or movie trailer? A very technical argument exists that these latter pieces of neuroimaging information do not constitute health information protected by the Privacy Rule because they do not relate to the physical or mental health or condition of an individual.

The second prong of the definition of protected health information requires the information to identify the individual or for there to be a reasonable basis to believe that the information could be used to identify the individual. The second prong would be satisfied in the context of functional neuroimaging if an fMRI scan contained a label with a (or contained an embedded) direct identifier, such as a patient or subject's name or date of birth. The second prong also would be satisfied if there is a "reasonable basis" to believe that the fMRI could be used to identify its subject.<sup>62</sup> Compared to the Common

<sup>61</sup> Ibid.

<sup>62</sup> Ibid., §§ 160.103, 164.514(a).

Rule, which provides that information does not involve human subjects if the investigator cannot "readily ascertain" the identity of the individual (because the code key has been destroyed before the research begins, the keyholder has agreed not to release the key to the investigator, an IRB-approved written policy prohibiting the release of the key exists, or other legal requirements prohibit the release of the key), the Privacy Rule's "reasonable basis" test for determining identifiability is much broader. Stated another way, information that is considered individually identifiable under the Privacy Rule might not be considered individually identifiable under the Common Rule.<sup>63</sup>

The Privacy Rule provides two different methods pursuant to which information can be de-identified and no longer protected by the Privacy Rule.<sup>64</sup> First, an expert in statistics can certify in writing that the risk is very small that the information could be used to identify the individual.<sup>65</sup> Second, the data holder can strip the information of 18 different identifiers relating to the patient or research subject, or of relatives, employers, or household members of the patient or research subject. The identifiers that must be stripped from the information include "full facial photographs" and "comparable images."<sup>66</sup> Thus, high-resolution MRIs from which the facial features of a patient or

<sup>63</sup> U.S. Department of Health and Human Services, Office for Human Research Protections, Guidance on Research involving Coded Private Information or Biological Specimens (2004), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-020.html (accessed February 16, 2006) ("Therefore, some coded information, in which the code has been derived from identifying information linked to or related to the individual, would be individually identifiable under the Privacy Rule, but might not be individually identifiable under the [Common Rule].").

<sup>&</sup>lt;sup>64</sup> 45 C.F.R. § 164.514(b) (2005).

<sup>65</sup> Ibid., § 164.514(b)(1).

<sup>66</sup> Ibid., § 164.514(b)(2)(Q) and (R). The other identifiers that must be removed from the information to satisfy the de-identification safe harbor include names; most geographic subdivisions smaller than a state except for certain zip codes; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death; all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older; telephone numbers; fax numbers; e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate or license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators; internet protocol address numbers; and biometric identifiers, including finger and voice prints. Ibid., §§ 164.514(b)(2)(A)-(R).

research subject can be reconstructed could be considered individually identifiable and protected by the Privacy Rule.

In summary, the Privacy Rule only regulates covered entities when they are using or disclosing protected health information. The Privacy Rule does not apply to individuals and organizations that do not fall within the definition of a covered entity, or covered entities when they are using or disclosing de-identified health information or identifiable information that does not relate to an individual's health. Other individuals and organizations may have ethical obligations or legal duties based on other state and federal laws, including tort law, to protect certain information, but the Privacy Rule is rather limited in its application and will only regulate some, but not all, scientists who conduct research involving fMRI.

#### **Confidentiality Protections**

With this background, the Privacy Rule's confidentiality protections can be examined in the context of treatment and research involving functional magnetic resonance imaging. Once a threshold determination has been made that a covered entity will be using or disclosing protected health information, the next step is to determine how the Privacy Rule regulates such uses or disclosures. Very generally, the Privacy Rule permits covered entities to use and disclose protected health information without prior authorization for the activities of treatment, reimbursement, and health care operations, as well as 12 enumerated public policy activities.<sup>67</sup> Reimbursement and health care operations activities are not too relevant in the context of functional magnetic resonance imaging, but treatment activities and the public policy exceptions do require some discussion.

Treatment is defined to include the provision, provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a

<sup>&</sup>lt;sup>67</sup> 45 C.F.R. §§ 164.501, 164.506(c)(1), 164.508, 164.512 (2005).

third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.<sup>68</sup> Again, the Privacy Rule permits covered entities to use and disclose protected health information for treatment activities without the prior permission of the subject of the information. The theory is that patients and research subjects who consent to treatment and clinical trials, respectively, impliedly authorize their physicians and scientists to use their health information as part of such treatment or research.

Unique confidentiality concerns are raised in the research setting when fMRI reveals collateral, unanticipated, or incidental information about a research subject. For example, what happens when a patient consents to research designed to test a hypothesis relating to the treatment of schizophrenia, but the covered scientist discovers through fMRI that the subject has an unrelated brain tumor? How can the scientist ensure that the research subject obtains treatment for the brain tumor while maintaining confidentiality as is required by the Privacy Rule (and the Common Rule and principles of medical ethics)?

The ability of fMRI and other neuroimaging technologies to reveal collateral, unanticipated, or incidental information (collectively, incidental findings)<sup>69</sup> about patients and research subjects has drawn significant attention in the neuroethics literature.<sup>70</sup>

<sup>&</sup>lt;sup>68</sup> Ibid., § 164.501.

<sup>&</sup>lt;sup>69</sup> Incidental findings have been defined as "observations of potential clinical significance unexpectedly discovered in healthy subjects or in patients recruited to brain imaging research studies and unrelated to the purpose or variables of the study." Judy Illes et al., "Incidental Findings in Brain Imaging Research," *Science* 311, no. 5762 (February 10, 2006): 783.

<sup>70</sup> Proceedings, Detection and Disclosure of Incidental Findings in Neuroimaging Research, Bethesda, MD, January 6-7, 2005, http://accessible.ninds.nih.gov/news\_and\_events/proceedings/ifexecsummary- pr.htm (accessed September 15, 2005); Judy Illes et al., "Discovery and Disclosure of Incidental Findings in Neuroimaging Research," *Journal of Magnetic Resonance Imaging* 20, no. 5 (November 2004): 743-47; Judy Illes et al., "Ethical Consideration of Incidental Findings on Adult Brain MRI in Research," *Neurology* 62, no. 6 (March 23, 2004): 888-90; Judy Illes et al., "Ethical and Practical Considerations in Managing Incidental Neurologic Findings in Functional Magnetic Resonance Imaging," *Brain and Cognition* 50, no. 3 (2002): 358-60; Gregory L. Katzman, Azar Dagher, and Nicholas Patronas, "Incidental Findings on Brain Magnetic

Several recent studies have analyzed the extent to which scientists have discovered arteriovenous malformations, brain tumors, developmental abnormalities, and other conditions in healthy controls who participate in neuroimaging research. A 2004 study designed in part to characterize the frequency and severity of incidental findings in brain MRIs detected incidental findings in 47% of the 151 scans examined and classified 6.6% of the scans as requiring clinical follow-up. The authors of a second study published in 2004 found substantial variability in investigators' procedures for handling and communicating unanticipated findings to the research subjects. Of six consent forms reviewed by the authors during the second study, four did not contain any language specifically addressing unanticipated findings, although one investigator whose procedures were reviewed did report unanticipated findings directly to the research subject's primary care provider according to provisions in the consent form explaining that such reporting would take place.

The question becomes, how does the Privacy Rule regulate such referrals and reports? If a covered scientist makes an incidental finding, is the scientist legally and ethically permitted or required to send the scan to a radiologist for review? To send the scan and the radiologist's report to the subject's primary care provider? To disclose the scan or radiologist's report to other persons and organizations? To notify the subject?

Because the Privacy Rule broadly defines treatment to include the coordination or management of health care by a health care provider with a third party, as well as consultations and referrals, <sup>76</sup> a covered scientist is legally permitted to disclose an

Resonance Imaging from 1000 Asymptomatic Volunteers," *Journal of the American Medical Association* 281, no. 1 (July 7, 1999): 36-39.

<sup>71</sup> Ibid.

<sup>72</sup> Illes et al., "Ethical Considerations of Incidental Findings," 889.

<sup>73</sup> Illes et al., "Discovery and Disclosure of Incidental Findings in Neuroimaging Research," 745.

<sup>&</sup>lt;sup>74</sup> Ibid.

<sup>75</sup> Ibid.

<sup>&</sup>lt;sup>76</sup> 45 C.F.R. § 164.501.

abnormal fMRI scan to another health care provider, including a primary care provider, neurosurgeon, or other physician, for treatment, even without the prior written authorization of the research subject. Although the scientist may have an ethical obligation to provide for follow-up, as discussed in more detail below, the Privacy Rule does not legally require a covered scientist to obtain follow-up or treatment for the subject because the Privacy Rule does not contain substantive reporting or treatment provisions. The Privacy Rule also would prohibit the scientist from disclosing the abnormal fMRI scan or related information to non-treating individuals and organizations, unless the subject authorized the disclosure in writing or satisfied another exception to the authorization requirement. Unless the subject requested the information, the Privacy Rule would not legally require (although it certainly would permit) the covered scientist to disclose the incidental finding to the subject.

The Privacy Rule addresses the minimum legal requirements that apply to covered scientists when they are using or disclosing neuroimaging information, including in situations involving incidental findings. Ethical rights and duties relating to confidentiality must be considered in addition to these legal requirements. Because a particular individual's understanding of the rights and duties relating to confidentiality can be influenced by her culture, ethnicity, age, socioeconomic status, gender, locale, the

<sup>&</sup>lt;sup>77</sup> Ibid., § 164.506(c)(2) ("A covered entity may disclose protected health information for treatment activities of a health care provider.").

<sup>&</sup>lt;sup>78</sup> 45 C.F.R. § 164.508(c)(1), (2) (2006).

<sup>&</sup>lt;sup>79</sup> Ibid. § 164.512(a)-(l). See text accompanying notes 91-115 in this chapter for a discussion of these exceptions.

<sup>80</sup> Ibid. § 164.502(a)(1)(i) ("A covered entity is permitted to use or disclose protected health information as follows . . . To the individual . . . "); ibid. § 164.502(a)(2)(i) ("A covered entity is required to disclose protected health information . . . To an individual, when requested . . . "); ibid. § 164.524(a)(1) ("an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set . . . "); ibid. § 164.524(a)(2)(iii) ("An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.").

nature and context of the research, and the unique social and political environment in which the research and information usage will occur,<sup>81</sup> a one-size-fits-all approach — which may satisfy minimum legal standards — likely will not satisfy ethical principles. Stated another way, providers and investigators cannot assume that each patient or research subject will regard the same things as confidential.<sup>82</sup> Depending on the individual and the information involved, breaches of confidentiality in the clinical and research contexts can result in psychological harm, such as worry, irritation, fear, embarrassment, and self-doubt; social harm, such as stigmatization; economic harm, such as unemployment or loss of benefits; and legal harm, such as arrest or conviction of a crime.<sup>83</sup>

Based on the ethical principle of respect for persons, scientists have an ethical duty to inform each subject during the informed consent conversation of the potential of incidental findings.<sup>84</sup> A legal document that identifies in writing the possibility of incidental findings does not, standing alone, satisfy this duty.<sup>85</sup> An ethically desirable informed consent process would make each subject personally aware of the possibility of incidental findings and the related confidentiality issues.<sup>86</sup> For example, the study representative could describe to the subject the types of incidental findings that have been

<sup>&</sup>lt;sup>81</sup> National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, 105.

<sup>82</sup> Ibid.

<sup>83</sup> Ibid., 105-06.

<sup>&</sup>lt;sup>84</sup> National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (April 18, 1979) ("Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents . . . To show lack of respect for an autonomous agent is to . . . withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.").

<sup>&</sup>lt;sup>85</sup> Paul J. Ford and Jaimie M. Henderson, "Functional Neurosurgical Intervention: Neuroethics in the Operating Room," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 226 ("The ethical issues cannot be reduced to or solved by impeccable informed consent or some formulaic ethics process.").

<sup>86</sup> Ibid.

discovered in the past, including arteriovenous malformations, brain tumors, and developmental abnormalities, as well as any findings that are likely in the context of the instant research. The potential subject also could be questioned regarding any fears that she has regarding psychological, economic, and legal harms associated with the disclosure of this research.

When an incidental finding occurs, the general consensus seems to be that it is ethically desirable to notify the subject of the incidental finding.<sup>87</sup> This consensus is based on the ethical principle of respect for persons as well as recent studies examining subjects' expectations regarding incidental findings in neuroimaging research.88 In one study published in February 2006, 105 healthy individuals who had previously participated in neuroimaging studies were questioned about their expectations and attitudes regarding incidental findings associated with such studies.89 The study authors found that 54% of the participants reported that they expected research scans to detect abnormalities if they existed, and that more than 90% of the participants reported that they would want incidental findings communicated to them.<sup>90</sup> These findings support the development during the informed consent process of a notification and referral process to be followed in the event of an unanticipated finding. One neuroscientist reportedly tells his subjects, "'If we find any gross abnormalities in your brain, would you like a radiologist to tell you about it? If you answer no, we cannot do the test.""91 Although this approach may be a bit blunt, a study representative behaving in an ethically desirable manner might request the subject to provide contact information for her preferred or primary medical care provider, which would limit the disclosure of protected health

<sup>87</sup> Illes et al., "Incidental Findings," 783.

<sup>88</sup> Ibid

<sup>&</sup>lt;sup>89</sup> Matthew P. Kirschen, Agnieszka Jaworska, and Judy Illes, "Subjects' Expectations in Neuroimaging Research," *Journal of Magnetic Resonance Imaging* 23, no. 2 (February 2006): 205-09.

<sup>&</sup>lt;sup>90</sup> Ibid., 207.

<sup>&</sup>lt;sup>91</sup> Eric Jaffe, "My Brain Is a Walnut," *Slate*, January 10, 2006, http://www.slate.com/toolbar.aspx?action+print&id=2134094 (accessed February 16, 2006).

information to a provider with which the subject already has a treatment relationship. If the subject does not identify a preferred or primary provider, the scientist could, in consultation with the radiologist who reviewed the abnormal scan, advise the subject regarding local provider groups that could be contacted for follow-up care. Although this process will not eliminate the possibility that a scientist will make an incidental finding, it may lessen the subject's perception that her privacy has been violated if and when a finding occurs. It also provides evidence that the subject agreed to an information disclosure to a particular provider that was made solely for purposes of obtaining follow-up or treatment, and not as a breach of confidentiality.

Treatment is just one of the activities for which covered providers and scientists are permitted to disclose protected health information without the prior authorization of the patient or research subject under the Privacy Rule. The Privacy Rule also permits covered entities to use and disclose protected health information without prior authorization for 12 enumerated public policy activities, which are also referred to as "exceptions" to the general authorization requirement. Because these exceptions provide examples of situations in which the confidentiality of fMRI records are not required to be maintained, a brief review of their provisions is worthwhile.

The first exception that is potentially relevant in the neuroimaging context relates to uses and disclosures of protected health information that are required by law. The Privacy Rule expressly permits covered entities to use or disclose protected health information without prior authorization if the use or disclosure is required by law and complies with and is limited to the relevant requirements of such law.<sup>93</sup> For example, if a covered entity discovers during the conduct of neuroimaging a condition that state law requires to be reported to a local health department or similar agency, then the Privacy

<sup>92 45</sup> C.F.R. § 164.512(a)-(l) (2005).

<sup>93</sup> Ibid., § 164.512(a)(1).

Rule permits, but does not require,<sup>94</sup> the entity to make the information disclosure. A specific example would be uncontrolled sleepiness or seizures associated with sleep apnea, narcolepsy, epilepsy, or other neurological disorders, which the State of Wisconsin requires diagnosing physicians to report to the Wisconsin Department of Transportation.<sup>95</sup>

The Privacy Rule permits disclosures required by another law if the disclosure "complies with and is limited to the relevant requirements" of such law. <sup>96</sup> If the information required by the law is a one-word diagnosis, the Privacy Rule thus would prohibit the disclosure of an underlying fMRI scan. However, many state laws require the disclosure of more than one-word diagnoses. The Wisconsin reporting form asks longer questions such as, "Does this person's neurological disorder involve movement disorder? If yes, please explain." The Wisconsin reporting form also asks for EEG (although not yet fMRI) results. <sup>98</sup>

A second exception relates to uses and disclosures of protected health information for public health activities. Among other activities, the Privacy Rule permits covered entities to disclose protected health information to a public health authority for the purpose of preventing or controlling disease, injury, or disability, and to make reports regarding the quality, safety or efficacy of a Food and Drug Administration regulated product or activity.<sup>99</sup> This provision expressly permits covered entities to report diseases, injuries, vital events, and the conduct of public health surveillance, public health investigations, and public health interventions to public health authorities such as the

<sup>&</sup>lt;sup>94</sup> The underlying state law would be the source of the reporting requirement and the source of civil, criminal, or administrative penalties for any failure to report, not the Privacy Rule.

<sup>95</sup> Wisconsin Department of Transportation, *Medical Examination Review*, Form MV3644 (December 2004) (photocopy).

<sup>96 45</sup> C.F.R. § 164.512(a)(1) (2005)

<sup>97</sup> Wisconsin Department of Transportation, Medical Examination Review, 2.

<sup>98</sup> Ibid.

<sup>99 45</sup> C.F.R. § 164.512(b) (2005).

federal Center for Disease Control and Prevention and state health departments.<sup>100</sup>
Among other things, this provision would allow a covered entity to disclose a disease or injury detected by functional magnetic resonance imaging to a local public health authority without prior authorization of the individual who is the subject of the image.

A third exception relates to uses and disclosures of protected health information for certain health oversight activities. Under this provision, covered entities are permitted to disclose protected health information to health oversight agencies, such as the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, the Food and Drug Administration, and the OHRP, for oversight activities authorized by law. <sup>101</sup> Oversight activities are defined to include audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; and other activities necessary for appropriate oversight of the health care systems. <sup>102</sup> For example, if the OHRP conducted an investigation of alleged research misconduct by a number of investigators at a particular institution, the investigators would be permitted to disclose their research records, including fMRI records, in response to a demand for such records by the OHRP.

A fourth exception relates to the disclosure of protected health information for judicial and administrative proceedings. This provision permits covered entities to disclose protected health information in the course of a judicial or administrative proceeding in response to an order of a court or administrative tribunal if the covered entity discloses only the protected health information expressly authorized by such order. <sup>103</sup> If a court orders a covered entity to disclose an fMRI scan, the Privacy Rule permits the entity to do so. This provision also permits covered health care providers and scientists to disclose protected health information in response to a subpoena, discovery

<sup>100</sup> Ibid., § 164.512(b).

<sup>&</sup>lt;sup>101</sup> Ibid., § 164.512(d)(1).

<sup>102</sup> Ibid.

<sup>103</sup> Ibid., § 164.512(e)(1)(i).

request, or other lawful process that is not accompanied by a court order if the covered provider or scientist receives certain assurances specified in the Privacy Rule from the party seeking the information.<sup>104</sup> Even without a court order, then, a covered entity is permitted to disclose an fMRI scan or related report in the litigation context if the entity obtains the specified assurances from the party seeking the information.

A fifth exception relates to disclosures of protected health information for law enforcement purposes. This provision permits covered entities providers and scientists to disclose protected health information to law enforcement officials for certain law enforcement purposes. One such purpose involves a law enforcement official's request for information about an individual who is or is suspected of being a victim of a crime. On the structural neuroimaging context, a relevant example might involve a radiologist who interpreted a neuroimage as revealing shaken-baby syndrome. On the functional neuroimaging context, a futuristic, speculative example might involve a scientist who interpreted an fMRI as revealing that certain areas of a rape victim's brain were activated when she was shown an image of a particular criminal or the scene of the rape. The Privacy Rule would permit the covered radiologist or scientist to disclose information needed by the law enforcement officer to enforce the laws relating to child abuse and rape.

A sixth exception relates to research activities. The Privacy Rule permits covered entities to use and disclose protected health information without prior authorization for four types of research activities. These include (1) retrospective research using the information of decedents, 108 (2) certain reviews of information that are preparatory to

<sup>104</sup> Ibid., § 164.512(e)(1)(ii), (iii), and (iv).

<sup>&</sup>lt;sup>105</sup> Ibid., § 164.512(f).

<sup>&</sup>lt;sup>106</sup> Ibid., § 164.512(f)(3).

<sup>107</sup> American Academy of Pediatrics, Committee on Child Abuse and Neglect, "Shaken Baby Syndrome: Rotational Cranial Injuries—Technical Report," *Pediatrics* 108, no. 1 (July 2001): 207-08.

<sup>&</sup>lt;sup>108</sup> 45 C.F.R. § 164.512(i)(1)(iii) (2005).

research,<sup>109</sup> (3) situations in which an IRB or privacy board has approved the waiver of the otherwise required authorization to use or disclose information,<sup>110</sup> and (4) situations in which the researcher will only be using a limited data set of information and the researcher has executed a data use agreement with the data holder.<sup>111</sup>

An example of the second type of research activity might involve an investigator who would like to review a class of protected health information, such as "all fMRI scans and records of patients who have had brain surgery in the last five years," to determine whether a sufficient number of patients exist to test a particular hypothesis relating to the assistance provided by fMRI in planning surgical routes or assessing surgical risk. Although the Common Rule would require an IRB to approve the investigator's research protocol before any recruitment activities relating to those patients may take place<sup>112</sup> (and the National Bioethics Advisory Commission has taken the position that "the mere act of contacting people about participating in a research study may be a violation of their privacy, particularly when the prospective participants are identified as having a stigmatizing condition"),<sup>113</sup> the Privacy Rule would permit a workforce member of the health care facility that holds the fMRI scans and records to contact and recruit the patients without prior IRB approval once the investigator has determined that her hypothesis is testable.<sup>114</sup> The Privacy Rule thus gives investigators access to identifiable patient data, including functional magnetic resonance images and related records, for

<sup>&</sup>lt;sup>109</sup> Ibid., § 164.512(i)(1)(ii).

<sup>&</sup>lt;sup>110</sup> Ibid., § 164.512(i)(1)(i).

<sup>&</sup>lt;sup>111</sup> Ibid., § 164.514(e)).

<sup>112</sup> U.S. Department of Health and Human Services, National Institutes of Health, *Clinical Research and the HIPAA Privacy Rule*, NIH Publication No. 04-5495 (February 2004), 6.

<sup>113</sup> National Bioethics Advisory Commission, "Ethical and Policy Issues in Research Involving Human Participants," 105.

<sup>114</sup> U.S. Department of Health and Human Services, "Clinical Research and the HIPAA Privacy Rule," 7.

certain preliminary research purposes without the authorization of the patients who are the subjects of the images.

A seventh exception relates to uses and disclosures of protected health information that are necessary to avert serious threats to health or safety. The Privacy Rule expressly permits a covered entity to use or disclose protected health information if the covered entity in good faith believes that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public and is to a person reasonably able to prevent or lessen the threat, including the target of the threat. To the extent fMRI technology advances this far, this provision would permit a covered provider or scientist who had interpreted a particular patient's fMRI to reveal imminent murderous tendencies to reveal that information to law enforcement authorities or the murder target.

An eighth exception relates to national security and intelligence activities. One portion of this provision expressly permits a covered entity to disclose protected health information to authorized federal officials for the conduct of law intelligence, counterintelligence, and other national security activities authorized by the National Security Act. 116 To the extent fMRI technology advances this far, this provision would permit a covered entity that interprets an fMRI to reveal an individual's knowledge of a terrorist activity to disclose relevant information to authorized federal officials without the prior permission of the individual.

These eight exceptions provide examples of ways in which covered providers and scientists are legally permitted to disclose otherwise confidential neuroimaging information to third parties without fear of civil and criminal penalties under the Privacy Rule. Although the Privacy Rule does not require covered entities to make any of these information disclosures, other state and federal laws may. If a particular covered investigator does not want to disclose confidential information pursuant to such

<sup>&</sup>lt;sup>115</sup> 45 C.F.R. § 164.512(j) (2005).

<sup>&</sup>lt;sup>116</sup> Ibid., § 164.512(k)(2).

underlying state or federal law, the investigator may attempt to obtain a certificate of confidentiality, discussed later in this chapter. If a covered physician or scientist wishes to use or disclose protected functional neuroimaging information for a purpose other than treatment, reimbursement, health care operations, or an enumerated public policy activity, the covered entity must obtain the prior written authorization of the subject of the neuroimage using a form that contains a series of detailed elements and statements.<sup>117</sup> Failure to obtain prior authorization, when required, can subject a covered provider or scientist to civil and criminal penalties.<sup>118</sup>

Unlike the Common Rule, the Privacy Rule provides significantly more guidance regarding the situations in which covered entities are permitted to use and disclose protected functional neuroimaging information. A companion set of regulations, known as the HIPAA Security Rule, provide additional guidance regarding the specific administrative, technical, and physical security procedures covered entities must establish to assure the integrity and confidentiality of electronic protected health information and to protect against security breaches and unauthorized uses and disclosures of electronic protected health information.<sup>119</sup> Electronic protected health information is defined as protected health information that is created, received, maintained, or transmitted in electronic format,<sup>120</sup> and would include functional magnetic resonance imaging data or related records that are maintained in or transmitted by computer.

<sup>&</sup>lt;sup>117</sup> Ibid. § 164.508(c)(1) and (2).

<sup>118 42</sup> U.S.C. §§ 1320d-5, 1320d-6 (2005). Complaints alleging violations of the Privacy Rule are filed with the Department of Health and Human Services' Office for Civil Rights (OCR). OCR has the authority to issue civil monetary penalties. OCR refers suspected criminal violations to the United States Department of Justice for possible prosecution.

<sup>119</sup> U.S. Department of Health and Human Services, "Health Insurance Reform: Security Standards," *Federal Register* 68, no. 34 (February 20, 2003): 8334-8381, codified at 45 C.F.R. § 164.302-.318 (2005).

<sup>120 45</sup> C.F.R. § 160.103 (2005). Electronic media includes electronic storage media, such as memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card, as well as transmission media used to exchange information already in electronic storage media, such as the internet, extranet, leased lines, dial-

Unlike the Common Rule, which does not identify any specific situations in which an investigator can breach confidentiality, the Privacy Rule identifies 12 situations in which a covered provider or scientist can make an unauthorized use or disclosure of protected health information, 121 and at least eight of these situations are potentially applicable in the functional neuroimaging context. Misunderstandings of the Privacy Rule have led some to argue that the Rule impedes access to health information for treatment and other purposes, but a careful analysis of the Rule shows just how many unauthorized disclosures of functional neuroimaging information are expressly permitted. Like the Common Rule, then, the Privacy Rule also establishes incomplete confidentiality protections for functional neuroimaging data.

#### STATE LAW

In addition to the confidentiality protections offered by federal laws such as the Common Rule and the Privacy Rule, many states have medical practice acts, hospital licensing laws, imaging center licensing laws, and other similar laws and regulations that require certain individuals and institutions to maintain the confidentiality of health information in their possession. How a particular state law applies to the functional neuroimaging context depends on whether the law's protections extend to scientists who do not provide health care as part of their research and whether the law protects social information in addition to medical records and other health-related information.<sup>122</sup> With some exceptions, the Privacy Rule preempts state laws that provide less stringent confidentiality protections, although more stringent state laws generally survive

up lines, private networks, and the physical movement of removable/transportable electronic storage media. Ibid.

<sup>&</sup>lt;sup>121</sup> Ibid., § 164.512(a)-(l).

<sup>122</sup> Although beyond the scope of this dissertation, a 50-state survey of health information confidentiality laws and regulations has been attempted by the Health Privacy Project. Health Privacy Project, *The State of Health Privacy*, 2<sup>nd</sup> ed. (Washington, D.C.: Health Privacy Project, 2002).

preemption.<sup>123</sup> State health information confidentiality laws usually contain injunction authority as well as civil, criminal, and administrative penalties for unauthorized disclosures of confidential patient information.<sup>124</sup>

## **CERTIFICATES OF CONFIDENTIALITY**

Congress initially provided for certificates of confidentiality in 1970 as part of the national war on drugs. <sup>125</sup> The certificates were designed to assure research subjects who participated in drug addiction and abuse studies that the information they shared with researchers would remain completely confidential. <sup>126</sup> Congress amended the Public Health Service Act in 1988 to authorize agencies within HHS to issue certificates of confidentiality to investigators engaged in all biomedical, behavioral, clinical, mental health, and other research studies, not just research relating to drug addiction and abuse. <sup>127</sup> Today, certificates of confidentiality allow investigators to withhold names and other identifiable data about research participants that otherwise may be summoned under federal, state, or local civil, judicial, administrative, legislative, or other proceedings. <sup>128</sup> The NIH has taken the position that certificates of confidentiality, which have been

<sup>123 45</sup> C.F.R. § 160.203(b) (2005).

<sup>124</sup> TEX. OCC. CODE §§ 165.001, 165.051, 164.101, 165.151 (West 2006) (establishing injunction authority as well as administrative, civil, and criminal penalties for violations of the physician-patient confidentiality requirement set forth in the Texas Medical Practice Act).

<sup>125</sup> Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (October 27, 1970), codified at 21 U.S.C. § 872(c) ("The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which such authorization was obtained.").

<sup>126</sup> Janlori Goldman and Angela Choy, "Privacy and Confidentiality in Health Research," in National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, vol. 2 (Bethesda, Md.: National Bioethics Advisory Commission, 2001), C-18.

<sup>127 42</sup> U.S.C. § 241(d) (1988).

<sup>128</sup> Ibid.

available for non-federally funded research since 1993,<sup>129</sup> supersede contrary state and federal laws, and at least one judicial opinion has upheld a certificate of confidentiality against an otherwise compulsory disclosure.<sup>130</sup>

Certificates of confidentiality can provide additional confidentiality protections in the functional neuroimaging context, but investigators must be knowledgeable about their application. A certificate of confidentiality can only be requested for a research project that involves the gathering of *sensitive* information from human subjects.<sup>131</sup> The NIH explains that information is sensitive if its disclosure could have adverse consequences for subjects, or damage their financial standing, employability, insurability, or reputation.<sup>132</sup> Examples of information the NIH has classified as sensitive include genetic information; information relating to the psychological well-being of human subjects; information on subjects' sexual attitudes, preferences, or practices; and data on substance abuse or other illegal risk behaviors.<sup>133</sup> Functional MRI has the potential to gather and reveal sensitive information about individuals, including their mental health, sexual preferences, and addictive tendencies, and speculation exists that employers, insurance companies, and others may attempt to obtain this information. Research involving fMRI thus may be ripe for the additional confidentiality protections provided by certificates of confidentiality.

<sup>129</sup> Joan E. Seiber, "Privacy and Confidentiality: As Related to Human Research in Social and Behavioral Science," in National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, vol. 2 (Washington, D.C.: National Bioethics Advisory Commission, 2001), N-18.

<sup>130</sup> People v. Newman, 298 N.E.2d 651 (N.Y. 1973) (holding that the New York state physician-patient privilege did not prohibit disclosure of information identifying individuals undergoing methadone treatment, but that the federal certificate of confidentiality provisions did).

<sup>131</sup> Office of Extramural Research, National Institutes of Health, Certificates of Confidentiality: Background Information (July 21, 2003), http://grants1.nih.gov/grants/policy/coc/background.htm (accessed February 16, 2006).

<sup>132</sup> Ibid.; Office of Extramural Research, National Institutes of Health, Frequently Asked Questions on Certificates of Confidentiality (March 15, 2002), http://grants1.nih.gov/grants/policy/coc/faqs.htm (accessed February 16, 2006).

<sup>133</sup> Ibid.

The NIH has clarified that certificates of confidentiality can be used to fill gaps in confidentiality protections left by the Privacy Rule's permitted public policy disclosures: "While the Privacy Rule does establish protections for covered entities' use and disclosure of PHI, it permits use or disclosure in response to certain judicial or administrative orders. Therefore, researchers/contractors may obtain Certificates of Confidentiality to protect them from being forced to disclose information that would have to be disclosed under the Privacy Rule." The NIH also has clarified that investigators can invoke the protections provided by certificates of confidentiality in response to a demand for information under the recently enacted Patriot Act. 135

Although certificates of confidentiality protect investigators from making otherwise compulsory disclosures, they do not prohibit investigators from making non-compulsory, unauthorized disclosures. Certificates of confidentiality thus are helpful when an investigator desires to maintain the confidentiality of her subjects' data, but the certificates are not especially helpful when an investigator intentionally or unknowingly breaches confidentiality in a situation not involving compulsion. Certificates of confidentiality, which are research project (and not investigator or institution) specific, also must be requested by the investigator from the applicable agency prior to the beginning of each research project, a requirement about which many investigators do not know or lack the diligence to discover. 137

Because certificates of confidentiality can fill some of the confidentiality gaps left by the Privacy Rule, investigators engaged in functional neuroimaging research should be encouraged to apply for certificates of confidentiality prior to the commencement of each

<sup>134</sup> Office of Extramural Research, National Institutes of Health, Frequently Asked Questions on Certificates of Confidentiality (July 21, 2003), http://grants1.nih.gov/grants/policy/coc/faqs.htm (accessed February 16, 2006).

<sup>135</sup> Office of Extramural Research, National Institutes of Health, Frequently Asked Questions on Certificates of Confidentiality (March 22, 2005), http://grants1.nih.gov/grants/policy/coc/faqs.htm (accessed February 16, 2006).

<sup>136</sup> Seiber, "Privacy and Confidentiality," N-18.

<sup>137</sup> Ibid.

research project. IRBs also should be educated regarding the protections provided by certificates of confidentiality and their application process, and should make investigators conducting functional magnetic resonance imaging research aware of the confidentiality opportunities offered by certificates of confidentiality.<sup>138</sup>

### **CONSTITUTIONAL LAW**

Chapter 5 examines when the inappropriate gathering of functional neuroimaging information by a state actor might implicate various privacy interests protected by the United States Constitution, including the First, Fourth, and Fifth Amendments. A confidentiality issue appropriate for discussion in the current chapter is whether the unauthorized disclosure of neuroimaging information that was appropriately collected also implicates the Constitution. If a state law, such as a Wisconsin Department of Transportation regulation, requires a physician to report certain neurological information revealed by functional magnetic resonance imaging, has the patient a constitutionally protected breach of confidentiality or privacy claim?

Except in rare situations, a constitutional allegation likely would not succeed. The United States Supreme Court reviewed in *Whalen v. Roe* a New York statute that required physicians to disclose to the state a copy of every prescription written for drugs that had a high potential of abuse and that established security measures for the information, once received by the state.<sup>139</sup> The Court expressly recognized that the duty to avoid unwarranted disclosures of information has its roots in the Constitution in certain circumstances.<sup>140</sup> However, Justice Stevens found that any such interest in *Whalen* was outweighed by the State of New York's interest in gathering the data and its establishment of adequate standards and procedures for protecting such information, which included the locking of computer tapes in cabinets, running computers off line to

<sup>138</sup> Ibid.

<sup>139</sup> Whalen v. Roe, 429 U.S. 589 (1977).

<sup>140</sup> Ibid., 605.

avoid access by others, and the disclosure of information to a limited number of officials.<sup>141</sup>

Although *Whalen* frequently is cited for the proposition that "no general fundamental constitutional right to privacy in personal medical information"<sup>142</sup> exists, a careful reading of *Whalen* reveals that the opinion is not that strong. *Whalen* expressly left the door open for situations involving unwarranted disclosures of confidential information, as well as situations in which the state actor had not established policies and procedures that sufficiently protected the confidentiality of the information in its possession: "We therefore need not, and do not, decide any question which might be presented by the unwarranted disclosure of accumulated private data whether intentional or unintentional or by a system that did not contain comparable security provisions. We simply hold that *this* record does not establish an invasion of any right or liberty protected by the Fourteenth Amendment."<sup>143</sup>

Judicial opinions issued after *Whalen* hint at the type of record that might possibly support a constitutional claim. The United States Court of Appeals for the Third Circuit's 1980 opinion in *United States v. Westinghouse Electric Corporation* is one example. The Third Circuit in *Westinghouse* reviewed an order by the United States under the Occupational Safety and Health Act directing Westinghouse Electric Corporation to disclose certain employee medical records as part of a health hazard investigation. The Third Circuit explained that the full measure of the constitutional right to privacy had not yet been delineated, but stated its belief that it extended to an individual's interest in avoiding disclosure of personal matters, including medical records:

<sup>&</sup>lt;sup>141</sup> Ibid., 593-94.

<sup>142</sup> Sherman v. Jones, 258 F. Supp.2d 440, 443 (E.D. Va. 2003) ("Whalen points persuasively to the conclusion that there is no general fundamental constitutional right to privacy in personal medical information.").

<sup>143</sup> Whalen, 429 U.S. at 605-06 (italicized emphasis added).

<sup>&</sup>lt;sup>144</sup> United States v. Westinghouse Electric Co., 638 F.2d 570 (3<sup>rd</sup> Cir. 1980).

There can be no question that an employee's medical records, which may contain intimate facts of a personal nature, are well within the ambit of materials entitled to privacy protection. Information about one's body and state of health is a matter which the individual is ordinarily entitled to retain within the "private enclave where he may lead a private life." It has been recognized in various contexts that medical records and information stand on a different plane than other relevant material. . . . This difference in treatment reflects a recognition that information concerning one's body has a special character. The medical information requested in this case is more extensive than the mere fact of prescription drug usage by identified patients considered in *Whalen v. Roe* and may be more revealing of intimate details. Therefore, we hold that it falls within one of the zones of privacy entitled to protection. 145

The Third Circuit then established a multi-factor test for determining when the constitutional right to privacy might apply in a situation involving medical records. The factors include the type of record requested, the information it does or might contain, the potential for harm in any subsequent nonconsensual disclosure, the injury from disclosure to the relationship in which the record was generated, the adequacy of safeguards to prevent unauthorized disclosure, the degree of need for access, and whether there is an express statutory mandate, articulated public policy, or other recognizable public interest militating toward access. Although the Third Circuit held in *Westinghouse* that the National Institute for Occupational Safety and Health had a strong interest in facilitating its health hazard investigation and related research, which justified the "minimal" intrusion into the privacy surrounding the Westinghouse employees' medical records, the application of the *Westinghouse* factors in the context of functional magnetic resonance imaging could lead to a different result.

In Westinghouse, "Most, if not all, of the information in the files [were] results of routine testing, such as X-rays, blood tests, pulmonary function tests, hearing and visual tests. This material, although private, is not generally regarded as sensitive." The

<sup>&</sup>lt;sup>145</sup> Ibid., 577.

<sup>146</sup> Ibid., 578.

<sup>&</sup>lt;sup>147</sup> Ibid., 579.

research studies discussed in Chapter 2 show that fMRI has the potential to reveal information that could be considered more sensitive than that revealed by x-rays and blood tests, such as information about sexual preferences, addictive behaviors, and mental health. The NIH has already recognized sexual preferences, addictive behaviors, and mental health status as particularly sensitive health information in the context of the Public Health Service Act's certificates of confidentiality.<sup>148</sup> A similar argument could be made in a constitutional claim.

The second *Westinghouse* factor relates to the potential for harm in any subsequent nonconsensual disclosure. The media reports summarized in Chapter 2 speculate that employers, insurance companies, and others will want to obtain functional neuroimaging information to make hiring, firing, underwriting, and similar business decisions. Employers and insurance companies already have attempted to obtain sensitive genetic information for use in business decision-making, 149 and it is not unreasonable to speculate that functional neuroimaging information might be used in a similar manner. The potential for harm resulting from a nonconsensual disclosure of neuroimaging information, such as failure to obtain employment or insurance coverage, could be great.

The third *Westinghouse* factor relates to the injury from disclosure to the relationship in which the record was generated. Prospective patients and research subjects who fear that their functional neuroimaging information will be disclosed to third parties might not consent to treatment or research, and current patients and research subjects whose functional neuroimaging is disclosed without authorization might lose

<sup>148</sup> Office of Extramural Research, National Institutes of Health, Frequently Asked Questions on Certificates of Confidentiality (March 15, 2002), http://grants1.nih.gov/grants/policy/coc/faqs.htm (accessed February 16, 2006)

<sup>149</sup> A 1992-1993 pilot study documented 206 instances of discrimination, including loss of employment and insurance coverage or ineligibility for benefits, as a result of access to genetic information. Janlori Goldman and Angela Choy, "Privacy and Confidentiality in Health Research," in National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, vol. 2 (Bethesda, Md.: National Bioethics Advisory Commission, 2001), C-10.

trust in their current providers and investigators. The unauthorized disclosure of functional neuroimaging information could injure the physician-patient or investigator-research subject relationship.

The application of the other *Westinghouse* factors – the adequacy of safeguards to prevent unauthorized disclosure, the degree of need for access, and the existence of an express statutory mandate, articulated public policy, or other recognizable public interest militating toward access – will depend on the particular facts of the situation. Although no authority currently establishes a constitutionally protected interest in functional neuroimaging information, the first three *Westinghouse* factors could form the basis of an argument in favor of such interest. Constitutional law thus serves as a possible, although perhaps unlikely, source of confidentiality protections for functional neuroimaging information.

#### **TORT LAW**

Chapter 3 considered the common law of torts as a source of rights and duties relating to confidentiality and privacy, and introduced four common law torts (intrusion, disclosure, false light, and appropriation) recognized by most jurisdictions. Two of these torts, disclosure and false light, have the potential to be implicated when a health care provider or scientist makes an unauthorized use or disclosure of a patient or subject's functional neuroimaging information.

The disclosure tort imposes liability on an individual who gives publicity to a matter concerning the private life of another if the matter publicized is of a kind that would be highly offensive to a reasonable person and the matter is not of legitimate concern to the public. The tort thus has three elements: publicity, of a highly offensive matter, that is not of legitimate public concern. Publicity, the first element, has been defined as "widespread dissemination." The matter either must be communicated

<sup>150</sup> RESTATEMENT (SECOND) OF TORTS, § 652D (1977).

<sup>151</sup> Murphy, "Property Rights," 2392.

to the public at large or to so many persons that it is substantially certain to become public knowledge.<sup>152</sup> The means of communication, whether oral or in writing, is not important.<sup>153</sup> What is important is that the communication reaches, or is sure to reach, the public.<sup>154</sup> Thus, the disclosure tort does not apply when a defendant communicates a matter to a single person, or even to a small group of persons.<sup>155</sup> The tort does apply if a defendant publicizes a matter in a newspaper or a magazine, even of small circulation, or in a handbill distributed to a large number of persons, or during a radio broadcast, or in a statement made in an address to a large audience.<sup>156</sup>

In the functional neuroimaging context, the disclosure tort probably would not apply if a particular health care provider without authorization disclosed a patient's neuroimaging information to one potential employer, a health or life insurance company, a government official, or a criminal justice officer.<sup>157</sup> However, the disclosure tort could apply if a scientist without authorization disclosed neuroimaging information about a particular research subject to a major newspaper, or during a lecture given in front of a large audience, such as a scientific conference that was later broadcast on the Internet.

The second element of the disclosure tort requires that publicity be given to matters concerning the private, as distinguished from the public, life of an individual. No disclosure liability exists if the defendant merely gives further publicity to information that is already public or that is a matter of public record, such as a person's date of birth, the fact of a person's marriage, a person's military record, the fact that a

<sup>152</sup> RESTATEMENT (SECOND) OF TORTS § 652D, Comment a (1977).

<sup>153</sup> Ibid.

<sup>154</sup> Ibid.

<sup>155</sup> Ibid.

<sup>156</sup> Ibid.

<sup>157</sup> The Restatement (Second) of Torts supports this conclusion in one of its illustrations: "A, a creditor, writes a letter to the employer of B, his debtor, informing him that B owes the debt and will not pay it. This is not an invasion of B's privacy..." Ibid., Comment a, Illustration 1.

<sup>158</sup> Ibid., Comment b.

person is admitted to practice law or is licensed to drive a taxicab, or to material contained in pleadings that have been filed in a lawsuit.<sup>159</sup> Disclosure liability also does not exist when the matter that has been publicized has been left "open to the public eye," such as when an individual walks down the street in her pajamas and a photograph of the individual walking down the street in her pajamas appears in the newspaper.<sup>160</sup> However, the Restatement (Second) of Torts would impose disclosure liability if a defendant newspaper published, without the plaintiff's consent, a picture of the plaintiff nursing her child,<sup>161</sup> or if a defendant hospital publicized (for non-educational purposes) a video of a woman giving birth, when the woman consented to the use of the video only for purposes of medical education.<sup>162</sup>

In the functional neuroimaging context, a physician or scientist's unauthorized disclosure of neuroimaging information that is interpreted to reveal sensitive information about a patient or research subject, such as her sexual preferences, poor mental health, or addictive behaviors, could be analogized to the Restatement's nursing and birth examples. To prevail, the patient or research subject must demonstrate that her sexual preferences, mental health condition, or addictive behaviors were not already a matter of public record and were not "open to the public eye." For example, a research subject who openly and actively participates in a gay and lesbian association might have difficulty proving that a scientist's unauthorized disclosure of neuroimaging information "showing" the subject's homosexuality was not already open to the public.

The final element of the disclosure tort is that the matter publicized must not be of legitimate public concern. Stated another way, courts have found that, "When the subject-matter of the publicity is of legitimate public concern, there is no invasion of

<sup>159</sup> Ibid.

<sup>160</sup> Ibid.

<sup>161</sup> Ibid., Comment c, Illustration 10.

<sup>162</sup> Ibid., Comment c, Illustration 11.

privacy."163 Legitimate public concern has been found in matters involving individuals who voluntarily place themselves in the public eye, such as professional athletes and public officers. 164 Legitimate public concern also has been found in matters involving involuntary public figures, including individuals who have not sought publicity or consented to it, but through their own conduct, usually criminal, have attracted attention.<sup>165</sup> For example, if a defendant is tried for murder, and a newspaper publishes daily reports of the trial that include accounts of the type of life the defendant led before the crime, as well as her home life and daily habits, those matters have been considered of legitimate public concern. The Restatement (Second) of Torts even finds the fact that a 12-year-old has given birth (as well as a photograph of the 12-year-old and her child) to be of legitimate public concern. 166 However, the Restatement recognizes some details, such as sexual relations, that even voluntary public figures have a right to keep to themselves.<sup>167</sup> In the functional neuroimaging context, fMRI scans of politicians, actresses, and criminals might be considered of legitimate public concern, unless they reveal information that is considered "as private" as sexual relations. Which mental functions are considered "as private" as sexual relations likely would be a litigated issue.

A second common law tort, false light, is implicated when an individual gives publicity to a matter concerning another that places the other before the public in a false light if the false light in which the other was placed would be highly offensive to a reasonable person and the actor had knowledge of or acted in reckless disregard as to the falsity of the publicized matter. Designed to protect reputation, the false light tort has three main elements: publicity, of a person in a false light, which would be highly

<sup>163</sup> Ibid., Comment d.

<sup>164</sup> Ibid., Comment e.

<sup>165</sup> Ibid., Comment f.

<sup>166</sup> Ibid., Comment f, Illustration 15.

<sup>167</sup> Ibid., Comment h.

<sup>168</sup> RESTATEMENT (SECOND) OF TORTS § 652E (1977).

offensive to a reasonable person. The first element, publicity, is given the same interpretation as the publicity element of the disclosure tort.<sup>169</sup> The second element, false light, protects the interest of an individual in not being made to appear before the public in an objectionable false position, or other than as she is.<sup>170</sup> The false light element would exist, for example, if a newspaper published an article about taxi drivers who cheat the public on fares and the article included a photograph of a particular taxi driver who does not cheat the public on fares.<sup>171</sup> The third element requires the position in which the person was placed to be highly offensive to a reasonable person.<sup>172</sup>

Although not broadly applicable in the functional neuroimaging context, the false light tort could be invoked in certain very limited circumstances. A July 1983 issue of *Vogue*, the popular fashion magazine, contained an article showing three colorful PET scans: one of a "normal" brain, one of a "depressed" brain, and one of a "schizo" brain. 173 If the article had placed a photograph of an individual next to the "depressed" or "schizo" images but the individual did not suffer from depression or schizophrenia, two elements of the false light tort claim (publicity and false light) would be satisfied. To prevail, the individual would have to prove that being considered depressed or schizophrenic is highly offensive to a reasonable, healthy person.

In addition to the disclosure and false light torts, many jurisdictions recognize a common law breach of confidentiality tort in the medical context. A relatively recent South Carolina decision described the tort as protecting patients against the unauthorized disclosure of confidential information by a physician.<sup>174</sup> Unlike the disclosure and false

<sup>169</sup> Ibid., Comment a.

<sup>170</sup> Ibid., Comment b.

<sup>171</sup> Ibid., Comment a, Illustration 2.

<sup>172</sup> RESTATEMENT (SECOND) OF TORTS § 652E(a) (1977).

<sup>173</sup> Joseph Hixson, "New Seeing-Eye Machines . . . Look Inside Your Body, Can Save Your Life," *Vogue* (July 1983), 238.

<sup>&</sup>lt;sup>174</sup> McCormick v. England, 494 S.E.2d 431 (S.C. Ct. App. 1997); Biddle v. Warren General Hosp., 715 N.E.2d 518 (Ohio 1999).

light torts, the common law breach of confidentiality tort generally does not require publicity, just an unauthorized disclosure. The tort also does not require the information disclosed to be highly offensive to a reasonable person. Thus, a neurologist who discloses a patient's fMRI scan to a third party without the patient's authorization may be subject to liability if the patient can prove damages. The burden would be on the patient to prove that the physician lacked the patient's authorization and that another state or federal law did not permit or require the disclosure.

The common law disclosure and false light torts thus offer an additional source of confidentiality protections to patients and research subjects whose providers and scientists make unauthorized disclosures of functional neuroimaging information. However, the torts only apply when a patient or research subject can prove widespread dissemination of a highly offensive matter that is not of legitimate public concern, or widespread dissemination of a false light that would be highly offensive to a reasonable person, respectively. In situations involving a one-time unauthorized or accidental disclosure of functional neuroimaging information by a provider or scientist, the patient or research subject would have difficulty proving the widespread dissemination element unless the information ultimately was published in a newspaper or similar media. The common law breach of confidentiality tort, usually applied in the context of physicianpatient relationships, could be argued to apply to the scientist-research subject relationship. Breach of all three common law torts could result in a court awarding the injured patient or research subject an injunction, preventing future unauthorized disclosures of neuroimaging information, as well as money damages for those plaintiffs who can prove actual damages, such as loss of future wages or lost health insurance coverage.

#### **SUMMARY**

A number of ethical and legal principles potentially apply to protect the confidentiality of functional magnetic resonance imaging information. All physicians

and scientists have an ethical duty to maintain the confidentiality of medical and study records in their possession. The Common Rule applies to many, but not all, investigators who conduct fMRI studies, but its three confidentiality provisions provide very little guidance for investigators and IRBs regarding how to protect functional neuroimaging information. The Privacy Rule provides significantly more guidance regarding when covered entities are permitted to use and disclose protected functional neuroimaging information. However, the Privacy Rule does not apply to all scientists and may not protect social information that does not rise to the level of health information. In addition, the Privacy Rule permits covered providers and scientists to breach confidentiality in numerous situations. State confidentiality laws, which vary from jurisdiction to jurisdiction, also do not regulate many non-provider scientists and may not protect social information. Constitutional law recognizes a limited interest in the confidentiality of health information, but so far that interest has not been strong enough to outweigh contrary state interests. The common law disclosure, false light, and breach of confidentiality torts have some applicability in the functional neuroimaging context. If obtained before research commences and upheld by the courts, certificates of confidentiality have the potential to fill some of the gaps created by the Privacy Rule and state confidentiality laws.

Advances in fMRI thus raise a number of confidentiality issues. Does the Common Rule adequately protect the confidentiality of neuroimaging information in the possession of scientists? Do the Privacy Rule and analogous state laws protect social information created and maintained by non-provider scientists? Can certificates of confidentiality fill the gaps created by the Privacy Rule and analogous state laws? If not, should Congress or state legislatures enact new laws providing heightened confidentiality protections for neuroimaging information? If so, how would such laws define the neuroimaging information to be protected?<sup>175</sup> How would those state laws reconcile such

<sup>175</sup> Henry T. Greely, "Prediction, Litigation, Privacy, and Property: Some Possible Legal and Social Implications of Advances in Neuroscience," in Brent Garland, ed., *Neuroscience and the Law:* 

heightened protections with other laws that allow the disclosure of confidential information without authorization for certain public policy purposes?<sup>176</sup> Would heightened confidentiality protections for neuroimaging information suggest that all neuroimaging information is sensitive or stigmatizing, even though it may not be?<sup>177</sup> Finally, what lessons can we learn from federal and state efforts to establish heightened confidentiality protections for genetic information?<sup>178</sup> These questions are addressed in Chapter 6.

Brain, Mind, and the Scales of Justice (New York: Dana Press, 2004), 144-45 (identifying five arguments against applying special confidentiality protections to neuroimaging information).

<sup>&</sup>lt;sup>176</sup> Ibid.

<sup>177</sup> Ibid., 144.

<sup>178</sup> Judy Illes and Eric Racine, "Imaging or Imagining? A Neuroethics Challenge Informed by Genetics," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 10-12; Benjamin S. Wilfond and Vardit Ravitsky, "On the Proliferation of Bioethics Sub-Disciplines: Do We Really Need 'Genethics' and 'Neuroethics'?" *American Journal of Bioethics* 5, no. 2 (2005): 20-21; Lynette Reid and Françoise Baylis, "Brains, Genes, and the Making of the Self," *American Journal of Bioethics* 5, no. 2 (2005): 22-23; Hubert Doucet, "Imagining a Neuroethics Which Would Go Further Than Genethics," *American Journal of Bioethics* 5, no. 2 (2005): 29-31.

## **CHAPTER 5: THE PRIVACY IMPLICATIONS OF FMRI**

Chapter 4 examined health care providers' and scientists' duty of confidentiality, including their ethical and legal obligation to prevent the unauthorized disclosure of functional neuroimaging information that was appropriately gathered in the clinical and research settings. The focus of this chapter is privacy, or the interest of individuals in avoiding unwanted intrusions, including the unauthorized or inappropriate gathering of their functional neuroimaging information. This chapter is structured according to the different contexts in which neurological privacy intrusions possibly could occur, including the clinical, research, employment, insurance, education, evidence, government, and private contexts.

### THE CLINICAL AND RESEARCH CONTEXTS

When a patient or research subject participates in treatment or a research study that involves functional neuroimaging, the confidentiality concerns discussed in Chapter 4 include the possibility that the physician or investigator could make an unauthorized disclosure of the neuroimaging information to a third party, such as an employer, an insurance company, a pharmaceutical company, or a marketing company. Privacy concerns also exist in the clinical and research settings. For example, if a research subject consents to a neuromarketing study the stated purpose of which is to test whether a particular automobile design activates the part of the brain known to be related to attention and interest, but the investigator also discovers that the subject has a brain tumor or interprets the subject's fMRI scan as revealing that the subject has a particular mental health condition, the subject arguably had a privacy interest in avoiding the unwanted intrusions into her physical and mental health conditions. After all, she only consented to have her brain studied to determine whether she found the automobile appealing.

The potential for neuroscience (or pseudoscience) to intrude on the privacy of patients and research subjects dates back almost two centuries. Practicing phrenologists

frequently "discovered" things that their subjects may have preferred to keep private, such as the complete lack of conscience in an individual later identified as a murderer, or Mark Twain's total absence of humor or his serious, tragic side. Functional MRI research already has revealed incidental findings such as arteriovenous malformations, brain tumors, and developmental abnormalities, and Chapter 2 suggests that fMRI has the potential to reveal additional information about an individual's character, personality, love interests, state of honesty, and physical and mental health. The question thus becomes how health care providers and scientists can protect the privacy of patients and research subjects who consent to functional neuroimaging.

Like confidentiality, privacy concerns vary by research type and context, and procedures designed to protect the privacy of patients and research subjects in one setting may not be sufficient in the functional neuroimaging setting. Factors such as culture, ethnicity, age, socioeconomic status, gender, locale, the nature and context of the research, and the social and political environment affect individuals' sense of privacy differently, providers and scientists cannot assume that each patient or research subject will regard the same things as private. As an illustration, some patients and research subjects freely share their sexual experiences with their providers and investigators, while a request for information regarding sexual practices may be offensive to others. Depending on the individual and the information involved, breaches of privacy in the clinical and research contexts can result in psychological harm, such as worry, irritation,

<sup>&</sup>lt;sup>1</sup> Madeleine B. Stern, *Heads and Headlines: The Phrenological Fowlers* (Norman: University of Oklahoma Press, 1971), 18.

<sup>&</sup>lt;sup>2</sup> Madeleine B. Stern, A Phrenological Dictionary of Nineteenth-Century Americans (Westport, Conn.: Greenwood Press, 1982), xix.

<sup>&</sup>lt;sup>3</sup> Illes et al., "Discovery and Disclosure of Incidental Findings in Neuroimaging Research," *Journal of Magnetic Resonance Imaging* 20, no. 5 (November 2004): 743.

<sup>&</sup>lt;sup>4</sup> National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants* (Bethesda: National Bioethics Advisory Commission, 2001), 105, http://www.georgetown.edu/research/nrcbl/nbac/human/oversumm.html (accessed February 16, 2006).

<sup>&</sup>lt;sup>5</sup> Ibid.

fear, embarrassment, and self-doubt; social harm, such as stigmatization; economic harm, such as unemployment or loss of benefits; and legal harm, such as arrest or conviction of a crime.<sup>6</sup>

Respecting privacy in the functional neuroimaging context thus requires more than obtaining consent to access and use neuroimaging information.<sup>7</sup> To respect privacy, providers, investigators, and IRBs must tailor privacy protections to the specific circumstances and methods used in each specific research study. Physicians and investigators must explain the privacy implications of their research and provide the opportunity for patients and research subjects to control, limit, or refuse access to their neuroimaging information, as appropriate.8 The primary and secondary sources of privacy identified in Chapter 3 recognize this principle generally, although they do not offer specific guidance regarding how privacy should be respected in the neuroimaging context. Privacy guidelines offered by other disciplines, including anthropology, psychology, and oral history, can be instructive.9 The Code of Ethics of the American Anthropological Association (AAA) recites by now what appears to be a basic privacy right: "Anthropological researchers must do everything in their power to ensure that their research does not harm the . . . privacy of the people with whom they work, conduct research, or perform other professional activities."10 Given the different types of anthropological research and the difficulty of establishing a one-size-fits-all solution to privacy, the AAA recommends that anthropological researchers carefully and respectfully

<sup>&</sup>lt;sup>6</sup> Ibid., 105-06.

<sup>&</sup>lt;sup>7</sup> Ibid.; Donald Kennedy, "Neuroimaging: Revolutionary Research Tool or a Post-Modern Phrenology?" *American Journal of Bioethics* 5, no. 2 (March-April 2005): 19 ("The medical relationship would provide the usual privacy protections, but treating physicians would incur additional ethical obligations with respect to informing patients about the technique and its limitations.").

<sup>&</sup>lt;sup>8</sup> National Bioethics Advisory Commission, Ethical and Policy Issues, 105-06.

<sup>&</sup>lt;sup>9</sup> Ibid., 106.

<sup>&</sup>lt;sup>10</sup> American Anthropological Association, *Code of Ethics* (Arlington, Va.: American Anthropological Association, 1998), § III(A)(1), http://www.aaanet.org/committees/ethics/ethicscode.pdf (accessed February 16, 2006).

negotiate the limits of each research relationship.<sup>11</sup> A similar negotiation approach could be applied in the clinical and research contexts in which fMRI is used.

For example, providers and scientists could clarify, as part of the informed consent conversation, the possibility of the discovery of unanticipated information, as well as the different classes of information that have been discovered in the past, including arteriovenous malformations, brain tumors, developmental abnormalities. Other types of health information, social information, and thought processes that could be revealed by fMRI could be described as accurately as then possible. The possibility of an inaccurate interpretation, and the possibility that such interpretation could mislead third parties who rely on the interpretation to make decisions, also could be disclosed to the subject.<sup>12</sup> The subject then could be asked to consider whether she would be comfortable authorizing access to this information as part of treatment or the research protocol, perhaps with limitations on the subsequent use and disclosure of the information, or whether she would prefer to keep these pieces of information to herself, in which case she could elect not to participate in the research. Although these procedures will not eliminate the discovery of incidental findings, they allow individuals to control access to their neuroimaging information and may lessen the chance that a provider or investigator will intrude on a particular individual's sense of neurological privacy.

#### THE EMPLOYMENT CONTEXT

Franz Josef Gall believed in the early nineteenth century that his brain maps could be used to advise employers regarding individuals with desirable qualities, <sup>13</sup> and Horace Greeley was so convinced of the usefulness of phrenology in the employment context

<sup>&</sup>lt;sup>11</sup> Ibid., § III(5).

<sup>&</sup>lt;sup>12</sup> Kennedy, "Neuroimaging," 19 ("The requirement for privacy expands in importance as doubt about the accuracy of the information rises. The potential for misleading subjects or others adds to the burden of truly informed consent.").

<sup>&</sup>lt;sup>13</sup> John D. Davies, *Phrenology: Fad and Science; A 19th-Century American Crusade* (New Haven: Yale University Press, 1955), 8.

that he argued in 1852 that railroad accidents could be reduced if trainmen were selected "by the aid of phrenology, and not otherwise." A handful of nineteenth-century American employers, apparently in agreement with Gall and Greeley, required applicants to submit to phrenological examinations as part of the hiring process. 15

There has been considerable speculation that modern employers will similarly require functional neuroimaging examinations to probe the minds of applicants and employees. Prominent bioethicists have even provided specific, futuristic examples of how fMRI might be used by employers. In one example, an airline requires one of its pilots to undergo a routine physical examination that includes a functional magnetic resonance imaging evaluation. During the evaluation, the pilot is asked to view a series of images, including the inside of a 747 cockpit, a target seen through a rifle's scope, and a photograph of Bill Clinton. The technician forwards the results to the pilot's employer. When the pilot reports for work the next day, her supervisor and an agent from the Federal Aviation Administration (FAA) inform her that her brain images show that she might develop schizophrenia and that she has a surprising familiarity with assault rifles. The FAA agent revokes her pilot's license and her supervisor promptly fires her. A second example refers to fMRI studies conducted at Emory University showing that women who undertake cooperative acts during Prisoner's Dilemma trials experience

<sup>&</sup>lt;sup>14</sup> Andrew E. Norman, introduction to *Phrenology: A Practical Guide to Your Head* (New York: Chelsea House Publishers, 1969), x.

<sup>15</sup> Davies, Phrenology, 39; Stern, Phrenological Dictionary, x.

Microelectronics and Medical Imaging Are Bringing Us Closer to a World Where Mind Reading Is Possible and Blindness Banished – But We May Not Want to Live There," Spectrum Online (June 2003), http://www.spectrum.ieee.org/WEBONLY/publicfeature/jun03/bio.html (accessed August 25, 2005).

<sup>17</sup> Ibid.

<sup>&</sup>lt;sup>18</sup> The Prisoner's Dilemma examines cooperation in a two-player game. In the Prisoner's Dilemma, both players win when both players cooperate. However, if only one player cooperates, the defector wins more. Jonathan D. Moreno, "Neuroethics: An Agenda for Neuroscience and Society," *Nature Reviews Neuroscience* 4, no. 2 (February 1, 2003): 152.

activation of dopamine rich neurons.<sup>19</sup> The speculation is that employers will use this information to recruit applicants for employment who experience more or less pleasure from cooperation, depending on the requirements of the job.<sup>20</sup> An *Economist* cover story similarly asked readers to "[s]uppose that job-recruiting agencies were fitted with fMRI machines (unlikely at the moment, given their expense, but not unimaginable) . . . "<sup>21</sup> The speculation goes on:

Brain-imaging lie-detection will most likely be used where absolute reliability is not needed and where a predominantly naïve population is under scrutiny. This includes pre-employment and employment-related testing for sensitive positions, or for informal investigative purposes in various employment and institutional contexts. Here the technology is likely to supplement or take the place of written honesty tests and polygraphy.<sup>22</sup>

The issue, then, is whether employers can and should be able to use fMRI in employment, including hiring, firing, promotion, and demotion decisions, or whether fMRI violates applicants and employees' interest in avoiding unwanted neurological intrusions.

#### The HIPAA Privacy Rule

Because of its name, many individuals believe that the HIPAA Privacy Rule is a source of privacy rights for employees and job applicants. Although the Privacy Rule attempts to protect the *confidentiality* of individuals whose brains have been scanned in some clinical and research settings (by requiring an individual to sign a prior written authorization before the covered entity can disclose the individual's neuroimaging

<sup>&</sup>lt;sup>19</sup> Ibid.; James K. Rilling, "A Neural Basis for Social Cooperation," *Neuron* 35 (July 18, 2002): 395.

<sup>&</sup>lt;sup>20</sup> Moreno, "Neuroethics," 152.

<sup>&</sup>lt;sup>21</sup> "The Ethics of Brain Science: Open Your Mind," *Economist* (May 23, 2002), http://www.economist.com/science/PrinterFriendly.cfm?Story\_ID=1143317 (accessed February 16, 2006).

<sup>&</sup>lt;sup>22</sup> Ronald M. Green, "Spy Versus Spy," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 54.

information to an employer or insurer), the Privacy Rule does not really protect the *privacy* of individuals whose brains have been scanned. Stated another way, the Privacy Rule does not prohibit non-covered entities, including employers and insurers, from requiring an individual to sign an authorization form releasing neuroimaging information as a condition of employment or insurance coverage.<sup>23</sup> Notwithstanding its name, the Privacy Rule thus offers few privacy protections for employees and job applicants.

#### The Americans with Disabilities Act

A second potential source of privacy rights for employees and job applicants is the federal Americans with Disabilities Act (ADA). Title I of the ADA prohibits certain employers from discriminating on the basis of disability against qualified individuals with disabilities.<sup>24</sup> As one way of preventing disability discrimination, Title I regulates employers' use of qualification standards, employment tests and other selection criteria that screen out or tend to screen out individuals with disabilities on the basis of such disabilities (the screening provisions).<sup>25</sup> Equal Employment Opportunity Commission (EEOC) regulations interpreting Title I define *disability* to include physical and mental impairments, including neurological disorders, mental illnesses, and specific learning disabilities, that substantially limit one or more major life activities of an individual.<sup>26</sup> EEOC regulations also clarify, however, that pedophilia, pyromania, kleptomania, compulsive gambling, homosexuality, bisexuality, transvestism, transsexualism, exhibitionism, and voyeurism, as well as certain other "physical, psychological, environmental, cultural, and economic characteristics," including "common personality

<sup>23 45</sup> C.F.R. § 164.508(b)(4)(ii) and (iii) (2005) (permitting health insurers and employers to condition health insurance coverage and employment on the execution of an authorization form for the disclosure of protected health information); Mark Rothstein, "Research Privacy under HIPAA and the Common Rule," *Journal of Law, Medicine and Ethics* 33 (Spring 2005): 155.

<sup>&</sup>lt;sup>24</sup> 29 C.F.R. § 1630.4 (2005).

<sup>&</sup>lt;sup>25</sup> 42 U.S.C. § 12112(b)(6) (2005); 29 C.F.R. § 1630.10 (2005).

<sup>&</sup>lt;sup>26</sup> 29 C.F.R. § 1630.2(g) (2005).

traits such as poor judgment or quick temper," do not constitute disabilities protected by the ADA.<sup>27</sup>

Applying these screening provisions to the functional neuroimaging context yields interesting results. The ADA's screening provisions would regulate a covered employer's use of fMRI in an attempt to screen out individuals who have depression, schizophrenia, or bipolar disorder if such conditions substantially limit a major life activity of the individuals tested. On the other hand, the screening provisions would not regulate employer attempts to screen out individuals based on fMRI "findings" of pedophilia, compulsive gambling, or homosexuality, because these qualities do not constitute impairments.

Title I of the ADA also regulates the conduct and timing of medical examinations and related inquiries.<sup>28</sup> A medical examination is defined as a procedure or test that seeks information about an individual's health or physical or mental impairments.<sup>29</sup> Although a number of factors are relevant in determining whether a procedure or test is a medical examination, the EEOC clarifies that the term includes tests that provide evidence leading to the identification of conditions listed in the American Psychiatric Association's most recent Diagnostic and Statistical Manual of Mental Disorders, including anxiety, depression, and certain compulsive disorders – conditions frequently studied by fMRI.<sup>30</sup> The EEOC also clarifies, however, that psychological tests designed and used only to measure honesty, tastes, and habits are not medical examinations.<sup>31</sup>

<sup>&</sup>lt;sup>27</sup> Ibid. § 1630.3(d)(1) (pedophilia not disability); ibid. § 1630.3(d)(2) (compulsive gambling not disability); ibid. § 1630.3(e) (homosexuality not impairment so not disability); Appendix to 29 C.F.R. Part 1630 (identifying additional "characteristics" that do not constitute disabilities under the ADA).

<sup>&</sup>lt;sup>28</sup> 42 U.S.C. § 12112(d) (2005); 29 C.F.R. §§ 1630.13-.14 (2005).

<sup>&</sup>lt;sup>29</sup> Equal Employment Opportunity Commission, *Enforcement Guidance: Preemployment Disability-Related Questions and Medical Examinations*, Notice No. 915.002 (October 10, 1995), http://www.eeoc.gov/policy/docs/preemp.html (accessed February 16, 2006).

<sup>&</sup>lt;sup>30</sup> Ibid.

<sup>31</sup> Ibid.

A determination of how the ADA's medical examination and inquiry provisions apply to an employer's use of a particular fMRI test will require application of the factors and interpretations set forth by the EEOC in its enforcement guidance. A likely interpretation is that the ADA would regulate the conduct and timing of fMRIs that are used to diagnose or measure anxiety, depression, and certain compulsive disorders, but that the ADA would not regulate the conduct or timing of fMRIs designed to identify or measure honesty or deception, tastes and preferences, or daily habits.

How stringently the ADA regulates employers' use of medical examinations depends on whether the examination is given during the pre-employment, post-offer, or employment stage. The ADA generally prohibits an employer from using a medical examination at the pre-employment stage to inquire or determine whether a particular individual has a disability, or the nature or severity of such disability.<sup>32</sup> However, after an offer of employment has been made but before the applicant begins employment (at the post-offer stage), a covered employer is permitted to require a medical examination and to condition an offer of employment on the results of the examination if all entering employees in the same job category are subjected to the same examination.<sup>33</sup> Medical examinations conducted at the post-offer stage do not have to be job-related or consistent with business necessity;<sup>34</sup> however, if certain criteria are used to screen out an individual with one or more disabilities as a result of the examination, the exclusionary criteria must be job-related and consistent with business necessity, and the individual must not be able to perform the essential job functions even with reasonable accommodation.<sup>35</sup> The terms "job-related" and "consistent with business necessity" are interpreted in accordance with the Civil Rights Act of 1964 and the Rehabilitation Act of 1973 and generally mean that the criteria must be related to the specific job and that applicants are eliminated from

<sup>&</sup>lt;sup>32</sup> 29 C.F.R. § 1630.13(a) (2005).

<sup>&</sup>lt;sup>33</sup> Ibid., § 1630.14(b).

<sup>&</sup>lt;sup>34</sup> Ibid., § 1630.14(b)(3).

<sup>&</sup>lt;sup>35</sup> Ibid., § 1630.14(b)(3).

consideration only when they are unable to perform the essential functions of the job.<sup>36</sup> These post-offer provisions were designed to recognize that, in many industries, such as air transportation or construction, applicants for certain positions are chosen on the basis of many factors including physical and psychological criteria, some of which may be identified as a result of post-offer medical examinations given prior to entry on duty.<sup>37</sup> Under the post-offer provisions, "[o]nly those employees who meet the employer's physical and psychological criteria for the job, with or without reasonable accommodation, will be qualified to receive confirmed offers of employment and begin working."<sup>38</sup>

Finally, the ADA establishes requirements that apply to medical examinations given during the employment stage. An employer can require a medical examination of a current employee, but only if the medical examination is job-related and consistent with business necessity.<sup>39</sup> For example, a covered employer can require a fitness-for-duty examination when there is a need to determine whether an employee is still able to perform the essential functions of her job.<sup>40</sup> Fitness-for-duty examinations are commonly required by employers of bus and truck drivers, airline pilots, and other air transportation personnel.

Applying these provisions in the context of functional neuroimaging can lead to unique results. The ADA would prohibit a covered employer from requiring an fMRI at the pre-employment stage to determine whether an individual suffers from depression,

<sup>&</sup>lt;sup>36</sup> Appendix to 29 C.F.R. Part 1630.

<sup>&</sup>lt;sup>37</sup> Ibid.

<sup>&</sup>lt;sup>38</sup> The EEOC provides several illustrations of this rule. For example, if an employer makes a conditional offer of employment to an applicant, and an essential function of the job is to be available to work every day for the next three months, but a medical examination given at the post-offer stage reveals that the applicant has a disabling impairment that will require treatment that will render the applicant unable to work for a portion of the three month period, the employer would be able to withdraw the employment offer without violating the ADA. Ibid.

<sup>&</sup>lt;sup>39</sup> 29 C.F.R. § 1630.14(c) (2005).

<sup>&</sup>lt;sup>40</sup> Appendix to 29 C.F.R. Part 1630.

although the ADA would not regulate the use of an fMRI to determine honesty or deception at the pre-employment stage because a test to detect honesty or deception is not considered a medical examination. At the post-offer and employment stages, the permissibility of a particular fMRI examination will depend on whether any exclusionary criteria or the examination itself are considered job-related and consistent with business necessity, respectively. For example, it may be job-related to use fMRI to test a fighter pilot's visual cortex response to certain stimuli, but it may not be job-related to use the same test for telephone operators and other positions that successfully can be performed by individuals who have visual impairments.

In summary, Title I of the ADA does provide some privacy protections for job applicants and current employees who wish to keep their neuroimaging information private. How these privacy protections apply in the context of functional neuroimaging depends on (1) whether the employer's proposed functional magnetic resonance imaging evaluation falls within the definition of a medical examination, (2) the stage (preemployment, post-offer, or employment) at which the employer requires the examination, and (3) whether the examination or any exclusionary criteria are job-related and consistent with business necessity.

### Title VII of the Civil Rights Act

Title VII of the Civil Rights Act of 1964 is another potential, although extremely limited, source of neurological privacy protections for employees and applicants. Title VII was enacted to eliminate discrimination in employment on the basis of race, color, religion, sex, or national origin (the enumerated factors),<sup>41</sup> although its principle of nondiscrimination later was extended to other classifications, such as age<sup>42</sup> and disability.<sup>43</sup> Applicable to all private employers with 15 or more employees, as well as

<sup>&</sup>lt;sup>41</sup> 42 U.S.C. § 2000e et seq. (2005).

<sup>&</sup>lt;sup>42</sup> Age Discrimination in Employment Act of 1967, Pub. L. No. 90-202, codified at 29 U.S.C. §§ 621-634 (2005).

<sup>&</sup>lt;sup>43</sup> See text accompanying notes 24-40 in this chapter.

federal, state, and local government employers, the Act makes it unlawful for a covered employer to fail or refuse to hire or to discharge an individual, or otherwise to discriminate against any individual with respect to her compensation, terms, conditions, or privileges of employment, because of an enumerated factor.<sup>44</sup>

That fMRI would be used by an employer to screen applicants or current employees for race, color, religion, sex, or national origin is nonsensical; if information regarding an enumerated factor is not available from a personal statement made by the applicant or employee ("I am African-American"), employers usually guess at the factors based on the existence of other factors, such as the appearance of the individual (an employee who has long hair and wears dresses) or the individual's name (Juan Trevino). Employers most certainly would not incur the expense associated with devising and subsidizing an fMRI test that could attempt to determine the existence of an enumerated factor. It is worth noting that the word "sex" in Title VII has been interpreted not to include the broader category of "sexual orientation."<sup>45</sup> Title VII thus would not prohibit an employer who tried to use fMRI to screen out applicants or employees who had certain sexual orientations or preferences (although at least 12 states, the District of Columbia, and approximately 50 cities have enacted laws prohibiting discrimination in private employment on the basis of sexual orientation and transgenderism).<sup>46</sup>

Although employers likely would not use fMRI in a manner that could violate Title VII, it is possible that applicants and employees may want to use fMRI as evidence of a particular employer's intent to discriminate based on an enumerated factor, such as race, which is not unthinkable in light of the popularity of the racial evaluation studies discussed in Chapter 2. Whether a plaintiff applicant or employee could introduce fMRI

<sup>&</sup>lt;sup>44</sup> Mark A. Rothstein and Lance Liebman, *Employment Law: Cases and Materials*, 5<sup>th</sup> ed. (New York: Foundation Press, 2003), 258.

<sup>&</sup>lt;sup>45</sup> DeSantis v. Pacific Telephone & Telegraph Co., 608 F.2d 327 (9<sup>th</sup> Cir. 1979).

<sup>&</sup>lt;sup>46</sup> Rothstein and Liebman, Employment Law, 416.

as evidence of a defendant's bias based on race, color, religion, sex, or national origin is addressed below.

### The Employee Polygraph Protection Act

A fourth potential source of protection for job applicants and employees who wish to keep their neuroimaging information private is the federal Employee Polygraph Protection Act (EPPA). The EPPA prohibits certain employers from requiring employees to submit to lie-detector tests,<sup>47</sup> defined to include polygraphs, deceptographs, voice stress analyzers, psychological stress evaluators, and "any other similar device . . . that is used, or the results of which are used, for the purpose of rendering a diagnostic opinion regarding the honesty or dishonesty of an individual."<sup>48</sup> The EPPA could be interpreted to prohibit employers from requiring functional neuroimaging examinations that could form the basis of an opinion regarding an individual's dishonesty, such as the deception tests discussed in Chapter 2.

However, the EPPA has a number of exceptions that almost swallow its general prohibition. The EPPA does not apply to the United States government, any State or local government, or any political subdivision of a State or local government, when it is acting as an employer.<sup>49</sup> The EPPA also does not prohibit the federal government from requiring a lie detector test of any employee, expert, or consultant under contract with, or assigned or detailed to, the Department of Defense, the Department of Energy, the National Security Agency, the Defense Intelligence Agency, the National Geospatial-Intelligence Agency, the Central Intelligence Agency, or the Federal Bureau of Investigation.<sup>50</sup> Finally, the EPPA does not prohibit the use of polygraph tests on prospective employees by any private employer whose primary business purpose involves the provision of armored car personnel; personnel engaged in the design,

<sup>&</sup>lt;sup>47</sup> 29 U.S.C. § 2002(1) (2005).

<sup>&</sup>lt;sup>48</sup> Ibid., § 2001(3).

<sup>&</sup>lt;sup>49</sup> Ibid., § 2006(a).

<sup>&</sup>lt;sup>50</sup> Ibid., § 2006(b).

installation, or maintenance of security alarm systems; or other uniformed or plainclothes security personnel whose functions include the protection of certain facilities relating to electric or nuclear power, the public water supply, radioactive or other toxic waste material, or public transportation.<sup>51</sup> The EPPA thus provides some protection for non-public sector employees who wish to keep the honesty or deceptiveness of their thoughts to themselves. However, the EPAA provides few privacy protections for federal, state, and local government employees, as well as applicants and employees that provide certain security services in the private sector. The companies that are developing fMRI lie detectors – No Lie MRI and Cephos – plan to take advantage of the EPPA's incomplete privacy protections by marketing their fMRI lie detectors to federal, state, and local law enforcement agencies.<sup>52</sup>

In summary, the ADA and the EPPA provide some protections for employees and applicants who wish to maintain the privacy of their neuroimaging information. However, comprehensive privacy protections for neuroimaging information in the employment context do not exist.

### THE INSURANCE CONTEXT

In genetics, one frequently discussed issue is the potential for genetic information to be gathered by health and life insurance companies and used in the underwriting decision making process. The question is not speculative given that a 1992-1993 pilot study documented 206 instances of discrimination, including loss of insurance coverage and ineligibility for benefits, as a result of insurers' access to genetic information.<sup>53</sup> Similar issues arise in the context of neuroimaging. Some speculate that health and life

<sup>&</sup>lt;sup>51</sup> Ibid., § 2006(e).

<sup>&</sup>lt;sup>52</sup> Steve Silberman, "Don't Even Think About Lying: How Brain Scans Are Reinventing the Science of Lie Detection," *Wired*, January 2006, http://www.wired.com/wired/archive/14.01/lying\_pr.html (accessed February 16, 2006).

<sup>53</sup> Janlori Goldman and Angela Choy, "Privacy and Confidentiality in Health Research," in National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, vol. 2 (Bethesda, Md.: National Bioethics Advisory Commission, 2001), C-10.

insurance companies will want to require applicants for insurance to submit to structural magnetic resonance imaging examinations to determine the existence of brain tumors or other medical conditions that might require coverage in the near future.<sup>54</sup> Others speculate that car insurance companies might require fMRI to predict drivers' propensity to violence, aggression, or conscientiousness.<sup>55</sup>

According to one count, approximately forty-five states restrict the use of genetic information by health insurers, and approximately eleven states restrict the use of genetic information by life insurers.<sup>56</sup> No similar, current laws or regulations restrict the use of neuroimaging information by health, life, or car insurers. In addition, the HIPAA Privacy Rule expressly permits a health insurance company to condition health insurance coverage on an applicant's execution of an authorization form for the disclosure of her protected health information.<sup>57</sup> Comprehensive privacy protections for neuroimaging information thus do not exist in the insurance context.

### THE EDUCATION CONTEXT

Primary and secondary schools, as well as undergraduate and graduate institutions, frequently use standardized tests to predict students' success. The issue becomes whether educational institutions also will want to gather, obtain, or use functional neuroimaging information in an attempt to identify applicants' cognitive abilities, predict their success in school, grant or deny them admission, or to "help"

<sup>&</sup>lt;sup>54</sup> Turhan Canli and Zenab Amin, "Neuroimaging of Emotion and Personality: Scientific Evidence and Ethical Considerations," *Brain and Cognition* 50, no. 3 (December 2002): 424.

<sup>55</sup> Helen Phillips, "Private Thoughts, Public Property," New Scientist 183, no. 2458 (July 31, 2004), 38.

<sup>&</sup>lt;sup>56</sup> Henry T. Greely, "Some Possible Legal and Social Implications of Advances in Neuroscience," in *Neuroscience and the Law: Brain, Mind, and the Scales of Justice*, ed. Brent Garland (New York: Dana Press, 2004), 124-25.

<sup>&</sup>lt;sup>57</sup> 45 C.F.R. § 164.508(b)(4)(ii) and (iii) (2005) (permitting health insurers and employers to condition health insurance coverage and employment on the execution of an authorization form for the disclosure of protected health information); Rothstein, "Research Privacy under HIPAA and the Common Rule," 155.

current students who have dyslexia and other conditions by ensuring that they obtain tutoring or other necessary assistance.<sup>58</sup>

Although the federal Family Educational Rights and Privacy Act (FERPA) establishes strong confidentiality protections for many students' education records (by prohibiting schools that receive funds from the United States Department of Education from making unauthorized disclosures of student records),<sup>59</sup> FERPA does not provide any privacy protections for current students and individuals who are applying for admission to an educational institution. Stated another way, FERPA does not prevent an educational institution from requiring a student or applicant to submit to an fMRI examination or to execute an authorization form releasing to the institution existing fMRI scans or related records.

The Civil Rights Act of 1964 also contains antidiscrimination provisions that apply in the educational setting. Under Titles IV and VI of the Civil Rights Act, educational institutions that receive federal financial assistance, including public schools and universities, are prohibited from discriminating against students or applicants on the basis of race, color or national origin.<sup>60</sup> Even if fMRI could be used in such a manner, educational institutions almost certainly would not incur the expense of using fMRI to identify an enumerated factor. However, and as discussed in more detail immediately below, an applicant who is denied admission to a covered educational institution might attempt to use fMRI as evidence of bias based on race, color, or national origin, perhaps in reliance on the research of Elizabeth Phelps and her colleagues. In summary, though,

<sup>58</sup> Kimberly Sheridan, Elena Zinchenko, and Howard Gardner, "Neuroethics in Education," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 265-75; Henry T. Greely, "The Social Effects of Advances in Neuroscience: Legal Problems, Legal Perspectives," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 248; Greely, "Prediction, Litigation, Privacy, and Property," 123.

<sup>&</sup>lt;sup>59</sup> 20 U.S.C. § 1232g (2005); 34 C.F.R. Part 99 (2005).

<sup>60</sup> Civil Rights Act of 1964, Titles IV and VI, in Pub. L. No. 88-352 (July 2, 1964).

few protections exist for students and applicants for admission to educational institutions who wish to protect the privacy of their neuroimaging information.

### THE EVIDENTIARY CONTEXT

The use of head charts, brain maps, and brain images as courtroom evidence dates back at least to the 1830's, in a case involving two elementary school children from Durham, Maine. 61 After being teased by eight-year-old David Crawford, nine-year-old Major Mitchell first tried to drown Crawford, and then proceeded to stuff leaves into his mouth, strip him naked, tie him to a tree, and cut his testicles with a piece of tin.62 In preparing Mitchell's defense, his attorney learned that when Mitchell was a baby, he had fallen on his head from a high chest.<sup>63</sup> At Mitchell's criminal trial, a physician who had studied phrenology was permitted to testify that Mitchell had a pronounced depression on his skull due to his childhood injury and that the injury changed Mitchell's intellectual and moral character and promoted feelings of destructiveness, irritability, and exasperation.<sup>64</sup> A second examined Mitchell's mother head and concluded that she also had a faculty for destructiveness, similar to her son. Although Mitchell's defense attorney highlighted the testimony of the physician and the phrenologist in his closing arguments, the attorney general prosecuting the case disputed the value of the phrenological evidence.65 Mitchell ultimately was found guilty and sentenced to nine years of hard labor in state prison.66

North American litigants began using x-ray images as evidence in both criminal and civil cases within one year of Röntgen's famous discovery. The first Canadian case

<sup>&</sup>lt;sup>61</sup> Laurence Tancredi, *Hardwired Behavior: What Neuroscience Reveals about Morality* (New York: Cambridge Press, 2005), 155.

<sup>62</sup> Ibid.

<sup>63</sup> Ibid.

<sup>64</sup> Ibid.

<sup>65</sup> Ibid.

<sup>66</sup> Ibid.

to allow an x-ray image (showing a bullet in the leg) into evidence was a criminal case tried in Montreal in 1896,67 and the first American case to allow an x-ray image (showing an impacted femur fracture) into evidence was a civil medical malpractice case tried in Denver that same year.68 In its written opinion upholding the admission of the femur x-ray into evidence, the Denver court noted that, "Modern science has made it possible to look beneath the tissues of the human body . . . We believe it to be our duty in this case to be the first, if you please to so consider it, in admitting in evidence the process known and acknowledged as a determinate science."

The Denver court did not provide any explanation of how x-ray had become "known and acknowledged as a determinate science," or the standard that was to be used to determine whether the next imaging technology should be so considered. But images produced by subsequent neuroimaging techniques moved swiftly into the courtroom. In the early 1980s, John Hinckley successfully admitted into evidence a CT of his own, allegedly "shrunken," brain.<sup>70</sup> Rodney King admitted a structural MRI showing the brain damage that resulted from his beating by four white policemen in the early 1990s.<sup>71</sup>

The potential for fMRI to be admitted as evidence in civil and criminal cases of proof or lack of knowledge, deception, intent, and other thought processes, and the ethical, legal, and social issues raised thereby, has received significant attention in the neuroethics literature.<sup>72</sup> Some speculate that criminal prosecutors will attempt to use

<sup>&</sup>lt;sup>67</sup> Bettyann Holtzmann Kevles, *Naked to the Bone: Medical Imaging in the Twentieth Century* (New Brunswick, N.J.: Rutgers University Press, 1997), 30-31.

<sup>&</sup>lt;sup>68</sup> Ibid., 31.

<sup>69</sup> Ibid., 32n18.

<sup>&</sup>lt;sup>70</sup> Lincoln Caplan, *The Insanity Defense and the Trial of John W. Hinckley, Jr.* (Boston: D. R. Godine, 1984), 85; Kevles, *Naked to the Bone*, 169.

<sup>71</sup> Keyles, Naked to the Bone, 175.

<sup>72</sup> Stephen J. Morse, "Moral and Legal Responsibility in the New Neuroscience," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 47-49; Henry T. Greely, "The Social Effects of Advances in Neuroscience: Legal Problems, Legal Perspectives," in *Neuroethics: Defining the Issues in Theory, Practice, and Policy*, ed. Judy Illes (Oxford: Oxford University Press, 2006), 249-53; Paul Root Wolpe, Kenneth R. Foster, and Daniel D. Langleben,

fMRI to prove which individuals are guilty of crimes. Others speculate that criminal justice officers will want to use fMRI to help predict future behavior in order to make decisions relating to plea bargaining, sentencing, probation, and parole.<sup>73</sup> Still others wonder whether criminal defendants will attempt to use fMRI to prove their innocence. Perhaps civil plaintiffs and defendants will want to use fMRI to prove important aspects of their cases, such as whether a medical malpractice plaintiff actually perceived the enormous pain and suffering alleged, whether a defendant employer really intended to discriminate based on race, or whether a particular witness' memory is true or false.<sup>74</sup> Others emphasize the reliability hurdle that fMRI must cross before it can play a role in forensics.<sup>75</sup>

Here, my focus is the privacy aspects of evidence law. Stated another way, does the law of evidence provide any privacy protections for participants in civil and criminal litigation who do not wish for their neuroimaging information to be revealed in the courtroom? The law regarding the admissibility of polygraph evidence is helpful in answering this question.<sup>76</sup>

<sup>&</sup>quot;Emerging Neurotechnologies for Lie-Detection: Promises and Perils," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 46-47; Henry T. Greely, "Premarket Approval Regulation for Lie Detections: An Idea Whose Time May Be Coming," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 51; Stephen J. Morse, "New Neuroscience, Old Problems," in *Neuroscience and the Law: Brain, Mind, and the Scales of Justice*, ed. Brent Garland (New York: Dana Press, 2004), 157-98; Greely, "Prediction, Litigation, Privacy, and Property," 114-56; Olson, "Brain Scans Raise Privacy Concerns," *Science* 307, no. 5715 (March 11, 2005): 1549.

<sup>&</sup>lt;sup>73</sup> Brent Garland, *Neuroscience and the Law: Brain, Mind, and the Scales of Justice* (New York: Dana Press, 2004), 14; Greely, "Prediction, Litigation, Privacy, and Property," 120; Olson, "Brain Scans Raise Privacy Concerns," 1549; Martha J. Farah and Paul Root Wolpe, "Monitoring and Manipulating Brain Function: New Neuroscience Technologies and Their Ethical Implications," *Hastings Center Report* 34, no. 3 (May 2004): 38.

<sup>&</sup>lt;sup>74</sup> Greely, "Prediction, Litigation, Privacy, and Property," 120.

<sup>&</sup>lt;sup>75</sup> Donald Kennedy, "Neuroimaging: Revolutionary Research Tool or a Post-Modern Phrenology?" *American Journal of Bioethics* 5, no. 2 (March-April 2005): 19.

<sup>&</sup>lt;sup>76</sup> See generally David L. Faigman et al., *Science in the Law: Standards, Statistics, and Research Issues* (St. Paul, Minn.: West, 2002), 1-65.

The first landmark decision addressing the admissibility of polygraph-like evidence was the 1923 opinion in *Frye v. United States*, which addressed the admissibility of a systolic blood pressure test, an unsophisticated precursor to the modern polygraph.<sup>77</sup> The proffered blood pressure test was based on the theory that truth is spontaneous and comes without conscious effort, while the statement of a falsehood requires a conscious effort that is reflected by a change in an individual's blood pressure.<sup>78</sup> The *Frye* court refused to admit the blood pressure test into evidence, reasoning that the proponent of the evidence failed to show that the science involved was generally accepted in the relevant scientific community from which it emerged:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs. . . .

We think the systolic blood pressure deception test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made.<sup>79</sup>

The *Frye* test, also known as the "general acceptance" test, became the standard for determining the admissibility of scientific evidence for the next 70 years.<sup>80</sup> Almost every federal and state court that considered the admissibility of polygraph evidence during this

<sup>&</sup>lt;sup>77</sup> Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

<sup>&</sup>lt;sup>78</sup> Ibid., 1014.

<sup>&</sup>lt;sup>79</sup> Ibid.

<sup>&</sup>lt;sup>80</sup> Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 585 (1993) ("In the 70 years since its formulation in the *Frye* case, the 'general acceptance' test has been the dominant standard for determining the admissibility of novel scientific evidence at trial.").

time period denied its admission, a result that led many to conclude that polygraph examinations were simply "per se inadmissible" in court.

The United States Supreme Court replaced the *Frye* general acceptance test in 1993. In *Daubert v. Merrell Dow Pharmaceuticals*, the Court held that the proper inquiry concerning the admissibility of scientific evidence should be whether the proffered evidence is relevant and reliable.<sup>81</sup> Factors to be considered in determining whether evidence is relevant and reliable include (1) whether the theory or technique on which the testimony is based is capable of being tested, (2) whether the technique has a known rate of error in its application, (3) whether the theory or technique has been subjected to peer review and publication, (4) the level of acceptance in the relevant scientific community of the theory or technique, and (5) the extent to which there are standards to determine the acceptable use of the technique.<sup>82</sup> According to *Daubert*, "The inquiry . . . is a flexible one. . . . The focus . . . must be solely on principles and methodology, not on the conclusions that they generate."<sup>83</sup>

Following *Daubert*, federal and state courts began to reconsider the admissibility of polygraph evidence. Today, some jurisdictions continue to deny the admission of polygraph evidence, while others admit polygraph evidence in certain circumstances.<sup>84</sup> For example, the Fifth Circuit overturned its per se rule against admission of polygraph evidence in 1995,<sup>85</sup> and the State of New Mexico is usually referred to as having the most

<sup>&</sup>lt;sup>81</sup> Ibid., 595.

<sup>82</sup> Ibid., 593-95.

<sup>83</sup> Ibid., 594-95.

<sup>&</sup>lt;sup>84</sup> United States v. A & S Council Oil Co., 947 F.2d 1128, 1134n4 (4<sup>th</sup> Cir. 1991) ("Circuits that have not yet permitted evidence of polygraph results for any purpose are now the decided minority."); Lloyd C. Peeples, Stephen P. Bell, and T. Michael Guiffre, "Exculpatory Polygraphs in the Courtroom: How the Truth May Not Set You Free," Cumberland Law Review 28 (1997-1998), 86-87 (summarizing different jurisdictional responses to Daubert).

<sup>85</sup> United States v. Posado, 57 F.3d 428, 433 (5th Cir. 1995) ("After Daubert, a per se rule is not viable.").

liberal rules regarding the admissibility of polygraph<sup>86</sup> because its courts admit polygraph evidence in the same manner as other expert evidence.<sup>87</sup>

In 1998, the Supreme Court considered whether Military Rule of Evidence 707, which prohibited the use of polygraph evidence in all court martial proceedings, interfered with the defendant's constitutional right to present a defense under the Fifth and Sixth Amendments to the Constitution.<sup>88</sup> In *United States v. Scheffer*, a four-Justice plurality of the Court (Thomas, Rehnquist, Scalia, and Souter) upheld Rule 707.<sup>89</sup> A four-Justice concurrence (Kennedy, O'Connor, Ginsburg, Breyer) agreed with the result based on the continuing disagreement among experts and courts regarding the reliability of polygraphs, although they disagreed with a per se rule excluding polygraph evidence.<sup>90</sup> Justice Stevens authored the lone dissent, in which he argued that a per se rule excluding polygraph evidence should never exist.<sup>91</sup> *Scheffer* frequently is referenced for its upholding of a per se exclusion of polygraph evidence,<sup>92</sup> although a close reading of all three opinions shows that 5 of 9 Supreme Court Justices expressly disagreed with a per se rule. The combined effect of *Daubert* and *Scheffer* was to leave the issue of the admissibility of polygraph and other similar examinations alive in the lower courts.

<sup>86</sup> Greely, "Premarket Approval Regulation for Lie Detections," 51.

<sup>87</sup> State v. Dorsey, 539 P.2d 204 (N.M. 1975); New Mexico Rule of Evidence, Rule 11-707(C) (permitting the opinion of a polygraph examiner to be admitted as evidence as to the truthfulness of any person called as a witness if, in the discretion of the trial court judge, the examination was performed by a person qualified as an expert polygraph examiner and (1) the polygraph examination was conducted in accordance with the provisions of this rule, (2) the polygraph examination was quantitatively scored in a manner that is generally accepted as reliable by polygraph experts, (3) prior to conducting the polygraph examination the polygraph examiner was informed as to the examinee's background, health, education and other relevant information, (4) at least two relevant questions were asked during the examination, and (5) at least three charts were taken of the examinee).

<sup>88</sup> United States v. Scheffer, 523 U.S. 303 (1998).

<sup>89</sup> Ibid., 305.

<sup>90</sup> Ibid., 320, (Kennedy, J., concurring).

<sup>91</sup> Ibid., 322, 325 (Stevens, J., dissenting).

<sup>&</sup>lt;sup>92</sup> Greely, "Premarket Approval Regulation for Lie Detections," 51 ("military courts are bound by a rule of evidence excluding such evidence").

Evidence law thus provides some protection for individuals who do not wish for their thoughts, including their deceptive thoughts, to be revealed by fMRI in the courtroom. For example, a litigant who wishes to protect the privacy of deceit captured by fMRI would emphasize the *Daubert* factors that favor the inadmissibility of fMRI, such as fMRI's current positive rate of error in detecting deception, the relatively low number of peer-reviewed studies finding that fMRI is an accurate method of detecting deception, the lack of acceptance of fMRI as a method of detecting deception, and the lack of standards to determine acceptable use of fMRI in detecting deception. The application of these factors likely will provide litigants with some privacy protection in light of the current state of the technology.<sup>93</sup> As fMRI technology advances, the privacy protections evidence law affords litigants will lessen.

The extent of protection provided by evidence law also will depend on the purpose for which fMRI is used. For example, MRI is generally accepted for its ability to image brain structure, as illustrated by Rodney King's success in admitting into evidence an MRI scan in the early 1990s to prove his brain damage (which he did under *Frye's* then-applicable "generally acceptable" test, a more stringent test than that established by *Daubert*). Functional MRI might be considered more accurate and accepted for certain purposes, such as identifying the areas of the brain responsible for visual and sensorimotor functions, but less accurate and accepted for its ability to detect other physical and mental health conditions, qualities, characteristics, or behaviors, such as pedophilia or homosexuality. The more accurate and accepted fMRI becomes in identifying or measuring a particular condition, quality, characteristic, or behavior, the less privacy protections are provided by evidence law. Evidence law thus serves as a

<sup>93</sup> Ronald M. Green, "Spy Versus Spy," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 54 ("... even good brain-imaging lie detection is likely to be no more admissible for legal purposes than polygraph testing has been.").

<sup>94</sup> Kevles, Naked to the Bone, 175.

current, but not necessarily complete, source of protection for litigants who wish to maintain the privacy of their thought processes.<sup>95</sup>

#### GOVERNMENTAL INTRUSIONS

In the sections above, I have addressed some of the privacy implications associated with using fMRI to gather neuroimaging information in the health care, research, employment, insurance, education, and courtroom evidence contexts, regardless of whether those considering the use of fMRI were private or government actors. In this section, I explore the legal implications of using fMRI to gather neuroimaging information when the fMRI is required, ordered, requested, or operated by a federal, state, or local government, or an official or agency on its behalf (hereinafter, government). It is worth noting that government-imposed fMRI is not just speculation. The United States Department of Defense and the Central Intelligence Agency (CIA) reportedly have invested millions of dollars in neuroimaging technologies that might be used in law enforcement and intelligence, with a particular emphasis on brain scans that might be used to identify terrorists.96 The Pentagon's Defense Advanced Research Projects Agency (DARPA) already supports research at Lockheed Martin and Rutgers University relating to "remote brain prints." DARPA also has funded research by an Oregon organization relating to the creation of brain sensors that would detect, transmit, and reconstruct certain brain signals.98 In each of these cases, the United States

<sup>95</sup> Charles N. Keckler, "Cross-Examining the Brain: A Legal Analysis of Neural Imaging for Credibility Impeachment," George Mason University School of Law Working Paper Series, Working Paper 16 (2005) (concluding that functional magnetic resonance imaging has not yet met the foundational requirements for the admissibility of scientific evidence).

<sup>96</sup> Olson, "Brain Scans Raise Privacy Concerns," 1549.

<sup>&</sup>lt;sup>97</sup> Jonathan D. Moreno, "Dual Use and the 'Moral Taint' Problem," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 52.

<sup>98</sup> Ibid.

Constitution and analogous state constitutional provisions might constrain the government's use of fMRI to probe individuals' brains.<sup>99</sup>

## Protecting the Privacy of Thought under the First Amendment

Perhaps best known for its express rights of freedom of speech and press, the First Amendment to the United States Constitution also protects other, lesser-known but related interests, such as the interest of political groups and social organizations in holding physically private meetings and in maintaining the privacy of their membership lists, as well as the interest of individuals in reading books and watching movies in their own homes, regardless of the content of such books or films. As discussed in detail in Chapter 3, these protections stem from the Supreme Court's recognition that the First Amendment protects "freedom of thought and solitude in the home" or, more generally, "privacy of thought." In *Stanley v. Georgia*, 101 its seminal "privacy of thought" case, the Supreme Court explained that, "also fundamental is the right to be free, except in very limited circumstances, from unwanted governmental intrusions into one's privacy." 102

Chapter 3 shows that the privacy protections offered by *Stanley v. Georgia* do not stand on their own. A plurality of the Court found in *Board of Education v. Pico* that the First Amendment is broad enough to encompass additional rights not enumerated in its terms, including a "right to receive information and ideas." Justice Cardozo stated in *Palko v. Connecticut* that, "freedom of thought . . . is the matrix, the indispensable condition, of nearly every other form of freedom." The Supreme Court stated in *West* 

<sup>&</sup>lt;sup>99</sup> Greely, "The Social Effects of Advances in Neuroscience," 253.

<sup>100</sup> Anita Allen-Castellitto, "Origins and Growth of U.S. Privacy Law," *Practising Law Institute* 701 (June 2002): 92.

<sup>&</sup>lt;sup>101</sup> Stanley v. Georgia, 394 U.S. 557 (1969).

<sup>102</sup> Ibid., 564.

<sup>103</sup> Board of Educ. v. Pico, 457 U.S. 853, 867 (1982) (plurality opinion).

<sup>104</sup> Palko v. Connecticut, 302 U.S. 319, 326-27 (1937).

Virginia State Board of Education v. Barnette<sup>105</sup> that the First Amendment gives a constitutional preference for "individual freedom of mind" over "officially disciplined uniformity for which history indicates a disappointing and disastrous end"106 and, in Jones v. Opelika that, "[f]reedom to think is absolute of its own nature; the most tyrannical government is powerless to control the inward workings of the mind."107 In his concurrence in United States v. Reidel, Justice Harlan stated that the First Amendment protects the right of the individual "to be free from governmental programs of thought control, however such programs might be justified in terms of permissible state objectives," and to be free "from governmental manipulation of the content of a man's mind . . . "108 In Abood v. Detroit Board of Education, the Supreme Court stated that, "freedom of belief is no incidental or secondary aspect of the First Amendment's protections . . . [A]t the heart of the First Amendment, is the notion that an individual should be free to believe as he will, and that in a free society one's beliefs should be shaped by his mind and his conscience rather than coerced by the State."109 And, just three years ago, the Supreme Court stated in Lawrence v. Texas that, "Liberty presumes an autonomy of self that includes freedom of thought, belief, expression, and certain intimate conduct."110

Although political groups and social organizations have successfully invoked the protections of the First Amendment in order to hold closed meetings and keep from public disclosure their membership lists, the question becomes whether individuals who may be required, ordered, or requested by a government actor to submit to fMRI similarly

<sup>105</sup> West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624, 642 (1943).

<sup>106</sup> Ibid., 637.

<sup>107</sup> Jones v. Opelika, 316 U.S. 584, 618 (1942).

<sup>&</sup>lt;sup>108</sup> U.S. v. Reidel, 402 U.S. 351, 359 (1971) (Harlan, J., concurring).

<sup>109</sup> Abood v. Detroit Board of Education, 431 U.S. 209, 234-35 (1977).

<sup>110</sup> Lawrence v. Texas, 539 U.S. 558, 562 (2003).

could invoke the First Amendment's "privacy of thought" protections as grounds for refusing the fMRI.

Research revealed no reported case in which a litigant has invoked the First Amendment as grounds for refusing to submit to a government-imposed fMRI. However, somewhat analogous arguments have been made in the context of individuals who have attempted to refuse medications, including antipsychotic drugs, ordered by the government to render an individual competent to stand trial for serious, but nonviolent, crimes. Sell v. U.S. is one such case.111 The subject of Sell was Charles Sell, once a practicing dentist, who had a long and unfortunate history of mental illness.112 Sell's illness manifested itself in various ways, including Sell's belief that the gold he used for tooth fillings was contaminated by communists and that leopards were located outside his dentistry practice. 113 The United States Government became involved when Sell submitted fictitious insurance claims to government health care programs, including the Medicaid program, for reimbursement in violation of a federal statute prohibiting such conduct.<sup>114</sup> A grand jury later indicted Sell and his wife on 56 counts of mail fraud, 6 counts of Medicaid fraud, and one count of money laundering.<sup>115</sup> A federal magistrate ordered a psychiatric examination of Sell, which revealed that Sell was competent but could suffer from future psychotic episodes.<sup>116</sup>

Unfortunately, Sell was not able to maintain his competency throughout the many hearings and other legal proceedings that he was required to attend, and he later requested the magistrate to reconsider his competence to stand trial.<sup>117</sup> The magistrate sent Sell to

<sup>&</sup>lt;sup>111</sup> Sell v. U.S., 539 U.S. 145 (2003).

<sup>112</sup> Ibid., 169.

<sup>113</sup> Ibid.

<sup>&</sup>lt;sup>114</sup> 18 U.S.C. § 1035(a)(2) (2005).

<sup>115</sup> Sell, 539 U.S. at 170.

<sup>116</sup> Ibid.

<sup>117</sup> Ibid.

the United States Medical Center for Federal Prisoners, which recommended that Sell take antipsychotic medication. Sell's refusal to do so, and the Medical Center's continued attempt to administer antipsychotic medications to Sell against his will was the subject of a case before the Supreme Court.

The Center for Cognitive Liberty and Ethics (CCLE) submitted an *amicus curiae* brief to the Supreme Court on behalf of Sell arguing, among other things, that the First Amendment guarantees freedom of thought and that the government medical center's attempt to force Sell to take antipsychotic medications violated the First Amendment's right to freedom of thought.<sup>119</sup> The CCLE recognized the government's right and need to regulate the *behavior* of individuals, including criminal conduct. However, the CCLE argued that a government cannot, consistent with the First Amendment, forcibly manipulate the *thought processes* of an individual who is not otherwise a clear and present danger to himself or others.<sup>120</sup> In a separate *amicus curiae* brief, the American Civil Liberties Union (ACLU) echoed the First Amendment argument of the CCLE.<sup>121</sup>

In its 2003 opinion in *Sell*, the Supreme Court did not specifically address the CCLE's or ACLU's argument that the government medical center's attempt to force Sell to take antipsychotic medications violated a freedom of thought protected by the First Amendment. The Court simply held that the Constitution could permit a government medical center involuntarily to administer antipsychotic drugs to render an individual competent to stand trial if the treatment was (1) medically appropriate, (2) substantially unlikely to have side effects that would undermine the trial's fairness, and (3) taking account of less intrusive alternatives, necessary to further important governmental trial-

<sup>&</sup>lt;sup>118</sup> Ibid., 171.

<sup>&</sup>lt;sup>119</sup> Brief of Amicus Curiae Center for Cognitive Liberty and Ethics, at 3-7, Sell v. United States, 539 U.S. 166 (2003) (No. 02-5664).

<sup>&</sup>lt;sup>120</sup> Ibid., 2.

<sup>121</sup> Brief of Amicus Curiae American Civil Liberties Union of Eastern Missouri, at 6-9, Sell v. United States, 539 U.S. 166 (2003) (No. 02-5664).

related interests.<sup>122</sup> The Supreme Court found that these criteria were not satisfied in Sell's case and concluded that the lower court erred in approving the government medical center's forced medication of Sell.<sup>123</sup>

Although *Sell* did not provide any specific language interpreting the First Amendment on which individuals attempting to avoid government-imposed fMRIs could definitively rely, *Sell* also did not foreclose the argument that the First Amendment protects government intrusions into thought. The door thus remains open for private individuals to argue that government-imposed fMRIs violate some type of constitutionally protected interest in cognitive privacy (or cognitive liberty or cognitive freedom), <sup>124</sup> although the weight the Supreme Court would give to that interest is unclear. If faced with such an argument, the Supreme Court likely would balance the interest of the private individual in avoiding the unwanted fMRI scan against the government's interest in ordering the scan. Which interest outweighed the other certainly would require a fact-intensive analysis. Factors that might be relevant to the Supreme Court's analysis include the purpose for which the government proposed to use the neuroimaging information, how intrusive the Supreme Court considers fMRI, whether less intrusive means of obtaining the desired information exist, and the accuracy of fMRI in obtaining the desired information.

In analyzing the use to which the neuroimaging information would be put, the Supreme Court probably would require proof of a legitimate governmental interest

<sup>122</sup> Sell, 539 U.S. at 180-82.

<sup>123</sup> Ibid., 186.

<sup>124</sup> The concept of cognitive privacy, also referred to as cognitive liberty and cognitive freedom, have been introduced and used elsewhere. Linda MacDonald Glenn, "Keeping an Open Mind: What Legal Safeguards Are Needed?" *American Journal of Bioethics* 5, no. 2 (March-April 2005): 61; Wolpe, Foster, and Langleben, "Emerging Neurotechnologies for Lie-Detection," 39–40; Richard Glen Boire, "On Cognitive Liberty (Part I)," *Journal of Cognitive Liberties* 1, no. 1 (Winter 1999-2000): 7-13; Martha J. Farah, "Emerging Ethical Issues in Neuroscience," *Nature Reviews Neuroscience* 5, no. 11 (November 2002): 1127; Michael S. Gazzaniga, "The Pope, the Rabbi, the Scientists and the Neuroethicist: Who Should You Believe and Why?," in *Neuroethics: Mapping the Field*, ed. Steven J. Marcus (New York: Dana Press, 2002), 269.

relating to the enforcement of criminal law, a bona-fide occupational qualification, or similar need or measure. Because our current criminal justice and social systems tend to punish or reward individuals based on their actions, not their thoughts, the government likely would have more difficulty establishing a legitimate need for thoughts, as opposed to past or potential future criminal actions. However, one certainly can think of dozens of sensitive positions relating to security, intelligence, and counter-terrorism to which an individual's thoughts, allegiances, or goals might be relevant. It is doubtful, however, that the Supreme Court would give substantial weight to a government's stated interest in monitoring or otherwise regulating just any individual's personal thoughts (in quite the same way that the Supreme Court has given little weight to the interest of the state in regulating an individual's ability to read or watch even "obscene" books or movies in her own home).

Other factors the Supreme Court might consider relate to the intrusiveness of fMRI and the existence of a less intrusive means of obtaining the information sought. Although non-contrast fMRI is considered minimal risk in the biomedical research context in part because it does not involve the injection of radioactive materials or the administration of sedation, an argument could be made that confining an individual to a loud, potentially claustrophobic environment is sufficiently intrusive. The existence of less intrusive means of obtaining the desired information, including questionnaires, interviews, and even polygraph, might weigh in the individual's favor.

The accuracy of fMRI in detecting the desired information also would be relevant. In the drunken driving context, courts allow the use of blood-alcohol tests, despite their relative intrusiveness, because of their accuracy in determining whether an individual's blood alcohol content exceeds the limits of state law. The ability of private individuals to interfere with the accuracy of fMRI test results by disregarding the mental task

<sup>125</sup> Schmerber v. California, 384 U.S. 757, 771 (1966) ("Extraction of blood samples for testing is a highly effective means of determining the degree to which a person is under the influence of alcohol.").

assigned, refusing to pay attention to particular stimuli, or otherwise thinking about something else during the examination likely would weigh in favor of the individual.

In summary, research revealed no case law or other authority that would render unreasonable an argument that a government-imposed fMRI violates some type of cognitive privacy interest protected by the First Amendment. In fielding such an argument, a court likely would balance several factors, included the interest of the private individual from freeing her mind from the unwanted fMRI intrusion, the interest of the government in obtaining the individual's neuroimaging information, and the accuracy of fMRI in detecting the information desired by the government.

# Protecting the Privacy of Incriminating Thoughts under the Fifth Amendment

Chapter 3 introduced the Fifth Amendment, which prohibits a person from being compelled in any criminal case to be a witness against herself. 126 The Fifth Amendment's privilege – better known as the privilege against self-incrimination – has been broadly interpreted to protect criminal suspects and defendants from having to take the stand or testifying in grand jury proceedings and criminal trials. 127 The privilege against self-incrimination also has been interpreted to protect suspects during informal proceedings, such as custodial interrogations. 128 In *Miranda v. Arizona*, a seminal case addressing the scope of the privilege, the Supreme Court recognized the Fifth Amendment as "a substantive right, a 'right to private enclave where he may lead a private life. That right is the hallmark of our democracy." 129 *Miranda* explained that the constitutional foundation underlying the privilege is the respect a state or federal government must accord to the dignity and integrity of its citizens: "[T]o respect the

<sup>126</sup> U.S. CONST. amend. V.

<sup>127</sup> Counselman v. Hitchcock, 142 U.S. 547 (1892).

<sup>128</sup> Miranda v. Arizona, 384 U.S. 436, 460-61, 467 (1966) ("Today, then, there can be no doubt that the Fifth Amendment privilege is available outside of criminal court proceedings and serves to protect persons in all settings in which their freedom of action is curtailed in any significant way from being compelled to incriminate themselves.").

<sup>&</sup>lt;sup>129</sup> Ibid., 460.

inviolability of the human personality, our accusatory system of criminal justice demands that the government seeking to punish an individual produce the evidence against him by its own independent labors, rather than by the cruel, simple expedient of compelling it from his own mouth."<sup>130</sup> *Miranda* concluded that the privilege against self-incrimination is fulfilled "only when the person is guaranteed the right 'to remain silent unless he chooses to speak in the unfettered exercise of his own will."<sup>131</sup>

Some have speculated that the Fifth Amendment might prohibit government-imposed fMRI scans of criminal suspects and defendants if the scans are interpreted to reveal incriminating evidence. In the functional neuroimaging context, the question thus becomes whether the right to remain silent, or the right not to speak, also includes the right not to reveal one's incriminating thoughts through fMRI. At first glance, Miranda's broad "all settings" language ("there can be no doubt that the Fifth Amendment . . . serves to protect persons in all settings . . . from being compelled to incriminate themselves"), I33 as well as similarly broad language in other Supreme Court opinions ("The right of freedom of thought and of religion as guaranteed by the Constitution against State action includes both the right to speak freely and the right to refrain from speaking at all . . . ") I34 would seem to support an affirmative answer to that question. However, a closer analysis reveals that the results of some functional neuroimaging examinations would have difficulty surviving the Schmerber "testimonial or communicative evidence" limitation on the Fifth Amendment.

In Schmerber v. California, a physician acting under police direction took a blood sample from defendant Schmerber, who had been arrested for driving while intoxicated

<sup>130</sup> Ibid.

<sup>&</sup>lt;sup>131</sup> Ibid.

<sup>132</sup> Greely, "The Social Effects of Advances in Neuroscience," 254.

<sup>133</sup> Miranda, 384 U.S. at 467.

<sup>134</sup> West Virginia State Board of Education v. Barnette, 319 U.S. 624, 645 (1943).

<sup>135</sup> Glenn, "Keeping an Open Mind," 61.

(DWI), for purposes of measuring Schmerber's blood-alcohol content. 136 The government attempted to introduce the blood test result into evidence during the DWI proceeding, but Schmerber argued that the involuntary blood test violated his Fifth Amendment right against self-incrimination.<sup>137</sup> A five-Justice majority of the Supreme Court disagreed, reasoning that the Fifth Amendment only protects against the compulsion of "testimony" or "communications," not against "compulsion which makes a suspect or accused the source of 'real or physical evidence.'"138 The Supreme Court acknowledged that the line between testimonial and physical evidence might not always be easy to draw. For example, "Some tests seemingly directed to obtain 'physical evidence,' for example, lie detector tests measuring changes in body functions during interrogation, may actually be directed to eliciting responses which are actually testimonial."139 The Supreme Court further stated that, "To compel a person to submit to testing in which an effort will be made to determine his guilt or innocence on the basis of physiological responses, whether willed or not, is to evoke the spirit and history of the Fifth Amendment."140 The majority opinion clarified, however, that the defendant's blood test, which was taken to determine intoxication, did not yield "even a shadow of testimonial compulsion upon or enforced communication by the accused."141 A four-Justice minority disagreed, arguing that blood involuntarily extracted is indeed "communicative" and obviously self-incriminatory. The minority reasoned that a person's private papers and diaries, which would be protected by the Fifth Amendment as testimony or communications, are no more revealing than a person's blood, and therefore

<sup>136</sup> Schmerber, 384 U.S. at 758-59.

<sup>137</sup> Ibid., 759.

<sup>138</sup> Ibid., 764.

<sup>139</sup> Ibid.

<sup>140</sup> Ibid.

<sup>&</sup>lt;sup>141</sup> Ibid., 765.

concluded that the privilege against self-incrimination should apply equally to a person's blood. 142

The majority opinion in *Schmerber* has been applied to find the privilege against self-incrimination inapplicable to urinalysis testing designed to determine intoxication, <sup>143</sup> a mental examination of a defendant accused of murder, <sup>144</sup> a stomach x- ray of a defendant accused of stealing (and swallowing) a ring, <sup>145</sup> fingerprints, <sup>146</sup> and a neutron activation test to determine the presence of gunpowder residue, <sup>147</sup> as well as numerous other photographs, measurements, physical movements, handwriting analyses, and even examinations by ultraviolet light. <sup>148</sup> With these holdings must be compared the *Schmerber* majority's clarification that lie detector tests, although measuring changes in body functions during interrogation, actually are designed to elicit testimonial responses.

The tricky question thus becomes whether fMRI is more like testimonial and communicative evidence (and possibly testimonial evidence elicited from lie-detector tests), or whether a better analogy is to blood tests, urinalysis testing, mental examinations, stomach x-rays, fingerprints, or neutron activation tests. Although research revealed no case law specifically applying *Schmerber's* Fifth Amendment limitation to fMRI, a court's analysis probably would depend on the information the fMRI was designed to elicit. For example, if a government official used fMRI to detect deception, the fMRI evidence might be considered "testimonial or communicative" evidence in accordance with the *Schmerber* majority clarification relating to lie detector tests. On the other hand, if a government official used fMRI in an attempt to detect a

<sup>142</sup> Ibid., 777 (Black, J., dissenting).

<sup>143</sup> Ridgell v. U.S., 54 A.2d 679 (D.C. App. 1947).

<sup>144</sup> State v. Myers, 67 S.E.2d 506 (S.C. 1951).

<sup>145</sup> Weeks v. State, 342 So.2d 1335 (Ala. Crim. App. 1977).

<sup>146</sup> Frances v. State, 316 N.E.2d 364 (Ind. 1974).

<sup>147</sup> State v. Ulrich, 609 P.2d 1218 (Mont. 1980) (overruled on other grounds).

<sup>&</sup>lt;sup>148</sup> W.E. Shipley, "Requiring Submission to Physical Examination or Test as Violation of Constitutional Rights," *American Law Reports* 25, 2<sup>nd</sup> ed. (2005): 1407.

mental health condition or measure familiarity with a victim or crime scene, perhaps the fMRI evidence would be considered "real or physical" evidence not protected by the Fifth Amendment. Functional MRI thus raises unique Fifth Amendment issues, the resolution of which will depend on the particular fMRI test design and the information sought by the government from the fMRI scans.

# Protecting Thoughts from "Search and Seizure" under the Fourth Amendment

In addition to arguing that a government-imposed fMRI violates the Fifth Amendment's privilege against self-incrimination, a private individual also could argue that a government-ordered fMRI scan should be excluded from evidence as the product of an unlawful search and seizure in violation of the Fourth Amendment. Questions regarding how the Fourth Amendment applies to the functional neuroimaging context already have been raised. These questions can be phrased in terms of whether the Fourth Amendment protects an individual's interest in maintaining the privacy of her thoughts, or whether the government can "search and seize" those thoughts.

The overriding function of the Fourth Amendment is to protect personal privacy and dignity against unwarranted intrusion by the government.<sup>150</sup> The values protected by the Fourth Amendment substantially overlap those protected by the Fifth Amendment.<sup>151</sup> Although government-ordered physical examinations will not always implicate the Fifth Amendment due to *Schmerber*, many such examinations will implicate the broadly interpreted search and seizure provisions of the Fourth Amendment.<sup>152</sup>

<sup>149</sup> Greely, "The Social Effects of Advances in Neuroscience," 254 ("Questions might well arise under at least the Fourth Amendment, which protects Americans against unreasonable searches and seizures . . . "); Richard G. Boire, "Searching the Brain: The Fourth Amendment Implications of Brain-Based Deception Detection Devices," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 62-63; Paul Root Wolpe, "Neuroethics," in *Encyclopedia of Bioethics*, 3rd ed., ed. Stephen G. Post (New York: Macmillan Reference, 2004), 1897. Compare Lawrence A. Farwell and Sharon S. Smith, "Using Brain MERMER Testing to Detect Concealed Knowledge Despite Efforts to Conceal," *Journal of Forensic Sciences* 46, no. 1 (2001): 1.

<sup>150</sup> Schmerber, 384 U.S. at 767.

<sup>151</sup> Ibid.

<sup>152</sup> Ibid.

The Fourth Amendment provides that, "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized." Although research revealed no case in which a private litigant has made such an argument, it would not be unreasonable to argue that a government-ordered fMRI constitutes a search of a person for purposes of the Fourth Amendment. After all, the Supreme Court recognizes that the government's administration of blood and urinalysis testing constitutes a search of a person. The question thus becomes when the government would be justified in requiring an individual to submit to an fMRI and whether the procedures followed by the government in scanning a particular individual's brain respected relevant Fourth Amendment standards of reasonableness.

The Fourth Amendment's proper function is to constrain, not against all intrusions as such, but against intrusions which are not justified in the circumstances, or which are made in an improper manner."<sup>155</sup> The Fourth Amendment thus has been interpreted to require police to obtain a search warrant<sup>156</sup> to search areas in which the suspect has a

<sup>153</sup> U.S. CONST. amend. IV.

<sup>154</sup> Recent literature also analogizes fMRI to hand-held thermal imaging devices secretly used by the police to detect home-grown cannabis. Boire, "Searching the Brain," 62-63. The analogy to thermal imaging devices would be appropriate if the government attempted to scan an individual's brain without her knowledge. In hypotheticals involving compulsory, non-secret fMRIs – fMRIs to which the defendant knew she was being subjected – the analogy to government-imposed blood and urinalysis testing might be more appropriate.

<sup>155</sup> Schmerber, 384 U.S. at 768.

not subject to the warrant and probable cause requirement. Examples include border and fixed checkpoint searches, routine traffic stops, sobriety checkpoints, searches of parolees and probationers, several types of student and school searches, and office searches of government employees. U.S. v. Martinez-Fuerte, 428 U.S. 543 (1976) (no probable cause or warrant needed to stop all cars at a fixed checkpoint); Vernonia Sch. Dist. v. Acton, 515 U.S. 646 (1995) (no probable cause or warrant needed before school district can require all student athletes submit to urinalysis drug testing). Instead, their imposition is reviewed according to a balancing test that weighs the individual's privacy interests against the government's interest in the search.

reasonable expectation of privacy, including intrusions in the body.<sup>157</sup> As discussed in Chapter 3, a person has a reasonable expectation of privacy if the person shows an actual, subjective expectation of privacy in the area, and the expectation is one that society recognizes as reasonable.<sup>158</sup> In addition, a search warrant can be issued only when there is probable cause. Probable cause exists when it is more likely than not that the specific items searched for are connected with criminal activities and such items will be found in the place that will be searched. Finally, a search warrant must be issued by a neutral judicial officer and must contain a description of the premises to be searched and the things to be searched. Any item that is the subject of a valid search warrant may be seized by the police executing the warrant. The requirement for a search warrant can be waived in an emergency, and frequently is in drunken driving cases in which the evidence, such as a high blood-alcohol content, might disappear quickly. However, the emergency exception probably would not apply too frequently in the functional neuroimaging context unless there is a possibility that the individual might forget something, perhaps due to a degenerative neurological disease or the elapse of a sufficient period of time.

In determining whether brain-scanning procedures followed by the government respect relevant Fourth Amendment standards of reasonableness, the courts will analyze several factors. One factor relates to whether the test chosen is reasonable in terms of safety and efficacy. For example, the Supreme Court has found in the context of drunken driving that extraction of blood samples for testing is a highly effective means of determining the degree to which a person is under the influence of alcohol. The Supreme Court also has found that blood tests are "commonplace in these days of periodic physical examination and experience with them teaches that the quantity of blood extracted is minimal, and that for most people the procedure involves virtually no

<sup>157</sup> Winston v. Lee, 470 U.S. 753 (1985) (compelled surgical intrusion into an individual's body).

<sup>158</sup> Gormley, "One Hundred Years of Privacy," 1374.

<sup>159</sup> Breithaupt v. Abram, 352 U.S. 432, 436n3 (1957).

risk, trauma, or pain."<sup>160</sup> Other cases have found that it is not reasonable to remove a bullet lodged an inch-deep in an individual's chest.<sup>161</sup> Factors that favor an individual's right to be free of a compulsory fMRI include fMRI's unknown rate of accuracy in identifying or measuring particular thought processes, the fact that fMRI probably is not considered "commonplace" in the same way blood tests are, and the fact that fMRI might be relatively uncomfortable for individuals who fear loud noises or claustrophobic situations. The fact that fMRI is considered minimal risk, at least in the context of biomedical research, would favor the government's interest in imposing an fMRI.

A second factor relates to whether the test was conducted in a reasonable manner. In the drunken driving context, the Supreme Court has found that blood-alcohol tests were conducted in a reasonable manner if the blood was drawn "by a physician in a hospital environment according to accepted medical practices." The Supreme Court has clarified in the drunken driving context that, "We are thus not presented with the serious questions which would arise if a search involving use of a medical technique, even of the most rudimentary sort, were made by other than medical personnel or in other than a medical environment -- for example, if it were administered by police in the privacy of the stationhouse. To tolerate searches under these conditions might be to invite an unjustified element of personal risk of infection and pain." Applying this test to the functional neuroimaging context likely would require the government to ensure that the fMRI is conducted by qualified medical personnel in a safe, metal-free environment, not by untrained government personnel.

A third factor relates to the individual's expectation of privacy, which always will be context-specific. In the public school context, for example, the Supreme Court has held that K-12 students have a somewhat lowered expectation of privacy because school

<sup>&</sup>lt;sup>160</sup> Schmerber, 384 U.S. at 771.

<sup>161</sup> Winston v. Lee, 470 U.S. 753 (1985).

<sup>162</sup> Schmerber, 384 U.S. at 771.

<sup>163</sup> Ibid.

authorities act *in loco parentis* and need to control the student body in order for the educational mission to be implemented. Thus, the Supreme Court has held that a school district may require all student athletes to submit to urinalysis drug testing as a condition of participation in interscholastic sports provided that the testing was conducted in a relatively unobtrusive manner.<sup>164</sup> An individual's expectation of privacy regarding functional neuroimaging will depend on the context in which the government attempts to impose it. For example, a government employee who holds a classified or sensitive position may be deemed to have a lowered expectation of privacy than an individual who holds a non-classified position.

Weighed against these interests is the government's interest in obtaining the information. For example, courts have given sufficient weight to a government's interest in fairly and accurately determining guilt or innocence, 165 and thus may give sufficient weight on an fMRI that could accurately determine whether an individual committed murder. On the other hand, a government-ordered fMRI the purpose of which was to ensure that government employees "get along in the workplace" likely would be given less, or perhaps even no, weight.

In summary, whether a particular fMRI test would violate a private individual's Fourth Amendment right to be free of unreasonable searches and seizures would require examination of several criteria, including the individual's expectation of privacy and whether that expectation is reasonable, whether the government had probable cause to and did obtain a search warrant, whether the fMRI test or "search" that was chosen by the government was reasonable, whether the test was conducted by qualified medical personnel in a safe environment, and the government's specific need to obtain the neuroimaging information.

<sup>164</sup> Vernonia, 515 U.S. at 664-65. See also Board of Education v. Earls, 536 U.S. 822 (2002) (allowing random and warrantless drug-testing of all middle and high school students who want to participate in any competitive extracurricular activity).

<sup>&</sup>lt;sup>165</sup> Winston, 470 U.S. at 762.

In summary, the First, Fifth, and Fourth Amendments to the Constitution potentially offer some protections for individuals who wish to maintain the privacy of their thought processes in the context of government-imposed fMRIs. Although the Supreme Court interprets the Constitution to permit minor intrusions into an individual's body, and perhaps brain and mind, under certain limited circumstances, the Constitution does not permit all intrusions. The constitutionality of a particular neuroimaging examination will depend on a fact-intensive application of the factors identified in each of the sections, above.

# PRIVACY INTRUSIONS IN OTHER CONTEXTS

Chapter 3 considered the common law of torts as a source of rights and duties relating to confidentiality and privacy, and introduced four common law privacy torts (intrusion, disclosure, false light, and appropriation) recognized by most jurisdictions. Two of these torts, intrusion and appropriation, are potentially applicable in other contexts in which an fMRI allegedly breaches an individual's neurological privacy.

The intrusion tort imposes liability on one who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns if the intrusion would be highly offensive to a reasonable person. The intrusion tort thus requires proof of (1) an intentional physical or other intrusion, (2) upon the solitude, seclusion, private affairs, or concerns of another, (3) that would be highly offensive to a reasonable person. Unlike the disclosure and false light torts discussed in Chapter 4, the intrusion tort does not require publicity, or the widespread dissemination of information about the plaintiff. Stated another way, a highly offensive intrusion into the personal affairs of another is sufficient to prove the tort, even if the defendant does not publish the information obtained during the intrusion. 168

<sup>166</sup> RESTATEMENT (SECOND) OF TORTS § 652B (1977).

<sup>167</sup> Ibid., Comment a.

<sup>168</sup> Ibid., Comments a and b.

The first element, an intentional physical or other intrusion, is frequently proved by the defendant's physical intrusion into a place in which the plaintiff has secluded herself, such as when the defendant forces his way into the plaintiff's hotel room or insists on entering the plaintiff's home over her objections. The element also may be proved by non-physical intrusions, such as when the defendant uses his senses, with or without mechanical aids, to oversee or overhear the plaintiff's private affairs, or when the defendant looks into the plaintiff's upstairs windows with binoculars, taps her telephone wires, or takes an unauthorized photograph of the plaintiff while she is in the hospital. The Restatement (Second) of Torts provides other examples of sufficiently intrusive behavior, such as opening the plaintiff's private or personal mail, searching her safe or wallet, examining her private bank account, or compelling her by a forged court order to permit an inspection of her personal documents.

The intentional intrusion element could be proved in several ways in the functional neuroimaging context. An investigator could intentionally intrude on a research subject by making an unauthorized study of the subject's personality or mental health when the subject had limited her consent to a brain scan the purpose of which was to study speech or language functions. If fMRI developed to the point where individuals' brains could be scanned without their knowledge or authorization, the unauthorized scans also could constitute non-physical intentional intrusions. Arguably any situation in which an individual is required to submit to functional magnetic resonance imaging over her objection could implicate the intentional intrusion element.

The second element of the intrusion tort requires the intrusion to be upon the solitude, seclusion, private affairs, or concerns of another.<sup>172</sup> Stated another way, a defendant will be subject to liability for intrusion only when she has intruded into a

<sup>169</sup> Ibid., Comment b.

<sup>170</sup> Ibid., and ibid., Illustration 7.

<sup>&</sup>lt;sup>171</sup> Ibid.

<sup>172</sup> Ibid., Comment c.

"private place" of the plaintiff, or has otherwise invaded a "seclusion that the plaintiff has thrown about [her] person or affairs." A defendant generally will not be subject to intrusion liability if she simply examines a public record concerning the plaintiff, or if she photographs the plaintiff while she is walking down a public street, because these activities are open to the public eye. Yeen in a public place, however, the tort will protect some matters about the plaintiff, "such as [her] underwear or lack of it, that are not exhibited to the public gaze," if there is an intrusion into such a matter. Yes

Thoughts, feelings, and other mental processes that are studied by fMRI arguably constitute "private affairs or concerns" for purposes of the second element of the intrusion tort. A classic example involves the feeling of love. If a woman loves a man, but she has not told anybody, including the man, about her feelings, the use of fMRI to identify such feelings could be considered an intrusion on her private affairs or concerns. A second, futuristic, example involves decision-making and game theory. If a prosecutor knew in advance whether a criminal suspect would plead guilty, or if a law school knew in advance whether a faculty candidate would accept its offer of employment, the prosecutor or law school could adjust its plea bargain or salary offer based on that information. Because criminal suspects and law school faculty candidates have an interest in minimizing their prison sentences and maximizing their salaries, respectively, they likely would desire to cloak their anticipated decisions in privacy. The second element of the intrusion tort arguably could be satisfied by an fMRI that intrudes on those private, anticipated decisions.

The final element of the tort requires the intrusion to be highly offensive to a reasonable person.<sup>176</sup> Case law interpreting this element requires the plaintiff to prove that the intrusion was "outrageous," or that the intrusion would have caused mental

<sup>&</sup>lt;sup>173</sup> Ibid.

<sup>174</sup> Ibid.

<sup>175</sup> Ibid.

<sup>176</sup> Ibid., Comment d.

suffering, shame, or humiliation to a person of ordinary sensibilities.<sup>177</sup> Although a structural MRI showing that an individual has a perfectly symmetrical skull might not be considered sufficiently outrageous, a functional MRI that is interpreted to reveal a "defect" in character or an "immoral" decision making process might be considered shameful or humiliating to a reasonable person.

Whether an fMRI will constitute an intrusion will depend on several factors, including the purpose of the fMRI, whether the patient voluntarily submitted to the fMRI, and the information that is obtained as a result of the scan. An unauthorized fMRI would seem to implicate the tort more frequently than an authorized fMRI; however, an authorized research fMRI that exceeds the scope of the subject's consent also could constitute an intrusion.

The second privacy tort, appropriation, has limited although possible applicability in the functional neuroimaging context. The appropriation tort creates liability for one who appropriates to her own use or benefit the name or likeness of another.<sup>178</sup> A plaintiff claiming appropriation thus must prove (1) a representation of her name or likeness (2) by the defendant for the defendant's benefit.<sup>179</sup> The right created by appropriation has been likened to a property right; to avoid liability, the defendant must obtain a license from the plaintiff to use her name or likeness.<sup>180</sup> The classic appropriation case involves a defendant who makes an unauthorized use of an attractive plaintiff's image to advertise the defendant's business or product, or for some similar commercial purpose, although not all jurisdictions require the defendant to commercially benefit from the use of the plaintiff's name or likeness.<sup>181</sup>

<sup>177</sup> Froelich v. Werbin, 548 P.2d 482, 485 (Kan. 1976).

<sup>178</sup> RESTATEMENT (SECOND) OF TORTS § 652C (1977).

<sup>179</sup> Ibid., Comment a.

<sup>180</sup> Ibid.

<sup>&</sup>lt;sup>181</sup> Ibid.

Relatively recent scholarship suggests a role for the appropriation tort in cases such as *Moore v. Regents of the University of California*. In *Moore*, the California Supreme Court decided in 1990 that plaintiff John Moore had no property rights in the valuable pharmaceutical products that his physicians derived from his spleen cells, which had been removed as part of Moore's treatment for leukemia. In so doing, the California Supreme Court overruled a lower court ruling finding that Moore had an appropriation cause of action based on the commodification of an aspect of his body (his DNA) that was so intimately bound up with his identity as to be analogous to his name or image. Recent scholarship considers how the Supreme Court could have applied the appropriation tort to inform and guide the legal management of Moore's DNA, and other cases involving genetic information and other information "regarded as intimately bound up with a subject's identity." Is identity." Is identity." Is identity." Is in the California.

Along these lines, the appropriation tort also might be used to inform and guide the legal management of neuroimaging information in certain limited situations. If a physician or investigator makes a neuroscientific discovery as a result of an fMRI of a particular individual's brain and benefits, commercially or otherwise, from the discovery, the patient or research subject could attempt to use the privacy tort of appropriation to the extent she did not license the particular benefit. To prevail, the patient or research subject would have to analogize her neurological identity to identity as typically represented by names or photographs, and then argue that the provider or investigator benefited from the unauthorized appropriation of such neurological identity.

<sup>&</sup>lt;sup>182</sup> Jonathan Kahn, "Biotechnology and the Legal Constitution of the Self: Managing Identity in Science, the Market, and Society," *Hastings Law Journal* 51 (July 2000): 909-952.

<sup>183</sup> Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990), reh'g denied.

<sup>184</sup> Ibid.

<sup>185</sup> Kahn, "Biotechnology and the Legal Constitution of the Self," 911.

## **CONCLUSIONS**

Although the precise privacy implications of fMRI will remain uncertain until the technology is fully developed, fMRI has the potential to intrude on an individual's neurological privacy in the health care, research, employment, insurance, education, evidentiary, government, and other private contexts. A number of ethical and legal principles potentially apply to protect the privacy of individuals' thought processes and neuroimaging information. All physicians and scientists have an ethical duty to maintain their patients and research subjects' privacy. Physicians and investigators should clarify, as part of the informed consent conversation, the types of health, social, and other information that can be revealed by fMRI and should specifically request the patient or research subject to consider these revelations in determining whether to grant, limit, or refuse access to this information. These procedures will not eliminate the discovery of incidental findings; however, they do respect the right of individuals to control access to their neuroimaging information and may lessen the chance that a physician or investigator will intrude on a particular individual's sense of neurological privacy.

The Americans with Disabilities Act and the Employee Polygraph Prevention Act provide some protections for employees and job applicants who wish to maintain the privacy of their neuroimaging information. However, comprehensive privacy protections for neuroimaging information in the employment context do not exist. Comprehensive protections also do not exist for applicants for insurance, applicants for admission to educational institutions, and current students who may wish to maintain the privacy of their functional neuroimaging information. The law of evidence does provide some privacy protections for litigants who wish to maintain the privacy of their neuroimaging information in the courtroom; however, these protections may decrease as fMRI becomes more accurate and accepted as a tool for identifying and measuring various physical and mental health conditions, social behaviors, and other characteristics and traits. The First, Fourth, and Fifth Amendments to the Constitution provide private individuals with some protection against government-ordered fMRIs; however, the permissibility of a particular

fMRI examination will depend on the application of a number of criteria that are designed to balance the individual's interest in maintaining the privacy of her neuroimaging information against the government's need to obtain the information. The Constitution thus does not provide complete privacy protections for private individuals in the neuroimaging context. Finally, the common law intrusion and appropriation torts may impose liability in certain limited situations in which an individual or organization uses fMRI to violate the cognitive privacy of an individual.

Advances in functional magnetic resonance imaging thus raise a number of privacy issues. Is neuroimaging information more or less worthy of privacy protections compared to other types of information? Do federal and state statutes and regulations, the United States Constitution and analogous state law provisions, and the common law of torts adequately protect the privacy of neuroimaging information? If not, should Congress or state legislatures enact new laws providing heightened privacy protections for neuroimaging information? These questions are addressed next.

# **CHAPTER 6: A CASE FOR NEURO EXCEPTIONALISM?**

A number of ethical and legal principles thus apply to protect the confidentiality of neuroimaging information and the privacy of individuals who consent or are required to submit to an fMRI. But, are these protections adequate? Are additional protections needed? To answer these questions, the scope of the confidentiality and privacy concerns raised by fMRI must first be addressed.

### A TECHNOLOGICAL STRAW MAN?

The scope of the confidentiality and privacy concerns raised by fMRI depends, in part, on the information the technology has the potential to reveal. If fMRI only was capable of mapping speech, language, and motor functions to assist with neurosurgery, or if it became capable of accurately identifying which individuals are suffering from major depression, bipolar disorder, or Alzheimer's disease, then the confidentiality and privacy concerns raised thereby would be very similar to those raised by traditional, albeit sensitive, medical record information. Policies and procedures designed to protect mental health records, alcohol and drug abuse treatment records, HIV/AIDS records, and genetic information would be instructive and, perhaps, sufficient to protect neuroimaging information if their application was extended. On the other hand, if fMRI somehow became a generally accepted technology for determining whether an individual is homosexual, a moral decision maker, engaged in deception, or racially prejudiced, the technology would challenge existing confidentiality and privacy schemes, which typically protect health information, not social characteristics and behaviors. Because we cannot predict exactly how quickly and accurately fMRI technology will develop, we are left to debate whether the threats to the confidentiality of neuroimaging information and

<sup>&</sup>lt;sup>1</sup> Thomas Buller, "Can We Scan for Truth in a Society of Liars?" *American Journal of Bioethics* 5, no. 2 (March-April 2005): 58.

to cognitive privacy are real or imagined.<sup>2</sup> The development of commercial fMRI lie detectors was believed to be years away at the time I began to write this dissertation. At least one company, No Lie MRI, now reports that it will open a "VeraCenter" adjacent to the University of Pennsylvania in July of this year.<sup>3</sup> This threat to cognitive privacy has gone from imagined to real in the space of one year.

The scope of the confidentiality and privacy concerns raised by fMRI also depends on the technology's perceived potential. Even though fMRI may never be capable of reading an individual's mind, confidentiality and privacy may be threatened if private organizations and governmental agencies believe that it is. A mandatory fMRI that accurately reveals an individual's thoughts is one thing. A mandatory fMRI that is incorrectly interpreted to reveal a thought, characteristic, or behavior that does not exist, and that is used to an individual's detriment in an employment, criminal justice, or insurance capacity, is another. Functional MRI, like other sophisticated technologies, possesses an illusory accuracy and objectivity that can be dangerous in the hands of employers, insurers, jurors, lawyers, judges, and government officials who lack the scientific and statistical training necessary to understand published fMRI studies and interpret fMRI test results. Yet, these are the individuals to whom commercial fMRI lie

<sup>&</sup>lt;sup>2</sup> Joseph J. Fins, "The Orwellian Threat to Emerging Neurodiagnostic Technologies," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 57 ("Is the threat of an invasion of cognitive privacy real or *imagined* in the minds of savvy neuroethicists looking to create a new variation on a bioethics theme?") (emphasis in original).

<sup>&</sup>lt;sup>3</sup> Gabriel Oppenheim, "Getting it to Market Too Early: Penn Licenses Technologies Before They Are Completely Prepared for the Marketplace," *DailyPennsylvanian.com*, February 3, 2006, http://www.dailypennsylvanian.com/vnews/display.v/ART/43e2fae4222ba (accessed February 19, 2006).

<sup>&</sup>lt;sup>4</sup> Steve Olson, "Brain Scans Raise Privacy Concerns," *Science* 307, no. 5715 (March 11, 2005): 1550 ("Probably the only thing worse than having people successfully reading your mind with brain imaging is having people unsuccessfully reading your mind with brain imaging and thinking that they can trust that information.").

<sup>&</sup>lt;sup>5</sup> Martha J. Farah, "Emerging Ethical Issues in Neuroscience," *Nature Reviews Neuroscience* 5, no. 11 (November 2002): 1127.

<sup>&</sup>lt;sup>6</sup> Henry T. Greely, "Prediction, Litigation, Privacy, and Property: Some Possible Legal and Social Implications of Advances in Neuroscience," in *Neuroscience and the Law: Brain, Mind, and the Scales of Justice*, ed. Brent Garland (New York: Dana Press, 2004), 118-20.

detectors are currently being marketed.<sup>7</sup> For these reasons, I do not believe that the act of identifying and carefully discussing the confidentiality and privacy implications of fMRI contributes to the creation of technological straw men.<sup>8</sup>

#### RESPONSIBLE DISCUSSION

In Chapter 2, I found that the scientists who conduct neuroimaging studies generally use care when publishing their findings, and that many of them expressly caution against inappropriate or too eager interpretations and applications of fMRI. However, I also found that descriptions of neuroimaging research in the popular media, including physicians', lawyers', and bioethicists' statements to the media, are not as constrained.9 I found that the public must wade through reports suggesting that fMRI is (or soon will be) capable of completely transforming neurosurgical interventions, distinguishing between PVS and MCS patients, determining which brain-injured patients will emerge from unconsciousness, identifying individuals' racial preferences and prejudices, determining deception on an individual level, selecting socially cooperative or competitive individuals from among a pool of applicants, and recognizing whether an individual is heterosexual or homosexual, capable of making moral and ethical decisions, or prefers a particular product. I also found that the public is increasingly confronted with reports that racial evaluation, deception, maternal and romantic love, violence, and mental disorders are "hardwired" in the brain, notwithstanding scientists' careful statements that their research simply examines the neural correlates of such conditions

<sup>&</sup>lt;sup>7</sup> Malcolm Ritter, "Brain Scans as Lie Detectors: Ready for Court Use?" *Live Science*, January 29, 2006, http://www.livescience.com/humanbiology/060129\_brain\_lie.html (accessed February 19, 2006) (reporting that the company No Lie MRI "will serve government agencies and 'anybody that wants to demonstrate that they're telling the truth," and that its competitor, Cephos, is "aiming to offer the fMRI service for use in situations like libel, slander and fraud where it's one person's word against another, and perhaps in employee screening by government agencies.").

<sup>&</sup>lt;sup>8</sup> Fins, "Orwellian Threat," 57 (""One wonders if bioethicist critics are creating another technological straw man to undermine.").

<sup>&</sup>lt;sup>9</sup> Mark Rothstein, "Applications of Behavioural Genetics: Outpacing the Science?" *Nature Reviews Genetics* 6 (October 2005): 793 (identifying a similar phenomenon in the context of genetics research).

and behaviors.<sup>10</sup> It is not surprising that the public may be confused regarding what is science and what is speculation.<sup>11</sup> I thus argued in Chapter 2 that scientists need to continue the care with which they describe their research findings and the diligence with which they identify appropriate and inappropriate uses of neuroimaging information.<sup>12</sup>

Here, I want to emphasize that neuroscientists have a role in the public, and not just the scientific, arena, which includes identifying limitations and cautioning against unwarranted extensions of research findings. Scientists, rather than non-scientifically trained lawyers and ethicists, are in the best position to clarify how research findings should be interpreted. In the context of genetics, some have proposed that scientists study during graduate school the history, as well as the ethical, legal, and social implications, of science. This proposal makes sense in the context of neuroscience too. Many graduate science students take a required one-credit course in the ethics of scientific research, which may cover topics such as the philosophy of science, the practice of scientific research, conflicts of interest, and the value conflicts that arise between scientists and society at large. The course I took did not specifically address how private and governmental institutions may attempt to incorporate scientific findings into their business decision making or the role scientists play in describing their research

<sup>&</sup>lt;sup>10</sup> Laurence Tancredi, *Hardwired Behavior: What Neuroscience Reveals about Morality* (New York: Cambridge Press, 2005); Rothstein, "Applications of Behavioural Genetics," 793 (identifying a similar effect in the field of genetics).

<sup>&</sup>lt;sup>11</sup> Rothstein, "Application of Behavioural Genetics," 793 (finding that the public continues to be confused regarding genetics research).

<sup>&</sup>lt;sup>12</sup> Ibid. (advising genetics researchers to make careful public pronouncements regarding their research and to temper their enthusiasm for the potential implications of preliminary research).

<sup>&</sup>lt;sup>13</sup> Jon Beckwith and Franklin Huang, "Should We Make a Fuss? A Case for Social Responsibility in Science," *Nature Reviews Biotechnology* 23, no. 12 (December 2005): 1479 (making an analogous argument in the context of genetics).

<sup>14</sup> Ibid.

<sup>15</sup> Ibid.

<sup>&</sup>lt;sup>16</sup> See, e.g., University of Texas Medical Branch, Graduate School of Biomedical Sciences, "Ethics of Scientific Research," *Course Descriptions*, http://www.utmb.edu/imh/GraduateProgram/gp.asp?show=Course-Req (accessed February 19, 2006).

to the media and identifying appropriate and inappropriate uses of scientific information. These topics can and should be included in graduate science education.

I have focused on the social responsibilities of scientists, but lawyers, bioethicists, and others who contribute to media reports and the neuroethics literature have equal responsibilities. We need to ensure that our excitement about fMRI, as expressed through statements to the media and during other public discussions, does not increase the risk of therapeutic illusions, therapeutic extravagance, and therapeutic futility. Therapeutic illusions exist when patients, family members, and other stakeholders believe that a particular medical treatment or research protocol will improve a patient's condition, when in all likelihood it will have no beneficial effect.<sup>17</sup> Therapeutic extravagance involves the provision of high-cost treatments that offer little or no benefit, and therapeutic futility refers to the provision of treatments that offer little or no benefit and, thus, are wasteful. 18 For example, non-scientists should not suggest that fMRI is capable of distinguishing between PVS and MCS patients, or assisting them in emerging from unconsciousness, when it cannot do so. 19 Non-scientists should expressly state that they are speculating when they are doing so, attempt to incorporate current science studies into any speculation in which they do engage, and avoid speculation that has no basis in the scientific literature. When New York Times reporter Benedict Carey stated on February 5, 2006, that, "At this rate, it seems that neuroscientists will soon pinpoint the regions in the brain where mediocre poetry is generated, where high school grudges are lodged, where sarcasm blooms like a red rose,"20 I realized that he was exaggerating

<sup>&</sup>lt;sup>17</sup> Stacey A. Tovino and William J. Winslade, "A Primer on the Law and Ethics of Treatment, Research, and Public Policy in the Context of Traumatic Brain Injury," *Annals Health Law* 14, no. 1 (Winter 2005): 2n5.

<sup>18</sup> Ibid.

<sup>&</sup>lt;sup>19</sup> Joseph J. Fins, "The Orwellian Threat to Emerging Neurodiagnostic Technologies," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 56.

<sup>&</sup>lt;sup>20</sup> Benedict Carey, "Searching for the Person in the Brain," *New York Times*, February 5, 2006, 41, http://www.nytimes.com/2006/02/05/weekinreview/05carey.html?ex=1296795600&en=bbc8fede11af6a48 &ei=5090&partner=rssuserland&emc=rss (accessed February 14, 2006).

given that my research had revealed no fMRI studies examining the neural correlates to poetry, high school grudges, or sarcasm. But, the general public may not have.

Of course, the need for caution in identifying and describing scientific findings must be balanced with the need to avoid over-conservative publication and reporting, which could increase the risk of therapeutic nihilism (the failure to recognize the possible benefits of treatment) and therapeutic neglect (a patient's lack of access to treatment from which she could benefit). For example, the findings of some fMRI deception studies have the potential to assist patients who have addictive disorders, in which deception, or the ability to conceal information, plays a prominent role. The findings of other fMRI studies involving known pedophiles may provide information that is valuable to their treatment. Although Chapter 2 identifies a handful of fMRI studies that have generated the most speculation about their application in non-research settings, the media has not referenced the thousands of other fMRI studies the goals of which are to further treatment of the studied conditions. Publication and accurate reporting of these studies is necessary for progress in medicine and science. Like so many other issues in ethics, then, scientific findings require balanced presentation by scientists and non-scientists.

## **NEURO EXCEPTIONALISM?**

#### The Analogy to Genetic Exceptionalism

In genetics, one issue that has been debated among federal and state legislatures, regulatory agencies, and academics is whether heightened confidentiality protections are

<sup>&</sup>lt;sup>21</sup> Tovino and Winslade, "A Primer," 2-3n5; Charles E. Rosenberg, "Belief and Ritual in Antebellum Medical Therapeutics," in *Major Problems in the History of American Medicine and Public Health: Documents and Essays*, ed. John Harley Warner and Janet A. Tighe (Boston: Houghton Mifflin, 2001), 112-13, 117 (exploring the history of "therapeutic nihilism").

<sup>&</sup>lt;sup>22</sup> B. Douglas Bernheim and Antonio Rangel, "Addiction and Cue-Triggered Decision Processes," *American Economic Review* 94, no. 5 (December 2004): 1558-90.

<sup>&</sup>lt;sup>23</sup> Harald Dressing et al., "Homosexual Pedophilia and Functional Networks—An fMRI Case Report and Literature Review," *Fortschritte der Neurologie-Psychiatrie* 69, no. 11 (2001): 539-44.

necessary to protect genetic information.<sup>24</sup> The idea that advances in genetics and the sensitivity of genetic information require special attention is known as "genetic exceptionalism," which builds on the idea of "HIV exceptionalism." Over forty states have passed statutes that prohibit genetic discrimination in health insurance, approximately two-thirds of states have passed legislation that prohibits genetic discrimination in employment, and a handful of other states have enacted various provisions addressing genetic discrimination in life insurance, genetic privacy, and genetic testing.<sup>26</sup> Congress also has attempted to pass legislation prohibiting genetic discrimination in both the health insurance and employment contexts.<sup>27</sup>

The question thus becomes whether implementation of a third generation of exceptionalism, "neuro exceptionalism," is desirable. Stated another way, are heightened confidentiality and privacy protections necessary to protect neuroimaging information and the individuals who consent to or are required to submit to fMRI? If so, what would such legislation or regulation look like? Seven main reasons have been given for heightened protections in the context of genetics, <sup>29</sup> and an analysis of these reasons, and their criticisms, can inform the neuro exceptionalism debate.

The first three reasons given for applying heightened confidentiality protections to genetic information are that genetic information has implications for family members, genetic information may have implications for reproduction and future generations, and

<sup>&</sup>lt;sup>24</sup> Mark Rothstein, "Genetic Exceptionalism, Legislative Pragmatism," *Hastings Center Report* 35, no. 4 (July-August 2005): 27.

<sup>25</sup> Thid

<sup>&</sup>lt;sup>26</sup> Rothstein, "Genetic Exceptionalism," 27; Greely, "Prediction, Litigation, Privacy, and Property," 143.

<sup>&</sup>lt;sup>27</sup> Genetic Information Nondiscrimination Act of 2003, S.1053, 108<sup>th</sup> Cong., 1<sup>st</sup> Sess. (introduced but not passed); Genetic Information Nondiscrimination Act of 2005, S.306, 109<sup>th</sup> Cong., 1<sup>st</sup> Sess. (introduced but not passed).

<sup>&</sup>lt;sup>28</sup> Ari Schick, "Neuro Exceptionalism," *American Journal of Bioethics* 5, no. 2 (March-April 2005): 36.

<sup>&</sup>lt;sup>29</sup> Rothstein, "Genetic Exceptionalism," 30.

genetic information may be predictive.<sup>30</sup> The argument is that genetic information is relevant not only to the patient's current health, but also to the health of current and future family members, as well as the patient's future health. It is these extra layers of relevance that are believed to require heightened confidentiality and privacy protections. Of course, critics argue that replication studies show that claimed associations between genetic variations and particular diseases do not always exist, many predictions are inaccurate, the strengths of accurate predictions vary greatly, and treatments do not exist for all of the conditions that can be predicted.<sup>31</sup>

Because some fMRI studies involve health conditions in which genes play a role, including Parkinson's disease and Alzheimer's disease, a brain scan that is used to study or is interpreted to reveal one of these diseases could have implications for current family members and future generations. Speculation that fMRI might be used to predict non-health related conditions, such as intelligence, likelihood of committing future crimes, and social behavior, <sup>32</sup> suggests that fMRI has predictive value too. The accuracy and strength of these predictions, as well as the availability of any "treatments," also must be considered. Thus, the first three reasons for genetic exceptionalism, as well as their criticisms, also apply in the functional neuroimaging context.

The fourth reason for heightened protections for genetic information is that genetic information carries a stigma, and that eugenics, racism, and genocide are the unfortunate results of the inappropriate use of genetic information.<sup>33</sup> It is fair to say that fMRI probably is still too new for functional neuroimaging information to carry a widespread stigma; however, this may rapidly change as fMRI extends outside of the research context and more functional neuroimaging information is created, used, and disclosed in the private and government sectors. And, although functional neuroimaging

<sup>30</sup> Ibid.

<sup>31</sup> Ibid

<sup>32</sup> Greely, "Prediction, Litigation, Privacy, and Property," 144.

<sup>&</sup>lt;sup>33</sup> Rothstein, "Genetic Exceptionalism," 30.

information may not currently carry a widespread stigma, fMRI scans have been interpreted to reveal neural activations that are correlated with certain mental health conditions, addictive behaviors, cognitive abilities, and sexual preferences, all of which the NIH considers sensitive or stigmatizing in other contexts.<sup>34</sup> Thus, the fourth reason for genetic exceptionalism also could support neuro exceptionalism, although research revealed no attempts to improve the human species by encouraging or permitting reproduction of only those individuals whose brain functions are judged desirable through review of fMRI scans (even though related speculation does exist).<sup>35</sup>

A fifth reason given for heightened protection for genetic information is that the public regards it as unique.<sup>36</sup> Although the public might not currently regard functional neuroimaging information as unique due to the relative newness of fMRI technology, the public may in the near future due to the frequency with which fMRI studies are covered by the media, including the *New York Times*, which has featured fMRI in approximately 45 articles.<sup>37</sup> Of course, relying on public regard as a reason for heightened confidentiality and privacy protections has been criticized on the grounds that it is self-fulfilling. Stated another way, the public might regard specific types of information as unique because information-specific legislation or regulation is passed.<sup>38</sup>

A sixth reason given for heightened protection for genetic information is that other sensitive or potentially stigmatizing types of health information have received special protection. Congress has enacted special protections that apply to certain alcohol

<sup>&</sup>lt;sup>34</sup> National Institutes of Health, Office of Extramural Research, Certificates of Confidentiality: Background Information (July 21, 2003), http://grantsl.nih.gov/grants/policy/coc/background.htm (accessed February 16, 2006); National Institutes of Health, Office of Extramural Research, Frequently Asked Questions on Certificates of Confidentiality (March 15, 2002), http://grantsl.nih.gov/grants/policy/coc/faqs.htm (accessed February 16, 2006).

<sup>&</sup>lt;sup>35</sup> Tancredi, *Hardwired Behavior*, 162-75 (describing a hypothetical legislative program set in the year 2100 that would attempt to create a "moral" brain).

<sup>&</sup>lt;sup>36</sup> Rothstein, "Genetic Exceptionalism," 30.

<sup>&</sup>lt;sup>37</sup> Westlaw *New York Times* database search results for query "fMRI" or "functional MRI" or "functional magnetic resonance imaging" (photocopy available) (performed February 19, 2006).

<sup>38</sup> Rothstein, "Genetic Exceptionalism," 30.

and drug abuse patient records,<sup>39</sup> many states have passed laws that provide special confidentiality protections for HIV and AIDS test results<sup>40</sup> and mental health records,<sup>41</sup> and even the HIPAA Privacy Rule, which generally applies one level of protection to all types of individually identifiable health information, provides heightened confidentiality protections for psychotherapy notes.<sup>42</sup> Of course, critics argue that genetic information is unlike alcohol and drug abuse records, HIV and AIDS test results, and psychotherapy notes, which can be separated from general medical records with relative ease.<sup>43</sup> Because genes play a role in many diseases and genetic information can be based on family history or revealed through thousands of different types of tests, it is more difficult for health care providers to separate genetic information from general health information.<sup>44</sup> Unlike genetic information, however, fMRI scans and their related reports could be maintained separately with relative ease.

The final reason given for heightened protection for genetic information is that greater political support exists for genetic nondiscrimination legislation than for more general legislation. However, critics of this argument emphasize that discriminating against an individual based on genetics is not less moral than discrimination based on other types of health information, and that complying with nondiscrimination laws that apply to health information generally is easier than complying with nondiscrimination laws that only apply to genetic information. Although those working within the field of neuroethics are clearly grappling with the pros and cons of neuro exceptionalism, it is

<sup>&</sup>lt;sup>39</sup> 42 C.F.R. Part 2 (2005).

 $<sup>^{40}</sup>$  Tex. Health & Safety Code §§ 81.103-.106 (West 2005).

<sup>&</sup>lt;sup>41</sup> Ibid., §§ 611.002-.003.

<sup>&</sup>lt;sup>42</sup> 45 C.F.R. § 164.508(a)(2) (2005).

<sup>&</sup>lt;sup>43</sup> Rothstein, "Genetic Exceptionalism," 30.

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> Ibid.

<sup>&</sup>lt;sup>47</sup> See, e.g., Schick, "Neuro Exceptionalism," 36.

unclear whether more (or any) political support exists for neuro-specific legislation compared to general confidentiality and privacy protections.

In summary, all seven reasons given for genetic exceptionalism could be used to support neuro exceptionalism, although many of the criticisms of genetic exceptionalism also apply in the neuroimaging context. Perhaps the most important factor – whether existing confidentiality and privacy protections adequately protect neuroimaging information and the individuals whose brains have been scanned – has been overlooked. In Chapters 3, 4, and 5, I found that a number of ethical and legal principles potentially apply to protect the confidentiality of neuroimaging information and the privacy of neuroimaging subjects. The adequacy of each of these protections must be considered in deciding whether heightened protections are needed.

# **Ethical Principles of Confidentiality and Privacy**

All physicians and scientists have an ethical duty to maintain the confidentiality of medical and study records in their possession, including functional neuroimaging records. Remember, Hippocrates told physicians to keep to themselves things they hear inside and outside of treatment, <sup>48</sup> and modern codes of medical ethics, such as the AMA's *Code of Medical Ethics*, require physicians to maintain the confidentiality of patient information to the greatest possible degree. <sup>49</sup> Stand-alone codes of research ethics, including the World Medical Association's *Declaration of Helsinki* and the CIOMS' *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, <sup>51</sup> also establish broad ethical duties of confidentiality and privacy that apply to

<sup>&</sup>lt;sup>48</sup> Ludwig Edelstein, *The Hippocratic Oath: Text, Translation and Interpretation* (Baltimore: Johns Hopkins Press, 1943), 3.

<sup>&</sup>lt;sup>49</sup> American Medical Association, *Code of Medical Ethics: Current Opinions with Annotations* (Chicago: American Medical Association, 1997), Opinion 5.059.

<sup>&</sup>lt;sup>50</sup> World Medical Association, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (Helsinki: World Medical Association, 1964), Principle 21.

<sup>&</sup>lt;sup>51</sup> Council for International Organizations of Medical Sciences, *International Ethical Guidelines* for Biomedical Research Involving Human Subjects (Geneva: Council for International Organizations of Medical Sciences, 2002), Guideline 18.

all human subjects research, including functional neuroimaging research. The issue is whether these principles need to be supplemented or strengthened to take into account advances in functional neuroimaging.

Because existing codes of medical and research ethics already apply to fMRI when used by physicians and scientists in the clinical and research contexts, I do not think that adding a provision stating that fMRI scans and related records are included within their protections would meaningfully add to the rights of patients and research subjects, although it certainly is one option. Physicians and scientists might, however, review existing ethical provisions to remind themselves of confidentiality and privacy duties that are particularly relevant in the neuroimaging context. For example, the APA's Ethical Principles of Psychologists and Code of Ethical Conduct require psychologists to discuss at the outset of a relationship the relevant limits of confidentiality and the foreseeable uses of information generated through their psychological activities, 52 and include in written and oral reports and consultations only information that is germane to the purpose for which the communication is made.<sup>53</sup> These provisions call for the behavior that I identified as ethically desirable in Chapters 4 and 5, such as making patients and research subjects aware of the social and behavioral information that fMRI has the potential to reveal, as well as how fMRI scans and related reports will be used and the procedures to be followed in the event of an incidental finding. The APA Principles also prohibit psychologists from disclosing any functional neuroimaging information that is not relevant to an otherwise permitted communication, which would effectively prevent a psychologist from disclosing functional neuroimaging information to private or governmental organization for non-treatment or reimbursement purposes without the patient's authorization.

<sup>&</sup>lt;sup>52</sup> American Psychological Association, *Ethical Principles of Psychologists and Code of Conduct* (Washington, D.C.: American Psychological Association, 2002), Ethical Standard 4.02(a) and (b).

<sup>53</sup> Ibid., Ethical Standard 4.04(a).

Like the APA *Principles*, the ACR *Code of Ethics* and the American Psychiatric Association's *Principles of Medical Ethics* also contain provisions with which radiologists and psychiatrists should re-familiarize themselves in light of advances in functional neuroimaging. For example, the ACR *Code* prohibits member radiologists from revealing any "deficiencies they may observe in the character of patients, unless they are required to do so by law or unless it becomes necessary to protect the welfare of the individual or of the community." In its *Principles of Medical Ethics*, the American Psychiatric Association recognizes that advances in technology and electronic record systems can threaten jeopardize patients' civil liberties, and reminds psychiatrists that the welfare of patients must be considered at all times:

Growing concern regarding the civil rights of patients and the possible adverse effects of computerization, duplication equipment, and data banks makes the dissemination of confidential information an increasing hazard. Because of the sensitive and private nature of the information with which the psychiatrist deals, he or she must be circumspect in the information that he or she chooses to disclose to others about a patient. The welfare of the patient must be a continuing consideration. <sup>55</sup>

In summary, existing codes of medical and research ethics not only apply to treatment and research involving fMRI, but they already contain provisions that would require the behavior I have identified as ethically desirable. Adding new language to the codes' general confidentiality principles stating that, "fMRI scans and related reports and interpretations" are included within such protections is one option, <sup>56</sup> although these provisions may not meaningfully add to the rights of patients and research subjects. A

<sup>&</sup>lt;sup>54</sup> American College of Radiology, *Code of Ethics* (Reston, Va.: American College of Radiology, 2003), § 1.

<sup>&</sup>lt;sup>55</sup> American Psychiatric Association, *Principles of Medical Ethics, with Annotations Especially Applicable to Psychiatry* (Arlington, Va.: American Psychiatric Association, 2001), § 4.

<sup>&</sup>lt;sup>56</sup> Center for Cognitive Liberty and Ethics, Comments on The Declaration on Universal Norms on Bioethics or Universal Declaration on Bioethics and Humanity (December 1, 2004), 2 http://www.cognitiveliberty.org/pdf/ccle\_un-comments04.pdf (accessed February 10, 2006).

second general option relating to privacy, the value of which also is not clear, would be to add language to existing codes of medical and research ethics clarifying that, "The right to privacy encompasses the inner domain of thought."57 A third option involves creating new ethical provisions that emphasize the sensitive and potentially stigmatizing nature of functional neuroimaging information, as well as the possibility that inaccurate neuroimaging interpretations could be used to a patient's detriment in a variety of private and government contexts. The AMA's Code of Medical Ethics already contains specific ethical provisions relating to the confidentiality issues raised by filming patients in the health care setting<sup>58</sup> and filming patients for the education of health professionals,<sup>59</sup> as well as confidential care for minors, 60 confidentiality issues raised by computers, 61 the disclosure of records to data collection companies, 62 and the use and disclosure of medical records by industry-employed physicians.<sup>63</sup> The AMA and other professional associations could consider adding additional provisions relating to the confidentiality and privacy issues raised by fMRI. These provisions could state that the creation, use, and disclosure of functional neuroimaging information requires the utmost respect for the patient's rights of confidentiality and privacy, and establish guidelines regarding the (1) removal of raw facial image elements and other identifiers from neuroimaging information, including information that is disclosed to neuroimaging data banks, (2) temporary and long-term storage of raw neuroimaging data, (3) management of incidental findings, including notification and referrals for treatment, (4) requirement for patient

<sup>&</sup>lt;sup>57</sup> Ibid., 3.

<sup>&</sup>lt;sup>58</sup> American Medical Association, *Code of Medical Ethics*, Opinion E-5.045.

<sup>&</sup>lt;sup>59</sup> Ibid., E-5.046.

<sup>60</sup> Ibid., E-5.055.

<sup>&</sup>lt;sup>61</sup> Ibid., E-5.07.

<sup>&</sup>lt;sup>62</sup> Ibid., E-5.075.

<sup>63</sup> Ibid., E-5.09.

authorization for non-treatment and reimbursement uses and disclosures of neuroimaging information, and (5) exceptions to the general requirement for patient authorization.

## The Common Rule

The Common Rule applies to all research involving human subjects that receives federal financial support from a signatory federal agency, research conducted in contemplation of a submission to the FDA for approval, and human subjects research conducted by an institution that has signed a multiple project assurance. Research projects regulated by the Common Rule must have adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, an informed consent form that describes the extent to which the confidentiality of records identifying the subject will be maintained, and procedures for informed consent to be waived if the only record linking the subject and the research would be the consent document and the principal risk involves the potential harms associated with a breach of confidentiality.

The Common Rule thus establishes a framework for protecting the confidentiality of neuroimaging research records and the privacy of human subjects. Scientists are supposed to develop study-specific confidentiality and privacy provisions and describe them in sufficient detail for the IRB to determine their adequacy. If it determines that the provisions are inadequate, the IRB must disapprove the research or require modifications of the provisions to ensure their adequacy.<sup>68</sup>

Notwithstanding this framework, the OHRP has found that some scientists do not develop adequate confidentiality and privacy protections or describe them in sufficient

<sup>&</sup>lt;sup>64</sup> Mark Rothstein, "Research Privacy under HIPAA and the Common Rule," *Journal of Law, Medicine and Ethics* 33 (Spring 2005): 155.

<sup>&</sup>lt;sup>65</sup> 45 C.F.R. § 46.111(a)(7) (2005).

<sup>&</sup>lt;sup>66</sup> Ibid., § 46.116(a)(5).

<sup>&</sup>lt;sup>67</sup> Ibid., § 46.117(c)(1).

<sup>&</sup>lt;sup>68</sup> Ibid., §§ 46.109(a), 46.111(a).

detail for the IRB to make a determination regarding their adequacy.<sup>69</sup> The OHRP also has found that many IRBs are not systematically and rigorously reviewing such provisions to determine their adequacy.<sup>70</sup> The problem, then, is not that the Common Rule does not address confidentiality and privacy, but that not all scientists and IRBs are adhering to applicable requirements.

Although it is tempting to recommend amendment of the Common Rule to establish heightened confidentiality and privacy protections that apply in the neuroimaging context, perhaps a more efficient recommendation would be to educate scientists and IRBs during IRB meetings and continuing medical education about the confidentiality and privacy issues raised by fMRI, and ensure that scientists and IRBs adhere to the Common Rule's existing provisions. IRBs could develop internal guidelines (and the OHRP could develop general guidelines) for developing, reviewing, and approving confidentiality and privacy provisions for functional neuroimaging research. These guidelines could (1) address the removal of raw facial image elements and other identifiers from neuroimaging information, including information disclosed to neuroimaging data banks, (2) identify best practices relating to the short and long-term storage of raw neuroimaging data, (3) require policies and procedures relating to incidental findings, including notification of the subject and referral for treatment, and (4) clarify that the subject's authorization is required for other uses and disclosures of neuroimaging information.

Notwithstanding the framework established by the Common Rule for ensuring confidentiality and privacy, experience with genetic exceptionalism shows that greater political support may exist for information-specific protections than renewed attention to

<sup>&</sup>lt;sup>69</sup> U.S. Department of Health and Human Services, Office for Human Research Protections, Division of Compliance Oversight, *OHRP Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance* (October 12, 2005), 3, http://www.hhs.gov/ohrp/compliance/findings.pdf (accessed February 16, 2006).

<sup>70</sup> Ibid.

existing protections.<sup>71</sup> To take into account this potential political support, HHS could consider amending the Common Rule through the administrative notice-and-comment rulemaking process to codify the guidelines identified in the previous paragraph. These guidelines could be located after the regulatory provisions addressing research involving pregnant women, human fetuses, and neonates,<sup>72</sup> prisoners,<sup>73</sup> and children<sup>74</sup> -- perhaps a new 45 C.F.R. § 46.501 in the HHS regulations. A proposal for such amendments likely would be criticized on the grounds that HHS already has determined that only vulnerable *populations*, not sensitive types of *information*, require heightened protections.

# The HIPAA Privacy Rule

The Privacy Rule only regulates covered entities (defined to include health plans, health care clearinghouses, and those health care providers that transmit health information in electronic form in connection with standard transactions), when they are using and disclosing protected health information (generally defined as individually identifiable health information). The relevant questions are whether HHS can and should amend the Privacy Rule to (1) regulate those scientists who are not currently covered, (2) clarify that neuroimaging information is protected health information, or (3) establish heightened confidentiality protections for neuroimaging information.

The class of persons and organizations HHS can regulate in its Privacy Rule is limited by statute. HIPAA only gives HHS the authority to regulate health plans, health care clearinghouses, and those health care providers who transmit health information in connection with the standard transactions.<sup>75</sup> HHS cannot unilaterally amend the Privacy

<sup>71</sup> Rothstein, "Genetic Exceptionalism," 30.

<sup>&</sup>lt;sup>72</sup> 45 C.F.R. § 46.201 et seq. (2005).

<sup>&</sup>lt;sup>73</sup> Ibid., § 46.301.

<sup>&</sup>lt;sup>74</sup> Ibid., § 46.401.

<sup>&</sup>lt;sup>75</sup> Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, Title II, Subtitle F, § 261 (August 21, 1996) ("Any standard adopted under this part shall apply, in whole or in part, to the following persons: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a [standard] transaction . . . ").

Rule to regulate all scientists who use fMRI; instead, an act of Congress would be required. Notwithstanding numerous public comments requesting expansion of HHS' regulatory authority, <sup>76</sup> as well as HHS' own belief that Congress was stingy in its delegation of authority, <sup>77</sup> neither Congress nor HHS has been willing to attempt to expand HHS' authority, <sup>78</sup> and a proposal to do so likely would be unsuccessful.

The information HHS can protect by its Privacy Rule also is limited by statute. HIPAA gave HHS the authority to protect only individually identifiable health information, defined to include information collected from an individual that is (1) created or received by a health care provider, health plan, employer, or health care clearinghouse, (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, and (3) identifies the individual; or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. However, not all fMRI scans and related reports will be created or received by health care providers, plans, employers, or clearinghouses. Some fMRI scans will be created by scientists who don't provide health care and, if No Lie MRI has its way, some fMRI scans will be received by

<sup>&</sup>lt;sup>76</sup> U.S. Department of Health and Human Services, "Standards for Privacy of Individually Identifiable Health Information, Final Rule," *Federal Register* 65 (December 28, 2000): 82,567 ("A number of commenters urged the Department to expand or clarify the definition of 'covered entity' to include certain entities other than health care clearinghouses, health plans, and health care providers who conduct standard transactions. For example . . . ").

<sup>&</sup>lt;sup>77</sup> U.S. Department of Health and Human Services, "Standards for Privacy of Individually Identifiable Health Information, Proposed Rule," *Federal Register* 64 (November 3, 1999): 59,968 ("We understand that this approach involves imposing burdens on covered entities rather than on researchers. . . . This is not the approach we advocate for new federal privacy legislation, where we would propose that standards be applied directly to researchers . . . ").

<sup>&</sup>lt;sup>78</sup> U.S. Department of Health and Human Services, "Standards for Privacy of Individually Identifiable Health Information, Final Rule," 82567 ("We understand that many entities may use and disclose individually identifiable health information. However, our jurisdiction under the statute is limited . . .").

<sup>&</sup>lt;sup>79</sup> Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, Title II, Subtitle F, § 261 (August 21, 1996).

federal and state governments. In addition, there is a question whether the definition includes fMRI scans that are interpreted to reveal non-health conditions, including one-time deception that does not rise to the level of pathological lying ("I do not have the 5 of Clubs card"), racial evaluation, and consumer preferences. Although HHS cannot unilaterally amend the Privacy Rule to protect information that does not fall within the statutory definition of individually identifiable health information, the Office for Civil Rights (OCR) can clarify whether fMRI scans and related reports that reveal only social information are protected through guidance or a response to a frequently-asked question. I have asked the OCR to do so.<sup>80</sup>

Even those physicians and scientists who are covered by the Privacy Rule are allowed to use and disclose otherwise protected fMRI scans and related reports without authorization for dozens of treatment, reimbursement, health care operations, and public policies activities<sup>81</sup> identified in Chapter 4. The question is whether HHS should consider amending the Privacy Rule to prohibit the use and disclosure of functional neuroimaging information for some or all of these health care operations or public policy activities.<sup>82</sup> One option is to give functional neuroimaging information the same level of protection that applies to psychotherapy notes. The Privacy Rule establishes a minimum level of confidentiality protections for all information that constitutes individually identifiable health information, except for psychotherapy notes, which receive more protection. Notwithstanding any other provision in the Privacy Rule, covered entities

W.S. Department of Health and Human Services, Health Information Privacy and Civil Rights Questions and Answers, http://healthprivacy.answers.hhs.gov/cgi-bin/hipaa.cfg/php/enduser/std\_alp.php?p\_cv=1.7%3B2.u0&%20p\_cats=7%2C0&%20cat\_lvl1=7&cat\_lvl2=0&p\_search\_text (accessed February 10, 2006). The OCR has not yet responded to my request.

<sup>81 45</sup> C.F.R. §§ 164.506(c)(2)-(5), 164.512 (2005).

Psychotherapy notes are defined as notes recorded in any medium by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session, if they are separated from the rest of the individual's medical record. Ibid. § 164.501. Psychotherapy notes do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of diagnosis, functional status, treatment plan, symptoms, prognosis, and progress to date. Ibid.

must obtain prior patient authorization for any use or disclosure of psychotherapy notes, except for a (1) use by the originator of the psychotherapy notes for treatment, (2) use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling, (3) use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual, (4) use or disclosure that is required by other law, (5) use or disclosure that is required for government oversight of the originator of the psychotherapy notes, (6) disclosures to coroners and medical examiners if the psychotherapy notes are needed to determining an individual's cause of death (such as suicide); and (7) uses and disclosures that are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.<sup>83</sup> These seven exceptions are the only exceptions for which covered entities can use and disclose psychotherapy notes without patient authorization; authorization is required for the dozens of other health care operations and public policies activities normally permitted without authorization.

Along these lines, HHS could amend section 164.508(a)(2) of the Privacy Rule to make this limited set of uses and disclosures applicable to neuroimaging information.<sup>84</sup>

<sup>83 45</sup> C.F.R. § 164.508(a)(2)(i), (ii) (2005).

<sup>84</sup> As amended, 45 C.F.R. § 164.508(a)(2) could provide:

<sup>(2)</sup> Authorization required: psychotherapy notes << and neuroimaging information>>. Notwithstanding any provision of this subpart, other than the transition provisions in Sec. 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes << or neuroimaging information>>, except:

<sup>(</sup>i) To carry out the following treatment, payment, or health care operations: (A) Use by the originator of the psychotherapy notes <<or neuroimaging information>> for treatment; (B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health and <<disciplines in which neuroimaging is conducted>> learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or (C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

<sup>(</sup>ii) A use or disclosure that is required by Sec. 164.502(a)(2)(ii) or permitted by Sec. 164.512(a); Sec. 164.512(d) with respect to the oversight of the originator of the psychotherapy notes <<or neuroimaging information>>; Sec. 164.512(g)(1); or Sec. 164.512(j)(1)(i).

The benefit of this approach is that a separate set of rules establishing exceptions to the otherwise required authorization for the use and disclosure of neuroimaging information does not have to be established, thus quelling concern about how to reconcile heightened confidentiality protections for neuroimaging information with the legitimate activities for which public policies and the law already support the disclosure of information. One criticism of this approach is that even these provisions would allow the disclosure of neuroimaging information in six non-treatment situations. Whether these non-treatment situations should be further limited might best be negotiated by interested stakeholders, including patient advocates, covered physicians, covered scientists, and other covered entities who will be using, creating, and disclosing neuroimaging information.

An amendment to the Privacy Rule establishing heightened confidentiality protections for neuroimaging information also would require a corresponding definition of *neuroimaging information*. In the genetics context, defining *genetic information* has proved difficult, in part because it requires a determination of whether genetic information should be narrowly defined to include only genetic test results, or broadly defined to include family history. Defining *neuroimaging information* should be easier, although decisions would still need to be made about the types of functional neuroimages, such as fMRI, PET, and SPECT scans, that would be included, whether structural MRI scans should be included in addition to fMRI scans, and the scope of included interpretations and reports. Stakeholders, including patient advocates, covered providers, and covered scientists who create neuroimaging information, are in the best position to develop an accurate definition, which could be added to the Privacy Rule at section 164.501. A definition that may be considered as a starting point provides:

<sup>&</sup>lt;sup>85</sup> Greely, "Prediction, Litigation, Privacy, and Property," 145; Judy Illes and Matthew P. Kirschen, "New Prospects and Ethical Challenges for Neuroimaging Within and Outside the Health Care System," *American Journal of Neuroradiology* 24, no. 10 (2003): 1933; Turhan Canli and Zenab Amin, "Neuroimaging of Emotion and Personality: Scientific Evidence and Ethical Considerations," *Brain and Cognition* 50, no. 3 (December 2002): 427-28.

<sup>&</sup>lt;sup>86</sup> Greely, "Prediction, Litigation, Privacy, and Property," 144.

Neuroimaging information means information that is a subset of protected health information and that includes (i) images of brain function produced by functional magnetic resonance, positron emission tomography, and single-photon emission computed tomography; and (ii) interpretations of and reports relating to images of brain function, including written and oral interpretations and reports regarding an imaged individual's past, current, and future physical or mental health; physiological processes; behavior; or social qualities, characteristics, and preferences.

It is worth noting that any modification to the Privacy Rule would have to survive the administrative notice-and-comment rulemaking process, which is notoriously slow. Encouraging HHS to consider modifying the Privacy Rule likely would be very difficult given that HHS already has issued two sets each of proposed and final rules and has given no indication that it is interested in considering additional changes.

# **Certificates of Confidentiality**

Certificates of confidentiality are an excellent means of assisting scientists in maintaining the confidentiality of neuroimaging information. Federal agencies are authorized to issue certificates of confidentiality to all scientists, including non-federally funded scientists, engaged in all biomedical, behavioral, clinical, mental health, and other research studies. The certificates allow scientists to withhold names and other identifiable data about research participants that otherwise may be summoned under federal, state, or local civil, judicial, administrative, legislative, or other proceedings. Because certificates of confidentiality can provide additional confidentiality protections in the functional neuroimaging context, especially in the context of non-federally funded studies to which the Common Rule may not apply, scientists should be made aware of their availability. During IRB meetings or continuing medical or ethics education, scientists should be told that the certificates are available for any research project that

<sup>87 42</sup> U.S.C. § 241(d) (1988).

<sup>88</sup> Ibid.

involves the gathering of sensitive information from human subjects, <sup>89</sup> and that many fMRI studies will involve the gathering of sensitive information. Scientists also should be told that the certificates are research-project specific, and must be requested from the applicable federal agency prior to the beginning of each research project. IRBs or departments of research compliance within universities or academic medical centers may wish to consider providing scientists assistance with completing the necessary paperwork. <sup>90</sup>

# Stand-Alone Confidentiality and Privacy Laws

Like the Privacy Rule, existing state confidentiality laws, which vary from jurisdiction to jurisdiction, do not regulate many non-provider scientists, may not protect social information that falls outside of the definition of health information, and typically contain numerous exceptions pursuant to which health information may be used and disclosed by health care providers without prior authorization. To fill these gaps, one option is for state legislatures and Congress to enact stand-alone confidentiality and privacy provisions, which could be loosely modeled after my proposal to amend the Privacy Rule, <sup>91</sup> that (1) establish stringent confidentiality protections for neuroimaging information that apply to any person or organization, including any private, commercial, and government organization, that creates, obtains, or maintains neuroimaging information, (2) specify the limited purposes for which these regulated entities can use and disclose functional neuroimaging information without the prior written authorization of the subject of the information, and (3) prohibit discrimination based on neuroimaging information in health insurance, life insurance, and employment. Although state legislatures could model these provisions after my federal proposal and existing state

<sup>&</sup>lt;sup>89</sup> Office of Extramural Research, National Institutes of Health, *Certificates of Confidentiality: Background Information* (July 21, 2003), http://grants1.nih.gov/grants/policy/coc/background.htm (accessed February 16, 2006).

<sup>90</sup> Ibid.

<sup>91</sup> A federal proposal is set forth at note 84 in this chapter.

laws that apply to genetic information, Congress would have to overcome the inertia it has demonstrated in the context of genetic non-discrimination legislation, and ensure that it only regulates action that substantially affects interstate commerce, as necessary to survive scrutiny under the U.S. Constitution's Commerce Clause. 92

The federal Employee Polygraph Protection Act<sup>93</sup> could serve as a model for Congress to use in developing a federal law that would prohibit the use of fMRI tests in the employment setting. The basic provisions of the federal law – perhaps the "Functional Neuroimaging Protection Act" – could provide:

It shall be unlawful for any employer engaged in or affecting commerce or in the production of goods for commerce directly or indirectly to:

- (1) require, request, suggest, or cause any employee or prospective employee to take or submit to any functional neuroimaging test;
- (2) use, accept, refer to, or inquire concerning the results of any functional neuroimaging test of any employee or prospective employee; and
- (3) discharge, discipline, discriminate against in any manner, or deny employment or promotion to, or threaten to take any such action against -- (A) any employee or prospective employee who refuses, declines, or fails to take or submit to any functional neuroimaging test, or (B) any employee or prospective employee on the basis of the results of any functional neuroimaging test.

The new federal law would require a definition of functional neuroimaging test as well as clarification regarding the neuroimaging technologies and testing procedures that would constitute functional neuroimaging tests. Congress could consider enacting similar laws in the insurance and education settings as well.

## **Application of Other Legal Frameworks**

Although codes of medical and research ethics, the Common Rule, and the Privacy Rule in theory could be amended to take into account the specific confidentiality and privacy concerns raised by fMRI, other legal frameworks, such as constitutional law

 $<sup>^{92}</sup>$  U.S. Const. art 1,  $\S$  8, clause 3.

<sup>93 29</sup> U.S.C. §§ 2001-2009 (2006).

and evidence law, generally will not change. The question thus becomes how the courts will apply the frameworks of constitutional and evidence law to cases involving fMRI. How the courts will apply constitutional law principles to an alleged breach of cognitive privacy will depend on a number of factors, including the individual's expectation of privacy, whether the expectation is reasonable, whether the government-ordered or imposed fMRI test was conducted by qualified medical personnel in a safe environment, the government's interest in ordering the fMRI scan, and whether the government had probable cause to and did obtain a search warrant prior to conducting the scan. Whether evidence law will allow a party to introduce an fMRI scan or a related report or interpretation will depend on a number of factors that will change over time, such as fMRI's current rate of error in identifying or measuring the condition or characteristic at issue, the number of peer-reviewed studies finding that fMRI is an accurate method of identifying or measuring such condition or characteristic, whether fMRI has obtained general acceptance as a method of identifying or measuring the condition or characteristic, and whether standards regarding the acceptable use of fMRI have been established and implemented.

## **CONCLUSIONS**

Americans value their rights of confidentiality and privacy and are concerned about the circumstances in which they will be asked to share information about themselves and, once shared, how their information will be further used and disclosed. Because fMRI poses minimal health risks, the technology's most significant risks may be the potential breaches of confidentiality and invasions of cognitive privacy. Although existing ethical and legal principles will protect some functional neuroimaging information and some individuals whose brains are scanned, my comprehensive and

<sup>94</sup> National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants, 104.

<sup>95</sup> Ibid.

detailed analysis of these principles in Chapters 3, 4, and 5 shows that major gaps in protection exist. I thus recommend (1) implementation and enforcement of existing confidentiality and privacy rights and duties, including certificates of confidentiality, while neuro exceptional proposals are being considered; and (2) the development of a comprehensive system of neuro exceptional provisions, which could be modeled after the proposals I have identified in this chapter.

Implementing and enforcing existing confidentiality and privacy rights and duties is an efficient interim measure that serves at least two functions. First, it preserves these general rights and duties for future use. Stated another way, if only information-specific, or exceptional, provisions existed, new types of information created by advances in science would lack protection. General, or generic, confidentiality and privacy protections are valuable because they can be applied to new technologies and new types of information without resorting to the expensive and time-consuming legislative and administrative notice-and-comment rulemaking process. Second, actually implementing and enforcing existing confidentiality and privacy duties takes into account the lessons learned from the HIPAA Privacy Rule. The stated goal of the Privacy Rule was to establish a federal "floor" of confidentiality protections, which took HHS over four years to adopt in final form and cost covered entities millions of dollars in compliance. As codified, several provisions within the Privacy Rule actually are less stringent than many state health information confidentiality laws that had been in place for dozens of years. If the old state laws had simply been followed and enforced, much of the Privacy Rule would have been unnecessary. We thus should take advantage of the guidance provided by existing ethical and legal principles, many of which contemplate behavior I identify as ethically desirable for purposes of protecting confidentiality and privacy in the context of functional neuroimaging.

Unfortunately, significant gaps in legal protections exist. Few or no regulations apply to scientists who do not conduct federally-funded research under the Common Rule, scientists who do not constitute covered entities under the Privacy Rule, and non-

scientist and non-provider individuals and organizations that wish to obtain, create, or use functional neuroimaging information for commercial and other purposes. Existing protections are best described as fragmented. To ensure that the confidentiality of functional neuroimaging information and the privacy of neuroimaging subjects is maintained, professional associations, legislatures, and regulatory agencies should consider adopting a comprehensive neuro exceptional program. Using the options I have identified in this chapter as a starting point, stakeholders (including patients, research subjects, health care providers, scientists, ethicists, and representatives of commercial organizations and government agencies) can negotiate the boundaries of functional neuroimaging-specific confidentiality and privacy rights and duties. Two of the most important issues that require attention are the situations in which fMRI scans and records may be used or disclosed without the prior written authorization of the subject and the class of neuroimaging information that is to be protected.

Additional considerations are necessary. For example, private and governmental organizations that are legally permitted<sup>96</sup> and are considering conducting fMRI tests or obtaining neuroimaging test results should consult with neuroscientists and other qualified individuals who understand the limitations of neuroimaging research and the meaning of fMRI test results.<sup>97</sup> By the same token, scientists have a role in informing the public about the proper uses of fMRI and permissible interpretations of test results.

Although advances in science and technology frequently raise new ethical, legal, and social issues, developments in neuroscience and neuroimaging technology are unique. The potential of fMRI to reveal thoughts, characteristics, and social behaviors poses a significant challenge to existing confidentiality and privacy provisions, many of which were designed to protect traditional medical and study records. Identification of

<sup>&</sup>lt;sup>96</sup> Chapters 3, 4 and 5 discuss the legal constraints that apply to the creation, use, and disclosure of neuroimaging information.

<sup>&</sup>lt;sup>97</sup> Rothstein, "Application of Behavioural Genetics," 797 (arguing that commercial and social institutions need to consult with experts before applying behavioural genetics to avoid limiting opportunities for individuals or stigmatizing them).

the considerable gaps in coverage can inform policy discussions about the need to protect confidentiality and privacy as attempts to transfer fMRI technology beyond the research context are made.

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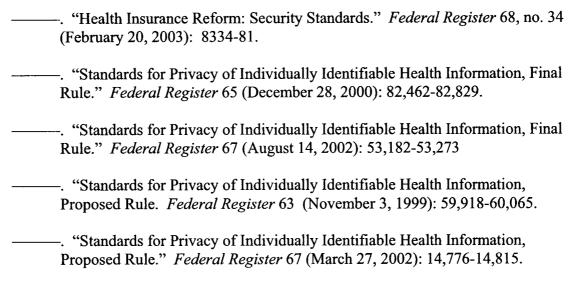
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Stacey Tovino was born on November 20, 1972, in Troy, New York. A member of the Tulane Honors Program and a Tulane Scholar, Stacey received her B.A. in economics, magna cum laude, from Tulane University in 1994, with certificates in law and economics and business law. Her undergraduate Honors Thesis, for which she received Departmental Honors, was entitled, "An Economic Analysis of Intellectual Property Rights: Optimal Patent and Copyright Scope." Stacey served as President of the Tulane Rowing Team from 1992 to 1993, and was a loyal Rowing Team member between 1990 and 1994.

Stacey received her J.D., magna cum laude, Order of the Coif, and Order of the Barons, from the University of Houston Law Center in 1997. During law school, she served as the publications editor of the Houston Law Review, brief writer for the Moot Court Team, and research assistant for the Health Law and Policy Institute. Stacey practiced law in the Health Industries Group at Vinson & Elkins in Houston, Texas, between 1997 and 2003, and matriculated at the University of Texas Medical Branch in 2003. As a graduate student, Stacey was selected to write a Palmer Saunders Essay, received the GSBS Associates Scholarship, and was elected to Phi Kappa Phi.

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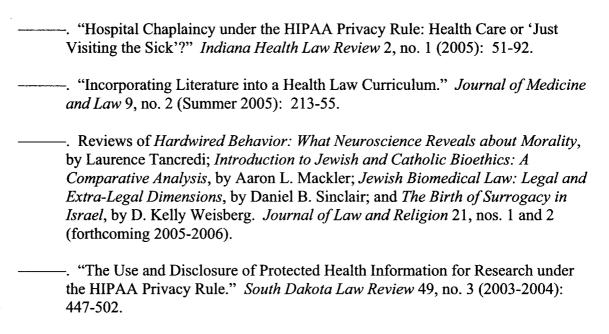
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