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### MRIs and the Perception of Risk

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# MRIs and the Perception of Risk

Steven Goldberg<sup>†</sup>

## I. INTRODUCTION

The most important safety decision concerning MRIs was to change the name of the procedure. In the late 1970s, the procedure known as nuclear magnetic resonance (NMR) became magnetic resonance imaging (MRI) because of the negative connotations the word “nuclear” invited.<sup>1</sup> Since then, the use of MRIs has flourished. The procedure is now routinely conducted to make medical diagnoses and to study the brain functioning of healthy volunteers participating in research studies devised by, among others, neuroscientists and economists.

There is nothing intrinsically wrong with changing a procedure’s name to respond to a public perception of risk, especially when experts do not share that perception. Yet, while MRIs rarely injure patients or test subjects,<sup>2</sup> there is reason to believe that they have important health and safety consequences not captured in standard informed consent forms. These concerns ironically involve perception of risk. On the one hand, unexpected incidental findings of clinically significant conditions in volunteer research subjects raise a host of ethical concerns. On the other hand, clinically irrelevant MRI findings sometimes lead to needless and dangerous interventions. In both cases, risk perception plays a role in understanding and dealing with the problem. The name change from NMR to MRI, however, will not exempt this procedure from difficult choices in the years ahead.

The following takes a closer look at the role risk perception plays in the use of MRIs to study brain functioning. Part II begins by describing the history of nuclear magnetic resonance, a history that illustrates the way basic research led to unimagined practical applications decades later. Part III turns to the history of the name change, which includes a formal vote by the American College of Radiology to remove the word “nuclear” from the procedure to allay public fears.<sup>3</sup> Part IV discusses the recent literature on the difficult problem of what to do when an MRI administered to a presumably healthy volunteer in a research setting reveals the possibility of a medical problem that may or may not be clinically relevant, but which will cause fear

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<sup>1</sup> See discussion *infra* Part III.

<sup>2</sup> See discussion *infra* Part IV.

<sup>3</sup> Thomas F. Meaney, *Magnetic Resonance Without Nuclear*, 150 *RADIOLOGY* 277, 277 (1984).

in either case. This problem—which has medical, legal and ethical dimensions—deserves the full attention of the research community. Finally, this article concludes with a brief summary of the legal implications of the risk perceptions of research subjects.

## II. HISTORICAL EMERGENCE OF NUCLEAR MAGNETIC RESONANCE

The development of MRIs began with early twentieth century research on the quantum mechanical nature of the atomic nucleus.<sup>4</sup> The story, in highly simplified terms, goes like this. In the 1930s, the physicist I. I. Rabi, working at Columbia University, began to study the magnetic properties of atoms.<sup>5</sup> He bathed lithium chloride molecules with magnetic fields and radio waves in a successful effort to induce and measure the resonance frequency that occurs when the nucleus absorbs energy from the radio signal that is equal to a particular change in its energy state.<sup>6</sup> This technique enabled Rabi to learn a tremendous amount about how atoms are bound together and how their nuclei are affected by nearby atoms.<sup>7</sup>

In the 1940s, Edward Purcell at Harvard and Felix Bloch at Stanford, working independently, each developed ways to observe the magnetic resonance of the proton—the nucleus of the hydrogen atom—in liquids and solids.<sup>8</sup> Rabi worked with isolated molecules. By working with solids and liquids, Purcell, Bloch, and researchers who followed, were able to probe the internal structure of a variety of materials, making it possible for chemists, biologists, and physicists to analyze the structure of molecules.<sup>9</sup> The technique pioneered by Purcell and Bloch came to be called nuclear magnetic resonance (NMR).

It was not until 1969 that Raymond Damadian, a physician at the Downstate Medical Center in Brooklyn, New York, began to do experiments designed to show that NMR could be used to probe living tissue for signs of disease.<sup>10</sup> It was not an obvious idea. NMR specialists at the time were accustomed to spinning their test-tube samples to achieve greater homogeneity. When Damadian proposed using NMR on people, he was asked, “How fast do you propose to spin the patient, Doctor?”<sup>11</sup>

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<sup>4</sup> This account of the scientific origins of MRI technology is drawn from two sources. The National Academy of Sciences has produced a series of articles on basic research entitled *Beyond Discovery*. See <http://www.beyonddiscovery.org/content/view.article.asp?=60> (last visited September 21, 2006). The article on Magnetic Resonance Imaging is my primary source. See Roberta Conlan, *A Life-Saving Window on the Mind and Body: The Development of Magnetic Resonance Imaging*, *BEYOND DISCOVERY*, Mar. 9, 2001, <http://www.beyonddiscovery.org/content/view.txt.asp?a=129> [hereinafter *NAS*] (last visited September 21, 2006). To a lesser degree, I relied on the far more detailed account in the leading text on the history of MRIs, JAMES MATTSON & MERRILL SIMON, *THE STORY OF MRI: THE PIONEERS OF NMR AND MAGNETIC RESONANCE IN MEDICINE* (1996) [hereinafter *Mattson*].

<sup>5</sup> *NAS*, *supra* note 4.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *MATTSON*, *supra* note 4, at 613.

Vital breakthroughs by the chemist Paul Lauterbur at the State University of New York at Stony Brook and the physicist Peter Mansfield at the University of Nottingham, England, made the application of NMR to humans possible.<sup>12</sup> Working in the early 1970s, they developed ways to use multiple magnetic fields in conjunction with radio frequencies to get remarkable results with living tissue.<sup>13</sup> In the 1980s, other researchers demonstrated that resonance imaging could capture an organism in action; in other words, it could show biological functioning such as changes in blood flow in the brain.<sup>14</sup>

The medical and research implications of these developments have exploded in recent decades. Today, doctors worldwide perform over sixty-million MRI procedures a year to identify tumors, diagnose brain disease, and so on.<sup>15</sup> Since the mid-1990s, neuroscientists have used this approach to study the roles played by various parts of the brain in recognizing visual patterns, processing emotions, and the like.<sup>16</sup> Economists and other social scientists have joined in, using brain scans to study the reactions of volunteers in experiments studying such matters as financial investment decisions, social rejection by peers, and moral judgments.<sup>17</sup>

This is a classic story of the nature of basic research. The early work on NMR was basic science at the highest level: Rabi, Purcell, Bloch, Lauterbur, and Mansfield all won Nobel Prizes.<sup>18</sup> The research began with a curiosity about the nature of the world rather than a search for practical applications. I. I. Rabi was thinking about the quantum states of the atom, not brain functioning, just as Einstein was not aiming for the creation of nuclear energy.<sup>19</sup> Yet the basic research was a vital precondition for the applications we see today. It is clear that George Pake, a student of Purcell, was correct when he said in 1993, “Without the basic research, magnetic resonance imaging was unimaginable.”<sup>20</sup>

### III. THE TRANSITION FROM “NMR” TO “MRI”

When magnetic resonance imaging was first applied to human patients, it was called Nuclear Magnetic Resonance (NMR).<sup>21</sup> By the early 1980s, when the procedure had begun to spawn a large commercial enterprise, the medical community dropped the word “nuclear” and began to speak simply of Magnetic Resonance Imaging (MRI).<sup>22</sup> In 1983, the American College of Radiology’s Commission on Nuclear Magnetic Resonance formally recommended dropping the word “nuclear” from the name of the procedure,

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<sup>12</sup> NAS, *supra* note 4.

<sup>13</sup> *Id.*

<sup>14</sup> *See id.*

<sup>15</sup> Tom Siegfried, *MRI Nobel Signals New Way to Teach Science*, DALLAS MORNING NEWS, Oct. 13, 2003, at 3E.

<sup>16</sup> John Cassidy, *Mind Games: What Neuroeconomics Tells Us About Money and the Brain*, THE NEW YORKER, Sept. 18, 2006, at 32.

<sup>17</sup> *See, e.g.*, Michael D’Antonio, *How We Think: Brain Researchers Are Using MRIs to Predict Our Decisions Before They Are Made*, L.A. TIMES MAGAZINE, May 2, 2004, at 18.

<sup>18</sup> NAS, *supra* note 4; Siegfried, *supra* note 15.

<sup>19</sup> *See* STEVEN GOLDBERG, *CULTURE CLASH: LAW AND SCIENCE IN AMERICA* 132 (1994).

<sup>20</sup> NAS, *supra* note 4.

<sup>21</sup> Meaney, *supra* note 3, at 277.

<sup>22</sup> NAS, *supra* note 4.

in part because “the deletion of ‘Nuclear’ may be helpful in eliminating undesirable connotations in the minds of the public.”<sup>23</sup> A National Academy of Sciences publication said of the name change, “‘Nuclear’ had been quietly dropped from the name . . . because of its unfavorable connotations.”<sup>24</sup> Joel D. Howell, an expert in the history of medicine, put it more bluntly:

It is of some interest that MRI has long been used for the study of inanimate objects under the name of NMR, for nuclear magnetic resonance. When the technology started to be applied to human beings, the name was changed to MRI so as not to frighten people by using a machine with the name “nuclear.”<sup>25</sup>

There is, however, a gain in clarity when the word “nuclear” is dropped from the name. For example, MRIs, unlike x-rays, do not expose patients to radioactivity.<sup>26</sup> The term “nuclear magnetic resonance” derived from the nature of the original basic research of Rabi and others, which concerned fundamental properties of the atomic nucleus.

One unintended consequence of dropping the word “nuclear” from the name of the now-common MRI procedure is that few people are aware of how research in theoretical physics led to this medical marvel. This has caused some grumbling in the physics community. The Nobel Laureate physicist Leon Lederman has long supported increased government funding for basic research.<sup>27</sup> In 1982, when MRIs were bursting onto the scene, Lederman wrote a letter to the *New York Times* after a story appeared touting the medical benefits of this new technology:

A November 28 news article by Jane Brody, “Magnetic Device Lifts Hopes for Diagnosis Without X-Ray,” treated front-page readers to a cogent account of a revolutionary medical diagnostic technique . . . . Your business section and many Wall Street publications have long been much taken with the predicted near-billion-dollar market for this remarkable scanning device. What is not made clear to either set of readers is the NMR is a classic example of the payoff of basic, abstract, pure research. The NMR technique was invented by E. Purcell (Harvard) and F. Bloch (Stanford) in 1946, based upon the atomic resonance work of I.I. Rabi (Columbia). All three were awarded Nobel Prizes for their work . . . .

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<sup>23</sup> Meaney, *supra* note 3, at 277.

<sup>24</sup> *Id.* The leading text on the history of MRIs says the name change was undertaken “primarily to avoid the misleading implication that the technology uses radioactive materials.” MATTSON, *supra* note 4, at 613.

<sup>25</sup> Joel D. Howell, *Symposium on Biomedical Technology and Health Care: Social and Conceptual Transformations: Technical Article: Diagnostic Technologies: X-Rays, Electrocardiograms, and CAT Scans*, 65 S. CAL. L. REV. 529, 529 n.2 (1991).

<sup>26</sup> See, e.g., Judith Vandewater, *Overused Technology Can Be Dangerous As Well as Expensive*, ST. LOUIS POST-DISPATCH, Sept. 26, 2004, at A11.

<sup>27</sup> He led an unsuccessful effort to fund the Super Collider. See STEVEN GOLDBERG, *SEDUCED BY SCIENCE: HOW AMERICAN RELIGION HAS LOST ITS WAY* 119 (1999).

This example of benefits to society of basic research—in better medicine and in taxes returned to the Treasury—needs to be told and retold; it is not easy to hold the attention of policy makers.<sup>28</sup>

But the real story about the transformation from NMR to MRI is not the story of research on the atomic nucleus, nor the impact on funding for basic research. Moreover, the “unfavorable connotations” of the word “nuclear” stem not just from x-ray exposure, but from more general concerns about the risks of nuclear energy. America’s nuclear power plants had become increasingly controversial in the 1970s, a process that culminated with the accident at Three-Mile Island in 1979.<sup>29</sup> It was just around this time that NMR understandably became MRI.

There are certainly analysts who believe that Americans are overly or irrationally risk averse when it comes to exposure to radiation.<sup>30</sup> But doctors who want to advance the use of a technology that does not expose patients to radioactivity can hardly be faulted for making a name change that removes the word “nuclear.” Fears, whether rational or not, are a part of the public’s decision-making, a reality that policy makers cannot easily avoid.<sup>31</sup> Even when radiation is present, proponents of a technology are not likely to tout that fact. For example, it is doubtful that there has ever been an advertisement for a “nuclear-powered” smoke detector, but in fact, most smoke detectors use americium-241, which emits small amounts of radiation.<sup>32</sup>

The word “nuclear,” however, is not the only word that researchers want to avoid. Some researchers are currently mounting a campaign to remove the word “cloning” from the name of a promising technique.<sup>33</sup>

At present, the phrase “human cloning” includes two distinct activities—reproductive cloning and therapeutic cloning.<sup>34</sup> They begin the same way. Nuclear material is taken from a woman’s egg while nuclear material from a donor’s somatic cells is introduced in its place.<sup>35</sup> The egg then begins to develop just as a traditional fertilized ovum does. In reproductive cloning (which may or may not be possible with humans), however, this developing embryo is implanted in a uterus and brought to term.<sup>36</sup> If a baby is born it would have essentially the same genetic make-up as the donor. Reproductive cloning is intensely controversial and has very few supporters.

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<sup>28</sup> Leon Lederman, *Basic Research’s Big Payoff: A Case In Point*, N.Y. TIMES, Dec. 19, 1982, § 4, at 16.

<sup>29</sup> GOLDBERG, *supra* note 19, at 96.

<sup>30</sup> See STEPHEN BREYER, *BREAKING THE VICIOUS CYCLE: TOWARD EFFECTIVE RISK REGULATION* 34 (1993) (exploring the difference between public and expert assessments of risk from nuclear accidents).

<sup>31</sup> For a detailed discussion and critique of current regulatory efforts to assess fear, see Matthew D. Adler, *Fear Assessment: Cost-Benefit Analysis and the Pricing of Fear and Anxiety*, 79 CHI.-KENT L. REV. 977, 980-81 (2004).

<sup>32</sup> See, e.g., The World of Nuclear Science, Household Uses of Radiation, <http://library.thinkquest.org/CO04606/applications/household.shtml>. (last visited Sept. 22, 2006).

<sup>33</sup> See Steven Goldberg, *Cloning Matters: How Lawrence v. Texas Protects Therapeutic Research*, 4 YALE J. HEALTH POL’Y L. & ETHICS 305, 306 (2004).

<sup>34</sup> *Id.* at 307.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

In therapeutic cloning, however, no one plans to bring the embryo to term. After a few weeks, the stem cells are removed and used for research.<sup>37</sup> This technique, while controversial, has many supporters,<sup>38</sup> as does stem cell research generally. It may have the advantage over ordinary stem cell research in that an individual suffering from a disease could be the donor, resulting in stem cells that might be particularly useful for studying or treating his ailment because they would match his genetic code.

Proponents of therapeutic cloning would very much like to separate it from reproductive cloning in the public mind, since the latter conjures up images of hundreds of genetically identical people created for some nefarious purpose. As a result, they have occasionally tried to have everyone refer not to “therapeutic cloning” but rather to “somatic cell nuclear transfer” or SCNT.<sup>39</sup> Time will tell whether SCNT will join MRI in popular usage.

#### IV. MRIs AND THE PERCEPTION OF RISK IN THE RESEARCH SETTING

MRIs have an enviable reputation for safety. On September 12–13, 2003, the American Association for the Advancement of Science and the Dana Foundation held an invitational workshop in Washington, D.C. on neuroscience and the law.<sup>40</sup> Scientists, judges, and academics discussed the legal and philosophical implications of the results coming from functional MRIs being given to thousands of patients and volunteers. At no point in the conference did anyone refer to any danger associated with MRIs, indeed no one even referred to any possible dangers at all.<sup>41</sup> An outside observer would have to have been forgiven for erroneously believing that taking an MRI was roughly as safe as getting on a scale to find your weight.

In terms of visible risk, it is not surprising that the leading text on the development of MRIs concludes that they operate “safely, comfortabl[y], and noninvasively.”<sup>42</sup> Of course, no technology is absolutely safe, and those who operate MRIs are well aware of that. Because the MRI exposes a user’s body to a powerful magnetic field, it is essential that the user remove metal objects such as keys, and that the user inform the staff if the user has a pacemaker, shrapnel in the user’s body, or any other material that might be attracted by a magnetic field.<sup>43</sup> The procedure is not generally used with pregnant women.<sup>44</sup>

<sup>37</sup> *Id.* at 307-08.

<sup>38</sup> *Id.* at 312.

<sup>39</sup> See, e.g., Peter Gorner, *Wisconsin Weighs Ban on Cloning: Both Sides Accused of Verbal Dishonesty in Stem Cell Debate*, CHI. TRIB., Sept. 19, 2005, at 16; Tom Pelton, *Ads Paint New Image For Cloning: Those Opposed to a Ban Stress Medical Benefits of Cells from Lab Embryos*, BALT. SUN, Apr. 25, 2002, at 3A.

<sup>40</sup> The report of the workshop, which was sponsored by the American Association for the Advancement of Science and the Dana Foundation, may be found at *NEUROSCIENCE AND THE LAW: BRAIN, MIND, AND THE SCALES OF JUSTICE* (Brent Garland ed., 2004).

<sup>41</sup> See *id.* at 107-108 (discussing future use of functional MRIs without mention of dangers).

<sup>42</sup> MATTSON *supra* note 4, at 729.

<sup>43</sup> See, e.g., Prithi Yeleja, *Up Close and Personal With an MRI Scan*, TORONTO STAR, Feb. 9, 2002, at Y13; RadiologyInfo, *Safety: Magnetic Resonance Imaging (MRI) 1-2*, (Jan. 10, 2005), [http://www.radiologyinfo.org/en/pdf/sfty\\_mr.pdf](http://www.radiologyinfo.org/en/pdf/sfty_mr.pdf) [hereinafter *RadiologyInfo*]. There is some concern that new EU safety rules designed to reduce exposure to electromagnetic fields might restrict some MRI usage. See James Meikle, *Science: Scientists’ Fears Force*



Moreover, as with any piece of equipment, an MRI scanner is dangerous if operated improperly,<sup>45</sup> and, even when properly performed, the procedure can trigger claustrophobia in some users.<sup>46</sup> These are more or less routine risks that are handled reasonably well through the usual informed consent process.<sup>47</sup> In recent years, however, a new problem has manifested.

Conducting research that uses MRIs on apparently healthy subjects results in a substantial number of findings that may be of clinical significance. Indeed, some studies suggest that such “incidental” findings may turn up in a remarkable 20% of the subjects.<sup>48</sup> In other words, it turns out that many research subjects may be sick without even knowing it. But the question remains: how should the research community react? To date, there is no uniform answer.<sup>49</sup>

Our understanding of this area depends in large part on the impressive pioneering work of Judy Illes of the Center for Biomedical Ethics at Stanford University. Building on work by Gregory L. Katzman and others,<sup>50</sup> Illes and her coauthors have published studies and organized workshops to discuss this problem.<sup>51</sup> They have identified both varying abilities among screening institutions to evaluate troubling findings, and inconsistent policies on what the study participants will be told when such findings occur.<sup>52</sup> The authors then argue that it is “ethically desirable” to disclose “suspicious incidental findings.”<sup>53</sup>

One relatively uncharted portion of this problem demands attention. As Illes wrote, after a recent National Institutes of Health workshop, “[t]he potentially harmful consequences of false-positive reports on normal volunteers have not been explored. Some members of the working group felt that the potential of false-positives rendered it unwise to communicate all but

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*Review of New Restrictions on MRI Scanners: Electromagnetic Exposure Limits Threaten Treatments: MPs find No Justification for Curbs on Medical Staff*, THE GUARDIAN, June 29, 2006, at 8.

<sup>44</sup> Yeleja, *supra* note 43, at Y13; RadiologyInfo, *supra* note 43, at 2.

<sup>45</sup> Ian Marland, *Fears Over MRI Scanners*, THE SCOTSMAN, May 19, 2003, at 2; U.S. Food and Drug Administration, MRI Safety (Sept. 18, 2001), <http://www.fda.gov/cdrh/safety/mrisafety.html>.

<sup>46</sup> See, e.g., Curtis v. MRI Imaging Serv. II, 956 P.2d 960, 961 (Or. 1998); Cassidy, *supra* note 16, at 37.

<sup>47</sup> For an example of standard informed consent language used for MRI research, see Standard Informed Consent Language for MRI Related Research, Memorial Hospital of Rhode Island Committee for Use of Human Subjects in Research, <http://www.brainscience.brown.edu/MRF/MR.Risks.pdf> (last visited Sept. 25, 2006).

<sup>48</sup> Jamie Talan, *The Ethics of Scan and Tell*, SCI. AM. MIND, June 2005, available at [http://www.sciammind.com/print\\_version.cfm?articleID=000F3D24-647A-128A-A3C683414B7F0000](http://www.sciammind.com/print_version.cfm?articleID=000F3D24-647A-128A-A3C683414B7F0000).

<sup>49</sup> *Id.*

<sup>50</sup> See Gregory L. Katzman et al., *Incidental Findings on Brain Magnetic Resonance Imaging From 1000 Asymptomatic Volunteers*, 282 JAMA 36, 36-39 (1999).

<sup>51</sup> See, e.g., Judy Illes et al., *Incidental Findings in Brain Imaging Research*, SCI., Feb. 10, 2006, at 783 (discussing research studies as well as an NIH workshop); Brian S. Kim et al., *Incidental Findings on Pediatric MR Images of the Brain*, 23 AM. J. NEURORADIOLOGY 1674, 1674 (Nov.-Dec. 2002) (studying “the prevalence of incidental findings in a healthy pediatric population”).

<sup>52</sup> Illes, *supra* note 51, at 783-84.

<sup>53</sup> *Id.* at 783.

the most certain incidental finding.”<sup>54</sup> In short, even if an MRI appears to show a dangerous tumor, there may be good reasons not to disclose this finding because it may be false.

No one knows how many false positives will turn up in research MRI screenings. In one setting, Illes wrote of an “established upper limit” for false positives of 2%.<sup>55</sup> Even higher rates have been found when high-risk women were given MRIs to detect breast cancer,<sup>56</sup> and substantial problems have resulted when MRIs appear to show problems with the lumbar spine even though these problems may not be “clinically relevant.”<sup>57</sup> There is no reason to suppose that MRIs used for research brain scans will be less prone to this problem.

What is so bad about a false positive? It can lead to what has been termed the “dreaded cascade effect”:<sup>58</sup> the apparent discovery of a problem that leads to riskier and costlier tests that may themselves be harmful, all triggered by a nonexistent problem.<sup>59</sup> Even when the later tests do not themselves cause harm or lead to unnecessary and risky interventions, “an erroneous positive result may cause unnecessary fear and concern in the individual . . . .”<sup>60</sup>

This creation of unnecessary fear is why the NIH working group was divided on how false positives bear on the ethical duty to notify.<sup>61</sup> It is a problem that deserves open debate in symposia like this one and open disclosure of whatever results are reached: it is not a problem that admits of a one-size-fits-all solution. We are back again to fear. In a society where the very word “nuclear” has to be avoided in the name of a procedure lest subjects mistakenly believe they will be given cancer, we can hardly be surprised that mistakenly telling subjects that they may have cancer is itself an enormous cost of that very procedure.

## V. CONCLUSION

It is widely known that the law regulates activities based not only on their actual risks, but on how those risks are perceived. Thus nuclear energy may be a safer way to generate electricity than coal, but the former is subject to much more stringent regulation than the latter because of public fears.<sup>62</sup> FDA regulation of food additives illustrates the same phenomenon;<sup>63</sup> indeed, Cass Sunstein, in a broad study of government policy and risk assessment, found

<sup>54</sup> *Id.*

<sup>55</sup> Judy Illes, ‘Pandora’s Box’ of Incidental Findings in Brain Imaging Research, 2 NATURE CLINICAL PRAC. NEUROLOGY 60, 60 (Feb. 2006).

<sup>56</sup> Press Release, Memorial Sloan-Kettering Cancer Center, MRI May Help Find Missed Breast Cancers in High Risk Women: High False Positive Rate Must Be Considered, available at <http://www.mskcc.org/mskcc/html/13823.cfm> (last visited Sept. 25, 2006).

<sup>57</sup> Richard A. Deyo, *Magnetic Resonance Imaging of the Lumbar Spine: Terrific Test or Tar Baby?*, 331 NEW ENG. J. MED. 115, 115 (July 14, 1994).

<sup>58</sup> Christopher P. Guzelian, *A Quantitative Methodology For Determining the Need for Exposure-Prompted Medical Monitoring*, 79 IND. L.J. 57, 84 (2004).

<sup>59</sup> *Id.* at 69.

<sup>60</sup> *Id.* at 84.

<sup>61</sup> Illes, *supra* note 51, at 783.

<sup>62</sup> See, e.g., Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025 (1983).

<sup>63</sup> See, e.g., Richard A. Merrill, *FDA’s Implementation of the Delaney Clause*, 5 YALE J. ON REG. 1, 76 n.367 (1988).

“dramatic disparities in amounts spent per life-year saved” in fields ranging from traffic safety to pollution controls.<sup>64</sup>

Similar issues arise when decisions are made on the proper scope of informed consent, as the debate over whether “the person affected should have the absolute right to his or her own risk assessment” before being vaccinated makes clear.<sup>65</sup> When Institutional Review Boards decide on what sort of consent from subjects is needed before a research program can go forward, the Boards “are engaged in a process of legal decisionmaking, insofar as they interpret specific regulatory requirements pursuant to authority that has been delegated to them by administrative agencies.”<sup>66</sup> Thus the law will be deeply implicated as we debate whether to inform subjects of incidental findings from MRIs that may generate enormous anxiety even when those findings are false positives or clinically irrelevant.

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<sup>64</sup> Cass R. Sunstein, *Which Risks First?*, 1997 U. CHI. LEGAL F. 101, 101 (1997).

<sup>65</sup> Karin Schumacher, Note, *Informed Consent: Should It Be Extended to Vaccinations?*, 22 T. JEFFERSON L. REV. 89, 119 (1999).

<sup>66</sup> Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZ. L. REV. 1, 4 (2004).