

# Case Histories of Significant Medical Advances: Magnetic Resonance Imaging

Amar Bhidé  
Srikant Datar  
Katherine Stebbins

Working Paper 20-001



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Amar Bhidé

Harvard Business School

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## Magnetic Resonance Imaging

Amar Bhidé, Harvard Business School

Srikant Datar, Harvard Business School

Katherine Stebbins, Harvard Business School

**Abstract:** We describe how and why Magnetic Resource Imaging (MRI) came to complement – and partially replace -- computed tomography (CT) imaging of soft tissue. Specifically we chronicle: 1) the development of foundational techniques and prototypes (through the 1970s); 2) how U.S. Food & Drug Administration (FDA) approval for the new device was secured (in the early 1980s); 3) post-approval commercial adoptions (in the late 1980s); and 4) growth in adoptions and MRI use --- after setbacks (in the 1990s).

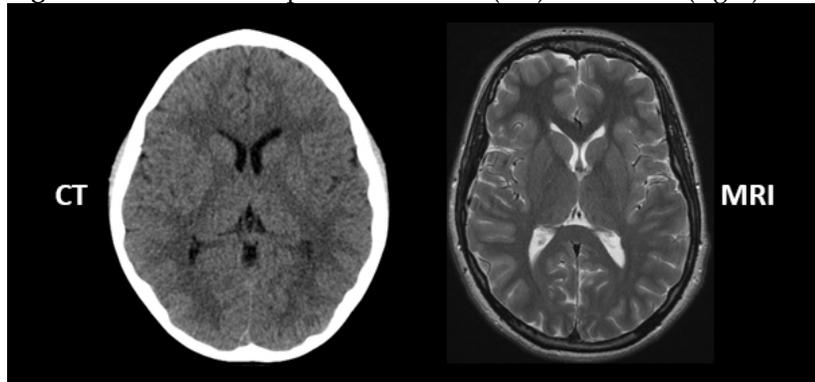
**Note:** This case history, like the others in this series, is included in a list compiled by Victor Fuchs and Harold Sox (2001) of technologies produced (or significantly advanced) between 1975 and 2000 that internists in the United States said had had a major impact on patient care. The case histories focus on advances in the 20th century (i.e. before this millennium) in the United States, Europe, and Japan -- to the degree information was available to the researchers. Limitations of space and information severely limit coverage of developments in emerging economies.

**Acknowledgments:** We would like to thank Kirby Vosburgh for helpful information and suggestions.

## Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) complements, and has to some degree replaced, computed tomography (CT) imaging. Like CT, MRI creates images of specific cross-sections or “slices” of the body – but MRI images offer significantly more detail, especially of muscles, veins, and other soft tissues. (See **Figure 1**). And, unlike CT, which uses X-rays, MRI scanning does not expose patients to potentially dangerous radiation. MRI also costs substantially more to purchase, install, and maintain, and scans take longer than CT.<sup>1</sup>

**Figure 1** Recent examples of a CT scan (left) vs. an MRI (right)



Source: Cincinnati Children’s Medical Center.

MRI scanners, like CT scanners, built on advances in physics and computational technologies, were developed mainly by companies with prior expertise in medical equipment, and were promoted by physicians in prestigious research hospitals. Sales of both devices have faced ups and downs because of regulation. As in CTs, MRI has long been dominated by a few large, multinational suppliers – many who are also leaders in CT. In spite of suppliers who have global marketing capabilities, we find significant regional variations in usage: as in CTs, Japan and the U.S. are the leading markets in per capita usage of MRIs.<sup>2</sup>

The next four sections of this case describe: the development of foundational techniques and prototypes (through the 1970s); the process of securing U.S. Food & Drug Administration (FDA) approval for the new device (in the early 1980s); post-approval commercial adoptions (in the late 1980s); and growth after setbacks (in the 1990s).

### 1. Development of Foundational Techniques and Prototypes (1970s)

MRIs are based on a scientific discovery made in the 1940s that magnetic fields induce distinctive resonances in the nuclei of different atoms. The discovery was first applied for industrial use: in the 1950s, Varian, a manufacturer of scientific instruments founded in 1948, developed machines to analyze the composition of petroleum and other chemicals.\*

Raymond Damadian, a physician and researcher at the State University of New York, pioneered efforts to harness magnetic resonance for medical diagnosis. In 1971, he published (in *Science*) an article purporting to show that magnetic resonance could identify cancerous cells. The following year, with the support of a National Institutes of Health (NIH) grant, Damadian filed for a patent for “an apparatus and method” that would use magnetic resonance to detect the presence and degree of malignancy in cancerous tissues. The

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\* These machines applied a uniform magnetic field to a very small sample, and then periodically transmitted radio waves through the sample to measure the resonance of individual atoms. The measurements revealed the sample’s chemical composition (as described in the box “Lauterbur’s and Mansfield’s Contributions”).

patent office approved Damadian's application in 1974, and the National Cancer Institute (NCI, which belongs to the NIH family) gave him an additional grant to build and test the apparatus he had patented.<sup>3</sup>

Damadian's 1971 article turned out to be based on a faulty premise – that cancer tissue had a distinctive resonance – and his patent application only claimed to detect malignancies, rather than to create images. However, soon after Damadian published, chemist Paul Lauterbur (from New York State's Stony Brook University) and physicist Peter Mansfield (from the University of Nottingham, England) provided the foundational ideas and techniques for imaging. (Their efforts may have been spurred to some degree by Damadian's article<sup>4</sup>, and as we will see, Damadian would become a pioneer in developing scanning devices for practical use).

The chemistry professor Lauterbur (who would share the Nobel Prize in medicine with Mansfield in 2003) had undertaken research on magnetic resonance since his college days that combined theorizing about the phenomena and developing the instruments necessary to test the theories. He had also helped a Varian engineer start a company to produce magnetic resonance instruments and then served as its temporary chief executive (while continuing to work with students on weekends). This experience was a turning point for the chemist, who would spend the next three decades working on medical applications of magnetic resonance.<sup>5</sup> Most notably Lauterbur pioneered a technique (outlined in an article he published in the spring of 1973)<sup>6</sup> to locate the positions of water molecules within the body\* which in turn could provide the basis of images of specific cross sections.

The Nottingham physicist Mansfield had also undertaken research since his college days on magnetic resonance that combined theorizing and instrument development with an additional twist: he had developed expertise in attaching computers to his apparatuses for rapid analysis of data produced. Mansfield's seminal contribution (see box "Lauterbur's and Mansfield's Contributions") was the development of techniques that vastly increased the speed and efficiency of creating images from the positions of water molecules (located through the techniques that Lauterbur had pioneered).<sup>7</sup>

### **Lauterbur's and Mansfield's Contributions** (excerpted from the Nobel Committee website)

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"In the late 1940s, Felix Bloch and Edward Purcell discovered nuclear magnetic resonance, or NMR, the concept that certain atomic nuclei behave like microscopic magnets, which can be manipulated by external magnetic fields and radio waves in a manner that can reveal the identity of the atoms in question. Since then NMR has been used to scrutinize the structure of [organic] compounds ... mainly through detecting the characteristic NMR signals transmitted from the hydrogen atoms ....

"An abundant source of hydrogen atoms, of course, is the water molecules that make up most of the content of our cells, and in the early 1970s Paul Lauterbur showed how these could be viewed using NMR signals. Rather than using ... uniform magnetic fields researchers traditional favoured for detecting hydrogen atoms ... Lauterbur deliberately introduced small variations, or gradients, in the strength of the magnetic field, and he showed these variations can distinguish hydrogen nuclei .... Applying these magnetic field gradients in different directions ... and combining the resulting NMR signals allowed Lauterbur to construct images that could pinpoint the ... locations of hydrogen nuclei.

"Peter Mansfield ... developed efficient ways by which to acquire NMR signals and construct these images; methods that have improved the resolution and speed of MRI to such an extent that images can now be captured in a matter of seconds, not hours. Mansfield's improvements have provided doctors with the opportunity to view many of life's essential functions, from the workings of the brain to the beating of a heart."

*From "A Glimpse of the Life Magnetic" by Joachim Pietzsch, for Nobelprize.org*

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\*The technique involved applying a gradient to the magnetic field (as described in the box "Lauterbur's and Mansfield's Contributions"). Mansfield would independently develop a similar technique before learning of Lauterbur's work at a conference in the fall of 1973.

Like Lauterbur, Mansfield reoriented his research after the early 1970s towards medical applications, securing a grant from Britain’s Medical Research Council in 1977.<sup>8</sup> By then, interest in diagnostic imaging had also prompted other researchers at Nottingham University – and in Aberdeen, Scotland; Zurich, Switzerland; and San Francisco, California – to try to develop MRI techniques and prototypes. Many of these researchers would later join or form companies to produce MRI machines (as discussed below and in Section 2).

In 1974, the British conglomerate, Electric & Musical Industries (EMI), became the first established company to start developing MRIs, in consultation with Mansfield<sup>9</sup> and his Nottingham colleagues.<sup>10</sup> EMI, whose main businesses had been in the entertainment industry, had pioneered CT scanners; the devices, which the company first sold in 1972, had enjoyed great success because in many applications they provided sharper images than traditional X-Rays.\* EMI management believed MRI had the “potential to rival its then burgeoning CT X-ray business.”<sup>11</sup>

Meanwhile, Damadian had switched from developing an instrument to detect malignant cells to building an imaging device. He financed the development with his NCI grant and money raised from family and friends. In the spring of 1977 his prototype<sup>†</sup> successfully produced a cross-section of the chest of a member of his research team, and, the next year, he founded FONAR<sup>‡</sup> Corporation to develop and manufacture MRI scanners.<sup>12</sup>

By the end of 1981, eleven more companies had followed FONAR and EMI into MRI development. (See **Table 1**) Eight already sold CTs and other diagnostic devices. One – Bruker – had made machines that used magnetic resonance to analyze chemicals, and two – Nalorac and Metriflow--were startups with ties to academic MRI researchers. Five entrants in this first wave--FONAR, Siemens, Philips, General Electric (GE), and Toshiba – would dominate the market; four (EMI, Technicare, Thomson-CGR, and Elscint) would sell off their MRI businesses to the market leaders. One of the startups, Nalorac, would shift its focus to selling the magnets used in MRIs, and the other, Metriflow, would dissolve in 1994 after failing to find a market for its scanners.<sup>13</sup>

**Table 1** Entrants, 1974-1981

Company (Location)	Related industry or University affiliation	Development Initiated
Nalorac (US)	University of Nottingham (startup)	1975
Pfizer* (US)	Pharmaceuticals, diagnostic devices (CT and X-ray machines)	1976
Bruker (GER)	Scientific instruments, including industrial MR analyzers	1976
Siemens (GER)	Diagnostic devices (X-ray, mammography, and CT machines)	1977
Philips (ND)	Diagnostic devices (X-ray machines)	1978
General Electric (US)	Diagnostic devices (X-ray, mammography, and CT machines)	1978
Johnson & Johnson/ Technicare (US)	Diagnostic devices (X-ray and CT machines)	1979
Thomson-CGR (FR)	Diagnostic devices (X-ray, mammography, and CT machines)	1979
Metriflow, Inc. (US)	Medical College of Wisconsin (startup)	1979
Toshiba (JPN)	Diagnostic devices (CT machines)	1980
Elscint (ISR)	Diagnostic devices (CT machines and gamma cameras)	1981

\*Pfizer sponsored MRI research at the UCSF Radiologic Lab.

\* Traditional two-dimensional X-rays gave prominence to bones, obscured soft tissues, and made it difficult to locate tumors or other problems. CT scanners also used X-rays, but scanned patients from several angles and used a computer to compile an image based on the information taken in all the scans. Therefore, CT could produce cross sections that showed soft tissues in addition to bones, such as the brain inside the skull. Ultrasound, another imaging technology available at the time, relied on sound waves but offered only rudimentary images and therefore did not present a viable alternative to CT or MRI.

† The prototype featured a huge, doughnut-shaped magnet to generate the necessary magnetic field around a person and a computer that compiled the data into an image like Lauterbur and Mansfield had proposed (and like a CT scan did). In order to make a human-sized MRI, Damadian and his team built their own electromagnet from scratch, but magnet producers like Oxford Instruments soon ramped up production to meet the new demand for the different types of magnets used in MRI.

‡ FONAR was originally an acronym that stood for “field focusing nuclear magnetic resonance,” Damadian’s method for producing MRI.

## 2. Securing FDA Approval for the New Devices (early 1980s)

Before manufacturers could sell any MRIs, however, the Food and Drug Administration (FDA) issued rules (authorized by the 1976 Medical Device Regulation Act<sup>14</sup>) requiring MRI to undergo clinical trials for safety and effectiveness.<sup>15</sup> The Act required the FDA to classify devices as new products or extensions of existing products. Devices classified as new had to undergo clinical trials (the results of which would be reviewed by the FDA) before they could be sold.<sup>16</sup> If, however, the FDA classified a device as an extension of an existing device, no trial was necessary; companies merely had to file a “510(k)” notification with the FDA ninety days before marketing of their device.

Clinical trials themselves required FDA approval; companies had to submit applications specifying how their trials would be conducted, which the FDA scrutinized for safety and trial design.<sup>17</sup> And, during the trial period, companies were prohibited from promoting their devices; charging more than necessary to recover costs of R&D, manufacture, and handling; and making claims of “safety” or “effectiveness.”<sup>18</sup>

In 1981, the FDA classified MRIs as new devices requiring clinical trials – the first ever such classification under the 1976 Act. Over a dozen companies then joined with their trade association<sup>19</sup> to challenge the FDA’s classification, claiming that MRIs were simply extensions of instruments used to analyze chemicals. However, they also took the precaution of applying to the FDA for permission to run clinical trials (in case their challenge failed).

In addition to securing permission from the FDA, MRI developers had to persuade hospitals to participate in the trials. Participating hospitals faced considerable expenses: even at manufacturers’ costs, prices for the machines were high.<sup>20</sup> Installing MRIs also required shielding rooms to contain the powerful magnetic field generated by the machines. And, commissioning an MRI could take more than a year.<sup>21</sup>

Nonetheless, American hospitals had incentives to participate in MRI trials. Participants could secure government- and company-funded research grants. Manufacturers offered attractive terms, such as allowing hospitals to defer full payment until they converted their MRIs from research use to clinical use. And some teaching hospitals could share costs with affiliated universities.<sup>22</sup>

Hospitals running trials may have also expected advantages in securing “Certificates of Need” (CONs).<sup>23</sup> CON rules (authorized under 1974 legislation intended to limit unnecessary purchases of expensive capital equipment) required hospitals to demonstrate that other providers in the same area did not have surplus capacity.\* Applying for CONs in the course of a trial,<sup>24</sup> before the FDA had approved MRIs for broad use, limited the possibility that another hospital would already have surplus capacity.

In spite of the difficulties presented by the rules requiring clinical trials, six startup businesses (with ties to academic research programs) initiated MRI development in the early 1980s. (**Table 2**) The startups may have been encouraged by the high valuation of stocks in small MRI companies,<sup>25</sup> which had experienced a boom between 1981 and 1983.† However, these second wave startups did not garner the same enthusiasm from investors, and they all eventually exited. Another six companies who were established producers of medical and scientific equipment also initiated MRI development in the 1980s (see **Table 2**), of which only two would achieve any success. (Hitachi, from Japan, would become a leader in next generation MRIs, as discussed in Section 4, and Instrumentarium, from Finland, would find a niche in low-cost scanners before being acquired by GE in 2003.)

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\* The law also applied to CT scanners. In March 1978, the federal government issued guidelines for CT CONs: new CTs could not be approved unless existing CTs in the area where the new CTs would be used were operating at a minimum rate of 2,500 scans per year. The guidelines helped trigger a 33% decline in CT sales in 1978.

† Stocks in small MRI companies sharply declined in late 1983 as analysts predicted that large, multinational medical imaging companies would take over the emerging MRI industry, as they had done in CT.

**Table 2** Entrants, 1982-1984

Company (Location)	Related industry or University affiliation	Development Initiated
M&D Technology (SCT)	University of Aberdeen (startup)	1982
OMR Inc. (US)	UCLA (startup)	1982
Field Effects (US)	Lawrence Berkeley Lab (U of C) (startup)	1982
JEOL USA (US/JPN)	Scientific instruments, including MR analyzers; sub of Mitsubishi	1982
ADAC Technologies (US)	Diagnostic devices (Gamma cameras)	1982
Fischer Imaging (US)	Diagnostic devices (Mammography machines)	1982
Advanced NMR Systems (US)	Nottingham, Harvard Law School, MIT (Sloan School) (startup)	1983
NMR Imaging (US)	University of Houston, Baylor (startup)	1983
Resonex Inc. (US)	Stanford (startup)	1983
Instrumentarium (FI)	Diagnostic devices (Dental X-ray and mammography machines)	1983
Matsushita (JPN)	Consumer electronics, industrial equipment	Early 1980s
Hitachi (JPN)	Consumer electronics, scientific instruments, diagnostic devices (Ultrasound machines)	Early 1980s

Sources: Steinberg and Cohen (1984) and Mitchell (1988).

### 3. Post-Approval Commercial Adoptions (late 1980s)

By 1984, eleven companies had run clinical trials on nearly 10,000 patients worldwide, and three more companies were preparing for trials.<sup>26</sup> By 1988, eleven of those fourteen companies had obtained approval from the FDA to sell their MRIs.<sup>27</sup> (See **Table 3**)

**Table 3** MRI Clinical Trials and FDA approvals to market, 1978-1988

Company	First Placement	Patients Enrolled	# Placed		FDA Approval Granted
			Inside US	Outside US	
Picker (via EMI)*	1978	NA	5	8	5/1984 (head and neck scanner) 1986 (whole body scanner)
FONAR*	1980	2,200	3	3	3/1984
Diasonics**	1981	NA	6	0	8/14/1984
Johnson & Johnson/ Technicare	1981	4,750	36	8	10/22/1984
Bruker	1982	100	3	2	(no record of approval)
GE	1982	600	19	1	9/10/1985
Philips	1982	300	6	12	2/5/1986
Siemens	1982	800	42	9	3/8/1985
Elsint	1983	NA	2	2	7/31/1986 (after revisions)
M&D Technology	1983	1,200	0	4	(no record of approval)
Nalorac	1984	NA	2	0	(no record of approval)
Thomson-CGR	ca. 1984	NA	NA	NA	12/29/1987
Instrumentarium	NA	NA	NA	NA	4/22/1987
Resonex	NA	NA	NA	NA	5/25/1988
<b>Total</b>		9,950	124	49	

\*Picker (GEC) "inherited" EMI's first placements at the University of Nottingham Hospital, Nottingham, England, and the HIRST Research Center, London, England. FONAR placed a single scanner at a freestanding imaging center in the U.S. in late 1980 (it was later removed).

\*\*Diasonics took over sponsorship of the UCSF Radiologic Lab from Pfizer in 1981.

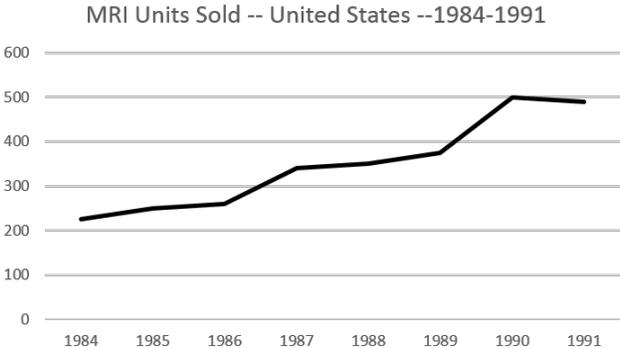
Sources: Steinberg and Cohen (1984), Mitchell (1988), Kleinfield (1985), company records, and the FDA approval database.

In 1988, four years after the FDA had first approved the commercial sale of MRI equipment that had satisfied the agency's clinical trial requirements, and after over a thousand MRIs had been used in normal clinical practice, the FDA relaxed the conditions for the marketing of any new MRI equipment. From then onwards, the FDA would treat any new MRIs as (relatively) low risk extensions of an existing technology. This freed manufacturers from having to undertake clinical trials.<sup>28</sup>

The main beneficiaries of the relaxed rules turned out to be companies that were already selling MRI equipment. Eight developers who hadn't secured approval to sell had already given up. Three Japanese companies—Toshiba, Hitachi, and Shimadzu—that had been selling MRIs in their home market used the rule revision to enter the U.S. market. And, leading MRI companies expanded their product lines, introducing accessories, parts, mobile scanners, higher-powered scanners, and lower-cost scanners.<sup>29</sup>

Annual units sold in the U.S. (after the FDA began approving commercial sales) more than doubled between 1984 and 1991\* (See **Figure 2**) in spite of MRI's high unit prices—between USD\$800,000 and USD\$2 million—and maintenance costs – which were estimated at up to USD\$415,000 annually.<sup>30</sup>

**Figure 2** MRI Units Sold in the United States – 1984-1991



Source: Hillman and Goldsmith (2010).

Researchers in prestigious hospitals (particularly those that had participated in trials) and professional associations supported this growth. Researchers codified and disseminated MRI techniques in books and journal articles, often with the support of grants from manufacturers. The American College of Radiology and other professional associations undertook educational initiatives.<sup>31</sup> In addition, these groups successfully lobbied for insurance coverage for MRI scans. By 1985, twenty-four private insurance companies and Medicare (a government-sponsored insurance program for the elderly) had started to reimburse for MRI scanning.<sup>32</sup>

MRI manufacturers also supported growth through training programs. Siemens, for instance, built a USD\$10 million, 70,000-sq.-ft. training facility, which employed 35 full-time instructors.<sup>33</sup>

Between 1986 and 1991, scanning performed in the U.S. increased more than four-fold, to 6.5 million MRI scans.<sup>34</sup> Physicians increasingly substituted MRI for CT when scanning the brain and spinal cord because MRIs produced superior images of soft tissues and fluids.† MRI scans became a routine method for diagnosing and monitoring patients with multiple sclerosis, a disease that affects the central nervous system, and Alzheimer’s, a disease that affects the brain. Orthopedic specialists also increasingly ordered MRIs for tendon and joint treatments.<sup>35</sup>

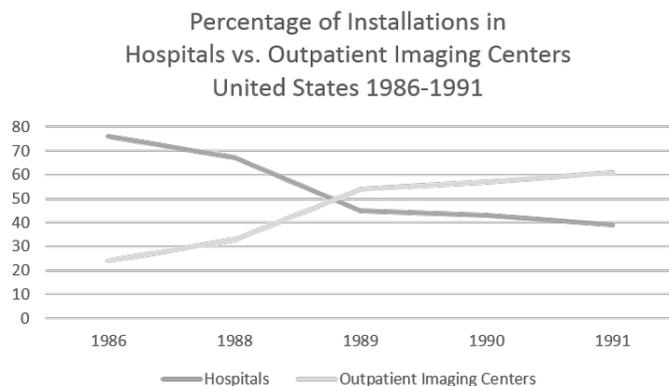
New, freestanding imaging centers that also offered CT and ultrasound‡ scanning accounted for increasing shares of MRI installations.<sup>36</sup> (See **Figure 3**)

\* Although the MRI market more than doubled in its first eight years, MRI adoption was slower than CT scanner adoption. Five years after the introduction of CT, over 900 devices were installed in U.S. hospitals. Five years after the introduction of MRI, over 350 devices had been installed in U.S. hospitals and imaging centers. Sources: The Office of Technology Assessment (1978) and Steinberg (1985).

† Nevertheless, CT scans continued to increase during the period.

‡ Ultrasound scanners use sound waves to create images of the soft tissues and organs inside the body.

**Figure 3** Share of Installations in Hospitals and Outpatient Imaging Centers

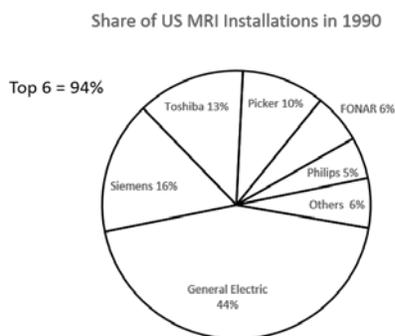


Sources: Cowley et al. (1994) and American Hospital Association statistics.

Standalone centers enjoyed three advantages over hospital-based facilities.<sup>37</sup> New constructions could be customized to accommodate large, complex machines. Centers were exempted from buying and reimbursement rules: they did not have to secure Certificates of Need (CONs) before acquiring MRIs (as hospitals did). And, Medicare did not limit reimbursement for scanning done at centers, as it did for hospitals.\* In addition, physicians could make referrals to the centers that they owned.

Five years after MRIs were first sold, the MRI market in the U.S. became highly concentrated.<sup>38</sup> (See **Figure 4**) Of the top six MRI manufacturers five also made CTs and other imaging devices; only Damadian's FONAR Corp. specialized in MRI.†

**Figure 4** Shares of US MRI installations by company



Sources: Hoppszallern, et al. (1991) and Cohen and Hanft (2004).

\* Medicare reimbursed freestanding imaging centers for every MRI performed, instead of paying a fixed flat fee for each patient's diagnosis as it did for hospitals. For example, if a patient was diagnosed with multiple sclerosis at a hospital, the hospital would be paid a flat fee no matter how many MRI scans were needed to make and confirm the diagnosis.

† FONAR was not profitable until the late 1980s, by which time it had begun to sue its much larger rivals for patent infringement. Although FONAR had mixed results in its first lawsuit against Technicare, the Supreme Court sided with FONAR in its suit against GE in 1997. Siemens, Shimadzu, Hitachi, Toshiba, and Philips all settled out of court with FONAR.

General Electric (GE) had secured leadership in part by acquiring rival Technicare\*; leveraging the sales, training, servicing, and financing capabilities of its other businesses; and facilitating the growth of imaging centers.<sup>39</sup> (See box “GE’s MRI Offerings”)

### GE’s MRI Offerings

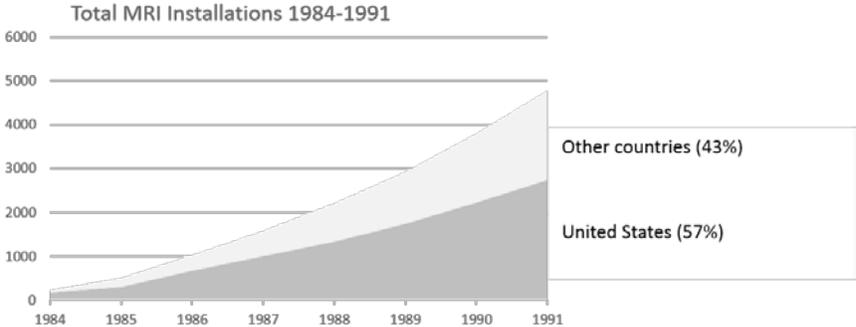
GE drew on the resources and expertise from its other businesses (such as GE Capital, GE Information Services, GE Consulting Services, and Employers Reinsurance) to offer a wide range of services to MRI buyers. These included:-

- Loans for freestanding imaging centers.
- Leases for equipment.
- Business insurance.
- Malpractice insurance.
- Office software and automation packages.
- Office systems design and consulting.
- Telephone and on-site technical and repair services (24-hours).
- Telemarketing.
- Automated ordering systems for supplies and accessories.
- Construction services for freestanding imaging centers.

GE also widened its product line to include cheaper MRIs produced by its Japanese joint venture, GE Yokogawa Medical Systems.

MRI installations in the rest of the world lagged, as in CTs, making the U.S. the largest market.<sup>40</sup> (See **Figure 5**) Regulators in six European countries—Belgium, France, Germany, Italy, the Netherlands, and the United Kingdom—restricted the number and use of scanners. Other countries, such as Denmark, Greece, and Luxembourg, had no explicit restrictions, but health facilities in those countries opted to limit their purchases of MRI scanners.<sup>41</sup>

**Figure 5** Distribution of MRI installations: US vs. Other countries



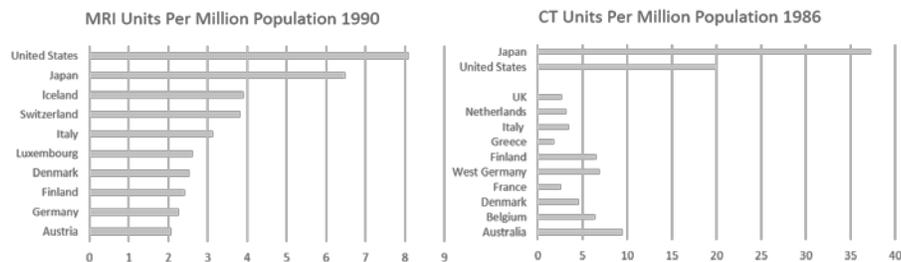
Source: The Organization for Economic Cooperation and Development (2015).

Japan, as in CTs, was an exception, however, with adoption per capita approaching U.S. levels by 1990.<sup>42</sup> (See **Figures 6 and 7**) Later, Japan would surpass U.S. levels of adoption (See **Figure 10**).<sup>43</sup> Japan had no CON-like regulations that limited purchases. And, low, government-mandated reimbursement rates (set at about

\* GE acquired Technicare from parent company Johnson & Johnson in 1986.

one-fifth of U.S. rates at the time) had encouraged Hitachi, Toshiba, and Shimadzu to design smaller, simpler systems that sold at about half of U.S. prices.\*

**Figures 6 and 7**



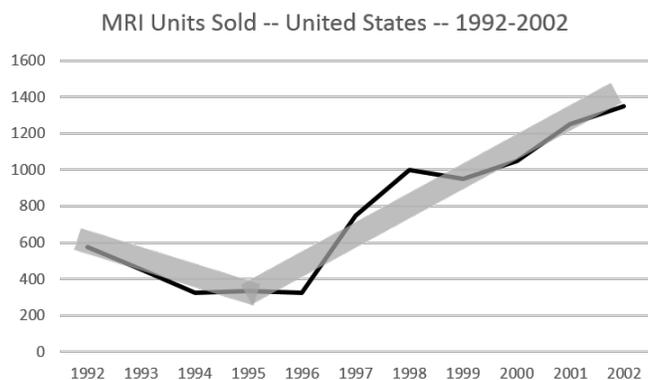
Sources: Lazaro and Fitch (1995), Stocking (1988), Le Gales, et al. (1988) and the Organization for Economic Cooperation and Development (2015).

**4. Growth after Setbacks (1990s)**

In the early 1990s, public and private insurance companies in the U.S. cut reimbursement rates for MRI significantly—some by as much as one half. Meanwhile, after some controversy, physicians were banned from referring patients to their own freestanding imaging centers.† The growth of new freestanding imaging centers slowed,‡ and some closed altogether.‡

For a few years, MRI sales declined, but starting in 1996 U.S. MRI sales rebounded and expanded dramatically.§ (See Figure 8)‡

**Figure 8** MRI Units Sold in the United States



Source: Hillman and Goldsmith (2010).

\* The Japanese government required all residents to buy health insurance (either through an employer or government-run program) and set the fee schedule for all health care providers.

† The 1989 and 1993 laws that limited physician self-referrals (in laboratory, imaging, and other services) are known as Stark I and II, after Congressman Pete Stark, who sponsored the legislation.

‡ During this period, many physicians sold their centers to corporations, some of which ran state- or region-wide networks of imaging centers.

§ Sales of CTs also expanded during the late 1990s.

New lower-cost designs that had been first introduced by Hitachi in Japan in 1987 and then by Diasonics in the U.S. in 1988 helped restore growth.<sup>46</sup> The designs were originally intended to reduce costs by using smaller, lower-powered magnets. Japanese scanning facilities with lower reimbursement rates and freestanding imaging centers struggling to survive in the U.S. eagerly adopted the designs (although small, low-power magnets reduced the quality of scans). The smaller magnets also unexpectedly helped increase patient acceptance. Previous MRI designs had enclosed patients in long, narrow tubes, inducing claustrophobia in some patients, who would then refuse follow-up MRIs.\* MRIs with smaller magnets were less confining. After manufacturers improved the quality of the scans produced by these so-called “open” MRI designs, radiology departments and centers could convince more patients to undergo MRIs.

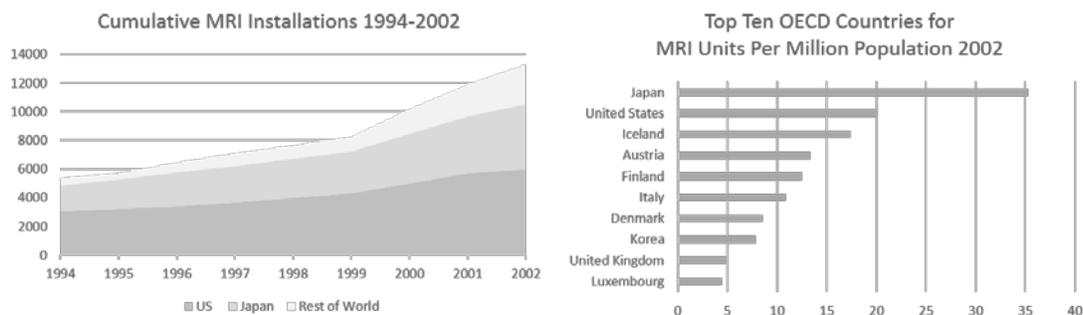
Open designs also expanded MRI’s utility. Siemens and GE developed MRIs in the mid-1990s to help surgeons perform minimally invasive surgeries (a technique that was then gaining popularity). And Damadian’s FONAR Corp. developed a scanner that allowed patients to sit or stand (instead of lying down), so physicians could see how patients’ backs and joints bore weight.

Competition from open MRIs spurred improvements in traditional (“closed”) MRIs.<sup>47</sup> Manufacturers developed smaller magnets and more compact cooling systems. These improvements reduced the size of the rooms required to house MRIs and installation time from months (for older model MRIs) to just one week.<sup>†</sup> And these systems often offered higher quality images than the open designs, increasing demand for their use in diagnosing and treating strokes, blood clots, and hip, back, and knee problems.

Demand for new MRIs was also stimulated by the need to replace older scanners; training provided by professional associations; an increase in “defensive” scanning to forestall malpractice suits (for failure to diagnose diseases like cancer); and marketing campaigns conducted by MRI producers encouraging consumers to ask their physicians for MRIs.<sup>48</sup>

Meanwhile, Japan overtook the U.S. in scanners per capita (though not in total units installed) as scanning facilities there continued to adopt low-cost machines.<sup>49</sup> (See **Figures 9 and 10**)

**Figures 9 and 10**



Source: The Organization for Economic Cooperation and Development (2015).

Adoption also increased in countries and regions where use had been low, such as post-Soviet Eastern Europe, India, Southeast Asia, Australia, and Brazil for a variety of reasons (see box “MRI Adoption Worldwide”).<sup>50</sup>

\* Early MRI machines were also loud, increasing patients’ discomfort.

† Companies also offered improved scanning software and hardware that allowed researchers to perform advanced techniques like fMRI, which tracks brain activity by measuring oxygen levels in blood flowing through the brain.

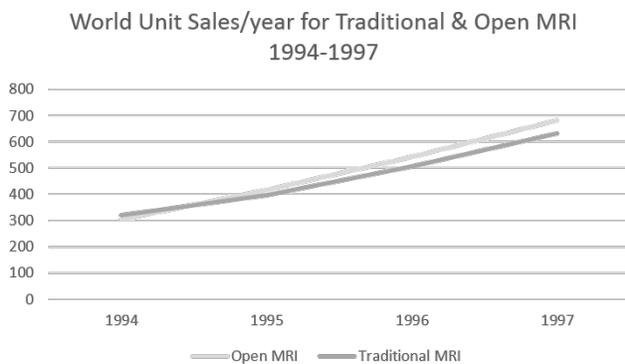
Global market growth was evenly divided between traditional and open MRIs.<sup>51</sup> (See **Figure 11**) Hitachi became market leader in open MRI, while Siemens and GE remained leaders in traditional MRI. \*<sup>52</sup> (See **Figure 12**)

### MRI Adoption Worldwide

Demand for MRI and other higher-cost health care resources increased in different regions of the world outside of the U.S. and Japan for a variety of reasons. These included:-

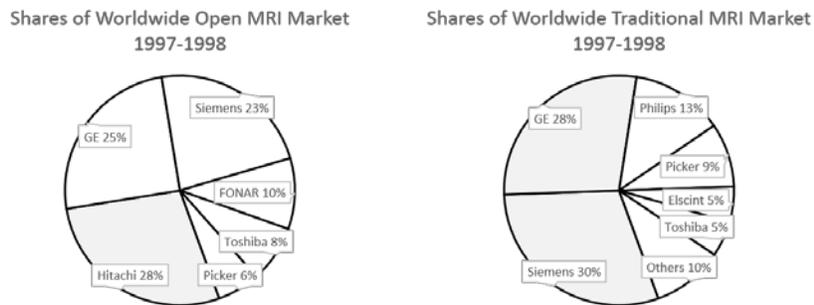
- Wider consensus among physicians, health care facility administrators, and regulators regarding the utility of MRI, especially in Australia.
- Growing middle and upper classes that demanded sophisticated health care, especially in India, Southeast Asia, and Brazil.
- Increases in health insurance coverage, especially in India and Brazil.
- Government incentives, investment, and mandates to modernize health care facilities, especially in Southeast Asia and Brazil.
- Opening of markets that were previously closed in post-Soviet Eastern Europe.
- Improved warranties and service plans offered by vendors, especially in India and Southeast Asia.

**Figure 11**



Source: Frost & Sullivan (1998).

**Figure 12**



Source: Frost & Sullivan (1998).

\* Picker acquired Elscint in 1998 and was bought by Philips in 2001.

## Endnotes

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<sup>1</sup> Our case study has been influenced here and throughout by the general accounts of MRI development in: Adrian Thomas, *The History of Radiology*, Oxford Medical Histories (Oxford: Oxford University Press, 2013), Chapter 7, see especially pages 117-118; Stuart S. Blume, *Insight and Industry: On the Dynamics of Technological Change in Medicine*, Inside Technology (Cambridge, Mass: MIT Press, 1992), 190-191; Bettyann Kevles, *Naked to the Bone: Medical Imaging in the Twentieth Century*, The Sloan Technology Series (New Brunswick, NJ: Rutgers University Press, 1997), 173-175; Kelly A. Joyce, *Magnetic Appeal - MRI and the Myth of Transparency* (Ithaca; London: Cornell University Press, 2004), 11-14.

<sup>2</sup> Although, unlike in CTs, the total number of MRIs is higher in the U.S. than in Japan.

<sup>3</sup> Raymond Damadian, "Tumor Detection by Nuclear Magnetic Resonance," *Science* 171, no. 3976 (1971): 1151-53; Raymond V. Damadian, United States Patent: 3789832 - APPARATUS AND METHOD FOR DETECTING CANCER IN TISSUE, 3789832, issued February 5, 1974, <http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=%2Fnetacgi%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F3789832>.

<sup>4</sup> Lauterbur had observed another researcher replicating Damadian's tissue analysis. Mansfield read Damadian's article as he prepared his own article for submission.

<sup>5</sup> "Paul C. Lauterbur - Biographical," accessed March 22, 2016, [http://www.nobelprize.org/nobel\\_prizes/medicine/laureates/2003/lauterbur-bio.html](http://www.nobelprize.org/nobel_prizes/medicine/laureates/2003/lauterbur-bio.html).

<sup>6</sup> P. C. Lauterbur, "Image Formation by Induced Local Interactions: Examples Employing Nuclear Magnetic Resonance," *Nature* 242, no. 5394 (1973): 190, <https://doi.org/10.1038/242190a0>.

<sup>7</sup> Mansfield had independently developed similar techniques which he had described in an article published in the fall of 1973, just months after Lauterbur had published his article. See: P. Mansfield and P. K. Grannell, "NMR 'diffraction' in Solids?," *Journal of Physics C: Solid State Physics* 6, no. 22 (1973): L422, <https://doi.org/10.1088/0022-3719/6/22/007>.

<sup>8</sup> "Sir Peter Mansfield - Biographical," accessed March 22, 2016, [http://www.nobelprize.org/nobel\\_prizes/medicine/laureates/2003/mansfield-bio.html](http://www.nobelprize.org/nobel_prizes/medicine/laureates/2003/mansfield-bio.html).

<sup>9</sup> While visiting EMI, Mansfield met CT pioneer, Godfrey Hounsfield. See: P. Mansfield, *The Long Road to Stockholm: The Story of Magnetic Resonance Imaging (MRI): An Autobiography*, Oxford Scholarship Online (Oxford: Oxford University Press, 2013), Chapter 8.

<sup>10</sup> EMI's lab started work in 1974. By 1977, EMI had built a prototype, but it worked so poorly, they had decided to start over in 1978 with additional funding from the British government. In 1978-1979, EMI incurred heavy losses in its music and medical imaging businesses, and the company sold medical imaging to Thorn Industries. The project continued, and EMI's MRI researchers succeeded in building an MRI scanner that produced good images. However, Thorn-EMI disbanded the department when it sold its medical imaging business to the British electronics company GEC (which had also recently acquired the American medical equipment maker Picker) in 1981.

<sup>11</sup> Ian R. Young, "Young, Ian R.: EMI's Venture into NMR - An Industrial Saga," in *eMagRes* (John Wiley & Sons, Ltd, 2007), <http://onlinelibrary.wiley.com/doi/10.1002/9780470034590.emrhp0203/abstract>. EMI's instinct was right--even today, most CT scanners cannot match MRI in imaging the soft tissues and fluids inside the body. (See Figure 1.)

<sup>12</sup> In 2003, Paul Lauterbur and Peter Mansfield shared the Nobel Prize for Medicine for their contributions to the development of MRI, but Raymond Damadian, who had tirelessly promoted MRI's diagnostic potential (and his role as its inventor) to lay and professional audiences from the 1970s onward, was excluded. The ensuing scientific controversy led to even more publicity for MRI and its producers.

<sup>13</sup> Jim Carolan, who had studied and worked at Nottingham, founded Nalorac in 1975. He sold the company to Nicolet Instrument Corp. in 1977. The company made two placements for clinical trials, however, they appear to have never obtained FDA approval for their device. In 1981, Carolan purchased part of the Nalorac business back from Nicolet. His new company, Nalorac Cryogenics Corp., made, sold, and serviced "magnetic resonance imaging instrumentation, superconductive magnets and high performance cryogenics" until 2002, when it was bought by Varian. See: "Carolans Chart New Course - Lamar University," accessed November 9, 2015, <http://www.lamar.edu/news-and-events/cardinal-cadence/2004-issues/carolans-chart-new-course.html>; Metriflow obtained 510(k) clearance from the FDA in 1988 for its specialized device, which was designed to measure blood flow through the cardiovascular system. In 1992, it made a push to market the devices to cardiologists and interventional radiologists, but by 1994, the company had begun filing paperwork to dissolve. "Metriflow Pioneers Trend to Market Niche MR | Physicians Practice," September 3, 1992, <http://www.physicianspractice.com/practice-management/metriflow-pioneers-trend-market-niche-mr/>; "METRIFLOW INC. (M037778)," accessed October 6, 2016, <https://www.wdfi.org/apps/CorpSearch/Details.aspx?entityID=M037778&hash=1502723515&searchFunctionID=92a301e1-cc2c-4602-8505-bb2602efd370&type=Simple&q=metriflow>; "METRIFLOW MEDICAL SYSTEMS, INC. (1M20678)," accessed October 6, 2016, <https://www.wdfi.org/apps/CorpSearch/Details.aspx?entityID=1M20678&hash=1633422590&searchFunctionID=3189a9ed-ac0c-4612-ade9-a4b21553a2c0&type=Simple&q=metriflow>. See also: Mitchell, "The Diagnostic Imaging Industry," Chapter 6, and Steinberg and Cohen, *Nuclear Magnetic Resonance Imaging Technology*, 130.

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<sup>14</sup> This act is sometimes referred to as the Medical Device Amendments of 1976, because it amended the Food, Drug, and Cosmetic Act of 1938.

<sup>15</sup> Earl P. Steinberg and Alan B. Cohen, *Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial, and Policy Analysis, Health Technology Case Study*, v 27 (Washington, D.C.: Congress of the U.S., Office of Technology Assessment, 1984); Ep Steinberg, "The Status of MRI in 1986: Rates of Adoption in the United States and Worldwide," *American Journal of Roentgenology* 147, no. 3 (September 1, 1986): 453–55, doi:10.2214/ajr.147.3.453; E. P. Steinberg, J. E. Sisk, and K. E. Locke, "X-Ray CT and Magnetic Resonance Imagers. Diffusion Patterns and Policy Issues," *The New England Journal of Medicine* 313, no. 14 (October 3, 1985): 859–64, doi:10.1056/NEJM198510033131405; Blume, *Insight and Industry*; Kevles, *Naked to the Bone*; Sonny Kleinfeld, *A Machine Called Indomitable*, 1st ed. (New York: Times Books, 1985).

<sup>16</sup> The FDA approval to sell new medical devices after clinical trials is known as "Pre-Market Approval" (or PMA).

<sup>17</sup> FDA approval of a trial is called a "Investigational Device Exemption" (or IDE). See: "Medical Devices; Procedures for Investigational Device Exemptions—Food and Drug Administration. Final Rule," *Federal Register* 45, no. 13 (January 18, 1980): 3732–59.

<sup>18</sup> Steinberg and Cohen, *Nuclear Magnetic Resonance Imaging Technology*, 90. See also: "Medical Devices; Procedures for Investigational Device Exemptions—Food and Drug Administration. Final Rule," *Federal Register* 45, no. 13 (January 18, 1980): 3732–59.

<sup>19</sup> The Association of Electrical Equipment and Medical Imaging Manufacturers (previously the National Electrical Manufacturers Association, or NEMA).

<sup>20</sup> Although sources do not state the exact prices of MRIs during the clinical trial stage, the magnets alone cost manufacturers between USD\$100,000 and USD\$500,000, and typically accounted for 30%-50% of the cost of the whole machine. In 1983, manufacturers estimated that post-approval pricing would start at USD\$800,000 per unit. As noted in the case, manufacturers offered hospitals discounts and other incentives during clinical trials.

<sup>21</sup> Steinberg and Cohen, *Nuclear Magnetic Resonance Imaging Technology*; Steinberg, Sisk, and Locke, "X-Ray CT and Magnetic Resonance Imagers. Diffusion Patterns and Policy Issues"; Steinberg, "The Status of MRI in 1986"; Blume, *Insight and Industry*, Chapter 6; Kevles, *Naked to the Bone*, Chapter 8.

<sup>22</sup> Steinberg and Cohen, *Nuclear Magnetic Resonance Imaging Technology*; Steinberg, Sisk, and Locke, "X-Ray CT and Magnetic Resonance Imagers. Diffusion Patterns and Policy Issues"; Steinberg, "The Status of MRI in 1986"; L. Tad Cowley et al., "Magnetic Resonance Imaging Marketing and Investment: Tensions between the Forces of Business and the Practice of Medicine," *Chest* 105, no. 3 (1994): 920; Blume, *Insight and Industry*, Chapter 6; Kevles, *Naked to the Bone*, Chapter 8. Steinberg and Cohen also suggest that university hospitals lent time on MRI scanners out to researchers who were not affiliated with their universities and who also contributed toward the costs of the machines. (See page 68)

<sup>23</sup> The 1974 law that mandated CONs nationwide was the Health Planning and Resources Development Act. About 20 states had CON laws prior to the 1974 Act (authorized under a section of an earlier Social Security law). The federal CON mandate was repealed in 1987, after which 14 states eliminated their CON laws.

<sup>24</sup> Hospitals could obtain exemptions from CON laws if hosting a device for a clinical trial, but many hospitals filed for both the exemption and CON approval at the same time, because they planned to continue to use their MRIs after the trials finished.

<sup>25</sup> Robert Metz. "Market Place: Cautious View on Fonar." *The New York Times*. October 15, 1982. Fred R. Bleakley. "Investing: The Volatile World of Medical Imaging." *The New York Times*. November 27, 1983.

<sup>26</sup> Steinberg and Cohen, *Nuclear Magnetic Resonance Imaging Technology*. See especially the appendices, which offer summaries of each company's progress toward a commercial system, as well as details of partnerships and clinical trials.

<sup>27</sup> Two of the companies (Picker and Elscint) were asked to revise and resubmit their applications before the FDA granted approval to sell. See: William Gordon Mitchell, "Dynamic Commercialization: An Organizational Economic Analysis of Innovation in the Medical Diagnostic Imaging Industry" (Ph.D., University of California, Berkeley, 1988), <http://search.proquest.com.ezp-prod1.hul.harvard.edu/docview/303668403/abstract?>; Mitchell, "The Diagnostic Imaging Industry"; Elscint Ltd., March 31, 1983. Form 10-Q, pages 15-16; Elscint Ltd., Annual Report for 1983, page 5; Elscint Ltd., 1985, Form 10-Q, pages 4-6, 14-15, and 22.

<sup>28</sup> 53 Fed. Reg. 7575 1988. Content downloaded/printed from HeinOnline (<http://heinonline.org>) Tue Nov 10 16:15:11 2015.

<sup>29</sup> According to the FDA 510(k) database, established companies that obtained 510(k) approvals during this period included: Instrumentarium, Philips, GE, Siemens, Diasonics, and FONAR. Many developers appear to have waited to apply for FDA approval under the new rules. Entrants at this stage included longtime developers like Bruker, Toshiba, Resonex, and Hitachi (in a joint venture with startup Summit World Trade Corporation), and only two new developers: Shimadzu Medical Systems, and Health Images Inc., a network of imaging centers, which got approval for their own brand of MRI. The two apparent startups were: Stein-Gates Medical Equipment, which obtained approval for a portable ventilator that used magnetic resonance technology, and MRT Inc., which obtained approval for an MRI therapeutic device. Other companies also received approvals for accessories and/or MRI-compatible supplies, such as: Ohmeda Medical (Datex-Ohmeda was division of Instrumentarium), Bio-Med Devices (makers of ventilators from the 1970s), Microbiological Research Corp (makers of test kits from the 1960s), Haynes Radiation (makers of radiation therapy equipment from the early 1980s), Medrad (makers of cardiac angiography injection equipment from the 1960s), and Atomic Products Corp (makers of

equipment used in radiation therapy and nuclear medicine, as well as accessories, from the mid-20th century on). Otsuka also planned entry into the U.S. market during this period. See: "Otsuka Plans Entree into MRI with High-Field Unit, Low-Field Price | Diagnostic Imaging," August 28, 1991. <http://www.diagnosticimaging.com/articles/otsuka-plans-entree-mri-high-field-unit-low-field-price>.

<sup>30</sup> Chart based on data published in Bruce J. Hillman, *The Sorcerer's Apprentice: How Medical Imaging Is Changing Health Care* (Oxford; New York: Oxford University Press, 2011), 97; R. G. Evens and R. G. Evens, "Analysis of Economics and Use of MR Imaging Units in the United States in 1990," *AJR. American Journal of Roentgenology* 157, no. 3 (1991): 603-7; R. G. Evens and R. G. Evens, "Economic and Utilization Analysis of MR Imaging Units in the United States in 1987," *Radiology* 166, no. 1 Pt 1 (1988): 27-30; R. G. Evens, R. G. Jost, and R. G. Evens, "Economic and Utilization Analysis of Magnetic Resonance Imaging Units in the United States in 1985," *AJR. American Journal of Roentgenology* 145, no. 2 (1985): 393-98; Cowley et al., "Magnetic Resonance Imaging Marketing and Investment," 920.

<sup>31</sup> MRI is a flexible technology. It could and can be tuned to "see" many things in the body. Observers argued that users needed to be thoroughly educated in the operational choices that they made, far more so than in the case of CT and ultrasound. *Ibid.*; Re: the lack of training available for radiologists and radiology technicians, see: Mary T. Koska, "Image Reading. (Magnetic Resonance Imaging Systems - User Education) (Special Report: Radiology)," *Hospitals* 62, no. 21 (1988): 58; For examples of journal articles produced in partnerships, see: D A Ortendahl et al., "Analytical Tools for Magnetic Resonance Imaging," *Radiology* 153, no. 2 (November 1, 1984): 479-88, doi:10.1148/radiology.153.2.6091173; D A Feinberg et al., "Multiple Spin-Echo Magnetic Resonance Imaging," *Radiology* 155, no. 2 (May 1, 1985): 437-42, doi:10.1148/radiology.155.2.3983396; C L Partain et al., "Nuclear Magnetic Resonance and Computed Tomography: Comparison of Normal Human Body Images," *Radiology* 136, no. 3 (September 1, 1980): 767-70, doi:10.1148/radiology.136.3.7403558. See also: Joyce, *Magnetic Appeal - MRI and the Myth of Transparency*, 37-38, 42; R G Evens, "Nuclear Magnetic Resonance: Another New Frontier for Radiology?," *Radiology* 136, no. 3 (September 1, 1980): 795-96, doi:10.1148/radiology.136.3.6101231; I. L. Pykett et al., "Physical Principles of NMR Imaging," *Current Problems in Cancer* 7, no. 3 (September 1982): 37-50; "Glossary of NMR Terms. American College of Radiology, Subcommittee on NMR Nomenclature and Phantom Development," *Magnetic Resonance Imaging* 2, no. 2 (1984): 131-46.

<sup>32</sup> Steinberg et al consider these numbers low. See: Steinberg, Sisk, and Locke, "X-Ray CT and Magnetic Resonance Imagers. Diffusion Patterns and Policy Issues."

<sup>33</sup> Koska, "Image Reading. (Magnetic Resonance Imaging Systems - User Education) (Special Report)"; "Siemens Medical Systems" in "The Gray Sheet," *MDDI Reports*, October 8, 1990, back page.

<sup>34</sup> While MRI growth was strong, it was not as dramatic as CT growth during the same period of diffusion. See: A. L. Hillman and J. S. Schwartz, "The Adoption and Diffusion of CT and MRI in the United States. A Comparative Analysis," *Medical Care* 23, no. 11 (November 1985): 1283-94; See also: Robert A. Bell, "Economics of MRI Technology," *Journal of Magnetic Resonance Imaging* 6, no. 1 (January 1, 1996): 10-25, doi:10.1002/jmri.1880060105; Evens, Jost, and Evens, "Economic and Utilization Analysis of Magnetic Resonance Imaging Units in the United States in 1985"; Evens and Evens, "Economic and Utilization Analysis of MR Imaging Units in the United States in 1987"; Evens and Evens, "Analysis of Economics and Use of MR Imaging Units in the United States in 1990."

<sup>35</sup> Robert Zivadinov and Rohit Bakshi, "Role of Magnetic Resonance Imaging in the Diagnosis and Prognosis of Multiple Sclerosis," in *Multiple Sclerosis*, ed. Michael J. Olek DO, *Current Clinical Neurology* (Humana Press, 2005), 55-89, <http://link.springer.com.ezp-prod1.hul.harvard.edu/chapter/10.1385/1-59259-855-2%3A055>; Sid Gilman, "Imaging the Brain," *The New England Journal of Medicine* 338, no. 12 (1998): 812-820, doi:10.1056/NEJM199803193381207; Sid Gilman, "Imaging the Brain," *The New England Journal of Medicine* 338, no. 13 (1998): 889-896, doi:10.1056/NEJM199803263381307; B P Drayer, "Imaging of the Aging Brain. Part II. Pathologic Conditions," *Radiology* 166, no. 3 (March 1, 1988): 797-806, doi:10.1148/radiology.166.3.3277248; Alan Jackson, "MRI Elucidates Dementias and Disorders of Cerebral Perfusion," *Diagnostic Imaging* 21, no. 4 (April 1999): 53; Brenda Tilke, "Technologies That Are Changing the Practice of Radiology," *Diagnostic Imaging* 21, no. 7 (July 1999): 66; I. Watt, "Magnetic Resonance Imaging in Orthopaedics," *The Journal of Bone and Joint Surgery. British Volume* 73, no. 4 (July 1991): 539-50; R. A. Baldor, M. E. Quirk, and D. Dohan, "Magnetic Resonance Imaging Use by Primary Care Physicians," *The Journal of Family Practice* 36, no. 3 (March 1993): 281-85; "Research News & Progress," National Multiple Sclerosis Society, accessed October 5, 2016, <http://www.nationalmssociety.org/Research/Research-News-Progress>; T. Erkinjuntti et al., "Do White Matter Changes on MRI and CT Differentiate Vascular Dementia from Alzheimer's Disease?," *Journal of Neurology, Neurosurgery & Psychiatry* 50, no. 1 (January 1, 1987): 37-42, doi:10.1136/jnnp.50.1.37; P. Scheltens et al., "Atrophy of Medial Temporal Lobes on MRI in 'probable' Alzheimer's Disease and Normal Ageing: Diagnostic Value and Neuropsychological Correlates," *Journal of Neurology, Neurosurgery & Psychiatry* 55, no. 10 (October 1, 1992): 967-72, doi:10.1136/jnnp.55.10.967.

<sup>36</sup> Figures based on the total installations reported in Cowley, compared with hospital installations recorded in the American Hospital Association's annual statistical reports for the period. See: Cowley et al., "Magnetic Resonance Imaging Marketing and Investment." For partial estimates and related discussion of this shift, see: Bell, "Economics of MRI Technology"; Evens and Evens, "Analysis of Economics and Use of MR Imaging Units in the United States in 1990"; L. C. Baker and S. K. Wheeler, "Managed Care and Technology Diffusion: The Case of MRI," *Health Affairs* 17, no. 5 (September 1, 1998): 195-207, doi:10.1377/hlthaff.17.5.195; A. L. Hillman and J. S. Schwartz, "The Adoption and Diffusion of CT and MRI in the United States. A Comparative Analysis," *Medical Care* 23, no. 11 (November 1985): 1283-94; Al Hillman and Js Schwartz, "The Diffusion of MRI: Patterns of Siting and Ownership in an Era of Changing Incentives," *American Journal of Roentgenology* 146, no. 5 (May 1, 1986): 963-69, doi:10.2214/ajr.146.5.963; Bruce J. Hillman et al., "The Diffusion of Magnetic Resonance Imaging Scanners in a Changing U.S. Health Care Environment," *International Journal of Technology Assessment in Health Care* 3, no. 4 (1987): 545-554, doi:10.1017/S026646230001117X; Steinberg, "The Status of MRI in 1986"; E. P. Steinberg et al., "Determinants of Acquisition of MR Imaging Units in an Era of Prospective Payment," *Radiology* 168, no. 1 (July 1988): 265-70, doi:10.1148/radiology.168.1.3380972; A. Hisashige, "MR Imaging in Japan and the United States: Analysis of Utilization and Economics," *AJR. American Journal of Roentgenology* 162, no. 3 (March 1994): 507-10, doi:10.2214/ajr.162.3.8109485; James B. Bautz et

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al., "Magnetic Resonance Imaging: Diffusion of Technology in an Ambulatory Setting," *International Journal of Technology Assessment in Health Care* 8, no. 2 (1992): 301-308, doi:10.1017/S0266462300013519; "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016.

<sup>37</sup> Cowley et al., "Magnetic Resonance Imaging Marketing and Investment"; Bell, "Economics of MRI Technology"; Evens and Evens, "Analysis of Economics and Use of MR Imaging Units in the United States in 1990"; Baker and Wheeler, "Managed Care and Technology Diffusion"; T. Matson, "Deployment of Outpatient Technologies. The Hospital-Based versus Freestanding Dilemma," *Administrative Radiology: AR* 10, no. 9 (1991): 30-33; Bautz et al., "Magnetic Resonance Imaging."

<sup>38</sup> Charts based on data collected in Hoppszallern, Hughes, and Zimmerman, "MRI," 5; Cohen and Hanft, *Technology in American Health Care*, 77; and "World X-ray and Computed Tomography Equipment Markets," Industry Research Report, 7 January 1999, Frost & Sullivan, accessed February 2016, Figures 10-27 and 10-34.

<sup>39</sup> For information about GE's businesses during this period, see GE's *Annual Reports* for 1984 through 1991. See also: Lindsey Gruson, "TECHNICARE'S CAT SCANNER WOES," *The New York Times*, June 19, 1983, sec. Business, <http://www.nytimes.com/1983/06/19/business/technicare-s-cat-scanner-woes.html>. "Ge To Buy 2 Johnson Divisions," *Tribunedigital-Chicagotribune*, accessed November 10, 2015, [http://articles.chicagotribune.com/1986-04-10/business/8601260383\\_1\\_capsule-imaging-technicare](http://articles.chicagotribune.com/1986-04-10/business/8601260383_1_capsule-imaging-technicare).

<sup>40</sup> Chart based on data available from the Organization for Economic Cooperation and Development. Years missing in between years reported estimated based on previous and subsequent growth in installations. See: Organization for Economic Cooperation and Development. "OECD Health Statistics 2015 - OECD," accessed July 28, 2015, <http://www.oecd.org/els/health-systems/health-data.htm>.

<sup>41</sup> Barbara Stocking. "EEC Workshop on Regulatory Mechanisms Concerning Expensive Health Technology: London," in *Expensive Health Technologies: Regulatory and Administrative Mechanisms in Europe*, Commission of the European Communities Health Services Research Series; No. 5 (Oxford; New York: Oxford University Press, 1988).

<sup>42</sup> Data for MRI based on P. Lazaro and K. Fitch, "The Distribution of Big Ticket Medical Technologies in OECD Countries," *International Journal Of Technology Assessment In Health Care* 11, no. 3 (1995): 552-570; and Stocking, "EEC Workshop on Regulatory Mechanisms Concerning Expensive Health Technology: London." For CT: Chart data from Japan from 1987; all other figures from 1986. Australia (1987), Japan (1987), and U.S. (1986) data from the PECD. West Germany (1985 and 1987) data from Stocking; see also Schenzler and Tuohy. France and density data for UK/England (1985) from Le Gales, et al, and Stocking. All other data from Stocking. (See following citations.) "OECD Health Statistics 2015 - OECD"; C. Le Galès et al., "Contrasted Diffusion and the Use of CT Scanner Equipment in France," *European Journal of Radiology* 8, no. 4 (1988): 203-7; Christoph Schenzler, "The Effect of Competition and Regulation on the Diffusion of Major Medical Technologies in German and United States Hospitals" (Ph.D., Vanderbilt University, 1998), <http://search.proquest.com.ezp-prod1.hul.harvard.edu/docview/304457501/abstract>; WILLIAM TUOHY, "West Germany Can't Count on Citizenry at Census Time," *Los Angeles Times*, March 2, 1987, [http://articles.latimes.com/1987-03-02/news/mn-4300\\_1\\_census-time](http://articles.latimes.com/1987-03-02/news/mn-4300_1_census-time); For standing as of 1990, see: P. Lazaro and K. Fitch, "The Distribution of Big Ticket Medical Technologies in OECD Countries," *International Journal Of Technology Assessment In Health Care* 11, no. 3 (1995): 552-570.

<sup>43</sup> Hisashige, "MR Imaging in Japan and the United States"; Masatoshi Matsumoto et al., "Geographic Distribution of CT, MRI and PET Devices in Japan: A Longitudinal Analysis Based on National Census Data: e0126036," *PLoS One* 10, no. 5 (May 2015), doi:<http://dx.doi.org.ezp-prod1.hul.harvard.edu/10.1371/journal.pone.0126036>.

<sup>44</sup> Hillman, *The Sorcerer's Apprentice*; Matson, "Deployment of Outpatient Technologies. The Hospital-Based versus Freestanding Dilemma"; See also: J. M. Mitchell, "The Prevalence Of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging," *Health Affairs* 26, no. 3 (May 1, 2007): w415-24, doi:10.1377/hlthaff.26.3.w415; "Curbing Growth of Physician Self-Referrals Requires Congress | News from Brown," accessed November 12, 2015, <https://news.brown.edu/articles/2015/01/conflict>; "Imaging: The Self-Referral Boom And The Ongoing Search For Effective Policies To Contain It," accessed December 21, 2015, <http://content.healthaffairs.org/content/29/12/2231.full>.

<sup>45</sup> Toshiba acquired Diasonics' MRI business the next year (in 1989) and continued to produce open MRIs based on Diasonics' designs. Chart based on data published in Hillman, *The Sorcerer's Apprentice*, 97; see also: Bell, "Economics of MRI Technology."

<sup>46</sup> "New Siemens and GE Scanners Put Interventional MRI on the Map | Diagnostic Imaging," November 17, 1993, <http://www.diagnosticimaging.com/articles/new-siemens-and-ge-scanners-put-interventional-mri-map>; Alicia Eckley and Wendy Basil, "Diasonics Inc.'s 'Open-Air' Magnetic Resonance Imaging System Receives FDA Approval to Begin Marketing," *Business Wire*, 1988, 1; Amal Kumar Naj, "MRI Makers Face New Demands on Their Equipment: Lower Costs, Versatility Are Crucial in Current Health-Care Environment," *Wall Street Journal* (1923 - Current File), November 15, 1994, <http://search.proquest.com.ezp-prod1.hul.harvard.edu/docview/904940655/abstract/41EA00C119D448FCPQ/101?accountid=11311>; Leslie Berkman, "Diasonics MRI Unit to Be Sold to Tustin's Toshiba America," *Los Angeles Times*, August 25, 1989, [http://articles.latimes.com/1989-08-25/business/fi-1158\\_1\\_toshiba-america-medical-systems](http://articles.latimes.com/1989-08-25/business/fi-1158_1_toshiba-america-medical-systems); David J. Bak, "Now There's MRI for the Masses: C-Shaped Magnet Helps Cut System's Size and Cost. (Magnetic Resonance Imaging) (Includes Related Article on Siemens Medical Device Called Magnetom Open) (Medical Report)," *Design News* 49, no. 11 (1994): 111; Philip Greenfield, "Siemens Changes the Face of MRI. (Siemens AG's Magnetom Open 0.2 T Magnetic Resonance Imaging System)," *Clinica*, no. 583 (1993): 19.

<sup>47</sup> Siemens also started offering multiple color options in an effort to improve the ambience of the MRI suite and alleviate patient anxieties. Martin Hedges, "Siemens Goes for Smaller and Lighter to Boost MRI sales.(Siemens Medical Systems, Magnetic Resonance

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Imaging)," *Clinica*, no. 776 (1997): 11; Scott Hensley, "MRI Renaissance," *Modern Healthcare* 27, no. 48 (1997): 56-8, 60, 62; James Brice, "Diagnostic Imaging at 30," *Diagnostic Imaging* 31, no. 11 (November 2009): 36-37,39,41,43.

<sup>48</sup> John C. Hayes, "20 Years of Diagnostic Imaging," *Diagnostic Imaging* 21, no. 12 (December 1999): 53; John C. Hayes, "The Education of a Malpractice Expert," *Diagnostic Imaging* 20, no. 9 (September 1998): 29; Joyce, *Magnetic Appeal - MRI and the Myth of Transparency*; Anita Raghavan and Kathryn Kranhold Staff Reporters of *The Wall Street Journal*, "GE Unveils \$9.5 Billion Deal To Acquire U.K.'s Amersham," *Wall Street Journal*, October 10, 2003, sec. News, <http://www.wsj.com/articles/SB106574018488408500>; "Joe Hogan Leads Technology Side of Newly Integrated GE-Amersham | Diagnostic Imaging," January 24, 2005, <http://www.diagnosticimaging.com/ct/joe-hogan-leads-technology-side-newly-integrated-ge-amersham>; J. C. Weinreb, "MR Accreditation Helps to Assure Quality Service," *Diagnostic Imaging* 22, no. 7 (July 2000): 39-43; Philip Ward, "Retiring Imaging Chief Reflects on Time with WHO -- Ostensen Got Radiologists and Radiographers Working Together and Established a Global Training Network and Structure, but No Successor Waits in the Wings," *Diagnostic Imaging* 23, no. 7 (July 2001): 23; "Abbott-GE Deal Reflects Evolving Character of Imaging Industry | Diagnostic Imaging," January 18, 2007, <http://www.diagnosticimaging.com/ge/abbott-ge-deal-reflects-evolving-character-imaging-industry>.

<sup>49</sup> Chart based on data available from the Organization for Economic Cooperation and Development. Years missing in between years reported estimated based on previous and subsequent growth in installations. See: Organization for Economic Cooperation and Development. "OECD Health Statistics 2015 - OECD." Y. Korogi and M. Takahashi, "Cost Containment and Diffusion of MRI: Oil and Water? Japanese Experience," *European Radiology* 7 Suppl 5 (1997): 256-58. For more information about Japanese adoption of imaging systems, including MRI, in the period immediately after this, see: Matsumoto et al., "Geographic Distribution of CT, MRI and PET Devices in Japan"; Masatoshi Matsumoto et al., "Geographic Distribution of Radiologists and Utilization of Teleradiology in Japan: A Longitudinal Analysis Based on National Census Data," ed. Toshiyuki Ojima, *PLOS ONE* 10, no. 9 (September 30, 2015): e0139723, doi:10.1371/journal.pone.0139723. Low-cost scanners also drove unusually high adoption in Finland, where second wave entrant Instrumentarium was located.

<sup>50</sup> Amit Prasad, *Imperial Technoscience Transnational Histories of MRI in the United States, Britain, and India, Inside Technology* (Cambridge, Massachusetts: The MIT Press, 2014 Baltimore, Md, 2014); Ajay Mahal, Anil Varshney, and Srinivas Taman, "Diffusion of Diagnostic Medical Devices and Policy Implications for India," *International Journal of Technology Assessment in Health Care* 22, no. 2 (April 2006): 184-190, doi:10.1017/S0266462306051002; "Market For Used & Refurbished Medical Products," *Biomedical Market Newsletter*, November 30, 1999; "Government Incentives Spur Adoption of Computed Tomography, Magnetic Resonance Imaging and Ultrasound Systems in Brazil, Finds Frost & Sullivan: MRI Market Expected to Grow Faster than Ultrasound and CT," *PR Newswire*, April 29, 2013, <http://search.proquest.com.ezp-prod1.hul.harvard.edu/docview/1346641319/abstract>; "Brazil's Medical Equipment & Device Market," *Biomedical Market Newsletter*, September 30, 1999; David Hailey, "Health Care Technology in Australia," *Health Policy, Special Issue: Health care technology and its assessment in eight countries: Australia, Canada, France, Germany, Netherlands, Sweden, United Kingdom, United States*, 30, no. 1-3 (October 1994): 23-72, doi:10.1016/0168-8510(94)00684-7; "Best Markets For Exporting Medical Equipment Worldwide," *Biomedical Market Newsletter*, August 1, 1995, <http://global.factiva.com/redirect/default.aspx?P=sa&an=bimn000020011024dr8100073&cat=a&ep=ASE>; "Nuclear Imaging Equipment Market Rises Above Other Imaging Modalities," *Biomedical Market Newsletter*, February 1, 1995, <http://global.factiva.com/redirect/default.aspx?P=sa&an=bimn000020011024dr210001b&cat=a&ep=ASE>. See also: "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016; Renaldo N. Battista, Robert Jacob, and Matthew J. Hodge, "Special Issue: Health Care Technology and Its Assessment in Eight Countries: Australia, Canada, France, Germany, Netherlands, Sweden, United Kingdom, United States Health Care Technology in Canada (with Special Reference to Quebec)," *Health Policy* 30, no. 1 (October 1, 1994): 73-122, doi:10.1016/0168-8510(94)00685-8; Claire Packer, Sue Simpson, and Andrew Stevens, "International Diffusion of New Health Technologies: A Ten-Country Analysis of Six Health Technologies," *International Journal of Technology Assessment in Health Care* 22, no. 4 (October 2006): 419-428, doi:10.1017/S0266462306051336.

<sup>51</sup> Source for data for chart: "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016.

<sup>52</sup> Shimadzu decided to pull out of the U.S. market in 1998 to focus on the Pacific Rim. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016; "Elsint Divestiture May Be Harbinger of More Medical Imaging Consolidation | Diagnostic Imaging," September 30, 1998, <http://www.diagnosticimaging.com/articles/elsint-divestiture-may-be-harbinger-more-medical-imaging-consolidation>; "Philips to Buy Marconi Medical Systems for \$1.1 Billion," AuntMinnie.com, accessed March 2, 2016, <http://www.auntminnie.com/index.aspx?sec=ser&sub=def&pag=dis&itemid=51101>; "Philips Buys Marconi Medical Systems Unit - Jul. 4, 2001," accessed March 2, 2016, <http://money.cnn.com/2001/07/04/europe/philips/>.