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# Case Histories of Significant Medical Advances: Magnetic Resonance Imaging

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Working Paper 20-001

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# Magnetic Resonance Imaging

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**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) initial commercialization and routine diagnostic use (in the 1980s); and 3) growth in sales and uses (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 and Kai Thomenius for helpful information and suggestions.

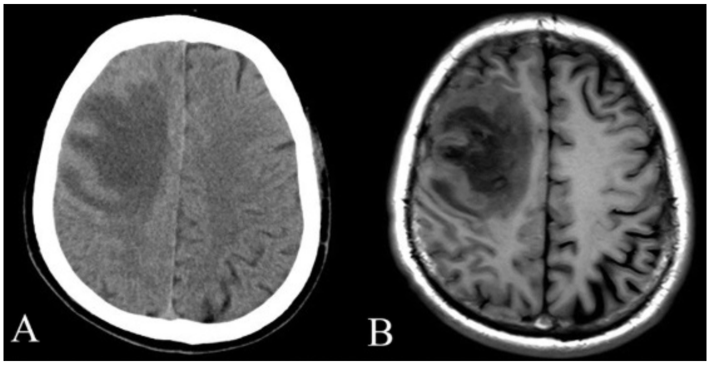
# Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) complements, and has partially replaced, computed tomography (CT) imaging. Like CT, MRI creates images of specific cross-sections or "slices" of the body – but with 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. Instead, MRIs beam pulses of radio waves at patients placed in a strong magnetic field. The pulses induce the nuclei of patients' cells to intermittently absorb and release energy. The released energy, also in the form of radio waves, is detected by receivers and then used to construct computerized images.

The Food and Drug Administration first approved MRIs for commercial sale in the U.S. in the mid-1980s. By the end of the 1990s more than 8,000 units, performing more than 20 million scans, had been installed worldwide. Meanwhile, costs and speed of MRI scans had declined significantly: for example, in 1985, a standard MRI brain exam would take an hour and (in the U.S.) cost about $1,500. By the late 1990s, the times and costs had halved.[1]

MRIs remained expensive, however. MRIs systems – that included magnets (to produce magnetic fields), coils (to beam and receive radio waves and regulate magnetic fields) and computers (to turn received radio waves into images)—cost between $1 million to $2 million. CTs sold for between $400k to $750k, had lower operating costs, and shorter scanning times.[2]

**Figure 1** Recent examples of a CT scan (A) vs. an MRI (B)




Source: Excerpted from Figure 2 in Huang, Wy., Wu, G., Chen, F. et al. "Multi-systemic melioidosis: a clinical, neurological, and radiological case study from Hainan Province, China." *BMC Infect Dis* 18, 649 (2018), https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-018-3569-8, accessed May 2021. CC BY 4.0 http://creativecommons.org/licenses/by/4.0/.

The main sections of this case history[3] describe 1) the development of foundational techniques and prototypes (through the 1970s); 2) initial commercialization and routine diagnostic use (in the 1980s); and 3) growth in sales and uses (in the 1990s).

## 1. Foundational techniques and prototypes (through the 1970s)

***Discoveries and Inventions.*** 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.[4]

In 1971 Raymond Damadian, a physician and researcher at the State University of New York, 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 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.[5]

The premise of Damadian's 1971 article – that cancer tissue had a distinctive resonance – was challenged and his patent application only claimed to detect malignancies, rather than to create images. However, soon after Damadian published his *Science* article, chemist Paul Lauterbur (from New York State's Stony Brook University) and physicist Peter Mansfield (from the University of Nottingham, England) provided foundational ideas and techniques for imaging. (Their efforts may have been spurred to some degree by Damadian's article.[6])

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 resonance 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 Lauterbur's research.[7] In 1973 he published a technique to locate the positions of water molecules within the body,[8] which in turn could provide the basis of images of specific cross sections. The chemist would spend the next three decades working on medical applications of magnetic resonance. (See **Exhibit 1**).

The Nottingham physicist Mansfield had also undertaken research since his college days on magnetic resonance that combined theorizing with developing instruments that used computers to analyze data. This experience led Mansfield to significantly extend the utility of Lauterbur's procedure:[9] Mansfield developed a computerized technique to quickly and efficiently create images from the positions of water molecules (located by their magnetic resonances).

Like Lauterbur, Mansfield reoriented his research after the early 1970s towards medical applications, securing a grant from Britain's Medical Research Council in 1977.[10] 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.

***Device Development.*** In 1974, the British conglomerate, Electric & Musical Industries (EMI), became the first established company to start developing MRIs, in consultation with Mansfield[11] and his Nottingham colleagues.[12] EMI, whose main businesses had been in the entertainment industry, had pioneered CT scanners[13] which it had first sold in 1972. EMI management believed MRI had the "potential to rival its then burgeoning CT X-ray business."[14]

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[15] produced a cross-section of the chest of a member of his research team, and the next year, he founded FONAR[16] Corporation to develop and manufacture MRI scanners.[17]

By the end of 1979, nine more companies had followed FONAR and EMI into MRI development. (See **Exhibit 2**). Six 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.

## 2. Commercialization and Routine Use (1980s)

***Clinical Trials.*** Eight companies, who had businesses in related fields, and six startups who collaborated with university researchers (See **Exhibit 3**) began developing MRIs in the early 1980s. (The startups may have been encouraged by the high valuation of stocks in MRI companies that had been started in the 1970s. However, after surging in 1981, 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.[18])

But, before manufacturers could sell any MRIs, the Food and Drug Administration (FDA) issued rules (authorized by the 1976 Medical Device Regulation Act[19]) requiring MRIs to undergo clinical trials for safety and effectiveness.[20] The Act distinguished between new devices, which had to secure "Pre-Market Approvals" (PMAs) from the FDA before they could be marketed[21] and extensions of existing devices that had been sold before 1976 or had been approved by the FDA. Manufacturers claiming their devices were extensions did not have to secure PMAs but they had to file a "510(k)" notification with the FDA ninety days before marketing their device.[22]

In 1981, the FDA classified MRIs as new devices requiring clinical trials[23]—the first ever such classification under the 1976 Act. Over a dozen companies then joined with their trade association[24] to challenge the FDA's classification, claiming that MRIs were simply extensions of instruments long used to analyze chemicals. However, they also applied to the FDA for permission to run clinical trials[*], in case their challenge failed. And EMI (in 1978) and FONAR (in 1980) had already started trials, before the FDA had required them.

[*] The 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. 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."

In addition to securing permission from the FDA for their trials, MRI developers had to persuade hospitals to participate. Hospitals participating in trials faced considerable expenses. FDA rules did not allow manufacturers to make a profit on devices used in a clinical trial. But even at cost, prices for the machines were high.[25] 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.[26]

Nonetheless, hospitals in the U.S. 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.[27]

Hospitals running trials may have also expected advantages in securing "Certificates of Need" (CONs).[28] CON rules 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.[29] Applying for CONs during a trial,[30] before the FDA had approved MRIs for broad use, limited the possibility of another hospital creating the surplus capacity.

In 1984 the FDA granted PMAs to Picker (which had acquired EMI's MRI business in 1978) and to FONAR. By the end of that year, nine other companies had run clinical trials and three more companies were preparing for trials.[31] By 1988, eleven of those fourteen companies had obtained approval from the FDA to sell their MRIs[32] (See **Exhibit 3**) and over a thousand MRIs had been used in clinical practice.

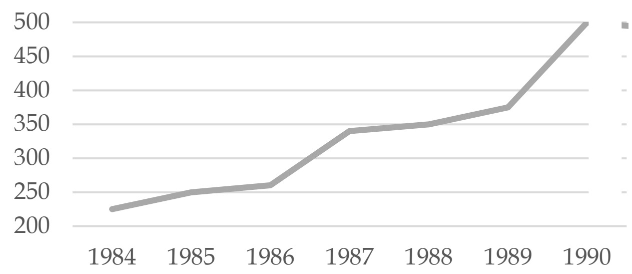
This usage persuaded the FDA that MRIs were no longer novel devices. Therefore, manufacturers proposing to sell any new MRI equipment would no longer have to secure PMAs after clinical trials – a 510 (K) notification would now be sufficient.[33]

As it happened the reclassification mainly helped companies that were already selling MRIs. Toshiba, Hitachi, and Shimadzu—that had been selling MRIs in Japan -- 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.[34]

Meanwhile eight developers who hadn't secured FDA approval before 1988 had already given up while one changed its focus to selling the magnets used in MRIs.[35] (Metriflow, a 1970s era startup, did use the 1988 FDA reclassification to market a specialized MRI to measure blood flow but eventually liquidated after failing to sell many units.)[36]

***Post-approval growth.*** Annual units sold in the U.S. (after the FDA first began approving commercial sales in 1984) more than doubled through the rest of the 1980s[37] (See **Figure 2**) in spite of MRI's high unit prices—between $800,000 and $2 million--and maintenance costs – which were estimated at up to $415,000 annually.[38] Correspondingly, the number of units installed rose ten-fold (from less than 200 in 1984 to over 2200 in 1990 as did the total number of scans performed (from 550,000 in 1984 to 5.5 million in 1990).[39]

**Figure 2** Annual sales of MRI units in the United States – 1984-1991




Source: Hillman, Bruce, and Jeff Goldsmith. *The Sorcerer's Apprentice: How Medical Imaging Is Changing Health Care*. Oxford University Press, 2010.

Researchers in prestigious hospitals (particularly those that had participated in trials) codified and disseminated MRI techniques in books and journal articles. MRI producers supported the publications with grants, and some offered their own training. Siemens, for instance, built a $10 million, 70,000-sq.-ft. training facility, which employed 35 full-time instructors.[40]

The American College of Radiology and other professional associations undertook educational initiatives[41] and 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.[42] And according to one 1990 survey of 72 facilities with the most experience in MR imaging, facilities that operated at a loss in 1985 were earning profits in 1990 because of increased charges for scans and operating efficiencies.

(The survey found that scheduling delays had decreased so that the typical MRI unit in 1990 operated about 66 hours per week to image 68 patients. With more than 3000 patients examined each year at a charge of approximately $750 per exam, each unit produced net revenues of almost $1.9 million. At an annual estimated operating cost of $1.3 million, the typical MR unit thus produced an annual net profit of approximately $500,000. In contrast MRI units had been losing approximately $400,000 annually in 1985).[43]

**Markets and Competitors.** 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.[44] (CT scans continued to increase along with MRI scans in the period nonetheless).

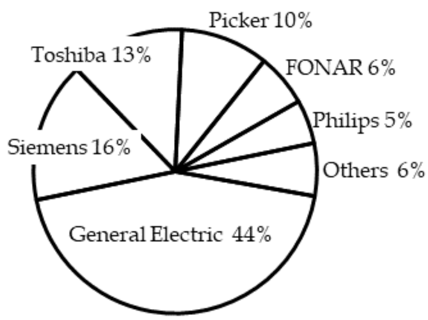
New, freestanding imaging centers (that also offered CT and ultrasound[45] scanning) installed more MRIs in the late 1980s than did traditional hospitals.[46] (See **Exhibit 4**). As described in a companion Note on CTs, Certificate of Need (CON) rules intended to discourage excessive purchases of CTs by hospitals had encouraged the growth of imaging centers that were exempt from CON rules. The imaging centers also had other advantages in setting up new imaging facilities[47] and could secure higher reimbursements from insurers for MRIs as well as for CTs.[48]

General Electric (GE) accounted for more than 40% of MRIs installed in the US in 1990. (**Figure 3**). It had secured the leading share after acquiring Technicare (from Technicare's parent company Johnson & Johnson) in 1986 and Thomson-CGR's medical equipment business in 1987[49] and by leveraging the capabilities of its other businesses.[50] Of the next five MRI manufacturers four also made CTs and other imaging devices.[51] Only Damadian's FONAR Corp., which had gone public in 1981 but was not profitable until the late 1980s, specialized in MRI.

MRI installations in the rest of the world lagged, as in CTs, making the U.S. the largest market.[52] (See **Exhibits 5 and 6**). 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.[53]

Japan, as in CTs, was an exception, however, with adoption per capita approaching U.S. levels by 1990.[54] Japan had no CON-like regulations that limited purchases. And low, government-mandated reimbursement rates (set at about 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.[55]

**Figure 3** Shares of US MRI installations (100% = 2,200 units) by company in 1990

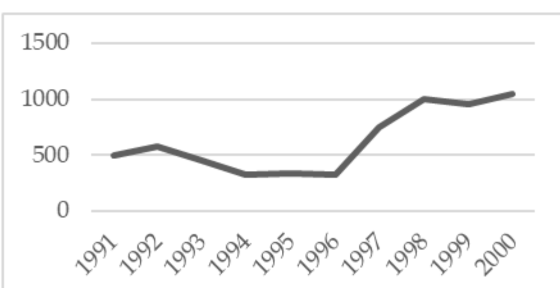



Source: Created by casewriter using data from Hoppszallern, S., C. Hughes, and R. A. Zimmerman. "MRI: Update on Technology Diffusion and Acquisition." Hospital Technology Series 10, no. 8 (April 1991): 1–32 and Cohen, Alan B., and Ruth S. Hanft. Technology in American Health Care: Policy Directions for Effective Evaluation and Management. University of Michigan Press, 2004.

## 3. Growth in sales and uses (1990s)

***Recovering from a decline.*** Frost & Sullivan reported in 1998 that, a "global economic recession" in the early 1990s produced a decline in worldwide MRI sales.[56] But, after bottoming in 1994-95, the industry made a "strong comeback,"[57] particularly in the U.S. (**Figure 4**).

**Figure 4** MRI Unit Sales in the US 1991-2000




Source: Hillman, Bruce, and Jeff Goldsmith. *The Sorcerer's Apprentice: How Medical Imaging Is Changing Health Care*. Oxford University Press, 2010

The Frost & Sullivan report credited the rebound to "innovative technologies" that "significantly increased" "cost-effectiveness" and "overall diagnostic capabilities."[58]

***Open, low-cost devices.*** Hitachi introduced cheaper MRIs with smaller, lower-powered magnets in Japan in 1987.[59] Previous advances had used magnets which produced increasingly higher magnetic fields to improve image quality. The first MRIs for example used resistive electromagnets that produced magnetic fields of typically less than 0.3 T ('T' is an abbreviation of 'tesla', a standard measure of magnetic field strength). They produced a magnetic field by running an electrical current through a copper coil. The current required a large power supply and systems to cool coils (whose electrical resistance produced heat). High electricity consumption made their operations expensive. Permanent magnets which followed did not require an electrical current and could produce magnetic fields of up to 1 tesla. But, made from up to 30 tons of iron they required rooms with very strong floors and producing powerful, yet stable and uniform magnetic fields was difficult.

MRIs with superconducting magnets in the early 1980s had field strengths from .35 to .6 Ts. In 1985 GE introduced "high field" 1.5T superconducting MRIs which became the "mainstay for commercial MR imaging"[60] (although the high-field category would extend down to 1 T MRIs). The superconducting magnets produced magnetic fields that were stronger than the fields produced by permanent magnets, as well as more stable, uniform, and larger and could thus produce high quality images with wider fields of view. (This was helpful for scanning spines, and later essential for imaging brain activity.[61]) And, like permanent magnets, superconducting magnets did not require running electricity through coils.

But superconducting magnets were expensive – and required costly cryogens (to produce near "absolute zero" temperatures.) In contrast, the low-cost MRIs introduced by Hitachi (and later by Diasonics) in the late 1980s used permanent magnets that did not require spending about $30,000 for cryogenic cooling annually.[62] Their scan quality was adequate for many applications although they could not produce the high magnetic fields needed for very sharp images.

Permanent magnets were also included in Toshiba's 0.064 T "Access," introduced in the late 1980s, with an innovative "open" design.[63] Previous MRI designs had enclosed patients in narrow, noisy tubes. Uncomfortable patients often could not remain still and required rescanning. Scanning infants, children and obese or claustrophobic patients was also problematic. Toshiba's Access did not enclose patients and provided extra space for obese and claustrophobic individuals, but it had "image-quality problems."[64]

A second generation of open MRIs using stronger (but still low-field) magnets introduced in 1994-95 (about 6-7 years after Toshiba's Access) by Hitachi, Picker, Siemens, and Damadian's FONAR Corp. improved image quality. FONAR's open scanner also allowed patients to sit or stand (instead of lying down), so physicians could see how patients' backs and joints bore weight. In April 1996, GE introduced a 0.2 tesla open MRI, and, at the end of the year, Toshiba announced a .35 tesla open MRI with a superconducting magnet that did not require expensive cryogenic cooling.[65]

Besides reducing costs and increasing patient comfort, open MRIs (with "C" or "horseshoe" shaped, rather than cylindrical magnets) gave physicians access to patients from all four sides while they were being scanned. This enabled "interventional" MRI applications. Notably, open MRIs helped surgeons perform minimally invasive surgeries that were gaining popularity in the 1990s. (Further growth of interventional scanning required surgical instruments that could be used alongside magnetic fields, which many traditional instrument suppliers struggled to develop.) [66]

***"Mid- and High-Field" Innovations*** Technological advances, in MRI components, such as coils and magnets, and overall designs, also improved "closed" (now often called "standard") MRIs. The early MRIs used "fairly simplistic" systems for transmitting radio-waves that induced resonance in target nuclei and receiving the signals produced by the resonance: a single large, radio frequency (RF) coil placed inside the hollow core (the "bore") of the MRIs magnet, surrounding the patients. The coils had to be manually tuned for each scan by adjusting them with wooden sticks. This system produced "decent image quality" of tissues close to the coil but not further away. Using multiple coils (to cover more tissue from closer distances) produced images blurred by "noise" that "added up" the noise of individual coils.[67]

In 1990, Peter Roemer, a GE researcher, filed a patent for "revolutionary" coil arrangements with multiple coils whose noise did not add up. The "phased array coils" – a term borrowed from radar technology – allowed scanning large regions with the same noise as with a single coil.[68] This, and other innovations that improved image quality made "mid-field" MRIs popular in the first half of the 1990s. These units, with field strengths between 0.2 to 0.6 tesla (first introduced in the 1980s) could be used for about 80% of scanning applications that previously required high-field (1 tesla plus) MRIs. Yet the mid-field MRIs, were lighter, smaller, and cheaper to purchase and operate and required less than 400 square feet for installation.[69] (These improvements also reduced installation time from months to as little as one week.)

Smaller ("short-bore") magnets then improved high-field MRIs. Phillips introduced the first short-bore, high-field MRI, the Gyroscan NT, in 1993. By 1998 Phillips had sold about 1,300 of these scanners around the world while Siemens, Picker, and GE had introduced their own short-bore models:[70]

- Siemens's 1-tesla "Magnetom Harmony" and 1.5 tesla "Symphony" used super-conducting magnets that were just 5 feet and 3 inches long, provided a new quiet cabinet cooling option, and in many setups did not require a dedicated computer room.
- Picker's 1.5-tesla short-bore "Eclipse" and 1-tesla "Polar" were 22 percent shorter and 30 percent lighter than Picker's previous generation MRIs and could be installed in 325 square feet of space.
- GE's 1 tesla and 1.5 tesla Sigma Horizon LX scanners required less than 250 square feet.

The new short-bore high-field units allowed radiologists to scan spines and extremities while the patient's heads remained outside the unit. The short-bore units also provided greater patient comfort, were lighter, and could complete scans more quickly.[71]

Specialized high-field devices broadened diagnostic and research applications. In 1997 Siemens received FDA approval to market its 1.5 tesla "Magnetom Vision" to diagnose problems in the brain's blood vessels.[72] High-end systems, with magnetic fields of 3 tesla and above were produced for imaging orthopedic injuries and for brain and heart research.[73] University medical centers, who usually had more resources than "non-academic" hospitals and imaging centers, purchased the expensive high-field MRIs for training and research. (In 1997, The Ohio State University Imaging Center installed the world's first 8-tesla whole body MRI – a 12-foot-long, 30-ton scanner. And before that 4.2 tesla and 4.1 tesla scanners, operating at Columbia University and the University of Minnesota respectively, had been the record holders for whole-body scanning.[74]

***Markets.*** By 1997, open MRIs were outselling standard devices in terms of worldwide number of units sold. (**Exhibit 6**). However, in dollar amounts, the more expensive standard units accounted for a majority of worldwide MRI sales. (Exhibit 8). And, as in the 1980s, country specific factors influenced the adoption of new MRI equipment and procedures in the 1990s:

In the U.S., deep cuts in reimbursement rates paid by public and private insurers —some by as much as one half – helped reduce demand for procedures and equipment in the first half of the 1990s. New laws passed by the US Congress also depressed demand. The laws, banning physicians from referring patients to their own imaging centers,[75] encouraged physicians to exit the business, sometimes by selling imaging centers to corporations that operated large networks. Fewer new freestanding imaging centers opened, and some centers closed altogether.[76] And, as MRI facilities struggled, they favored open, low-cost low field MRIs. Their "economic appeal" also made open MRIs attractive to facilities buying a second MRI system.[77]

MRIs sales in the US stabilized in the mid-1990s and then grew dramatically (as shown in **Figure 4** at the start of this section). Besides the technological improvements describe earlier, several factors supported the rebound: 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. [78] And as demand rebounded, MRI facilities initially favored the new mid-field MRIs over cheaper low-field MRIs. High-field "small-bore" then in turn became more popular than mid-field MRIs.[79] By 1997, about 46% of MRIs were high-field (1 tesla and above), 30% were low field (below 0.4 tesla), and 24% were mid-field.[80]

Japan overtook the U.S. in scanners per capita (though not in total units installed) in the 1990s.[81] (See **Exhibits 7** and **10**). Low reimbursement rates had, as in the U.S., initially encouraged buying of low-field MRIs (first introduced as mentioned in the late 1980s by Hitachi and Toshiba.) Later, the Japanese government increased reimbursement rates. This "led to a marked increase in the purchase of [high-field] 1T and 1.5T machines." Brain research at Japanese universities also increased demand for high-field MRIs.[82]

European sales had grown from a low base in the 1980s, because according to Frost & Sullivan, health care purchasers had become aware of the savings from using "effective diagnostic methods" while an aging population was increasing health care costs. And, as in the US and Japan, many high-field systems were being used for research.[83]

A variety of factors (See **Exhibit 12**) increased adoption in other parts of the world where it had previously been negligible: "Growing economies, such as South Korea, India, Taiwan, and China, {we]re realizing the importance of MRI" and had "established budgets for hospitals and universities for the purchase of high-field MRI systems."[84]

In South-East Asia MRI installations jumped from just 10 units in 1987 to about 800 in 1997.[85] And while buyers in the US and other rich countries switched from mid-field (standard) MRIs to the small-bore, high-field MRIs, buyers in middle- and low-income countries preferred the cheaper mid-field MRIs. Makers of the cheaper, more versatile, open MRIs also targeted Asian markets. Some open systems were sold in 1996 and 1997, but an Asian financial crisis in late 1997 "changed manufacturers' expectations."[86]

***Competitors.*** According to a 1998 Frost & Sullivan report six "major" and four other "active" competitors sold standard design MRIs. The top three producers accounted for 71 percent of worldwide sales (See **Figure 5**).[87] Each of the other three "majors" had single digit shares of standard MRIs sold.

According to the report, the leading producer, Siemens, was the only major producer whose market share was trending up in 1998. Frost & Sullivan attributed Siemens's success to "continuously developing new programs to enhance the value of its products and services." It also "worked closely… with its suppliers to offer a wide range of services that [we]re beneficial to customers and cost-effective in the process." As of 1998, Siemens was in the process of opting out of mid-field scanners while (according to other reports) it had started offering multiple color options to improve the ambience of MRI suites and alleviate patient anxieties.[88]

Elscint, according to Frost & Sullivan, was the only major producer of standard MRIs whose market share was trending down in 1998.[89] The company "invest[ed] heavily in research and development" and "sold five standard MRIs – the most of any major competitor – ranging from the 0.3 tesla Magna to the 2.0 tesla Prestige." But, according to the Frost & Sullivan report, its "market presence" was "restricted by the increasing dominance of other market participants such as Siemens, GE Medical, and Philips Medical Systems. With their aggressive market strategies and sales force (sic) these companies [had] restricted the growth of other market participants like Elscint."[90]

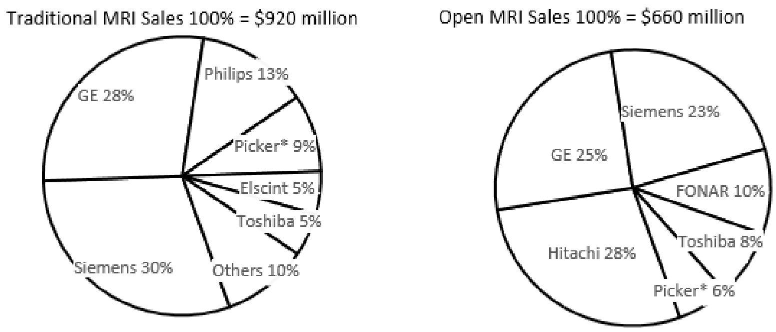
In open MRIs, Frost & Sullivan listed just six "major" competitors and no other "active" competitors. While Hitachi was the worldwide market leader, the Frost & Sullivan reported its market share "trend" in 1978 was "flat" while GE's was "up." GE sold two open MRIs, the SIGNA Profile and the SIGNA SP. The 0.2 tesla Profile used a resistive magnet, while the SP used a superconductive magnet to produce a 0.5 Tesla field (the highest of any open MRI then available). The SP was also the only open MRI to offer "vertical access" to patients.[91]

Frost & Sullivan attributed GE's rising market share to "faster customer responsiveness through customer satisfaction teams and enhanced training programs; global expansion through direct sales and service organizations; value innovation at all price levels; and greater competitiveness through productivity and people." (According to Frost & Sullivan, the market share for Picker, the smallest "major" producer of open MRIs, was trending down although the report did not explain why.)

Damadian's FONAR was the only major competitor in open MRIs excluded from Frost and Sullivan's list of "major" competitors in standard MRIs. (although it did remain on the "active" standard MRIs list). FONAR was also the only major in either category to just sell MRIs. The others all sold a range of diagnostic products (such as CTs and ultrasound).[92] Many (e.g., GE, Hitachi, Phillips, Siemens, and Toshiba) in fact were even more widely diversified in medical, industrial, and consumer products and services.

Although FONAR had not secured a significant share of MRI sales it had won legal victories. FONAR had begun to sue its competitors for patent infringement in the late 1980s. Although it 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 then settled out of court with FONAR.[93]

**Figure 5** Market shares of worldwide traditional and open MRI sales – 1997-1998




Source: Compiled from data in Frost and Sullivan. 1998. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016.

* Elscint acquired Picker in 1998.

***Magnets, Coils and Contrast Media.*** MRI markets, broadly defined, included magnets, coils, and contrast media whose sales had grown, and technologies evolved along with their "base" MRI devices. (See **Appendix**).

## Prospects for the 2000s

According to Frost & Sullivan's 1998 report, the MRI industry was "in an exciting new stage." New technologies had expanded uses and changed the perception of MRIs from "a very expensive investment" to "cost-effective."[94] The report predicted that combined worldwide sales across all product categories (complete "standard" and "open" systems, magnets, coils, and contrast agents) would more than double from $2.03 billion in 1997 to $4.35 billion in 2004 (the final year of the report's forecast).[95]

The report based its forecast on several "drivers" and "restraints" of growth summarized below:

***"Drivers."*** MRI guided interventional procedures would increase open system sales. Currently, CTs were the main imaging devices used to guide interventional procedures. But CT could only produce images as slices in a single plane, whereas MRI could produce images in three planes improving guidance for procedures. Therefore, according to Frost & Sullivan open MRIs were "all set to supersede" CTs, the "current gold standard," in several procedures, such as endoscopy. MRIs would also be favored in emerging treatments that used lasers and targeted freezing (produced by cryogenic materials) and heat (generated by radio-frequency electromagnetic waves) to remove unwanted tissues (such as tumors).[96]

More brain imaging ("functional" MRIs)* and "diffusion imaging" (for strokes) would help increase demand for high field standard MRIs, as would their declining prices. Overall, Frost & Sullivan expected the average price of standard MRIs to fall from $1.5 million in 1997 to $ 1.3 million by 2004. But it did not expect significant decreases in open MRI prices.

* Functional Magnetic Resonance Imaging (fMRI) helped determine which areas of the brain "activate" (consume more oxygen) during various cognitive tasks. This could help assess neurological status and risks.

Aging populations would help increase MRI demand in the US, Japan, and Europe while South America and South-East Asia would offer a "lucrative market for mid-field systems"[97] compensating for their declining sales in advanced economies.

***"Restraints."*** Open MRI sales would reduce standard MRI sales, and both would face more competition from CT and ultrasound. (As mentioned, CTs were less expensive to buy and operate and ultrasound devices were even cheaper, with unit prices ranging from about $20,000 to $300,000.)

Used equipment would reduce new equipment sales. Previously, sales of refurbished MRIs were "unheard of" as users sold their old units for scrap. Now, as research universities sold their older systems after a few years of use and resellers of used equipment had improved quality, hospitals and imaging centers could buy used devices at 40% below new unit prices.[98]

Consolidations of US hospitals had "saturated" the market. Previously independent institutions were sharing imaging equipment and facilities so sales to hospitals would mainly be "replacement sales." Restrictions imposed by "managed care" organizations and Medicare on reimbursements would increase the price consciousness of equipment purchasers. Financial pressures would also encourage delays in replacing existing units.

The European market was also "saturated" and "cost containment" measures would limit buying of new MRIs by hospitals and imaging centers.

Some developing countries in South East Asia and South America lacked "qualified medical professionals" to operate MRI systems and effectively diagnose patient readings." The financial crisis that hit Asia in late 1997 was also "bound to hinder [the…] growth rate of MRI Systems."[99]

The report also gave, on an "intensity of competition" scale of 1 to 10, an "8" rating in standard MRIs[100] and a "7" in open MRIs[101] and predicted this intensity would further increase. Similarly, the report expected the market shares of market leaders to continue rising while "small or weak companies" would not remain profitable.[102]

Exhibit 1 Lauterbur's and Mansfield's Contributions (excerpts from Nobel Committee Website)

"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."

Source: Excerpted from Joachim Pietzsch "Glimpse the Life Magnetic." NobelPrize.org. Nobel Media AB 2020. Thu. 3 Dec 2020. https://www.nobelprize.org/prizes/medicine/2003/speedread/, accessed November 2020.

**Exhibit 2** Companies developing MRIs from 1974-1979 and 1980-1983

| **Company (Location)** | **Related industry or University Affiliation** | **Development Initia** |
|---|---|---|
| EMI (UK) | CT pioneer | 1974 |
| Nalorac (Texas) | University of Nottingham (UK) | 1975 |
| Damadian/Fonar (US) | State University of New York | ~1975/76 |
| Pfizer (US) [1] | Pharmaceuticals, CT and X-ray machines | 1976 |
| Bruker (GER) | NMR analyzers and other scientific instruments | 1976 |
| Siemens (GER) | X-ray, mammography, and CT machines | 1977 |
| Philips (ND) | X-ray machines and other medical equipment | 1978 |
| General Electric (US) | X-ray, mammography, and CT machines | 1978 |
| Johnson & Johnson/ Technicare (US) | X-ray and CT machines | 1979 |
| Thomson-CGR (FR) | X-ray, mammography, and CT machines | 1979 |
| Metriflow Inc. (Wisconsin) | Medical College of Wisconsin | 1979 |

| **Company (Location)** | **Related industry or University Affiliation** | **Development Initia** |
|---|---|---|
| Toshiba (JPN) | X-Rays. CT machines | 1980 |
| Elscint (ISR) | CT, gamma cameras, and radiation therapy machines | 1981 |
| JEOL USA (US/JPN) | NMR analyzers; sub of Mitsubishi | 1982 |
| ADAC Technologies (US) | Gamma cameras and radiation therapy machines | 1982 |
| Fisher Imaging (US) | Mammography and other Medical Equipment | 1982 |
| Instrumentarium (FI) | Dental X-ray and mammography | 1983 |
| Matsushita (JPN) | Consumer electronics, industrial equipment | Early 1980s |
| Hitachi (JPN) | Consumer electronics, medical and scientific instruments | Early 1980s |
| M&D Technology (Scotland) | University of Aberdeen | 1982 |
| OMR Inc. (California) | UCLA | 1982 |
| Field Effects (US) | Lawrence Berkeley Lab (U of C) | 1982 |
| Advanced NMR Systems (US) | Nottingham, HLS, MIT (Sloan) | 1983 |
| NMR Imaging (US) | University of Houston, Baylor | 1983 |
| Resonex Inc. (US) | Stanford | 1983 |

Source: Compiled by casewriter 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), "OECD Health Statistics 2015 - OECD." Accessed July 28, 2015. http://www.oecd.org/els/health-systems/health-data.htm, and Mitchell, William Gordon. "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?

[1] Pfizer sponsored MRI research at the UCSF Radiologic Laboratory.

**Exhibit 3** MRI Clinical Trials and FDA approvals, 1978-1988

| Company | First placements of Trial MRI Units | # of units placed Inside US | Outside US | Patients Enrolled in Trials | FDA Approval Date |
|---|---|---|---|---|---|
| 1. icker (via EMI)[1] | 1978 | 5 | 8 | NA | 1984 (head and neck) |
| 2. | | | | | 1986 (whole body) |
| 3. ONAR[2] | 1980 | 3 | 3 | 2200 | Mar-84 |
| 4. iasonics[3] | 1981 | 6 | 0 | NA | 8/14/1984 |
| 5. echnicare | 1981 | 36 | 8 | 4750 | 10/22/1984 |
| 6. ruker | 1982 | 3 | 2 | 100 | No record |
| 7. E | 1982 | 19 | 1 | 600 | 9/10/1985 |
| 8. hilips | 1982 | 6 | 12 | 300 | 2/5/1986 |
| 9. iemens | 1982 | 42 | 9 | 800 | 3/8/1985 |
| 10. lscint[4] | 1983 | 2 | 2 | NA | 7/31/1986 |
| 11. &D Technology | 1983 | 0 | 4 | 1200 | No record |
| 12. alorac | 1984 | 2 | 0 | NA | No record |
| 13. homson-CGR | NA | | | NA | 12/29/1987 |
| 14. nstrumentarium | NA | | | NA | 4/22/1987 |
| 15. esonex | NA | | | NA | 5/25/1988 |
| 16. | | | | | |
| 17. 1984) | Total (Through | 124 | 49 | 9950 | |

Source: Created by casewriter using data from 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), Mitchell, William Gordon. "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?, and Kleinfield, Sonny. *A Machine Called Indomitable*. 1st ed. New York: Times Books, 1985

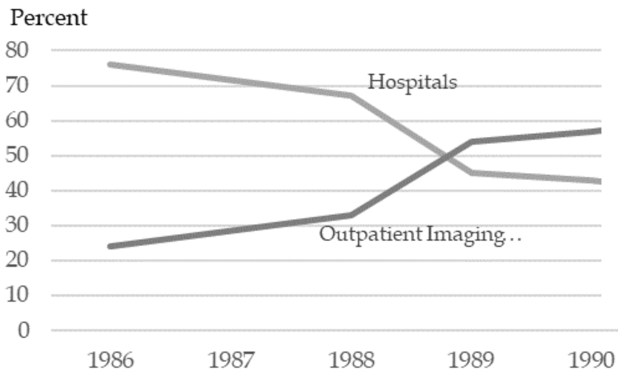
[1] In 1978, before its acquisition by Picker, EMI had placed two MRIs in two UK hospitals.

[2] FONAR placed a single scanner at a freestanding imaging center in the U.S. in late 1980 (it was later removed).

[3] Diasonics took over sponsorship of the UCSF Radiologic Lab from Pfizer in 1981.

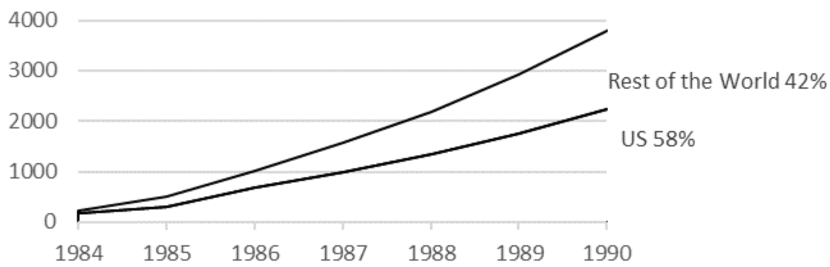
[4] Elscint secured FDA FDA approval after revising its application.

**Exhibit 4** Percentage of MRI installations in Hospitals and Outpatient Imaging Centers



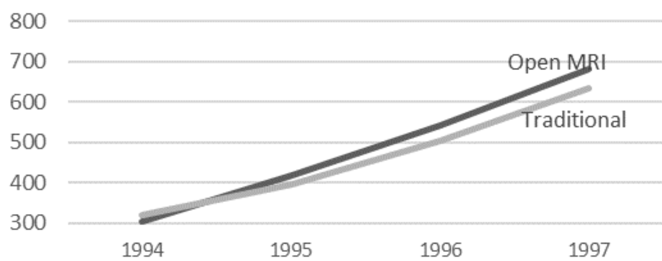

Source: Created by casewriter using data from Cowley, L. Tad, Hope L. Isaacs, Stuart W. Young, and Thomas A. Raffin. "Magnetic Resonance Imaging Marketing and Investment: Tensions between the Forces of Business and the Practice of Medicine." *Chest* 105, no. 3 (1994): 921, and American Hospital Association. (1991). *American Hospital Association Hospital Statistics*

**Exhibit 5** MRI units installed in the US and the rest of the world from 1984-1990




Source: Created by casewriter using data from "OECD Health Statistics 2015." Accessed July 28, 2015. http://www.oecd.org/els/health-systems/health-data.htm.

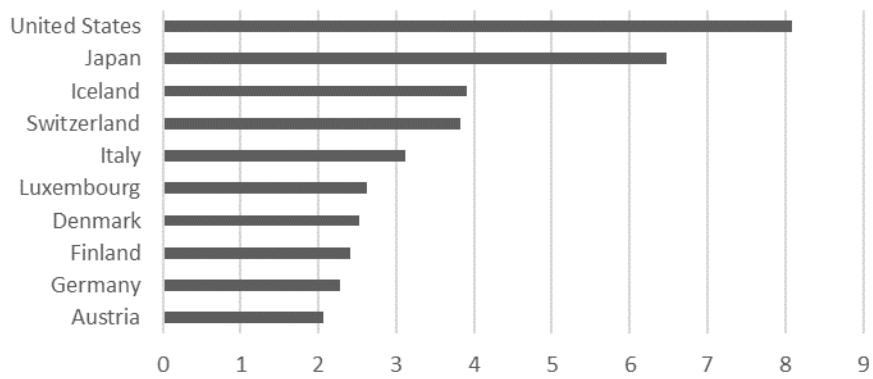
**Exhibit 6** Number of Open and Traditional MRI Units sold worldwide, 1994-1997



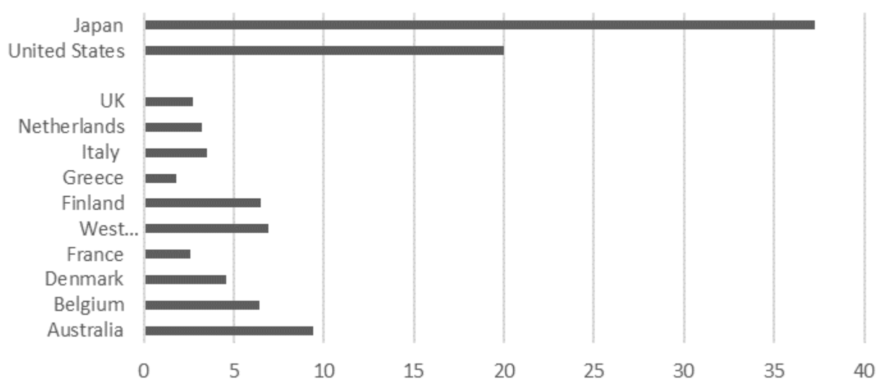

Source: Created by casewriter using data froim Frost and Sullivan. 1998. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016.

**Exhibit 7** MRI and CT installations per million of population in OECD countries circa 1990

MRI units installed per million of population




CT units installed per million of population




Source: Created by casewriter using data from Lazaro, P., 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; Le Galès, C., C. Lefaure, F. Fagnani, and F. Héran. "Contrasted Diffusion and the Use of CT Scanner Equipment in France." *European Journal of Radiology* 8, no. 4 (1988): 203–7, Stocking, Barbara, and England) EEC Workshop on Regulatory Mechanisms Concerning Expensive Health Technology : London. *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, and "OECD Health Statistics 2015." http://www.oecd.org/els/health-systems/health-data.htm.

**Exhibit 8** Estimated actual and forecast MRI sales by type and region (1994-2004)

| | | | | | Forecast (Made in 1998) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 |
| Worldwide MRI Sales and average per unit selling prices | | | | | | | | | | | |
| Standard ($ millions) | $500 | 610 | 760 | 920 | 1,090 | 1,280 | 1,470 | 1,660 | 1,850 | 2,030 | 2,220 |
| Open ($ millions) | $300 | 410 | 530 | 660 | 790 | 910 | 1,030 | 1,140 | 1,250 | 1,330 | 1,420 |
| Total ($ millions) | $800 | 1,020 | 1,290 | 1,580 | 1,880 | 2,190 | 2,500 | 2,800 | 3,100 | 3,360 | 3,640 |
| Standard (# of units) | 320 | 396 | 505 | 633 | 751 | 881 | 1,052 | 1,186 | 1,367 | 1,561 | 1,704 |
| Open (# of units) | 304 | 417 | 543 | 682 | 816 | 939 | 1,068 | 1,191 | 1,298 | 1,386 | 1,478 |
| Total (# of units) | 624 | 813 | 1,048 | 1,315 | 1,567 | 1,820 | 2,120 | 2,377 | 2,665 | 2,947 | 3,182 |
| Standard MRI price ($ millions) | $1.56 | $1.54 | 1.50 | 1.45 | 1.45 | 1.45 | 1.40 | 1.40 | 1.35 | 1.30 | 1.30 |
| Open MRI price ($ '000s) | $0.99 | $0.98 | 0.98 | 0.97 | 0.97 | 0.97 | 0.96 | 0.96 | 0.96 | 0.96 | 0.96 |
| *Standard/Total Sales* | *63%* | *60%* | *59%* | *58%* | *58%* | *58%* | *59%* | *59%* | *60%* | *60%* | *61%* |
| *Standard/Total (units) Sales* | *51%* | *49%* | *48%* | *48%* | *48%* | *48%* | *50%* | *50%* | *51%* | *53%* | *54%* |
| *Standard/Open Price* | *158%* | *157%* | *154%* | *150%* | *150%* | *150%* | *145%* | *146%* | *141%* | *136%* | *136%* |
| US Sales | | | | | | | | | | | |
| Standard ($ millions) | $143 | 195 | 265 | 359 | 469 | 589 | 709 | 818 | 919 | 1,014 | 1,110 |
| Open ($ millions) | $92 | 116 | 145 | 176 | 210 | 239 | 264 | 283 | 298 | 308 | 316 |
| Total US Sales ($ millions) | $234 | 311 | 410 | 535 | 679 | 829 | 973 | 1,101 | 1,217 | 1,322 | 1,426 |
| *Standard/Total US Sales* | *61%* | *63%* | *65%* | *67%* | *69%* | *71%* | *73%* | *74%* | *75%* | *77%* | *78%* |
| Japan Sales | | | | | | | | | | | |
| Standard ($ millions) | $136 | 169 | 209 | 235 | 261 | 295 | 331 | 373 | 415 | 462 | 511 |
| Open ($ millions) | $90 | 115 | 143 | 170 | 194 | 215 | 237 | 254 | 266 | 274 | 279 |
| Total Japan Sales ($ millions) | $226 | 285 | 352 | 405 | 456 | 510 | 567 | 627 | 681 | 736 | 790 |
| *Standard/Total Japan Sales* | *60%* | *60%* | *59%* | *58%* | *57%* | *58%* | *58%* | *59%* | *61%* | *63%* | *65%* |
| Europe Sales | | | | | | | | | | | |
| Standard ($ millions) | $131 | 151 | 170 | 190 | 212 | 235 | 262 | 290 | 322 | 353 | 385 |
| Open ($ millions) | $56 | 86 | 121 | 161 | 186 | 210 | 234 | 255 | 272 | 282 | 294 |
| Total Europe Sales ($ millions) | $187 | 237 | 291 | 351 | 398 | 445 | 496 | 545 | 594 | 636 | 679 |
| *Standard/Total European Sales* | *70%* | *64%* | *58%* | *54%* | *53%* | *53%* | *53%* | *53%* | *54%* | *56%* | *57%* |
| Rest of the World (ROW) Sales | | | | | | | | | | | |
| Standard ($ millions) | $87 | 99 | 115 | 134 | 146 | 158 | 170 | 181 | 190 | 200 | 209 |
| Open ($ millions) | $61 | 89 | 119 | 155 | 197 | 242 | 296 | 351 | 409 | 466 | 530 |
| Total ROW Sales ($ millions) | $148 | 189 | 234 | 289 | 343 | 401 | 467 | 532 | 599 | 666 | 739 |
| *Standard/Total ROW Sales* | 59% | 53% | 49% | 46% | *43%* | *40%* | *37%* | *34%* | *32%* | *30%* | *28%* |

Source: Created by casewriter using data from Frost and Sullivan. 1998. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016.

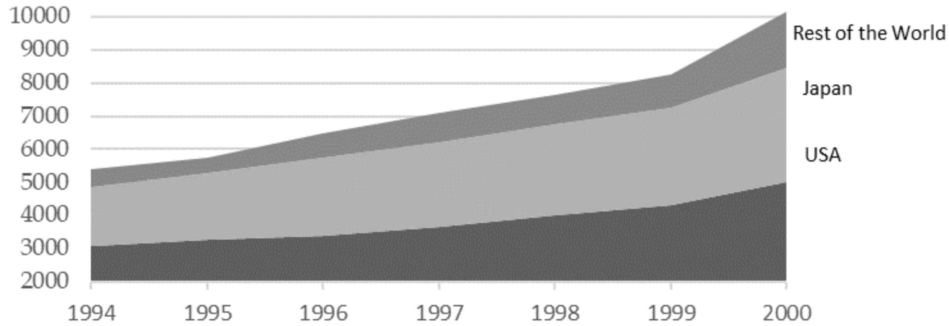
**Exhibit 9** Products offered by 'Key industry participants' in 1998

| Company | Products Offered (marked by 'x') | | | | |
|---|---|---|---|---|---|
| | Standard MRI | Open MRI | Magnets | Coils | Contrast Agents |
| Fonar Corporation | x | x | | | |
| GE Medical Systems | x | x | x | x | |
| Hitachi Medical America | x | x | | x | |
| Picker International | x | x | | x | |
| Siemens Medical Systems | x | x | | x | |
| Toshiba America | x | x | | x | |
| Elscint | x | | x | x | |
| Philips Medical Systems | x | | | x | |
| Shimadzu | x | | | | |
| Caprius | x | | | | |
| Oxford Instruments | | | x | | |
| Intermagnetics Corp. | | | x | x | |
| Magnex Corporation | | | x | | |
| Sumitomo Electric | | | x | | |
| Mitsubishi Electronics America | | | x | | |
| Applied SuperConetics | | | x | | |
| Medrad | | | | x | |
| MRI Devices Corporation | | | | x | |
| Schering AG | | | | | x |
| Nycomed Amersham plc | | | | | x |
| Bracco Diagnostics | | | | | x |
| Advanced Magnetics | | | | | x |
| Abbott Laboratories | | | | | x |
| Mallinckrodt Medical | | | | | x |
| Guerbet SA | | | | | x |
| E-Z-EM | | | | | x |
| Eisai Co | | | | | x |
| Eiken Chemical Company | | | | | x |
| Pharmacyclics | | | | | x |
| Daichii Pharmaceuticals | | | | | x |

Source: Adapted from Frost and Sullivan. 1998. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan Figure 3-8.

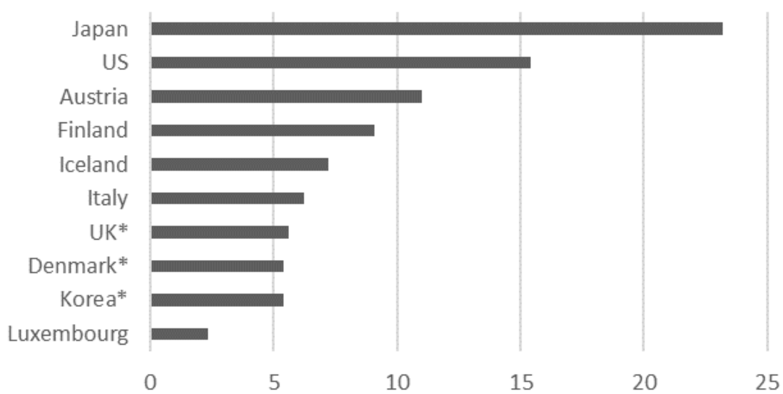
Note: One of Philips Medical Systems "standard" models had "open" features.

**Exhibit 10** MRI units installed in the US and the rest of the world from 1994-2000




Source: Created by casewriter using data from "OECD Health Statistics 2015." Accessed July 28, 2015. http://www.oecd.org/els/health-systems/health-data.htm.

**Exhibit 11** Top 10 OECD countries for MRI installations per million of population in 1999




Source: Created by casewriter using data from "OECD Health Statistics 2015." Accessed July 28, 2015. http://www.oecd.org/els/health-systems/health-data.htm.

* Data from 1999 unavailable. 2000 data used instead.

**Exhibit 12** Reasons for MRI adoption in the 1990s outside the US, Japan, and the European Union.

Demand for MRIs increased in the 1990s post-Soviet Eastern Europe, India, Southeast Asia, Australia, and Brazil for a variety of reasons including:

- 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 warrantees and service plans offered by vendors, especially in India and Southeast Asia.

Source: Compiled by casewriter from 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/redir/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/redir/default.aspx?P=sa&an=bimn000020011024dr210001b&cat=a&ep=ASE .

## Appendix A: Magnets, Coils, and Contrast Agents (in the late 1990s)

### *Magnets.*

As indicated in the main text, standard "high-field" MRIs used cylindrical, superconducting magnets, while open MRIs used 'C' or horseshoe shaped magnets which could be permanent or resistive (for field strengths for up to 0.3 tesla) or superconducting (for up to 0.5 tesla).

According to Frost & Sullivan's 1998 report four companies produced 93% of these magnets. Oxford Instruments was the largest producer, selling its magnets through a joint venture ('Oxford Magnet Technology') that it had formed with Siemens Medical Systems. Siemens sourced the magnets it used in its MRIs from the joint venture as did Picker International. GE, the second largest producer, made magnets for its own MRIs. Philips bought its magnets from Intermagnetics General, the number three producer and Toshiba from Applied SuperConetics. Smaller producers included Elscint which made some of its own magnets; Magnex (which sold Elscint the magnets it did not make for itself); Mitsubishi Electronics, and Sumitomo Electric.

The report estimated that magnet prices which had been "around $250,000" in 1995 fell to "around $220,000" in 1997[103] while "market revenues" had increased and would continue to grow through 2004. (Figure x).

**Figure A-1** Estimated actual and forecast sales for MRI magnets, coils, and contrast agents

| | | | | | Forecast (Made in 1998) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 |
| MRI magnets* ($ millions) | 254 | 273 | 294 | 319 | 345 | 373 | 405 | 440 | 477 | 517 | 562 |
| Coils ($ millions) | 39 | 48 | 59 | 72 | 87 | 102 | 116 | 127 | 138 | 147 | 156 |
| Contrast agents ($ millions) | 331 | 361 | 395 | 432 | 473 | 512 | 549 | 584 | 617 | 650 | 684 |

Source: Created by casewriter using data from Frost and Sullivan. 1998. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998

Note: Magnet estimates appeared to include the magnets GE made for its own use, but the report did not provide details of how it valued this house production.

### *Coils.*

MRI scanners included several coils of wire serving different purposes "stacked or nested like a set of Russian dolls." Thus, the outermost coils and windings (in MRIs with resistive or superconducting magnets) would help produce the "main" magnetic fields. Further in, would successively follow:

"Shim" coils to improve the uniformity ("homogeneity") of the magnetic field.

"Gradient" coils to create a gradient in what the shim coils could otherwise make a fully homogenous magnetic field. (The gradient causes the resonances in the target nuclei to vary with their position. Varying resonances in turn provide the "signals" from which MRIs compile images.)

"Radio-frequency" (RF) coils that: 1). transmit pulses of electromagnetic waves (of radio frequency) causing targeted nuclei to 'resonantly' absorb and emit radio waves (at frequencies depending on the positions of the nuclei) and 2) receive these emitted waves.[104]

Frost and Sullivan classified the market for these coils into two segments: "systems integrator" coils sold as part of the MRI system and "end-user" RF coils sold as accessories to hospitals and imaging centers. The RF coils could be large "volume" coils which completely surrounded the body being imaged or smaller "surface" coils for particular parts such as knees, necks, wrists or feet. Some small, flexible surface coils could be "wrapped around nearly any part of the human body." [105]

Phase arrays (described in the main text) and other such innovations had significant improved surface coils. The improved coils could produce sharper images of specific body parts and make MRI systems more versatile in their diagnostic capabilities. As a result, according to Frost & Sullivan's 1998 report, they were in great demand; some imaging facilities were buying more or newer coils instead of complete MRI systems. Selecting – and effectively using -- the right coils for a particular scan or patient did require skill and experience, however.

Coil prices had been slowly declining and, according to Frost & Sullivan's 1998 estimates, ranged from $7,900 to $20,000 depending on their design and complexity. For example, coils for heads and necks (which were complicated to image) cost about $20,000, while simpler coils for spines, shoulders, and elbows were priced at between $10,000 to $15,000. Frost & Sullivan predicted continued price declines, to about $10,000 for the "average" coil in 2004 from about $14,000 in 1997. Meanwhile coil producers were developing better and more specialized coils (e.g. for knees, necks, shoulders, ankles, feet, and breasts) in "dozens of configurations." [106] And with more coils purchased (albeit at lower average prices) the Frost & Sullivan report predicted worldwide sales to increase from $ 72.1 million in 1997 to $155.8 million in 2004.[107]

As with magnets, some MRI producers made all their coils 'in-house' while others purchased some of the coils they included in their systems or sold as accessories for specialist producers. Specifically, Hitachi, Elscint, Toshiba, and Siemen manufactured all their coils in-house whereas Picker, GE, and Philips bought of some coils from third-party producers.[108] Three third party producers Medrad, Intermagnetics General, and MRI Devices accounted for 44%, 12%, and 7% of worldwide coil sales respectively. GE (15%) Siemens (10%) and Phillips (5%) accounted for another 30% of world-wide coil sales. [109]

The top producer, Medrad, "aggressively" marketed its coils through its sales force and independent dealers and had also made "strategic agreements" with GE, Siemens, and Philips to resell its products. [110] Yet, although Medrad and the other third-party producers made coils for MRIs produced by different manufacturers, coils were generally not interchangeable. They had to be designed for specific models of MRIs for each manufacturer.

### *Contrast Agents*

Contrast agents had first been developed for X-rays. While x-rays could easily produce images of bones and other dense structures, images of soft tissues, which varied in their ability to block x-rays, were faint or blurry. Contrast agents (which were ingested or injected) contained substances that absorbed x-rays making them (usefully!) visible on x-ray images. For example, injecting a contrast agent containing iodine into the bloodstream could help produce images of blockages in blood vessels and ingesting barium-based contrast agents could help produce images of stomachs.[111] Contrast agents were also later used for CT scans (which also relied on X-rays)

Technical issues with using existing contrast agents for X-rays and CT and concerns about costs had initially discouraged the development of contrast agents for MRIs. Yet, in 1988, a German multinational pharmaceutical company, Schering AG, launched the first commercial contrast agent, 'Magnevist' for MRIs of the central nervous system. Administered by intravenous injection, the contrast agent blended readily with blood (and after scanning) was easily purged by the patient's kidneys. It also reduced imaging times by two-thirds.

Within just three months after its introduction Magnevist was used in about 10% of brain scans. Later regulators in the US and Europe approved its use for whole body scans and in oral form for imaging the gastrointestinal tract. About 90% of usage however remained confined to brain and spinal cord scanning.

For about four years after its introduction, Magnevist was the only commercially marketed contrast agent. Then in 1992 the US drug company Bristol Myers Squibb introduced Prohance (marketed by Bracco) and Nycomed (a Swiss, originally Norwegian, drug company) introduced Omniscan for scanning the central nervous system. In 1993 the FDA approved 'Imagnet' for other parts of the body and European regulators 'Guerbet' for a wide range of applications. Later, in the mid- 1990s, Nycomed launched an oral contrast agent for gastrointestinal scanning as did Advanced Magnetics (which also launched an intravenously administered agent for scanning livers).

Frost & Sullivan reported "12 key industry participants" selling MRI contrast agents in 1997 with several other companies developing products they had not yet launched.[112] Yet, contrast agents were used in a "still low" 25-30 percent of MRI scans, in part because of "cost pressures."[113] And the pioneer Schering's Magnivest continued to dominate; with its 60% market share leaving "insufficient room for other competitors" the next largest producers such as Nycomed and Bracco, were "turning toward group purchasing organizations to boost the sale of their products."[114]

The report predicted that the launch of a dozen new MRI contrast agents in the next few years would "dramatically affect" diagnosis and treatment. Many of the new agents were "organ specific" that would help MRIs guide the delivery of drugs to diseased organs. Currently, "organ-specific diseases often [did] not receive effective treatment." The expanded clinical applications would support the steady growth of the contrast market from $432m in 1997 to $684 m in 2004.[115]

Source: Casewriter and sources referenced in the Endnotes including but not limited to Frost and Sullivan. 1998. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998.

## Endnotes

[1] Frost and Sullivan. 1998. "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016 p. 8-5

[2] Frost and Sullivan. 1998. Op cit. p 4-13

[3] 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.

[4] 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 Exhibit 1 "Lauterbur's and Mansfield's Contributions").

[5] 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=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F3789832 .

[6] Lauterbur had observed another researcher replicating Damadian's tissue analysis. Mansfield read Damadian's article as he prepared his own article for submission.

[7] "Paul C. Lauterbur - Biographical," accessed March 22, 2016, http://www.nobelprize.org/nobel_prizes/medicine/laureates/2003/lauterbur-bio.html.

[8] The technique involved applying a gradient to the magnetic field (as described in Exhibit 1 "Lauterbur's and Mansfield's Contributions"). 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.

[9] 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.

[10] "Sir Peter Mansfield - Biographical," accessed March 22, 2016, http://www.nobelprize.org/nobel_prizes/medicine/laureates/2003/mansfield-bio.html.

[11] 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.

[12] 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.

[13] As mentioned in the CT Note, traditional X-rays gave prominence to bones, obscured soft tissues, and made it difficult to locate tumors or other problems. CT scanners could produce cross sections that showed soft tissues in addition to bones, such as the brain inside the skull.

[14] 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.)

[15] 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.

[16] FONAR was originally an acronym that stood for "field focusing nuclear magnetic resonance," Damadian's method for producing MRI.

[17] 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.

[18] 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.

[19] This act is sometimes referred to as the Medical Device Amendments of 1976, because it amended the Food, Drug, and Cosmetic Act of 1938.

[20] 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 Kleinfield, *A Machine Called Indomitable,* 1st ed. (New York: Times Books, 1985).

[21] 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.

[22] The Act authorized the FDA to grant (or deny) PMAs after reviewing the results of clinical trials of the safety and efficacy the new device, whereas with 510(k) notifications the FDA would determine whether the device was actually an extension of an existing device (that would exempt the device from clinical trial and PMA requirements.)

[23] 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.

[24] The Association of Electrical Equipment and Medical Imaging Manufacturers (previously the National Electrical Manufacturers Association, or NEMA).

[25] 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.

[26] 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.

[27] 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)

[28] 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.

[29] As mentioned in the Note of CTs 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.

[30] 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.

[31] 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.

[32] 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.

[33] 53 Fed. Reg. 7575 1988. Content downloaded/printed from HeinOnline (http://heinonline.org) Tue Nov 10 16:15:11 2015.

[34] 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.

35 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;

36 Metriflow obtained 510(k) clearance from the FDA in 1988 for its specialized device 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.

37 MRI adoption was slower than CT scanner adoption, however. Five years after the introduction of CT, over 900 devices were installed in U.S. hospitals. Five years after the introduction of MRI, about 500 devices had been installed in U.S. hospitals and imaging centers. Sources: The Office of Technology Assessment (1978) and Steinberg (1985).

38 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.

39 Installed unit numbers from Cowley et. al (1994) "Magnetic Resonance Imaging Marketing and Investment." and number of scans estimated by casewriter from graphs published in 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

40 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.

41 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.

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

43 Evens and Evens (1991) "Analysis of Economics and Use of MR Imaging Units in the United States in 1990" *AJR*: 157

44 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.

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

[46] 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 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.

[47] As described in the CT Note, many centers were owned by radiologists who could direct patients to 'their' centers. And newly constructed centers could be designed for new imaging equipment whereas traditional hospitals required retrofitting.

[48] As with CTs, Medicare reimbursed freestanding imaging centers for every MRI performed, instead of paying a fixed 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.

[49] As part of this transaction GE sold its consumer electronics business to Thomson-CGR, netting $800 million overall. https://www.nytimes.com/1987/07/23/business/company-news-ge-a-pioneer-in-radio-and-tv-is-abandoning-production-of-sets.html

[50] 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.

[51] 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.

[52] 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.

[53] 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).

[54] 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; 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.

[55] As mentioned in the CT Note. 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.

[56] Frost and Sullivan. 1998. Op cit. p. 1-2

[57] 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.

[58] 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.

[59] “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; 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.

[60] Edelman, Robert R. “The History of MR Imaging as Seen through the Pages of *Radiology*.” *Radiology*, vol. 273, no. 2S, Nov. 2014, pp. S181–200. *DOI.org (Crossref)*, doi:10.1148/radiol.14140706. p. S-182-3

[61] Edelman, Robert R. “The History of MR Imaging as Seen through the Pages of *Radiology*.” *Radiology*, vol. 273, no. 2S, Nov. 2014, pp. S181–200. *DOI.org (Crossref)*, doi:10.1148/radiol.14140706. p. S-182-3

[62] Frost and Sullivan. 1998. Op cit. p 6-11

[63] Diasonics followed with its lower-powered devices in the U.S. in 1988. Toshiba acquired Diasonics' MRI business the following year and used Diasonics's designs for its open MRIs..

[64] Frost and Sullivan. 1998. Op cit. p 5-2

[65] Frost and Sullivan. 1998. Op cit.

[66] Frost and Sullivan. 1998. Op cit. p 2-4

[67] Edelman (2014) S-184

[68] Edelman (2014) S-184

[69] Frost and Sullivan. 1998. Op cit. p 4-5.

[70] Frost and Sullivan. 1998. Op cit. p 4-20-21

[71] A Siemens study claimed a short-bore unit could scan three additional patients each day. **F 4-20-21**

[72] Frost and Sullivan. 1998. Op cit. p 4-21

[73] “Frost and Sullivan. 1998. Op cit. p. 4-4

[74] “World Magnetic Resonance Imaging Markets,” Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016. 4-23

[75] 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.

[76] 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.

77 "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016. 5-6

78 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.

79 According to Frost & Sullivan's 1998 report, "with the introduction of shot-bore magnets, it is evident that mid-field systems sales are diminishing due to the popularity of high field systems that incorporate the short bore magnets. Also, open systems are taking sales away from low-field closed systems. (Frost and Sullivan. 1998. Op cit. p. 2-6

80 "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016., 3-7

81 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.

82 "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016.4-32

83 "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016. 4-32.

84 Frost and Sullivan. 1998. Op cit. p. 4-32

85 "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016.4-16.

86 "World Magnetic Resonance Imaging Markets," Industry Research Report, 27 August 1998, Frost & Sullivan, accessed March 2016. 2-3

87 Frost and Sullivan. 1998. Op cit. p 4-7

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

90 Frost and Sullivan. 1998. Op cit. p 4-28 and 29

91 Frost and Sullivan. 1998. Op cit. p 5-22

92 Frost and Sullivan. 1998. Op cit. p 1-16

93 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; "Elscint Divestiture May Be Harbinger of More Medical Imaging Consolidation | Diagnostic Imaging," September 30, 1998, http://www.diagnosticimaging.com/articles/elscint-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/.

[94] Frost and Sullivan. 1998. Op cit. p 3-2

[95] Frost and Sullivan. 1998. Op cit. p 2-3

[96] Frost and Sullivan. 1998. Op cit. p 5-7

[97] Frost and Sullivan. 1998. Op cit. p 1-4

[98] Frost and Sullivan. 1998. Op cit. p 2-4 and 2-5

[99] Frost and Sullivan. 1998. Op cit. p 4-12

[100] Frost and Sullivan. 1998. Op cit. p 4-7

[101] Frost and Sullivan. 1998. Op cit. p 5-4

[102] Frost and Sullivan. 1998. Op cit. p 2-3

[103] Frost and Sullivan. 1998. Op cit. p 6-15

[104] Some RF coils just transmitted or received, while others did both.

[105] Frost and Sullivan. 1998. Op cit. p 7-3

[106] Frost and Sullivan. 1998. Op cit. p 7-18

[107] Frost and Sullivan. 1998. Op cit. p 7-6

[108] Frost and Sullivan. 1998. Op cit. p 3-13

[109] Frost and Sullivan. 1998. Op cit. p 7-19

[110] Frost and Sullivan. 1998. Op cit. p 7-21

[111] Factsheet on CT scans posted in December 2019 by National Institute of Biomedical Imaging and Bioengineering. https://www.nibib.nih.gov/science-education/science-topics/computed-tomography-ct#pid-1031

[112] Frost and Sullivan. 1998. Op cit. p 3-14

[113] Frost and Sullivan. 1998. Op cit. p 3-4

[114] Frost and Sullivan. 1998. Op cit. p 8-2

[115] Frost and Sullivan. 1998. Op cit. p 8-2