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SUNSHINE PROPOSALS FOR IMAGING OWNERSHIP AND DRUG/MEDICAL DEVICE MANUFACTURER RELATIONSHIPS: PHYSICIAN DISCLOSURES AND THE LIMITS OF CONSUMERISM IN HEALTH CARE

Jackson Williams*

As the health care system contends with higher costs arising from growth in imaging services and the use of expensive pharmaceuticals and medical devices, policymakers have focused on possible conflicts-of-interest on the part of physicians. Physicians are responsible for ordering imaging studies, prescribing drugs, and choosing medical devices for implantation, and it is widely believed that physicians' decision making can be influenced by their financial interests.¹

Researchers studying physician ownership of imaging equipment have found that physicians who perform their own imaging are 1.7 to 7.7 times as likely to order imaging as peers who do not.² Studies on the impact of gifts and honoraria from drug manufacturers have concluded that recipients are quicker to prescribe new drugs and more likely to prescribe brand medications with no demonstrated advantage over cheaper generic drugs.³ Payments by medical device manufacturers to surgeons who implant their products have resulted in both civil litigation and criminal prosecutions.⁴

A study by the McKinsey Global Institute estimated that the proliferation of advanced imaging equipment in the U.S., driven by physician ownership, adds $40 billion to America’s health care costs annually; and found that prescription of new, brand medications for diabetes and pulmonary conditions by U.S. doctors is nearly double the rate of their peers in the

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4 Janet Moore, Medical device payments to doctors draw scrutiny, MINNEAPOLIS STAR-TRIB., September 8, 2008.
Legislation introduced in Congress would address these issues by mandating disclosure of financial interests. One bill, the Medicare Imaging Disclosure Sunshine Act,\(^6\) would require that when a physician self-refers for advanced imaging, the referring physician inform the patient in writing that the patient may obtain the services elsewhere and provide the patient with a written list of other suppliers.

Another proposal, the Physician Payments Sunshine Act,\(^7\) would require drug and device manufacturers to report gifts and payments to physicians, with the information made available to patients and the general public through an online database.

Are disclosures of physician financial interests to patients a practical method of improving the efficiency and quality of health care? This article reviews the problems that the current proposals are intended to address and evaluates the legislation in light of experience with and expert opinion on disclosures to consumers and patients. It will also touch upon possible alternative policy approaches.

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7 S. 301, 111th Cong. (2009).
9 Id.
10 Id.
The notion of an informed consumer choosing among multiple options in a competitive marketplace has been the goal of consumer protection policy in many sectors of the economy, but the consumerist model is a relative newcomer to health policy. For about two decades, the prevailing thought in health policy circles has been that the complexity of health care militated in favor of macro-level competition among health plans that would serve as intermediaries between patients and providers and manage their care. Measures of health plan quality, such as CAHPS and HEDIS, are well-developed, and price competition is simplified at the health plan level. By contrast, the measures of individual provider quality and efficiency necessary to enable consumer-directed care are still in their infancy.

The two sunshine proposals follow the consumerist paradigm to differing degrees. The drug and device disclosure bill is compatible with both models, as it would inform decisionmaking by health plans as well as by consumers. But the imaging disclosure bill very explicitly contemplates decisionmaking by the individual consumer, in a context that, I will argue later, pushes the limits of what degree of engagement is reasonable to expect from patients.

Each proposal would expand on earlier private or state initiatives. Indiana and Texas are among states that have required disclosures of self-referrals to some facilities, and physician owners of ambulatory surgical centers have the option of disclosing their interests to patients to avoid violating the federal Anti-Kickback Statute. A number of states have required drug manufacturers to report payments to physicians, although consumer advocates have found these early efforts unsatisfactory, and two manufacturers have agreed to begin disclosing some arrangements voluntarily.

14 See Ariel Winter & Jeff Stensland, Public reporting of physicians' financial relationships: Policy options, Staff presentation to the Medicare Payment Advisory Commission (Sept. 4, 2008).
15 IND. CODE ANN. § 25-22.5-11-3 (West. 2008).
19 E-mail from Allan Coukell, Community Catalyst, to Sarah Thomas, AARP Public Policy Institute Oct.
Disclosures to consumers can be mandated with two general effects in mind. One possible intention of such laws can be for disclosure to have a "chilling" effect on the disclosing parties and deter them from pursuing the activity in the first place. Referrals to facilities in which a physician has a financial interest (often called "self-referrals") are already illegal under many circumstances.\(^{20}\) Physician acceptance of gifts or payments from drug and device manufacturers is controversial\(^{21}\) and many physicians voluntarily decline to accept them for ethical reasons.\(^{22}\) When there is general disapproval of an activity, but policymakers feel constrained from outlawing it entirely, disclosure is a middle-ground policy option.\(^{23}\) The intended effect is a sense of shame or embarrassment on the part of the provider that will lead to eventual curtailment of the activity. This effect could be magnified by the ability of researchers to study disclosure data and publicize findings that inform policymaking.

The second possible intention is for the consumer to consider the provider's conflict of interest in deciding whether to follow the provider's recommendation (in this case, of an imaging facility or prescription drug or medical device). In the contexts in which such disclosures have typically been mandated, such as financial services, the consumer is expected to use the information to decide whether to seek a better bargain elsewhere, usually based on price. In the health care context, however, the disclosure engages the patient in evaluating the medical advice he or she is given—an even more complex task than shopping for loans or inquiring about financial advisors' fees.

THE RELATIONSHIP BETWEEN PHYSICIAN FINANCIAL INTERESTS AND HEALTH CARE COSTS

According to the Government Accountability Office, Medicare spending for imaging services more than doubled from 2000 to 2006.\(^{24}\)

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20 The discussion here focuses on gifts and payments that do not appear reasonably related to any work done by the physician. A physician may have had a bona fide role in investigating the efficacy of drug or inventing a medical device, which roles differ from that of paid endorser. Further, patients are likely to have a different reaction to being informed that their physician played an intellectual role in developing the treatment which they will undergo, as opposed to receiving a gratuity.
22 See, e.g., Surgeons for Sale: Conflict and Consultant Payment in the Medical Device Industry: Hearing before the U.S. Senate Special Committee on Aging 110th Cong. 16 (2008) (Testimony of Dr. Charles D. Rosen, President, Ass’n for Ethics in Spine Surgery).
23 However, there is in fact legislation pending in Congress to completely abolish the exception to Stark. See H.R. 2962, 111th Cong. (2009).
GAO’s analysis of the 6-year period linked this spending growth to imaging services provided in physician offices under an exception to the federal law banning self-referral. GAO found that the proportion of Medicare spending on imaging services performed in physicians’ offices grew from 58 percent to 64 percent, and that physicians were earning an increasing share of their Medicare revenue from imaging services.

That all imaging services may not be necessary or appropriate is suggested by the substantial variation in imaging spending per beneficiary across geographic regions of the country. In 2005, spending per beneficiary on advanced imaging ranged from $126 in Vermont to $280 in Florida. Spending on in-office imaging varied even more—almost eight-fold between those states. No knowledgeable observer believes that differences in health among patients explain the wide variation.

In addition to the $14 billion cost of physician imaging services to the Medicare program (and billions more to private insurers), questions about safety and quality are also raised by the growth in imaging. Some imaging procedures expose patients to radiation which, over the long term, may increase the incidence of cancer. Inspections of outpatient imaging facilities have found that their compliance with quality standards compares unfavorably to that of hospitals.

While spending on prescription drugs continues to rise, primarily due to price and utilization increases, spending growth has been curtailed through utilization management and other efforts of health plans, pharmaceutical benefit managers, state-sponsored “academic detailers” and mass retailers to encourage substitution of generic drugs for more expensive branded drugs. However, brand-name pharmaceutical companies continue to vigorously combat these efforts with aggressive marketing tactics.
By one estimate, drug manufacturers spent nearly $30 billion on marketing in 2005, about 85 percent of which was devoted to promoting drugs directly to physicians. According to the Kaiser Family Foundation, the industry spends between $8,000 and $13,000 per physician per year on such marketing. Spending takes the form of free meals, sports tickets, continuing education seminars, travel reimbursement, and consulting fees, with the most generous payments made to physicians thought to be opinion leaders in their field or who sit on committees that promulgate practice guidelines or formularies.

The generic fill rate improved in 2007 to about 67%. (A point of reference: the generic fill rate could rise as high as 80% without adversely affecting patients, although this is a moving target as a growing proportion of prescriptions are for specialty drugs with no generic equivalent.) Further increases in generic utilization could result in substantial cost savings; consulting firm IMS Health has estimated that a 1 percent increase in generic utilization would yield almost $4 billion in savings. Further savings could come from prescribing within-class and across-class alternatives. Some experts argue that drugs are over-prescribed in the first instance, to patients who don’t really benefit from them, and that these prescribing practices are fueled by pharmaceutical companies’ payments to doctors.

THE IMPACT OF DISCLOSURE ON CONSUMER CHOICES

Financial interest disclosures have long been prominent in consumer protection laws governing real estate and investment transactions. These transactions are in some ways analogous to those in the health care context. First, the consumer is relying on the advice of an expert who is in a position to make referrals. Second, payments are made on fee-for-service basis, so that each individual service represents an opportunity for some

36 Prescription Drug Trends, FACT SHEET (Kaiser Family Foundation, Menlo Park, CA), Sept. 2008, at __
37 Id.
41 E-mail from Allan Coukell, Community Catalyst, to Sarah Thomas, AARP Public Policy Institute (Oct. 28, 2008)(on file with author).
service provider to gain revenue and for the referring party to potentially capture some share of that revenue.

In the consumer financial services context, the disclosure of the referring party’s conflict of interest is intended to alert the consumer to the possibility that a service or product might be obtained for a lower price elsewhere. Scenarios that might require disclosure include a real estate broker’s referral to a title insurer, a mortgage broker’s referral to a lender, or a registered investment advisor’s referral to a stock broker. In the first of these examples the broker may self-refer to a title agency she owns herself; in all three examples there is the possibility of side payments made to the referring party.

There are two principal differences between the consumer financial services setting and the health care setting. The first is that price competition has less prominence in the health care context. For instance, a CT or MRI scan will cost most insured patients the same—the amount of the applicable co-payment, or co-insurance in Medicare—regardless of where they obtain it. In contrast, a cost-conscious and savvy consumer can find or negotiate lower title insurance or loan fees, especially because price disclosures under the Real Estate Settlement Practices Act (RESPA)\textsuperscript{43} and Truth in Lending Act (TILA)\textsuperscript{44} facilitate some degree of price comparison. Price competition is a factor in choosing between generic drugs and brand drugs, but the physician has the last word on what drug to prescribe.

The second difference is that referrals in the consumer financial services setting are generally made for products that are obtained as a matter of course rather than recommended through the referring party’s exercise of professional judgment. The mortgage broker does not tell a homebuyer that he needs a loan; the consumer has already determined that for himself. A real estate broker or attorney does not decide that title insurance must be purchased; that service is required in all real estate transactions involving a lender. The consumer’s primary concern is getting the best price, not being sold an unnecessary product.\textsuperscript{45}

By contrast, the primary issue implicated in the health care context is whether a recommended product or service is necessary or instead constitutes over-utilization influenced by the physician’s financial interest. Also relevant to a greater degree is the quality of the service to be provided—

\textsuperscript{43} Real Estate Settlement Practices Act, 12 U.S.C. § 2601, et seq.
\textsuperscript{44} Truth in Lending Act, 15 U.S.C. § 1601 et seq.
\textsuperscript{45} Notable exceptions are subprime mortgage refinancings and credit life insurance; however, these are products, unlike a course of medical treatment, that a layperson can ordinarily decide whether to purchase without receiving expert professional advice.
the performance records of a title insurer or lender are of little concern to
the consumer purchasing those services, but the quality of an imaging scan
and its interpretation could be a matter of life and death for the patient.
Evaluating a doctor’s prescription of a brand drug or medical device
involves considerations of price, quality and safety, and its necessity in the
first place. Untangling these matters requires questioning a physician’s
professional judgment and/or good faith—an “awkward conversation to
have”\textsuperscript{46}—and a degree of knowledge or research on the patient’s part that
would go far beyond calling for price quotes.

**EVALUATING THE DISCLOSURE PROPOSALS**

Miller and Sage offer a framework for evaluating proposals for re-
quiring disclosure of physician financial incentives.\textsuperscript{47} Their immediate
concern, writing in the era of managed care’s zenith, was physician incen-
tives to limit treatment due to capitation.\textsuperscript{48} They noted, however, that in-
centives to over-provide in a FFS setting were of equal concern, and
opined that “patients need basic information about financial incentives to
understand how different approaches to physician compensation might
shape treatment options presented to them.”\textsuperscript{49} They put forth four basic
principles that apply to the proposals discussed here:

\begin{itemize}
  \item “enrollees need a context for disclosed information,”\textsuperscript{50}
  \item “disclosure needs are likely to differ by population, according
to variables such as age, health, and socioeconomic status,”\textsuperscript{51}
  \item “disclosed information must not be so detailed that it confuses
readers or obscures essential points,”\textsuperscript{52}
  \item “disclosure must be customized to achieve specific goals.”\textsuperscript{53}
\end{itemize}

Over all, they argue, “disclosure of incentives should not be done in
isolation but should be part of an integrated communications strategy.”\textsuperscript{54}

\textsuperscript{46} Ibbi Caputo, *Probing Doctors’ Ties to Industry*, WASH. POST, August 18, 2009, available at
\textsuperscript{47} Tracy E. Miller and William M. Sage, *Disclosing Physician Financial Incentives*, 281 JAMA 1424
(1999).
\textsuperscript{48} Id. at 1425.
\textsuperscript{49} Miller & Sage, *supra* note 47, at 1425.
\textsuperscript{50} Id.
\textsuperscript{51} Id.
\textsuperscript{52} Id.
\textsuperscript{53} Id.
\textsuperscript{54} Id.
The Medicare Imaging Disclosure Sunshine Act

S. 3343 would require that when a physician self-refers for advanced imaging, "the referring physician [must] inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than [the doctor eligible for the ancillary services exemption from the Stark law] and provide such individual with a written list of suppliers... who furnish such services in the area in which such individual resides."

In one respect the disclosure contemplated by this bill resembles the one that must be made by real estate brokers and attorneys when they refer a client to an affiliated title insurer for settlement services. Under that requirement, found in a rule promulgated by HUD under the Real Estate Settlement Practices Act, a self-referring party in real estate must make the following disclosure in writing:

This is to give you notice that (referring party) has a business relationship with [settlement services provider(s)]. Because of this relationship, this referral may provide [referring party] a financial or other benefit. Set forth below is the estimated charge or range of charges for the settlement services listed. You are NOT required to use the listed provider(s) as a condition for [settlement of your loan on] [or] [purchase, sale, or refinance of] the subject property. THERE ARE FREQUENTLY OTHER SETTLEMENT SERVICE PROVIDERS AVAILABLE WITH SIMILAR SERVICES. YOU ARE FREE TO SHOP AROUND TO DETERMINE THAT YOU ARE RECEIVING THE BEST SERVICES AND THE BEST RATE FOR THESE SERVICES.

Both of these disclosures are intended to alert the consumer that other service providers are available. But there are crucial differences. First, given that Medicare fees are the same in an area, there is no reason for beneficiaries to shop for a better price. Second, while it is possible to make rudimentary quality determinations about imaging providers, this information is not readily available to patients. Medicare has no quality comparison tools for imaging. Quality determinations are usually made by private insurers or by accrediting bodies. And if self-referred imaging in an in-office facility is offered immediately, the disclosure would not occur in a time frame encouraging research or reflection.

57 Id. at § 3500 App. D.
58 America's Health Insurance Plans, supra note 30.
As Miller and Sage noted, for disclosures to be useful the patient must be given context and the disclosure should be customized to achieve its goal. The disclosure mandated by the bill contains no context, i.e., the beneficiary is not informed that physician owners of imaging equipment order many times more studies, nor about any potential harm from radiation. By giving the patient a list of providers it obscures the essential point, because price and quality competition are not implicated. It is not customized to achieve the intended goal: for patients to obtain imaging studies that are warranted by clinical evidence and are not wasteful or duplicative.

Indeed, whether any disclosure could accomplish this goal is questionable. Alerting patients to the problems behind self-referral—the possibility that the procedure is unnecessary or unsafe—might not meet another Miller/Sage goal, striking the proper balance "between educating patients and alarming them." Finally, it is not clear that patients have the tools to evaluate the physician’s judgment call that a test is needed. In some cases there may be consensus clinical guidelines to follow, but patients are unlikely to have the wherewithal to determine whether a guideline applies to the patient’s circumstance nor whether the doctor complied with it.

Some insurers have instituted utilization review or credentialing of physicians to curtail unnecessary imaging. Utilization review attempts to apply guidelines to individual circumstances. Credentialing programs discern a tendency for over-utilization from a physician’s overall pattern of ordering, not individual appropriateness within a likely grey area. These processes enlist knowledgeable intermediaries rather than laypersons as battlers for health care efficiency. As advocates of the “managed competition” paradigm argue, such intermediaries may be better positioned to assemble and synthesize information about medical evidence and practitioner proclivities than patients who are likely to be preoccupied by worries over the symptoms that sent them to see a doctor in the first instance. Using intermediary techniques is an alternative to the disclosure approach, and has been endorsed in the reports of the GAO and the health insurers’ trade association, America’s Health Insurance Plans, cited above.

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59 Miller & Sage, supra note 47, at 1428. See also, Daylian Cain, George Loewenstein, & Don A. Moore, The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest, 34 J. LEGAL STUD. 1 (2005).
60 See America’s Health Insurance Plans, supra note 30.
61 Id.
62 Id.
S. 301 would require drug and medical device manufacturers to report cash payments and in-kind transfers to physicians, including gifts, food, entertainment, travel, honoraria and consulting fees. The disclosures would be made to the federal government, and would be made public on a searchable Internet website. The intent is to create a public disclosure regime similar to those governing campaign finance and publicly-held corporations. As with those disclosure systems, it is expected that the media, researchers, and institutional stakeholders, rather than individuals, would be the primary audience. However, one sponsor, Senator Claire McCaskill, stated that “empowering patients to talk with their doctors about the drugs they are prescribed” was a purpose of the bill. Ideally, disclosures would act synergistically, with media reporting spurring patients to initiate individual research and conversations.

Compared to the proposal for imaging disclosure, disclosures of relationships with drug and device manufacturers offer, at least theoretically, greater potential for allowing patients to act on the disclosed information. Patients could access the information prior to beginning a relationship with a physician or before any visit to the physician for which the information would be relevant. They could also access the information after a visit but before filling a prescription (e.g., after learning of a medication’s status on their insurer’s formulary). But such scenarios may be over-optimistic, as research has indicated that even patients for whom drug costs are an issue seldom initiate conversations with their doctors about alternatives to expensive prescriptions.

There is considerable contextual information available for evaluating the disclosures, such as Consumer Union’s Best Buy Drugs or Public Citizen’s Best Pills, Worst Pills publications. Drug costs are typically reflected in insurers’ tiered co-payment structures, allowing consumers to assess, with relative ease, cost-effectiveness of competing therapies within a common or related therapeutic class(es).
If the goals of the disclosure system are to encourage the prescription of generic drugs when possible, avoid unnecessary prescribing, and delay the prescription of newer brand drugs until they show a demonstrable advantage over cheaper ones, the disclosures seem as well-tailored as one could hope to achieving those goals. A recent survey concluded that at least half of all Americans have searched online for healthcare-related information, and that about half of those have discussed information found online with their doctor. It is not hard to imagine that the disclosures could be considered by patients when choosing a doctor (as well as considered by health plans in recommending doctors). It would seem especially likely that patients would seek out and consider the information when a doctor has recommended an invasive or relatively risky procedure such as implantation of a medical device.

CONCLUSION

A decision to use financial interest disclosure as a tool for health care cost containment should not be taken lightly. Crafting appropriate disclosure formats is in itself a complex task. For instance, HUD, in its multi-year effort to refine RESPA disclosure requirements to encompass conflicts of interest on the part of mortgage brokers, conducted six rounds of consumer testing of various iterations to ensure that the financial interest disclosure did not obscure bottom-line price considerations. (The Federal Trade Commission conducted an additional round of testing.)

Devising an appropriate disclosure in the health care setting adds even more complexity. Financial interest disclosures by physicians could assist patients’ participation in treatment decisionmaking, or distract it. It must be borne in mind that increasing patient involvement in decisionmaking has other goals besides lowering costs. For instance, motivating medication compliance is one such goal; one research team has suggested that cynicism about physicians’ relationships with pharmaceutical companies could be a factor discouraging compliance.

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68 Press Release, Harris Interactive, Number of “Cyberchondriacs” – Adults Going Online for Health Information – Has Plateaued or Declined (July 29, 2008).
70 U.S. DEPT. OF HOUSING AND URBAN DEVELOPMENT, FTC STAFF COMMENT ON PROPOSED AMENDMENTS TO THE REGULATIONS IMPLEMENTING THE REAL ESTATE SETTLEMENT PROCEDURES ACT (“RESPA”), DOCKET No. FR-5180-P-01, at 20 (June 11, 2008).
71 Vikki Entwistle & Ian Watt, Patient involvement in treatment decision-making: The case for a broader conceptual framework, 63 PATIENT EDUC. COUNSELING 268 (2006).
72 Sarah L. Goff et al., Patients’ Beliefs and Preferences Regarding Doctors’ Medication Recommenda-
Consistent with the Miller/Sage framework, disclosure requirements should be part of an integrated communications strategy. Disclosures relevant to price and quality should be presented to patients accompanied by guidance on how to find and use price and quality information. If disclosure is chosen as a means for combating overutilization, presenting patients with contextual information will be difficult in the absence of evidence-based guidelines or reports comparing the physician’s utilization compared with peers. It may prove to be the case that intermediaries, such as health plans, are the only actors capable of discerning real value in these areas.

Finally, it is worth noting that financial interests involving ancillary products or services are primarily of concern when those items generate separately billed fees. When all services relevant to an overall transaction—whether it is a financial transaction or an episode of care—are grouped together and examined as a whole, allowing bottom-line price and quality comparisons, the referring party is constrained from earning excess benefits from additional fees.\(^\text{73}\) Thus, consumer advocates have encouraged “mortgage package offers” in the real estate setting\(^\text{74}\) and “wrap fees” in the investment advice setting\(^\text{75}\) to discourage referral arrangements that make transactions more costly. Health insurers have taken a similar tack by charting the resources used by physicians across an episode of care.\(^\text{76}\) Physicians who too readily order diagnostic tests or prescribe expensive drugs can be excluded from insurers’ preferred networks. Another option is to give providers a single bundled payment for an episode of care.

The availability of these options demonstrates a superior ability of the managed competition model to remedy the problems addressed by the sunshine proposals. Managed care organizations have greater resources and advantages to identify overuse of care; although, to be sure, they also have incentives to be excessively punctilious in doing so. But it is also evident that sunshine measures—particularly as they relate to imaging—ask a great deal of the patient in harnessing his or her suspicions about physicians’ financial interests to advance the cause of health care cost contain-


\(^{75}\) Conrad de Aenlle, New Broker Fee: Bad Rap or Bad Wrap?, INT’L HERALD-TRIB., May 9, 1992.

\(^{76}\) Hoangmai H. Pham, Paul B. Ginsburg, Kelly McKenzie & Arnold Milstein, Redesigning Care Delivery in Response to a High-Performance Network: The Virginia Mason Medical Center, 26 HEALTH AFF. 532 (2007).
ment. Already the consumerism model asks patients to choose providers using rather scanty information. While hospital quality measures are fairly well-developed, physician quality measures are relatively primitive and price information, because it relates to visits and procedures rather than episodes of care, may be less than worthless.

Also provoking skepticism is the lack of any track record of previous physician disclosure laws, such as those in Indiana and Texas, having an impact on patient or provider behavior. This author can find no indication that common sources of advice to consumers, such as Consumer Union or personal finance and health beat journalists, have been able to give meaningful guidance to patients in reacting to those disclosures.77

In sum, lawmakers should be skeptical disclosure requirements, as opposed to alternative policy approaches and managed care techniques, will achieve cost containment with maximum effectiveness and minimal confusion to patients.

77 Cf. Gina Kolata, Good or Useless, Medical Scans Cost the Same, N.Y. TIMES, Mar. 2, 2009.