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The Business Model of Medicine

Modern Health Care's Awkward Flirtation with the Marketplace

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JAMES P. WHALEN

A current advertisement on the radio says that a new diagnostic tool, electron beam tomography (EBT, a scanner that is much more rapid and capable of showing more detail than the better-known CT scanner), can detect lung cancer in its early stages, thereby possibly increasing the survival rate for this common form of cancer from 14 percent to 80 percent over a period of five years (Heart Check America n.d.). If the claim is true, this new way of diagnosing lung cancer that improves the survival rate almost sixfold will be a dramatic breakthrough in the treatment of this devastating disease.

This ad is an example of one of the many approaches to marketing medical goods and services that has become a major and accepted practice of the health care industry in the past ten years or so. Indeed, the corporate approach in general is becoming such a prominent feature of health care that medicine may be losing its identity as a social service and slipping into the business model of providing service. Is this change a good thing?

To answer this question, we must decide whether it is good to sell as much product as possible in order to maximize profits. Undoubtedly it is if you are General Motors. Is it good to purvey as many medical services as possible, however? Not in

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The Independent Review, v. VIII, n. 2, Fall 2003, ISSN 1086-1653, Copyright © 2003, pp. 259-270.

every case—and there are many reasons for this conclusion. They include evidence that high-powered advertising techniques used in the marketing of medical goods and services have a serious defect and that the advisability of allowing Darwinian competition to determine the availability of these goods and services is debatable. Also at issue is whether increasingly significant financial ties between industry and academic medicine best serve the national research agenda. In fact, these issues and many others call into question the wisdom of allowing the business model of medicine to be the operating paradigm for modern health care in the United States.

Medical Screening Sold Directly to the Public

Consider the radio ad for the fancy scanner. In the best capitalist tradition, the organization (a major university medical center) that purchased the air time hopes to create work that is well reimbursed and therefore highly profitable. Prospective patients, most of them probably smokers, will get a scan for themselves (no need for a doctor's order), and if the scan indicates probable cancer, they will be referred for further diagnosis and treatment at the sponsoring medical center. The \$400 price for the EBT is not the prize. In fact, that sum may barely cover the costs of performing and interpreting the scan. The real bonanza lies in the treatment. In contrast to many medical services that are of proven benefit and therefore important to the health of the population, surgery for lung cancer is well reimbursed. So health care organizations, always looking for ways to improve their precarious bottom lines, have every financial incentive to find and treat people with lung cancer.

This arrangement would be splendid if it helped people, but the science of screening for disease in the hope of improving therapeutic outcomes reveals that determining the value of the procedure is far trickier than the radio ad would have us believe. The typical consumer of health services, however, generally has limited means to weigh the complexities.

For example, proper evaluation of the usefulness of an early diagnostic intervention requires understanding of some crucial concepts in screening (which can be defined as some type of medical test administered with a view toward early detection of disease). The first concept is “lead-time” bias, which is the belief that early detection has bestowed a benefit on mortality, when in fact the benefit is only apparent (Patz, Goodman, and Bepler 2000). In lung cancer, the lead-time bias operates as follows.

A microscopic focus of cancer begins to grow in the lung at a point in time—say, the year 1996. There is presumably a period of time (the length of time in this cancer, and in most cancers, is generally unknown) when the cancer grows before it causes a symptom, such as coughing up blood, that prompts medical attention. Suppose this symptom occurs in the year 2000 (these intervals are presented purely for the purpose of illustration—they may bear no resemblance to reality), which would be the point at which diagnosis and treatment are conventionally undertaken. With current means of

treating lung cancer, death may occur in 2002, typically after a great deal of *Sturm und Drang*. A patient with this experience would be counted as having a two-year survival.

An entirely equivalent patient may undergo screening with EBT in 1998, get treatment, and live until 2002. This latter patient, however, is considered to have a four-year survival rate from the time of diagnosis, even though he or she lives no longer than the patient whose symptoms prompted medical attention two years after the onset of the cancer. The screening test has resulted only in apparent benefit: the second patient lives no longer than if there had been no screening. If such experience is what tends to happen with early screening, therapeutic results that show an advantage to screening are biased. The beguiling notion that early detection and treatment of lung cancer results in favorable mortality rates is just not true. Presumably the lung cancer spreads prior to becoming radiologically evident, rendering local removal futile.

Untrained observers may conclude confidently that survival in the screened patient has been increased by 100 percent because life after the diagnosis has been increased from two to four years. This difference is a rather dramatic advance, in anyone's estimation. Until now, however, no one has been able to demonstrate convincingly that lead-time bias is not at play here. In scientifically rigorous studies that deal with this difficulty (randomized, controlled trials), screening smokers with yearly chest X-rays simply has not resulted in lower mortality (Patz, Goodman, and Bepler 2000).

The idea of early detection (find the cancer before it spreads and cut it out) is so compelling, however, that researchers continue to look for effective screening techniques that are more sensitive than conventional X-rays. So they are using technology such as EBT to find lung cancers to which routine radiography is blind. Results? Unknown. Even though EBT is advertised on the radio and has leaked into the current screening armamentarium of medicine, no one knows if it works to save lives. In the words of researchers at Duke University Medical Center, scientifically valid studies have to be completed and carefully analyzed "before CT screening for lung cancer can be accepted as the standard of care" (Patz, Goodman, and Bepler 2000). Neither these authors nor any other serious cancer investigators are calling for cessation of research into this potentially important diagnostic technique. They are simply saying that investing huge amounts of dollars in an unproved approach is not warranted until clinical trials demonstrate a true reduction in mortality from lung cancer.

Other subtleties also cloud the assessment of a screening procedure. The "over-diagnosis" bias, for example, refers to the inflated survival rate that results from the discovery of cancers that were never destined to have any effect whatsoever on a person's life (Patz, Goodman, and Bepler 2000). Numerous postmortem studies have shown that people often die of causes unrelated to cancers incidentally discovered on autopsy. A patient with such a cancer might undergo surgery after early screening and then be identified improperly as a success. This important issue bedevils the research into truly effective screening techniques for many cancers.

“Length-time” bias (Patz, Goodman, and Bepler 2000) is yet another pitfall in assessing the usefulness of a diagnostic screening test. This concept refers to the idea that slow-growing cancers, which have a good prognosis, are more likely to be detected with screening procedures and are therefore more likely than aggressive tumors to be included in favorable statistical analysis of the screening tool. The aggressive tumors that carry the highest mortality rate have a lesser chance of getting into the screening statistics because the entire cycle of clinical symptoms, diagnosis, treatment, and death can occur between screening intervals. The resulting systematic exclusion of these types of cancers from analysis exaggerates the apparent benefit of the test.

In the debate on the benefit of medical screening tools, an appreciation of the complexities that these biases introduce reveals that assessment is a complicated undertaking best left to trained professionals rather than to uncritical, frightened consumers (creatures formerly known as “patients” when medicine was not a business). The radio ad for lung cancer screening is extraordinarily carefully worded and therefore is technically not false, but it is nonetheless misleading because it ignores or blurs subtleties that indicate that the test may actually be worthless.

What does the business model, in this case direct-to-the-consumer advertising of a diagnostic tool, do for the health of the public? Screening tests for lung cancers have no known effect on mortality. They do result in the consumption of more resources and a longer period for the patients to bear the psychological burden of a serious diagnosis. Some doctors worry about even more serious consequences of useless screening tools—in particular, a false sense of security (Maguire 2002). It is not difficult to picture hard-core smokers getting their negative scans and continuing smoking because they believe they have dodged the cancer bullet once again. This dynamic also works to deprive them of trying the singular magic bullet in the otherwise dreary story of the prevention, diagnosis, and treatment of lung cancer: the cessation of smoking (Bailar and Gornick 1997; Smith and Glynn 2000).

Drug Marketing to Doctors

Another form of advertising, which is skyrocketing in use, also highlights how the business model of medicine is changing the profession of medicine. This is the marketing of drugs to health care professionals, especially doctors. The pages of even the most respected medical journals brim with slick ads, and pharmaceutical personnel trying to sell their latest products overrun doctors’ offices and clinics. In 2000, the pharmaceutical industry spent \$4.8 billion on “detailing,” deploying representatives to hospitals, physicians’ offices, and medical conferences to herald the purported benefits of new drugs (Barry 2002a). In all, the industry spent \$15.7 billion on the promotion (including detailing, consumer advertising, samples, and so forth) of prescription drugs in 2000 (Centers for Medicare and Medicaid Services n.d.b, table 3), which was equivalent to approximately 13 percent of the nation’s entire expenditure for prescription drugs. This latter cost was \$121.8 billion in 2000 and amounted to

9.3 percent of the entire cost of health care in the United States (Centers for Medicare and Medicaid Services n.d.a). Thus, promotion of drugs alone was 1.2 percent of the nation's cost for health care. This expense will grow geometrically because spending on prescription drugs, which increases by more than 15 percent per year, is the fastest-growing item in health care expenditure (Barry 2000a).

The monetary expense of this aggressive marketing is obviously enormous, but it is only part of the cost to society. Other costs may be much more telling. Consider the beta-blocker story, which is the saga of drug use gone awry, probably in part because of the pharmaceutical industry's advertising practices.

Beta-blockers, available for clinical use for approximately forty years and therefore long unprotected by patents, constitute a class of drugs used originally for hypertension (high blood pressure). Their side effects are well known and manageable; they are affordable; and they are extremely useful in the hands of knowledgeable physicians. In the past twenty years or so, researchers have found new applications for these drugs, including use in atherosclerotic heart disease, or the hardening of the arteries that leads to heart attacks. As study after study has demonstrated, judicious use of these drugs for individuals who have suffered myocardial infarction (MI, or heart attack) leads to an improved survival rate and less need for subsequent care (Yusuf, Wittes, and Friedman 1988).

Yet physicians use beta-blockers in only approximately 50 percent of the clinical instances in which they should be prescribed (Marciniak et al. 1998). This fact has provoked many editorials in medical journals urging doctors to increase the use of these life-saving medications (Weichel 2000). The medical profession may be making some slow progress in this regard, but even the most successful interventions designed to increase appropriate use have resulted in far less than adequate use (Marciniak et al. 1998). Why the poor showing?

For one thing, the use of beta-blockers can be tricky in patients with other common diseases, such as asthma, emphysema, diabetes, and heart failure (Radford and Krumholz 1998). Clinical circumspection on the part of doctors alone, however, is not sufficient to account for the underuse of these drugs. Doctors use drugs that require skill and knowledge all the time. There must be other factors, and the urge to look to the marketing practices of drug companies for an explanation is irresistible. First, a primer on advertising of pharmaceuticals.

Because the profit on drugs for which the patents have lapsed is lower than the profit on drugs that retain their patent protection, the money that a pharmaceutical company spends on marketing a drug that goes off-patent is much less than the amount it spent during the period it owned the exclusive rights to that drug (typically in the five to seven years after the drug is first introduced). In 2000, the industry spent \$2.26 billion on direct-to-consumer advertising of the top 50 most highly advertised drugs, while spending less than \$117.1 million on the promotion of all other 9,850 prescription drugs. This advertising resulted in sales of these 50 drugs that amounted to 31.1 percent of retail prescription drug sales in 2000. The manufacturer of Vioxx (an anti-

inflammatory drug for arthritis that deserves an important, but small, role in the treatment of patients who suffer from both joint pain and ulcer disease) spent \$160.8 million marketing this drug, and that expenditure paid off in sales of \$1.518 billion. To put the advertising effort in perspective: Budweiser spent less money on advertising during the same year; Pepsi spent less on advertising than did the manufacturer of Celebrex, an anti-inflammatory agent nearly identical to Vioxx (NIHCM 2001).

Are doctors susceptible to the pressure of these ad campaigns? Yes. In fact, they are so susceptible that they do not even know it. Physicians, on whom the drug industry lavishes more than \$5 billion in promotions per year (NIHCM 2001), say that aggressive marketing does not affect their prescribing practices. The marketers know better. For instance, doctors who attended a medical meeting designed to promote a particular drug increased their use of that drug after the conference by 60 percent (Orlowski and Wateska 1992).

How are the foregoing facts relevant to beta-blockers? In the early 1990s, the drug industry was heavily promoting a new class of drugs known as calcium channel blockers, useful in hypertension and a variety of cardiac conditions. These drugs, however, were not proven to have the same benefit that beta-blockers have in the post-heart attack scenario. Somehow, probably in major part as a result of the advertising initiative, doctors began to use calcium channel blockers in the post-heart attack setting, and when they prescribed calcium channel blockers, they tended to omit the beta-blocker (Krumholz et al. 1998). The calcium channel blockers were probably not directly harmful to people who had suffered heart attacks, but the omission of beta-blockers in favor of the highly touted calcium channel blockers resulted in a predictable diminution in survival (Marciniak et al. 1998).

Drug companies did nothing to discredit beta-blockers directly. By plugging calcium channel blockers, they were simply acting in the best entrepreneurial manner and trying to sell drugs that reaped the greatest profits. Doctors, however, in the haze of marketing efforts that descended on them, unconsciously began to substitute the newly patented drugs for beta-blockers in the post-MI situation. After all, how could one resist the cleverly named calcium channel blocker “Procardia”? It is “for” the heart, so it must be good. The substitution, however, resulted in the unnecessary loss of lives.

Beta-blockers are still underused. One has to connect the dots to see the adverse effect of marketing on the use of these tried-and-true drugs, but the evidence for their underuse is indisputable. No one can argue that drug companies are doing anything to help the situation. Why should they? There is no money in it. The money is in drugs that still enjoy patent protection. The business model of maximizing profits has served the drug industry remarkably well, but in the case of beta-blockers it has not served the health of the public.

Neonatal Intensive Care Units

Aggressive marketing, both direct to the consumer and to medical professionals, is but one feature of the corporate model of health care that leads to dislocations in care.

Another hallmark of the business model that fits awkwardly into the practice of medicine is competition. When health care organizations must compete in the marketplace to achieve financial viability, profitable undertakings tend to be overdone at the cost of necessary but less-lucrative services. The proliferation of neonatal intensive care units (NICUs) is a case in point.

Rare outside of university medical centers thirty years ago, these units have come into routine use and have lowered mortality rates of sick or premature infants (Goodman et al. 2002). However, they have become so ubiquitous that one must question seriously whether additional units confer any additional health benefit for the population. In a study reported in a 2002 issue of the *New England Journal of Medicine* (Goodman et al. 2002), investigators found that the growing supply of specialized neonatology services (neonatologists and NICUs) no longer has a strong correlation with need. Moreover, at a critical point already surpassed by most regions in the country, additional numbers of neonatologists have provided no improvement in neonatal mortality rates.

Why then the growing number of neonatal intensive care services? According to Dr. Kevin Grumbach of the University of California, San Francisco, editorializing in the same edition of the journal, the answer is money. NICUs are such reliable cash cows that hospitals have a significant incentive to create them. Pediatricians are eager to specialize in neonatology because neonatologists have higher incomes than general pediatricians. Grumbach states that the expansion in neonatal services is occurring regardless of what the community at large needs and that this superfluous provision of services reflects a central problem of our health care system. A system that relies on the free market rather than on careful public planning, he argues, predictably results in services that are profitable rather than services that are needed. In his words, “Overgrowth of specialty services such as neonatal intensive care often comes at the expense of underinvestment in less glamorous primary care and public health services that avert poor birth outcomes” (Grumbach 2002, 1575).

Drug Industry Influence on Academic Medical Research

Not even the ivory tower of academic medicine is insulated from the pressures of the marketplace. Investigators used to conduct their research with an objectivity that was both admirable and effective. The best researchers won highly competitive grants (mainly from the National Institutes of Health, the primary federal government funding agency for medical research) for basic research that led to the development of many of the important drugs we use now. These people were rewarded with good salaries (albeit decidedly academic salaries), handsome research facilities, and perquisites that included speaking engagements and extensive travel. They published their research findings in the most respected journals and were invited regularly to write editorials and medical review articles that synthesize complex treatment issues for busy practitioners. For this latter activity, impartiality is important, so editors of journals sought review authors who had no relationship to a company whose product they were reviewing and who thus had no conflict of interest in making recommendations.

Then, starting a decade or so ago, the drug industry began to have a de facto influence that contaminated the academic purity of the procedure for publishing these editorials and reviews. Financial arrangements between academic doctors and the industry had become so common that finding academically qualified authors without these ties to the drug industry became nearly impossible. Medical journals accordingly began to change their standards on possible sources of bias in the writing of these types of articles. The *New England Journal of Medicine*, for example, recently changed a longstanding editorial policy on conflict of interest in the publication of review articles and solicited editorials. The old rule was that no one who wrote a review article or editorial could have any financial interest in a company that made a product discussed in the article. When this policy became virtually impossible to execute, the journal changed its rule in June 2002 to conform with the expectation “that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article.” How much is significant? Reviewers may receive \$10,000 in annual income from a drug company before being automatically disqualified as review writers (Drazen and Curfman 2002).

Is the lowering of standards a big deal? Some seasoned observers of the academic-industrial relationship think so. In a letter to the editor commenting on the change in policy, Dr. Arnold Relman, former editor in chief of the journal, wrote that he thought the \$10,000 limit “still allows total payments large enough to influence authors’ attitudes.” He thought the policy should not have been changed (Relman 2002). The director of the Public Citizen Health Research Group, Dr. Sidney Wolfe, said: “The bias introduced by drug companies paying writers of review articles a large amount of money can have the consequence of slanting articles and influencing physicians in a way that isn’t really in the best interests of their patients” (qtd. in Gottlieb 2002, 1474). Another physician commented that the change in policy constituted a betrayal of the public trust and that reviewers “may not be willing to criticize their sponsors, whose final responsibility is to shareholders, not to patients or physicians” (Bittl 2002, 1043). On the whole issue of corporate infiltration of academic research, this doctor quoted the long-time editor of *The Scientific American*, Gerard Piel: “The intrusion of market forces compromises work in the life sciences especially. Whole university medical-school departments now operate as subsidiaries of pharmaceutical companies” (qtd. in Bittl 2002, 1043). The *New England Journal of Medicine* itself had previously published a study on conflict of interest that demonstrated “a strong association between authors’ published positions on the safety of calcium-channel antagonists and their financial relationships with pharmaceutical manufacturers” (Stelfox et al. 1998).

Health Care Failings

Apologists for the business model of medicine take the Panglossian position that health care in the United States is all for the best in this best of possible worlds. If corporate enterprise were society’s sole concern, they would be right. The drug companies,

happy beneficiaries of operating in the most profitable industry in America (Barry 2002b), think everything is just dandy. Health care bureaucrats, especially the CEOs, find the system equally compelling. After all, bureaucracy now eats up 30 percent of our health care budget (Woolhandler and Himmelstein 2002). Lobbyists for the drug industry are also getting fat: the \$197 million spent on lobbying and campaign contributions in 2000 was more than the expenditure of any other industry (Barry 2002a).

For consumers of health care, the picture is much darker. Left to the capriciousness of the business model of medicine that has commanded the main stage for the past fifteen years or so, health care in the United States leaves 41.2 million citizens without medical insurance (U.S. Census Bureau 2002), a number that increased by 8 million during the 1990s despite the booming economy. Those who have insurance are paying ever-higher rates (private health insurance premiums are currently rising at a rate of about 13 percent per year) and getting less for it, as employers cap their contributions to the costs of the premiums (Angell 2002). With their insurance options in a constant state of flux, Americans must constantly navigate a labyrinth of choices, not the least of which is identifying a doctor who remains in their employers' ever-shifting health care plans. And the doctors? They are snowed under with paperwork and unhappy about it (Remier, Gray, and Newhouse 2000). Their pique with the system is not lost on young people: for the past four years, medical school applications have been falling (Josefson 2001).

It must also be noted that our system is fraught with overuse, underuse, and misuse of resources (Chassin and Galvin 1998). It is a health care system that the World Health Organization (WHO) rates as thirty-seventh best in the world (WHO n.d.a, annex table 1) and one that helps Americans to enjoy only the twenty-fourth best rating among WHO member nations for quality of years lived (WHO n.d.b) It is also a system that exacts a per capita cost for health care that is almost twice that of any other country in the world (Associated Press 2000).

Conclusion

Our society has decided that provision of certain services is best left to the government and out of the marketplace. It is ridiculous to think of multiple water systems, for example, competing to bring drinking water to individual households. It is equally unthinkable to subject fire departments to the economic dictates of competition: we certainly do not want fire chiefs to be creating more demand for their work. We do not choose to divvy up national defense between competing suppliers of armed services, for obvious reasons. Alternatives to these types of public services just do not fit into the corporate model that works so well for consumer goods and services. They are either too expensive, lacking in overall benefit to the entire populace, or just plain too chaotic.

Should health care be any different? Do we want the consumer-driven marketplace to rule in such a way that untrained, vulnerable individuals can order for themselves

expensive medical tests that have no proven benefit and may carry incalculable opportunity costs? Do we want entrepreneurial efforts to increase consumption of highly profitable drugs, regardless of cost and any consideration of what might be best for medical care? Do we want a system that rewards the creation of expensive and profitable services, such as NICUs, without consideration of need? Do we want to continue to witness the compromise of the integrity of basic medical research in the name of profit?

As these questions are framed, the answers are obvious. Clearly, it is necessary to overhaul our health care system so that decisions are made to improve health, not the bottom lines of corporate enterprises. Current issues in health care that politicians debate (universal health insurance, medical malpractice reform, a drug benefit for senior citizens) are important, but dealing with them will constitute mere tinkering with a system that needs more than a patch here and a stitch there. Rather, fundamental assumptions about medicine's role in our society need to be considered. It is a wonder that we allow such a flawed system to persist. It is a greater wonder that the basic question of what health care should be, a business or a social service, is not even on the national agenda.

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Acknowledgments: The author thanks Christopher Johnson and Carolyn Kalina, M.D., for their careful reviews of the manuscript and their many constructive suggestions.