

*Virtual Mentor*  
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# Virtual Mentor

American Medical Association Journal of Ethics  
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## FROM THE EDITOR

### **The Empowered Patient: Consumerism in American Medicine**

Consumerism arises when purchasers acquire goods and services from sources other than experts. In medicine, this means patients' receiving health services and information from sources like the Internet and direct-to-patient advertising.

At its best, consumerism fosters empowerment, a focus on consumer rights. The assumption here is that consumers are better able to make decisions when they have more information, choice, and autonomy. Medical apps, physician-rating websites, personalized health records—all of these are meant to decrease the information asymmetry (“doctor knows best”) between patients and their doctors.

However, these trends pose an ethical dilemma for physicians. On one hand, our role is to help patients become better informed. To that end, I am not only impressed when a patient knows a great deal about his or her illness and desired treatment; I am also relieved because it means that I do not have to explain as much as I would to an uninformed patient. On the other hand, what if the information a patient has is irrelevant or incorrect? How do we balance patient empowerment with quality of care? As more technologies and patient-centered metrics come about, concerns about patient information will require more and more of physicians' time and energy. This issue of *Virtual Mentor* explores the many ways in which growing patient consumerism is challenging the patient-physician relationship, medical record-keeping, and even fair allocation of the scarcest of resources—human organs.

The Internet is at the heart of ethical debates over consumerism. Whereas the physician was once the undisputed source of all information medical, today the information that doctors spend years of medical school and residency learning can be accessed by patients at the click of a mouse. Are these sources always right, and what if they are not? Teo Forcht Dagi, MD, DMedSc, MPH, discusses how physicians could approach patient requests based on questionable sources. The Internet also offers a forum to broadcast patients' experiences with and opinions of physicians and other clinicians. Jim E. Sabin, MD, discusses how physicians struggle to balance patient expectations of care with clinical appropriateness in this new era of transparency.

Of course, consumerism happens beyond the physician's office as well. The rise of the retail clinic—an easily accessible clinic run by nurse practitioners in the back of your local pharmacy—has led patients to seek not only information but medical services from sources other than physicians. Rachel O. Reid, MD, MS, and Ateev Mehrotra, MD, MPH, discuss the tensions that primary care physicians face between

wanting to serve as a “medical home” for their patients while still respecting their agency in choosing to go elsewhere for treatment.

The ethics cases provide the practical framework for more specific instances of patient empowerment. Personalized genetics has been a hot topic in previous *Virtual Mentor* issues because it offers the potential to use patient-specific information to develop personalized therapeutics. In this month’s journal discussion, Susan P. Pauker, MD, describes guiding a patient through deciding whether to use whole-exome sequencing.

With the rise of the smartphone, consumerism has leapt into an entirely new orbit. Whereas computers have limited portability and ability to track real-time patient data, smartphones can measure your heart rate and blood pressure (among other things) anywhere and at a moment’s notice. Michael A. Batista and Shiv M. Gaglani give us a bird’s eye view of smartphone diagnostics. It is easy to argue that these technologies are no match for a physician’s diagnostic capability, but Batista and Gaglani explain how such technologies can actually improve the patient-clinician relationship.

The natural response to worries about patient consumerism is to implement broad policies regulating it, but this can be difficult in practice. Bo Wang, PharmD, and Aaron S. Kesselheim, MD, JD, MPH, highlight the need to certify the reliability of information in direct-to-consumer advertisements (DTCA) of drugs. Richard Weinmeyer, JD, MPhil, fills in the DTCA picture with a review of legislation on the practice. In a policy forum article, Tara LePage, MPH, and O’Neil Britton, MD, give an overview of personalized health records (PHRs). Designed to engage patients in the management of their own health, PHRs face several barriers to implementation, and LePage and Britton offer strategies for encouraging adoption. In a final policy piece, Eitan Neidich, Alon B. Neidich, David A. Axelrod, MD, and John P. Roberts, MD, discuss the market inefficiencies of organ procurement for the purpose of transplantation and whether a free-market solution is possible or ethical in this area.

The last few articles of this issue take up more general considerations of patient consumerism. Patient satisfaction is cited as the primary method for evaluating the “patient-centeredness” of medical care. In fact, the Centers for Medicare and Medicaid Services now tie hospital reimbursement to comparative performance on patient satisfaction scores. In our history of medicine piece, Richard B. Siegrist, Jr., MBA, MS, CPA, discusses how this metric came about and popular misconceptions about patient satisfaction metrics. In the medicine and society piece, Nancy Tomes, PhD, takes a broad look at the pros and cons of consumerism and how it can shape doctors’ perceptions of “good” and “bad” patients. Finally, Richard J. Zeckhauser, PhD, and Benjamin D. Sommers, MD, PhD, close our issue with an essay—their prescription for how physicians can embrace consumerism, despite some of the inefficiencies it causes.

Patient consumerism is broad in its reach and that is reflected by the variety of articles and topics covered in this issue. I am confident that these articles will help physicians see the benefits and the costs of the empowered patient.

Ravi B. Parikh  
MS-IV  
Harvard Medical School  
Boston, Massachusetts

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# Virtual Mentor

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## ETHICS CASE

### Responding to Patients' Requests for Nontraditional or Unproven Treatments

Commentary by T. Forcht Dagi, MD, DMedSc, MPH

Dr. Jeffries is a neurologist in private practice in a Virginia suburb. One day Ms. Ballard, a patient with a history of recurrent migraines, comes to his office in the midst of another splitting, pulsing headache centered on her right forehead and typical of her previous migraines. This is her third episode in the past month.

Ms. Ballard is frustrated and discouraged that her migraine regimen has been so ineffective. While reasonably well controlled for the past 3 years with beta blockers, her migraines have increased in frequency and severity over the past 6 months. They have been somewhat relieved but not eliminated with a variety of pain-relieving medications including nonsteroidal anti-inflammatories and triptans.

On this visit, Ms. Ballard brings up “feverfew,” a supplement from the sunflower family that she says has been shown to be effective in preventing migraines. She first found out about feverfew from *The Dr. Oz Show*, a popular daytime television show whose host is a surgeon. “Dr. Jeffries,” she explains, “I saw on *Dr. Oz* that feverfew has been tested in clinical trials and helps prevent migraines. And you can get it online for \$12!”

Dr. Jeffries has no idea what feverfew is. After quickly stepping out to conduct a quick online search, he finds one published clinical trial that suggests that feverfew compares reasonably well with beta blockers as preventive therapy. However, its side effects include allergic reaction and painful rebound headaches, and it is not known whether it interacts with the antihypertensive and oral hypoglycemic that Ms. Ballard is currently taking.

Ms. Ballard is desperate to try the new medication. Furthermore, she has not had any history of medication abuse, and she and Dr. Jeffries have enjoyed a good relationship over the past 3 years.

## Commentary

This case is about one of the most common, yet difficult, situations in the patient-doctor relationship: issues that arise when a patient is equipped only with poor, incomplete, or incorrect information yet seeks to change therapy on that basis.

The physician is unfamiliar with the preparation his patient is interested in, but upon preliminary review of its pharmacological properties, concludes it may be efficacious. On the other hand he has reason to be concerned about potential

interactions with other medications prescribed for the patient and about the possible side effects in her specific circumstances.

This case may not be uncommon, but it is ethically complex. It touches on patient autonomy and informed decision making, paternalism, professionalism, the effects of disparities of power and asymmetries of knowledge, implicit promise making, stereotyping, and ultimately, on trust and the patient-physician relationship. It also touches on the importance of thoughtful and effective negotiation in communicating with patients.

### **Clinical Context**

It is useful to review briefly the subject of migraine headaches, the condition from which Ms. Ballard is said to suffer. Migraines affect some 28 million Americans. They are more common in women. Up to 25 percent of all women with migraines suffer four or more attacks per month, and 35 percent suffer between one and four severe attacks a month. Migraines can last from hours to days and take many forms [1].

The diagnosis is primarily clinical. The personal and family histories are key. There are no reliable diagnostic markers or radiological findings. Nevertheless, in the United States, almost every patient who reports migraine headaches is subject to neuroimaging studies (CT or MRI) at some point, if only to exclude an underlying vascular lesion, space occupying mass, or other treatable pathology. Treatment is aimed at preventing attacks, breaking the cycle leading to debilitating pain once the aura sets in, and relieving the headache if all else fails.

Treatment typically includes dietary and environmental modification, prophylactic medications, analgesics, and, more invasively, chemical or surgical denervation procedures. The combination of diet, prophylaxis, and analgesic is reasonably effective for the majority of patients, but not for all [2-4]. Patients often turn to nutritional supplements, over-the-counter medications, herbal preparations, and folk remedies to supplement conventional measures. Some of these substances may have analgesic or anti-inflammatory properties, but most are of questionable value [5-6].

Many migraine sufferers experience periods of inadequate headache management. Episodic or not, these can be debilitating. A particularly unfortunate few never seem to find adequate relief. Ms. Ballard exemplifies the kind of patient for whom good solutions seem particularly elusive.

Patients who have migraines are at risk for being stereotyped, once the diagnosis has been given. They are often perceived to be and described as “difficult” personalities, whether or not they are, because their condition is difficult or impossible to treat. It is all too easy to disregard new or changing symptoms and to dismiss potentially important and portentous clinical signals.

The dynamic of a call or visit to the physician in the course of a migraine attack is complicated. From the physician's perspective, there are two challenges. The first is to determine whether the current (or any other) episode of headache is different enough from the norm to warrant investigation. The purpose of the investigation (which in practice generally starts with neuroimaging and goes on from there) is to prove that the headache is "only" a migraine by means of a negative study. The second challenge is to find an effective treatment acceptable to the patient. It takes an open mind and keen clinical judgment to meet these two challenges.

It is critical to think through the meaning of the patient's complaints. Do they signal a new and potentially serious event such as an intracranial hemorrhage? The key is to ascertain that the event may be discontinuous with (it does not quite "fit" or "match") earlier events in the patient's history. Should they throw into question existing assumptions about diagnosis? For example, a patient with migraine headaches may develop temporal arteritis and experience headaches from that cause. Temporal arteritis is an autoimmune disease with potentially serious consequences, but one that has nothing to do with migraine headaches. Both can occur in the same patient, but they are treated very differently. Or are the symptoms communicating something altogether different, such as emotional stress or depression?

From the patient's perspective, the conscious dynamic is usually simpler. Many patients hope that, miraculously, each headache will be the last, which means each recurring headache gives rise to an emotional storm that includes disappointment, frustration, anxiety, anger, and fear. It goes without saying that patients look not only for ways to prevent and relieve attacks, but also for control. They would rather not need a doctor. The call to the doctor is an appeal for care because the means available to them have failed. For that reason, somewhere in the background, there not infrequently resides the fear that the physician too might fail. Psychologically, that is a terrifying prospect.

Physicians are generally more focused on diseases and conditions. Patients, however, will be focused on how they feel and, subconsciously if not overtly, on what they fear. This difference may be narrowed by skilled practitioners, but it almost never disappears entirely.

### **Ethical Context**

On the surface, this is about the management of a patient who comes with questionable health information. When we start to look at all the elements of the case, it becomes much more nuanced.

*Autonomy and risk.* Let us start with the matter of patient autonomy and informed decision making. Autonomy and informed decision making are usually invoked in the context of positive coercion—an attempt on the doctor's part to persuade a patient to agree to a certain course of action or to act in a certain way. Patient autonomy and informed decision making are protective principles. Patients are permitted to decide what to do with, and what may be done to their bodies. The

corresponding obligation on the part of the physician is to obtain voluntary informed consent when a patient is to be subjected to surgery and, increasingly, to some nonsurgical interventions as well.

There is no real broad parallel with respect to protecting a patient of sound mind from risky activities undertaken voluntarily, at his or her own discretion and on his or her own initiative. Physicians have an inconsistent record on that score, leaving aside suicide and other forms of self-destructive behavior associated with emotional illness. Substance abuse and smoking prevention are diligently opposed by most physicians, but less so extreme sports, even though the risk of injury is very high. Even boxing, whose purpose is to create concussion, and football, whose injuries have begun to attract critical attention, have not been the object of consistent and concerted medical protest. How then can one object to an herbal preparation which has presumably passed some regulatory scrutiny by the U.S. Food and Drug Administration (FDA), may be classified by the FDA as GRAS (“generally regarded as safe”), is sold over the counter without prescription and has been endorsed by celebrities? One can only begin to formulate an answer to that question by looking at each patient and each drug separately.

*Communication.* It is not necessary, nor is it necessarily helpful, to disparage the preparation. It is important, however, for the physician to consciously focus on the patient and to communicate as much. It makes more sense for Dr. Jeffries to spend more time educating Mrs. Ballard about why he is concerned for her and less time about why he is concerned about the preparation. Time is better spent in creating a trusting relationship than in giving an immediate and categorical reply.

Dr. Jeffries should not be shy about admitting to Ms. Ballard that he needs more time to study the drug in the light of her personal situation and medications. Patients do not generally mind when physicians confess that they want to know more in order to help them. The physician may want to compliment her for her wisdom, thank her for consulting with him and express appreciation for her trust. He should probably spend time acknowledging her frustration with medications that do not work adequately, and express to her his interest in a collaboration that will optimize *her* control of the pain. Dr. Jeffries’s interest should be Ms. Ballard’s well-being, not the drug.

It is entirely fruitless (not to mention antagonistic) to criticize Ms. Ballard for coming with incomplete or inaccurate information. After all, she has relied on national authority figures’ endorsements and turned to her physician for more advice. The power of marketing to create confidence and product demand cannot be overestimated. Dr. Jeffries might find the advertising fatuous, but Ms. Ballard does not.

We are not informed in this case of the relative social standing of the physician and the patient or of Ms. Ballard’s level of education. Nevertheless, there is always the risk that disparities of power and asymmetries of knowledge may affect the tenor of the patient-physician relationship by hampering autonomy or encouraging

paternalism. By the same token, it is important to guard against making promises about prevention and relief that are difficult or impossible to fulfill. Finally, Dr. Jeffries's perception of Ms. Ballard is vulnerable to stereotyping, both because of her diagnosis, and because she is asking to act independently outside of conventional therapeutic practice. This must be guarded against. If he thinks she is vulnerable, he should try to engage her, not protect her.

This situation presents the perfect temptation to engage in a form of well-meaning and seemingly benign paternalism. After all, the patient *did* come to Dr. Jeffries and ask for his opinion. It would be easy for him to say, "I wouldn't take this drug and you shouldn't either." And yet, that kind of response does not serve the patient. Next time, she won't come for advice and the preparation she chooses might be unsafe. The objective must be not only to prevent the patient from trying potentially unsafe medications, it must be to educate the patient about the risks of such preparations.

*Next steps.* If Dr. Jeffries's research indicates that this is less of a risk for Ms. Ballard than he initially imagined, he might decide to test it with her if, after learning about the potential side effects, risks, and alternatives, she continues to request and consent to a trial. (Formal informed consent in this case might be advisable not only for ethical reasons but in order to transmit to the patient the seriousness of the physician's concerns.) By working with her to explain his concerns and what he was looking for, Dr. Jeffries would educate her both about the drug and the process by which he would determine whether the drug was safe and effective in her particular case. Communication is paramount.

It is essential that Dr. Jeffries remain professional and objective, however strongly he advises against taking the drug (assuming that's where his opinion lands). He might think about referring Ms. Ballard to a migraine specialist for a second opinion. Whether it confirms his therapeutic approach or suggests a modification, and whether it allows or dismisses the herbal preparation, the consultation will help fulfill Dr. Jeffries's ethical duties of both beneficence and respect for persons and is likely to further improve the patient-physician relationship.

### **Conclusion**

The ethics of this case cannot be cleanly separated from the clinical issues in the management of Ms. Ballard. That is not an unusual situation. What makes this case important and interesting is how clearly the elements of clinical decision making and the elements of ethical decision making dovetail and overlap. The successful ethical management of this case depends on Dr. Jeffries's interest in optimizing communication and investing in a trusting patient-physician relationship. How that relationship is negotiated for the long run will be what matters.

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T. Forcht Dagi, MD, DMedSc, MPH, is distinguished scholar and professor at the School of Medicine, Dentistry and Biomedical Sciences at Queen's University Belfast and holds an appointment in the Division of Medical Ethics in the Department of Global Health and Social Medicine at Harvard Medical School in Boston. Dr. Dagi is an editor of *Neurosurgery* and of the *Journal of Clinical Ethics*. He is a neurosurgeon, medical educator, and medical ethicist with particular interests in the ethics of uncertainty, diversity, and international disaster assistance.

#### **Related in VM**

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[Physician-Rating Websites](#), November 2013

[Physicians' Responsibility to Understand Patients' Pain](#), May 2013

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# Virtual Mentor

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## ETHICS CASE

### Physician-Rating Websites

Commentary by James E. Sabin, MD

Dr. Jones is a family practitioner in a suburban Chicago group practice. At a staff meeting, he recently learned from a colleague that some patients of their practice have been rating their physicians on a popular doctor-rater website. Several of the physicians are concerned about the low ratings they received.

The next day during his lunch break, Dr. Jones decides to look to see if he has been rated. He is shocked to find that he has only been rated only 2 out of 5 stars. Specifically, he has received the lowest possible scores in “Time spent with patient” and “Helps patient understand his/her condition.” He realizes this score is based on the ratings of only 2 patients. Dr. Jones is disappointed because he strives to provide the best care possible for his patients, and he thought he had great relationships with all of them.

Exploring the site further, Dr. Jones thinks, *these ratings are subjective and largely based on measures not directly in the doctor’s control, anyway!* For example, patients are asked to rate doctors on mostly nonclinical criteria such as waiting time, rapport, and patient satisfaction. The site rating system also seems to prioritize treating diseases over watchful waiting.

He stops his Internet search when his next patient, Mr. Jenkins, comes in for a regular checkup. Dr. Jones asks him whether he has heard of the rating website. Mr. Jenkins replies, “Sure I’ve heard of it—haven’t you seen the commercials?”

Mr. Jenkins has had a cough for the past 2 days and asks for antibiotics. Dr. Jones, in a hurry because he is quite overbooked that afternoon, believes Mr. Jenkins has a simple viral infection. He thinks, *I never prescribe antibiotics in this situation, even though some doctors might, and they don’t seem indicated this time. But Mr. Jenkins already knows about the website, and might be upset that I’m not dealing with his symptoms. What if this guy rates me poorly for not following his request? Could stuff like this drive future patients away from my practice?*

## Commentary

Web-based physician-rating sites are rapidly expanding in number and scope. One site, RateMDs, grew from rating 2,475 physicians in January 2005 to rating 112,024 in January 2010, representing approximately 16 percent of all practicing U.S. physicians [1]. Another site, HealthGrades, claims 7 million visits per month. A recent study of 500 randomly chosen urologists found that 80 percent had at least

one online rating [2]. And Medicare's Physician Compare website will start to include physician quality reports in 2014.

Further expansion is inevitable. According to the Pew Internet project, 85 percent of U.S. adults use the Internet. Of this group, 72 percent reported that they had looked for health information online during the past year. [3] But, while 8 in 10 Internet users have researched a product or service online, to date only about 20 percent have consulted patient reviews of clinicians and medical treatments. And while 32 percent have posted a review of a non-health-related product or service, only 3 to 4 percent have reviewed a clinician, hospital, or treatment. From the perspective of digital entrepreneurs, online physician rating is a market with substantial growth potential.

### **Discussion of the Case**

Dr. Jones, who has only recently learned about online physician-rating sites, is stunned by his poor 2-star rating. Like most physicians, he works hard and takes pride in what he does. We physicians are socialized into having a strong sense of responsibility. This is as it should be, given the impact of our work. As a result, we're vulnerable to shame when our performance is criticized. The 2-star "grade" bruises Dr. Jones's self-image and creates a narcissistic injury.

His initial reaction, while understandable, is not constructive. He gets defensive and blames the poor rating on factors "not directly in the doctor's control." But the factors he cites—waiting time, rapport, and patient satisfaction—are matters over which he does have substantial control. If his defensive reaction persists, Dr. Jones will not be able to learn from the ratings as the quality improvement movement teaches us to do—reflected in the aphorism "every defect is a treasure."

Dr. Jones's reaction to Mr. Jenkins's request for an antibiotic is driven by his anxiety and sense of vulnerability. His clinical assessment is that Mr. Jenkins has a viral upper respiratory infection for which an antibiotic is not indicated. But in his anxious state he falls into what cognitive therapists call "catastrophizing." He imagines that (a) Mr. Jenkins will rate him poorly if he does not prescribe the antibiotic, (b) this will lead to more poor ratings on the website, ultimately (c) causing a loss of patients in the future. It's as if his whole future turns on whether or not he prescribes a nonindicated antibiotic for Mr. Jenkins.

Let's hope that Dr. Jones has learned to monitor his subjective reactions and not to act impulsively. He should not prescribe the antibiotic. He should explain his thinking to Mr. Jenkins and respond to Mr. Jenkins's questions and concerns. In the absence of new information suggesting that an antibiotic is called for, he should seek a negotiated agreement with Mr. Jenkins about how to proceed.

Doing this will take time. It won't be an easy afternoon for Dr. Jones. He's overbooked, and taking time for the valuable exchange with Mr. Jenkins will put him behind in his schedule. But achieving "efficiency" either by writing a prescription he

doesn't believe in or failing to capitalize on the teachable moment in Mr. Jenkins's care is the wrong way to go.

The anxiety and the harried afternoon of practice create a teachable moment for Dr. Jones and his group practice colleagues, too. A constructive response would involve:

1. Acknowledging and addressing the psychological impact of a poor public rating. This initial rating comes from two patients in a large practice, but the public nature of the web can make the rating feel like a spotlight of shame. Dr. Jones won't be able to deal with the situation in a productive manner until he can get past his hurt and anxiety.
2. Seeing what can be learned from the patients' feedback. The case tells us that Dr. Jones "thought he had great relationships with all of [his patients]." But the case also tells us that Dr. Jones feels hurried, which isn't at all unusual in a busy primary care practice. It's not surprising that some patients felt their time with Dr. Jones was too limited and did not allow for adequate explanation of their conditions. Apparently others in the group received similar ratings.
3. Strategizing with colleagues about constructive responses to their patients' concerns. Insofar as Dr. Jones and his colleagues accept that their patients are truly concerned about time and understanding, they can consider the underlying causes. There are probably many. Can the actual time spent with patients be extended by reengineering flow? Can adjuvant supports like educational handouts and videos be created for common issues such as Mr. Jenkins's request for an antibiotic for a viral infection? Are there communication skills that can be strengthened? Can patients in the practice be enlisted in the quality improvement process? A thoughtful collegial analysis of the poor ratings the group has been getting will almost certainly point to constructive actions.

### **Underlying Ethical Issues**

Web-based physician-rating sites should be seen as part of a multidecade cultural shift in the relationship between physicians, patients, and society. In the era of paternalism, doctors were idealized in paintings by Norman Rockwell and dramas like *Dr. Kildare*, and patients were expected to follow "doctor's orders." In the era of consumerism, doctors were taken off the pedestal, and power shifted to patients, who rate the physician on websites and demand antibiotics for viral upper respiratory tract infections. But a system in which "patient's orders" reign is just as lopsided as one that puts "doctor's orders" in the driver's seat. The desirable state is collaboration, a goal medical students are now educated about from the first day of medical school.

Online rating systems can be a thorn in our sides, but they are not going away, and we physicians will have to learn to live with them. In his recent book *Establishing, Managing, and Protecting Your Online Reputation: A Social Media Guide for Physicians and Medical Practices* [4], Dr. Kevin Pho advises physicians to use social media to cultivate a positive image of themselves and their practices. Organizations like Medical Justice [5] and Physician's Reputation Defender [6]

monitor web ratings for their clients and advise how best to use Google, Facebook, Twitter, and other social media sites. Done right, developing an active presence on the web is consistent with responsible professionalism.

The American Medical Association and other professional organizations can and should advocate for responsible governance of the sites. As examples, sites could be asked not to post ratings for individual physicians unless a minimum number—perhaps 5 or 10—have been received and to take reasonable care to ensure that competitors are not masquerading as disgruntled patients posting critical comments.

Given that public assessment of quality of care and patient satisfaction is both desirable and inevitable, the best response to haphazard for-profit websites will be the development of scientifically valid, carefully developed, responsibly managed public sites. Such sites will be a source of anxiety for us, but could be developed in ways that allow for physician response. When a book receives a negative review, it is common for authors to explain why they believe the review is mistaken. Patients are entitled to objective information on quality and satisfaction. And as anxiety-provoking it may be for us physicians, we should receive that kind of feedback as well.

Some physicians have asked patients to sign a “contract” promising not to write on public websites as a requirement for being treated. The impulse to do this is entirely understandable, but for two reasons I have advised colleagues against taking this step. First, it introduces an element of antagonism and distrust into the patient-doctor relationship. Second, it’s highly unlikely that such a contract has legal standing.

Insofar as heightened transparency about quality and satisfaction lead to more attentive communication with patients and better explanation of our diagnoses and treatment proposals, it is all to the good. But there’s also a downside. Just as malpractice litigation can foster defensive medicine, online ratings can encourage behaviors like prescribing an antibiotic for a viral infection to avoid getting a “bad grade” from our patients. We know that patients tend to equate more tests and treatment with better care and more costly interventions with better quality. Insofar as defensive practice caters to misguided beliefs of this kind, rating sites could, paradoxically, lead to worse and more costly practice.

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James E. Sabin, MD, is a clinical professor in the Departments of Population Medicine and Psychiatry at Harvard Medical School in Boston, a member of the American Medical Association Council on Ethical and Judicial Affairs, and the director of the ethics program at Harvard Pilgrim Health Care, a not-for-profit health plan. His research interests include the ethics of health care resource allocation. Dr. Sabin blogs on ethics at [healthcareorganizationalethics.blogspot.com](http://healthcareorganizationalethics.blogspot.com) and on aging issues at [www.over65.thehastingscenter.org](http://www.over65.thehastingscenter.org).

#### **Related in VM**

[Patient Satisfaction: History, Myths, and Misperceptions](#), November 2013

[Primary Care Practice Response to Retail Clinics](#), November 2013

[Securing Patient Satisfaction](#), December 2008

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# Virtual Mentor

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## ETHICS CASE

### Primary Care Practice Response to Retail Clinics

Commentary by Rachel O. Reid, MD, MS, and Ateev Mehrotra, MD, MPH

You are chief of pediatrics at a New York City community health center. Your center has a particularly high census and is fully booked for appointments for the next 3 weeks.

One day, Dr. Colbert, a recent addition to the staff, walks into your office looking concerned. “Chief, what are we going to do about all of these CareNow patients?”

Confused, you ask for clarification. Dr. Colbert explains that because the clinic has been fully booked and has had unusually long wait times for urgent appointments, several patients on the panel have been getting checkups and care at the local CareNow, a retail clinic located in a pharmacy that is staffed by nurse practitioners. The CareNow providers are able to see patients sooner than the community health center can and write prescriptions to treat common illnesses such as strep throat and ear, eye, sinus, bladder, and bronchial infections. Minor wounds, abrasions, and joint sprains are treated, and vaccinations for common viral infections such as influenza, tetanus, pneumonia, and hepatitis A and B are also available.

“I just had a patient come in with a severe case of strep throat who had been prescribed a course of antibiotics, and I never even knew about it,” Dr. Colbert says. “What if he’d been allergic to the medication, or what if the nurse didn’t fully examine him? I had to spend an extra 20 minutes just getting the details of a medical problem I didn’t even know about, and I’m the kid’s pediatrician! What’s our policy for patients going to these clinics?”

As a seasoned physician, you are sympathetic to Dr. Colbert’s concerns about the quality of care at retail clinics. Furthermore, you realize that, since your practice’s electronic medical records are not synced with those of CareNow, there is no way to know what treatments patients actually receive. Most importantly, you want your clinic to be your patients’ “medical home,” and that means keeping tabs on all of your patients’ health interventions. At the same time, you realize that the CareNow clinic can usually treat patients faster than they can be seen in a doctor’s office, and some problems just don’t need to be dealt with by a physician. You struggle to come up with formal policy concerning the CareNow clinics in your practice.

## Commentary

This scenario asks us to consider how a busy pediatric clinic should respond to their patients visiting CareNow, a retail clinic, a type of clinic physically located within a

pharmacy or big box store. Before considering the scenario, it is useful to understand that retail clinics differ in significant ways from traditional primary care physician (PCP) offices. Retail clinics offer walk-in visits with a nurse practitioner or physician assistant for a limited range of simple acute conditions and, increasingly, some chronic and preventive services. Retail clinics are also distinct from but related to urgent care centers. Both offer walk-in care for acute medical conditions; however, urgent care centers are generally freestanding, are staffed by a mix of physicians, physician assistants, and nurse practitioners, and typically have a broader scope of practice than retail clinics and PCP offices, inasmuch as they can provide intravenous medications and laboratory and radiology services. Although they have only existed since 2000, there are more than 1,400 retail clinics nationwide, which record 6 million visits per year [1, 2].

Dr. Colbert's concerns about his patients' use of retail clinics are representative of those of many practicing physicians. Indeed, the American Academy of Pediatrics, American College of Physicians, American Academy of Family Practitioners, and the American Medical Association all have formal positions on retail clinics [3-6]. There are three general concerns of the clinic chief and professional societies: (1) unease regarding quality and safety of care, (2) apprehension regarding potential impact on coordination and continuity of care, and (3) anxiety regarding scope, oversight, and interaction with traditional PCPs.

Some research has already addressed these concerns. Retail clinics have been shown to deliver care that is comparable in quality and lower in cost than primary care offices [7, 8]. Among pediatric patients, visiting a retail clinic in lieu of a PCP is associated with less continuity of care in the following year, less likelihood of having a routine physical in the following year, and less likelihood of seeing a PCP at all in the following year [9]. There has been little empirical research on the interaction with PCPs. However, just under half of all pediatric patients who visit retail clinics report having no PCP [10]. Therefore, many children or adolescents are not making a choice to visit a retail clinic in lieu of their own PCPs.

Given this background and physician concerns, it might be tempting to create a policy banning patients from visiting a retail clinic. It is important to recognize that this is unrealistic. For the health center in the scenario, a 3-week wait for an acute care appointment is not acceptable or fair from a patient's perspective. For a given patient, retail clinics are also only one of many alternatives to visiting his or her own PCP. Patients visit other physicians or nurse practitioners within the same practice, emergency departments, and urgent care centers as well. Currently, for patients of all ages, only 42 percent of acute care visits are to a patient's personal physician [11]. Other alternatives to traditional visits with PCPs such as phone visits and telemedicine are emerging and will also attract new patients [12]. The goal of any policy towards retail clinics (or other such alternatives), therefore, is to balance patients' need for access to care with physicians' desire to serve as their patients' medical homes to achieve the shared goal of high-quality primary care.

In light of this, one prudent component of a health center's response to retail clinics would be to encourage efficient exchange of information between PCPs and retail clinics and other providers in the community. This exchange may not entirely replace the relationship continuity one has with a PCP [13], but the health center could attempt to improve informational continuity by reaching out to the retail clinics and other providers frequented by their patient population and establish a procedure for exchanging summaries after a visit. Retail clinics currently employ a variety of follow-up responses, from transmitting information between different electronic medical records (EMRs) to faxing visit summaries directly to physicians to providing hard copies of these summaries to patients [14]. The health center in the scenario could work with retail clinics in the area to formalize the most convenient or effective method for their workflow. This would only represent a one-way flow of information, however, and may not address the safety concerns raised by Dr. Colbert in the scenario. We are not told much about the health system that this health center might be a part of or about their electronic health records. However, bidirectional information flow might be achieved by providing patients access to their own health records, improving electronic health record interoperability or exchange capacity, or, lastly, by establishing a more formal partnership with local retail clinics, as UCLA and the Cleveland Clinic, among others have done [15, 16]. Such relationships may also make it easier for retail clinics to refer a patient lacking an established primary care relationship to a PCP. Indeed, the same strategies that enable informational continuity between PCPs and retail clinics may facilitate achieving the patient-centered medical home principle of coordination and integration of care [17].

Another component of any response to retail clinics requires PCPs to explicitly acknowledge what patients' behavior already makes clear: primary care is often not provided exclusively in the context of a one-on-one relationship, but rather by a broader team that sometimes includes retail clinics. This especially true for acute care, in which the time-sensitive nature of an illness often precludes a visit with a patient's own PCP due to scheduling constraints. While many retail clinics have procedures in place to send visit summaries to PCPs, many patients do not give retail clinics their PCPs' names, worried that their doctors will be upset about or uninterested in the retail clinic visit [14]. Indeed, some PCPs have reportedly adopted a policy of not seeing patients in follow-up after a retail clinic visit, not wanting to "clean up their messes" [14].

We question such policies that actively project animosity and prohibition towards retail clinics; they are detrimental to both patient safety and access to care and do not reflect a patient-centered approach to coordination of care. We also feel that it is inappropriate to single out retail clinics in this regard; visits to urgent care clinics, emergency departments, and specialists without referrals all can substitute for visits to PCPs and may warrant primary care follow-up afterwards. Moreover, many retail clinics have codified phone follow-up procedures (i.e., calling patients to check for improvement or additional problems after their visit) [14], and patients do not appear more likely to seek early follow-up care after retail clinic visit than a physician office visit [18-20]. If patient safety and continuity are paramount, then PCPs should

consider: (1) openly acknowledging their understanding that patients do sometimes need to see other providers, (2) ensuring that patients understand the importance of information being shared between providers in these instances, and (3) empowering their patients to facilitate this sharing when possible.

A final component of a potential response to retail clinics could be to use this time of deliberate evaluation of the health center's relationship with retail clinics as an opportunity to consciously consider differences between the two care delivery models. Adopting some of the attributes that attract patients to retail clinics—i.e., walk-in availability and extended hours—would be well aligned with creating the patient-centered medical home principle of enhanced access [17, 21]. It may be possible to work towards open-access scheduling, to create evening or weekend appointment slots, or to build non-visit-based mechanisms for communication (e.g., e-visits, e-mail communication with clinicians, electronic or telephonic management of chronic conditions). By making it more convenient to seek care at the health center, these strategies may increase continuity.

We are not told about the staffing or empanelment practices at this health center, but it is reasonable to assume that visits are primarily staffed by physicians. The health center chief acknowledges that “some problems just don't need to be dealt with by a physician.” Patients' implicit recognition of this fact is evidenced in their choosing to visit retail clinics at all. Perhaps strategies to staff walk-in appointments with nurse practitioners or to move toward physician-led teams including advanced practice nurses and other clinical staff for panels of patients with needs of varying complexity could be pursued to allow enhanced access while still maintaining physician-led continuity. Such strategies could free physicians to attend the complicated cases. Indeed, some have argued that retail clinics themselves serve this function, to free primary care physicians to be providers of complex care [15].

For the physicians in the scenario, development of a policy towards retail clinics and efforts to serve as a medical home could call upon many common strategies. Both require recognition of the role the PCP can play as a coordinator of the larger medical neighborhood and that a key part of that role is maintaining informational continuity. Both necessitate acknowledgement that the very nature of acute conditions requires timely and convenient access to care. The extended hours, walk-in or same-day appointment availability, and short wait times offered by retail clinics and many medical home practices better accommodates the schedule and timing constraints many patients face when seeking care for an unforeseen acute illness. Understanding why patients seek simple acute care at retail clinics and creating a medical home to provide enhanced access to comprehensive primary care services also both require physicians to recognize patients' agency in seeking health care and to more fully appreciate patients' needs and preferences regarding care delivery. An effective policy towards retail clinics and acute care in a primary care practice should address patients' need for timely and convenient acute care; enhance PCPs' role in facilitating communication and continuity between their clinics, retail clinics, and the

larger medical neighborhood; and build capacity for enhanced access to acute care within the primary care clinic itself.

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Rachel O. Reid, MD, MS, is a resident physician in the Department of Medicine at Brigham and Women's Hospital and a clinical fellow in medicine at Harvard Medical School in Boston. Dr. Reid's research interests encompass the primary care delivery system and how cost and quality data relate to decisions in health care.

Ateev Mehrotra, MD, MPH, is an associate professor in the Department of Health Care Policy at Harvard Medical School in Boston. Dr. Mehrotra's research focuses on the impact of innovations in delivery on the costs and quality of health care.

### **Related in VM**

[Physician-Rating Websites](#), November 2013

[Patient Satisfaction: History, Myths, and Misperceptions](#), November 2013

[Medical Ethics and Retail Clinics](#), September 2011

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# Virtual Mentor

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## THE CODE SAYS

### **AMA Code of Medical Ethics' Opinions on Patient Requests for and Use of Non-Prescribed Treatments**

#### **Opinion 8.20 - Invalid Medical Treatment**

The following general guidelines are offered to serve physicians when they are called upon to decide among treatments:

- (1) Treatments which have no medical indication and offer no possible benefit to the patient should not be used.
- (2) Treatments which have been determined scientifically to be invalid should not be used.
- (3) Among the treatments that are scientifically valid, medically indicated, and offer a reasonable chance of benefit for patients, some are regulated or prohibited by law; physicians should comply with these laws. If physicians disagree with such laws, they should seek to change them.
- (4) Among the various treatments that are scientifically valid, medically indicated, legal, and offer a reasonable chance of benefit for patients, the decision of which treatment to use should be made between the physician and patient.

Issued June 1998 based on the report "Invalid Medical Treatment" adopted December 1997.

#### **Opinion 8.045 - Direct-to-Consumer Diagnostic Imaging Tests**

Diagnostic imaging services that have not been scientifically validated for screening purposes are being offered without prior referral by a personal physician. Examples include total body scanning, electron beam computed tomography (CT) for determining coronary artery calcification, spiral CT for lung cancer screening, and CT colonography for colon cancer screening. Physicians and relevant specialty societies should advocate for the conduct of appropriate trials aimed at determining the predictive power of the tests, and their sensitivity and specificity for target abnormalities. When adequate data regarding a screening diagnostic imaging service become available, the profession has a responsibility to develop suitable guidelines, as has been done for mammography.

The following ethical guidelines apply to physicians providing screening imaging services that have not been scientifically validated, without referral from another physician:

(1) Performance of a diagnostic imaging test at the request of an individual is justifiable only if, in the judgment of the physician, the potential benefits of the service outweigh the risks.

(2) Once a physician agrees to perform the test, a patient-physician relationship is established with all the obligations such a relationship entails.

In the absence of a referring physician who orders the test, the testing physician assumes responsibility for relevant clinical evaluation, as well as pre-test and post-test counseling concerning the test, its results, and indicated follow-up. Post-test counseling may also be accomplished through referral to an appropriate physician who accepts the patient.

In obtaining the patient's informed consent, the testing physician should discuss, in a manner the patient can understand, the usual elements of informed consent as well as:

the inaccuracies inherent in the proposed test,

(a) the possibility of inconclusive results,

(b) false positives or false negatives, and

(c) circumstances which may require further assessment and additional costs.

(3) Physicians who hold financial interests in imaging facilities must not place those interests above the welfare of their patients. Moreover, physicians who advertise diagnostic imaging services should ensure that advertisements are truthful and not misleading or deceptive.

Issued November 2005 based on the report "Direct-to-Consumer Diagnostic Imaging Tests," adopted June 2005.

**Related in VM**

[Responding to Patients' Requests for Nontraditional or Unproven Treatments](#), November 2013

[Direct-to-Consumer Advertising of Drugs](#), November 2013

[The Role of Direct-to-Consumer Pharmaceutical Advertising in Patient Consumerism](#), November 2013

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# Virtual Mentor

American Medical Association Journal of Ethics  
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## THE CODE SAYS

### *AMA Code of Medical Ethics' Opinion on Organ Transplantation*

#### **Opinion 2.16 - Organ Transplantation Guidelines**

The following statement is offered for guidance of physicians as they seek to maintain the highest level of ethical conduct in the transplanting of human organs.

(1) In all professional relationships between a physician and a patient, the physician's primary concern must be the health of the patient. The physician owes the patient primary allegiance. This concern and allegiance must be preserved in all medical procedures, including those which involve the transplantation of an organ from one person to another where both donor and recipient are patients. Care must, therefore, be taken to protect the rights of both the donor and the recipient, and no physician may assume a responsibility in organ transplantation unless the rights of both donor and recipient are equally protected. A prospective organ transplant offers no justification for a relaxation of the usual standard of medical care for the potential donor.

(2) When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient's physician. Death shall be determined by the clinical judgment of the physician, who should rely on currently accepted and available scientific tests.

(3) Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory. The physician should ensure that consent to the procedure is fully informed and voluntary, in accordance with the Council's guidelines on informed consent. The physician's interest in advancing scientific knowledge must always be secondary to his or her concern for the patient.

(4) Transplant procedures of body organs should be undertaken:

(a) only by physicians who possess special medical knowledge and technical competence developed through special training, study, and laboratory experience and practice, and

(b) in medical institutions with facilities adequate to protect the health and well-being of the parties to the procedure.

(5) Recipients of organs for transplantation should be determined in accordance with the Council's guidelines on the allocation of limited medical resources.

(6) Organs should be considered a national, rather than a local or regional, resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.

(7) Patients should not be placed on the waiting lists of multiple local transplant centers, but rather on a single waiting list for each type of organ. Issued prior to April 1977; updated June 1994 based on the report “Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients,” adopted June 1993.

**Related in VM**

[Consumerist Responses to Scarcity of Organs for Transplant](#), November 2013

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# Virtual Mentor

American Medical Association Journal of Ethics  
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## STATE OF THE ART AND SCIENCE

### The Future of Smartphones in Health Care

Michael A. Batista and Shiv M. Gaglani

Smartphones are quickly becoming a nearly ubiquitous technology. In 2009, approximately 64 percent of physicians in the U.S. owned smartphones [1]. Just 1 year later, a separate investigation found smartphone ownership among health care professionals in the U.S. at 81 percent, growing to 91 percent in 2012. Smartphone ownership among European health care professionals grew at an even faster rate, from a lower initial penetration of 44 percent in 2010 to 81 percent by 2012 [2].

Closely associated with mobile technology and equally important for mobile health care are tablet computers, which exhibited an equally impressive climb in usage by physicians from 30 percent in 2011 to 62 percent in 2012 to more than 72 percent in 2013 [3]. The rapid ascendance of the tablet is not surprising, given that 51 percent of health care professionals use tablets for accessing electronic health records (EHRs), the second most frequent use after sending emails [4]. These clear trends towards mobile device adoption, both in general society and within the medical community, have positive implications for patients' health and the patient-clinician relationship.

#### Out-of-Clinic Use

The first frontier of mobile health care technology is out-of-clinic patient use of software applications (apps) and peripheral hardware that plugs into or attaches to a smartphone or tablet. Already, smartphone-compatible medical devices such as weight scales, blood pressure cuffs, and pulse oximeters are making their way into patients' homes. By providing health information and instructions for use in a user-friendly interface, smartphone-synced devices empower patients to take an active role in their own health. Unlike older generations of at-home monitoring equipment that required manual record keeping, these smartphone devices provide associated apps through which patient data are automatically recorded and stored in personalized profiles that can be transmitted securely to the patient's medical home. These apps also present patient data in comprehensive visual formats such as graphs that convey trends over time and often include explanations of appropriate ranges for a health metric, given patient-specific factors such as age, weight, and sex. By eschewing the need for tedious data collection and putting the emphasis on educating the patient about his or her own health, such apps may ultimately enhance patient engagement.

Currently, there are myriad such medical devices on the market, each of which interfaces with its own app. Looking forward, the next generation of mobile

technology needs take into account multiple-device integration and the tech-savvy patient trying to keep track of data from different devices. Some apps are already moving in this direction [5-8], for example interfacing with both a scale and a blood pressure monitor in addition to monitoring health and fitness activities, providing back-end cloud-based health information management that can interface with any smartphone medical device [9], or putting forth an all-in-one tool to measure temperature, blood pressure, and blood oxygenation [10]. With one app at the center of a family of devices, patients can centralize their at-home health care.

In addition, smartphone compatibility has put even more powerful medical devices, previously found only in doctor's offices and hospitals, directly into patients' hands. Visual acuity assessment, optic disc visualization (ophthalmoscope), inner ear visualization (otoscope), lung function (spirometer), heart function (ECG), body sound analysis (stethoscope), and even sonography (ultrasound) can all now be conducted using an app or peripheral hardware, and most of these are already—or are on their way to becoming—FDA approved [11]. However, these devices are not meant to replace visits to a clinician. They simply make it easier to collect clinically relevant data and in turn allow clinicians to spend more time analyzing and interpreting data, counseling, and developing treatment plans.

### **In-Clinic Use**

As smartphone-enhanced medical devices continue to be integrated into patients' lives at home, the next step is clinical adoption. Early adopters will be clinicians who already use many of the devices and are confident in the capabilities and the accuracy of the technology. Dr. Eric Topol, for example, who has twice diagnosed arrhythmias on airplanes using a mobile electrocardiogram (ECG) [12], is a leading supporter of smartphone-based health care. Mobile physicians, such as those in emergency medicine, will find clear value in portable devices that can, for example, capture focused assessment with sonography for trauma (FAST) images and send them through a smartphone to the hospital ahead of the patient for pre-arrival diagnosis by a physician [13].

Primary care clinicians may also find value in using mobile technology in the clinic. One of the biggest challenges with any new device is its potential to distract the clinician and alienate the patient, ultimately emphasizing technology over people. When the clinician becomes too focused on the data collection process, he or she begins to lose the personal connection that lies at the heart of the patient-clinician relationship. For at least two reasons, the smartphone offers the potential to usher in a new era of medical devices that reverses this trend. First, smartphone-based medical devices are typically less invasive and easier to use than their predecessors. For example, a single-channel ECG can be integrated directly into a durable iPhone case. Though a one-lead ECG will of course not provide as comprehensive an assessment of heart function as the twelve-lead ECG, it can quickly and easily perform basic heart monitoring without being cumbersome—ideal for quick screenings or event monitoring. Likewise, plug-and-play blood pressure cuffs connect directly to a smartphone; the clinician does not need to simultaneously

manipulate both a stethoscope and sphygmomanometer while trying to speak to the patient. Instead, the clinician can focus on engaging the patient about his or her health and not be distracted by the data collection process.

Second, the apps of smartphone-based devices typically provide a visual or auditory representation of the collected data that can be shared, allowing the patient to better understand what the doctor is looking at and listening for. For example, when a doctor uses a standard ophthalmoscope to examine a patient's eye, the patient has no idea what the doctor is seeing. With mobile digital imaging and recording apps [14], on the other hand, the doctor can record a snapshot of the patient's optic disc, which can then be shown and explained to the patient and included in the patient's EHR along with the doctor's notes. Similarly, whereas stethoscopes allow only the doctor to hear a patient's body sounds, digital stethoscopes [15] not only record and play the sounds but also present a visual representation of them.

While these smartphone-based clinical tools have much potential, there are clear obstacles to their widespread adoption [16], including potentially disrupted clinical communication, social disengagement, technology failures, and patient harm. Is this last category, not only do smartphones and associated devices have the potential to spread nosocomial infections but they may also lead to breached confidentiality. Clinicians must determine whether they should collect and exchange patient data using their own personal devices or adopt devoted clinical devices for such activity. The mobile health industry has indicated its understanding of this privacy issue, so many device manufacturers have prioritized patient data security by integrating HIPAA-compliant communication systems [17].

In summary, smartphone- and tablet-based medical devices and apps have significant potential to affect the patient-clinician relationship and improve the efficiency of the health care system. Moving forward, it will be important for early adopters to address the problems associated with these devices in both the ambulatory and clinical setting and to optimize workflow so the broader clinical and patient communities may adopt them.

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Shiv M. Gaglani is a second-year MD/MBA student at the Johns Hopkins School of Medicine in Baltimore and Harvard Business School in Boston. He is the co-founder and CEO of the medical education technology company Osmosis and an editor of the medical technology blog *Medgadget*. Shiv curated the Smartphone Physical exhibit that was featured at TEDMED 2013.

Michael A. Batista is a second-year doctoral student in the Center for Bioengineering Innovation and Design at Johns Hopkins University in Baltimore, where his work focuses on the translational development of new medical technologies and tools. He was a founding team member of the Smartphone Physical exhibit, which has been featured at conferences and events across the country to promote mobile-based health care technologies.

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# Virtual Mentor

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## STATE OF THE ART AND SCIENCE

### Letting Patient Values Guide Shared Decision Making

Susan P. Pauker, MD

A bright healthy woman sought the opinion of one more geneticist as she neared the end of her reproductive life. Dedicated to disallowing her major birth anomaly from defining her, she was grappling with the ethical, moral, personal, financial, and career impact that having a similarly affected child would have on her and her husband. Copious testing including DNA microarray and consultations over the years had failed to define a syndrome, etiology, or potential recurrence risk. Maybe it was teratogenic. Maybe it was an unidentified autosomal dominant mutation with a 50 percent recurrence risk to her potential children, or maybe it was not genetic.

After decades of supporting individualized decision making in prenatal diagnosis and pre-conception pregnancy planning, this was the first case in which I felt that whole-exome testing might be clinically indicated. (Whole-exome testing looks at all parts of the patient's genome that are known to contribute to physical and health-related traits.) Although clarification of this woman's diagnosis would be most unlikely to suggest treatment or cure, at least we might narrow the zero-to-50 percent estimate of recurrence risk while she was still fertile. Having identified a reliable commercial lab, I invited the patient and her husband back to consider her values about further diagnostic testing.

The visit began as usual: "There is no *right* answer to this problem of whether or not to do this genetic test; there is only the answer *you* choose as most consistent with your own values. I will help with the decision analysis. We will care for you, whatever you decide." The patient's husband stated his unconditional love and support for his bride; he considered her very beautiful and would welcome and care for a child with his wife's birth anomaly. Having lived with her functional deficits longer than she had known her husband, the patient was not so clear about how the shame-blame-guilt feelings might play out if her baby were born similarly affected.

Whole-exome sequencing (WES) would have the possible benefit of "ending the diagnostic journey." Stigmatization and life insurance discrimination already existed for this patient and would not deter testing. The prevention of recurrence could justify an appeal to her health insurer to cover the test, since finding a causative DNA mutation could be utilized for prenatal diagnosis by first trimester chorionic villus sampling (CVS), second trimester amniocentesis, or by preimplantation genetic diagnosis (PGD) after in vitro fertilization (IVF). However, the patient was adamant about not terminating an established pregnancy with or without the deleterious mutation and not "throwing out" affected embryos after IVF with PGD.

She had already rejected other options of adoption, donor egg implantation, and bypassing prenatal diagnosis of a known mutation altogether. She would be sad if her child were mercilessly teased in school as she was, but she felt uniquely prepared to help a child with those issues.

If we found a putatively responsible DNA mutation by WES, we would need to study the patient's unaffected parents to see if one or both also carried the mutation; presence in one unaffected parent would disqualify genetic inheritance as the cause. They lived in rural Portugal—who would pay for their testing? What if the parents felt guilty, believing that they might have caused a mutation by their own behaviors or fetal exposures? Facing a diagnostic answer with an associated increased recurrence risk, would the patient decide against having biological children? If we did not find a likely mutation, some months would be wasted waiting for results. Having waited, the patient might hope for the diagnostic promise of the next great test “sometime next year.”

“What else would we learn from this test?” asked the husband. “Might we find out if my wife carries other mutations, like some of the mutations you explained from the preconception screen?” Aha! The essential question! Yes, of course, everything found on a medical test belongs to the patient. It is his or her medical record. It is his or her test result. Not knowing what we were looking for, we would be casting a large, nonspecific net and be likely to uncover collateral information. As the ordering physician, it would be my obligation to share those results with the patient, taking the time to describe what may and may not be significant, based on current knowledge, anticipating that knowledge to change and require reinterpretation over time. We may well have a DNA finding of unknown significance, except as the preliminary results of research. Variants of unknown clinical significance abound on DNA microarray testing. How would we know what was significant if we didn't look? On the other hand, how would we explain massively unknowable results to the patient or her children?

Faced with receiving uninterpretable test results, and given the value they placed on having their own child together, regardless of birth anomalies, the couple decided to decline WES at the time. After more than 3 hours of consultation and much discussion at home, they hoped that there was no risk of the patient's congenital anomaly recurring and confined themselves to choosing among the bewildering genetic screening and testing options related to their advanced parental ages.

Was enough time spent clarifying the issues? What if the discussions had occurred through an interpreter? How can a dysmorphologist or clinical geneticist or genetic counselor spend adequate time helping a single patient understand such complexities? What if the discussion needs to start by defining DNA? How can sensitive, individualized decision making about genetic testing be made available nationally? The very nature of medical ethics includes more questions than answers, but with for-profit companies advertising to the public, time for appropriate, skilled, objective but caring, decision support becomes the significant commodity.

McGuire et al. [1] recommend that the ordering physician limit study of the exome or genome to a specific set of genes to reduce confusion and false findings. When it is possible to know where to look, we do order a “DNA panel,” or sequence the suspected DNA. Unfortunately, as in the case of the patient above, we oftentimes have no indication of where those genes might be, or what else we might find. Explaining this is an essential element of truly informed consent to testing, but many people want as much information as they can get, without consideration of the myriad *true positives* they may also receive.

No field in American medicine has exploded with new information in so short a time as clinical genetics. In the dyad of the patient and doctor, it has been challenging to explain that a one-in-four recurrence risk equals a three-out-of-four chance that the problem will *not* occur. Concern for the language skills, education, culture, gender, expectations, values, and abilities of the patient is still critical. Implications of test results for the patient, the current family, and future children are daunting. It is vastly rewarding to “get it right,” helping a person choose the best path, utilizing whole-genome and -exome sequencing, under conditions of increasing uncertainty. Perhaps the next generation will learn if the answers are right.

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Susan P. Pauker, MD, is an associate professor at Harvard Medical School, chief of medical genetics at Harvard Vanguard Medical Associates (formerly HCHP), and a member of the Genetics Unit at Massachusetts General Hospital, where she trained as a genetics fellow. She is a founding fellow of the American College of Medical Genetics and has served on its board. Dr. Pauker specializes in individual decision support for prenatal and preconception prevention of birth anomalies.

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# Virtual Mentor

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## HEALTH LAW

### Direct-to-Consumer Advertising of Drugs

Richard Weinmeyer, JD, MPhil

We've all seen them. Every time you turn on your television, open up a magazine, or head to WebMD during a hypochondriac episode, there they are: glossy advertisements for countless prescription drugs that promise the possibility of relief from whatever ails you. Whether their messaging takes the form of a honeybee with a Castilian accent who's concerned about your nasal allergies, or a group of stylish young women—one of whom always seems to be a physician—talking about fertility control over fluorescent cocktails, these informational vehicles drive home a single, uniform message: "If you suffer from [insert any condition], talk to your doctor about whether [insert any drug name] is right for you."

Direct-to-consumer advertising (DTCA) is a promotional cornerstone for drug companies who are introducing novel and revamped therapies to the American public and wish to boost demand for their products. And DTCA is, at times, a useful avenue for consumers plagued by illness and anxious to learn about unexplored treatment options when existing drug regimens have not provided reprieve from their sickness and discomfort. The regulatory framework that defines the restrictions on pharmaceutical marketing tactics has changed considerably over several decades. This article briefly examines the evolution of DTCA oversight in the United States, elucidating how the modern-day legal schematic for regulating DTCA, on television in particular, came into being. It then touches on the continuing controversy surrounding DTCA in the sphere of prescription drugs and why DTCA proponents and opponents both have defensible arguments.

### History

*The Wild West (and East)*. Drug makers have been advertising their products directly to the public for as long as the practice of medicine has been in existence. In the United States, starting in the eighteenth century, it was commonplace for newspapers to run advertisements for patent medications—chemical compounds and concoctions that had little-to-no curative effect—that were paid for and pitched by medicine companies and supposed physicians [1, 2]. In fact, by the early 1800s, patent medicine DTCA was so lucrative that newspapers received most of their advertising revenues from these medicine manufacturers [1, 2]. Knowledge about the effectiveness of these touted cure-alls was nonexistent, however, given that they were disseminated in an environment where drug makers had no legal obligation to prove the accuracy of their product claims [3]. The drug market was an untamed frontier where medicine men entranced the public with the promise of miracle snake oils [3].

Because of the regulatory vacuum in which drugs were created, marketed, and sold to the public, the federal government had little ability to screen effectively for harmful items being introduced into commercial streams. In 1906, Congress passed the Pure Food and Drug Act in an attempt to fill this void [4], yet the statute proved largely impotent in shielding consumers from innocuous and even dangerous chemicals because it did not require that manufacturers prove a drug's effectiveness and safety [5]. Furthermore, the 1906 act only regulated labels, not advertising [5].

*Decades of legislative reform.* In 1938, Congress enacted and President Franklin D. Roosevelt signed into law the Food, Drug, and Cosmetic Act (FDCA) [6], which to this day serves as the foundational legal authority for protecting the safety of food, drugs, and cosmetics in the United States and charges the U.S. Food and Drug Administration (FDA) with the enforcement of these laws [7]. The act gave the FDA control of drug labeling and the power to require that all drugs be screened and approved for their safety [3].

Advertising for drugs was deemed an entirely different issue. Considered to be a matter of guarding against consumer fraud, oversight of drug marketing was placed in the hands of the chief federal agency charged with consumer protection enforcement, the Federal Trade Commission [5].

Over the next several decades, Congress recognized the distinction between over-the-counter medications and prescription drugs and, via the 1962 Kefauver-Harris Drug Amendments [8], authorized the FDA to regulate prescription drug marketing, while keeping over-the-counter drug advertising under the control of the Federal Trade Commission [1, 3, 8]. Through the 1962 Amendments, two requirements were set forth for prescription drug ads: (1) a drug advertisement must have a "summary" describing a drug's side effects, contraindications, warnings, and directions for use, and (2) the advertisement, as a whole, must provide a "fair balance" of information about a drug's effectiveness, safety, and risk [1, 3, 8].

Given the paternalistic nature of the physician-patient relationship until the mid-1980s, DTCA was primarily geared toward physicians [3]. Drug companies simply advertised their drugs to doctors who, in turn, told their patients what drugs to take [3]. The commercial behavior of pharmaceutical companies began to shift during the 1980s, however, as manufacturers couched their desire to reach the American public in terms of educating consumers about the drugs they were taking and empowering patients to become active, informed medical decision makers [1]. Wary of these rationales, the FDA told drug companies that they would have to abide by the 1962 Amendment requirements, including a "brief summary" of a drug's side effects, effectiveness, contraindications, and so forth in order for DTCA to be placed in the mainstream media [1, 3]. While such a condition may not sound harsh, the FDA's pronouncement was seen as particularly onerous by the medical industry because a 30-second television commercial was simply inadequate for drug makers to convey lengthy and scientifically complex information about prescription drugs to the public [1]. In 1997, following considerable debate within the medical industry and among

regulators, the FDA held a public hearing and set forth a final determination on what DTCA actions were allowed by drug manufacturers [9]. The marketing rules laid out in that determination were finalized in 1999 and guide DTCA practices today.

### **Current DTCA Requirements**

Based on the FDA's final guidance on DTC broadcast advertisements, drug makers must provide the name of a drug, the conditions it treats, and the risks associated with taking it, referred to as the "adequate provision requirement" [9]. There is considerable flexibility, however, in how this risk information can be conveyed. Drug manufacturers must still disclose all of the important risks in a product claim advertisement, but they need not provide all of that information in a single commercial segment [9]. Instead, they can list additional resources where people can obtain more information about the drug. Such informational vehicles include toll-free phone numbers, websites, or referral to physicians or pharmacists who people can consult about whether a drug is appropriate for them [9]. Finally, under current federal law, manufacturers are not required to seek preapproval from the FDA before a DTCA campaign is launched [3]. Instead, drug makers must only provide advertising materials when a drug reaches the marketplace [3]. Despite what the law requires, data suggest that many companies submit their advertising campaigns for FDA approval before making their drugs available to consumers to establish good rapport with the agency and the public [10].

### **The Practical Impact of DTCA Laws**

As federal law governing DTC drug advertising has evolved over the last century, the presence of these campaigns has increasingly become a salient feature in the lives of Americans who turn on their televisions to watch a reality show, only to be bombarded with drug commercials about managing Crohn disease. The renewed impetus behind DTCA was supposed to endow average consumers with an ability to make better choices about what drugs they wanted to treat their health conditions and, overall, create a healthier nation. But what has actually come about from DTCA remains an open point of contention among policymakers, scholars, and medical professionals.

*In favor of DTCA.* Those in favor of DTCA have spoken to the promise of having an informed and healthy population, touting DTCA's ability to give consumers access to multiple sources of health information and encourage patients to explore a much wider range of treatment options than simply relying on information from their physicians [11]. Proponents also claim that patients who have a bounty of health information at their fingertips are more likely to seek the advice of their physicians [12] and approach their doctors about conditions they may have neglected to bring up in previous appointments [13]. Some data suggest that these claims are true. In a 2004 survey conducted by the FDA, 53 percent of physicians said that, because of DTCA, they engaged in better conversations with their patients about medical treatment options and noted that their patients asked more thoughtful and educated questions relating to their medical care [13]. Other proponents argue that DTCA may reduce underdiagnosis and undertreatment of certain conditions [14], help to reduce

the stigma associated with some illnesses [15], and possibly encourage patients' adherence to their current treatments [16].

*Not in favor of DTCA.* Critics of DTCA efforts contend that these marketing tactics increase the rates of clinically inappropriate prescriptions; doctors, they claim, are prompted by patients to prescribe medications that offer little, if any, benefit [14]. Indeed, several studies have in fact demonstrated that physicians are more likely to fill DTCA-triggered patient requests for medications deemed medically inappropriate, often in an effort to accommodate patient preferences [14]. An additional concern pertaining to DTCA is that it can lead to the medicalization of nonmedical conditions and subsequently result in unwarranted diagnoses [17]. Several scholars have argued that mass marketing has medicalized symptoms not previously associated with illness and created novel conditions, such as overactive bladder or social anxiety disorder, for which DTCA drugs are positioned as the prospective remedy, ultimately promoting the pharmaceutical industry rather than the public's health [18, 19].

### **Conclusion**

DTCA has existed in some form or another for several centuries, and it will clearly be a contentious topic for lawmakers, drug companies, physicians, and patients to battle over as the delivery of health care and the role of patients evolve in the coming decades. The laws that currently determine just how consumers are exposed to DTCA have given drug makers greater leeway in how they reach their audience, allowing them to target prospective "customers" by beaming ads directly into their homes. Such access has had a profound impact on the provision of medical care in the United States. Pharmaceuticals will always have a place in the life of the American patient, but how the patient is introduced to those drugs will continue to be reimagined and refined as the boundaries of DTCA are nudged forward with each new drug and television commercial.

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Richard Weinmeyer, JD, MPhil, is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs. Mr. Weinmeyer received his law degree from the University of Minnesota, where he completed a concentration in health law and bioethics and served as editor in chief for volume 31 of the journal *Law and Inequality: A Journal of Theory and Practice*. He obtained his master's degree in sociology from Cambridge University and is completing a second master's in bioethics from the University of Minnesota Center for Bioethics. Previously, Mr. Weinmeyer served as a project coordinator at the University of Minnesota Division of Epidemiology and Community Health. His research interests are in public health law, bioethics, and biomedical research regulation.

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## POLICY FORUM

### The Role of Direct-to-Consumer Pharmaceutical Advertising in Patient Consumerism

Bo Wang, PharmD, and Aaron S. Kesselheim, MD, JD, MPH

In 2012, pharmaceutical and medical device manufacturers spent more than \$4 billion in the U.S. to promote their products to patients [1]. These direct-to-consumer advertisements (DTCA) are disseminated via television and radio, magazines and newspapers, and—increasingly—the Internet. DTCA has important implications for the consumerism movement in health care. High-tech media like smartphones and the growth in wireless Internet connectivity are allowing more patients to access promotional information about potentially beneficial treatments, but the lack of firm regulatory guidelines governing DTCA may lead to suboptimal treatment decisions and health and economic outcomes.

#### Background

DTCA has been widespread in the U.S. for as long as prescription drugs have been for sale [2]. The U.S. Food and Drug Administration (FDA) was first granted regulatory authority over pharmaceutical DTCA in the 1962 Kefauver-Harris Amendments, which authorized the agency to oversee prescription drug labeling and advertising [3]. In the 1980s, a large increase in print DTCA was spurred by a combination of the rise in patient proactiveness in medical decision making, a political environment that favored deregulation, and 1985 FDA guidance establishing the form by which a brief summary of risks could appropriately be provided in print media [4]. However, the FDA's "fair balance" standard for DTCA—requiring a "brief summary" listing of all product risks in cases where a specific claim was made about a prescription drug product—made broadcast advertising of prescription drugs prohibitively expensive.

The landscape changed again in 1997 when the FDA issued a preliminary guidance document (finalized in 1999) that allowed broadcast advertising to satisfy the fair balance requirement by including far simpler side effect profiles via "major statements," as long as sources for more complete information (e.g., a concurrent print advertisement or a toll-free number) were identified [5]. After this regulatory reinterpretation, pharmaceutical DTCA spending accelerated, increasing from less than \$1 billion in 1997 to a peak of \$5.4 billion in 2006 [6].

#### Controversy over DTCA

As DTCA of medical products has evolved, it has remained a controversial subject [7]. Proponents of the advertising point to surveys showing that physicians believe that DTCA educates patients and gives them confidence to take a more active role in

their care [1, 8]. In addition, DTCA can reduce stigma associated with the advertised diseases and thus reduce underdiagnosis and undertreatment [3]. Some have also suggested that DTCA can enhance patient adherence, although the empirical evidence on this point is limited [1, 9]. While surveys of patients and physicians reveal that DTCA can make patients feel better about their prescriptions and can remind patients to have their prescriptions refilled, studies attempting to quantify this effect on prescribing patterns or patient outcomes have drawn no clear conclusions [1, 9].

DTCA has also been criticized for interfering with effective patient-doctor relationships. Some physicians have pointed out that addressing information patients bring from drug advertisements makes patient visits longer and less efficient [8]. In one survey, one-third of responding physicians reported that DTCA made patients less confident in their clinical judgment [10], for example when the physician recommended a therapy other than the one the patient was exposed to in the DTCA.

In addition, while DTCA provides some information about disease entities and their therapies, it often fails to do so in a balanced manner. First, the promotion of high-cost, patent-protected drugs puts the spotlight on disorders treated by these products, regardless of whether they are widespread or severe. It can also undermine patient confidence in competing generic drugs or other effective alternative treatments [11]. Second, advertisements also tend to overemphasize benefits and minimize risk. Recent work in social psychology examining the influence of implicit content in DTCA found that the inclusion of positive stimuli—such as children playing happily on a grass field during an asthma inhaler advertisement or a photogenic person stating the side effects of a drug—may subconsciously foster unjustified beliefs about safety and efficacy and unduly influence the viewer’s choice of therapy [12].

Whatever physicians and patients may think about DTCA, studies show that it stimulates prescribing. In one national survey, physicians reported filling 75 of 108 (69 percent) DTCA-prompted patient requests for interventions that they considered inappropriate [8]. A randomized controlled study that investigated the effect that patients’ DTCA-related requests had on rates of prescribing antidepressants found that prescribing rates were 22 percent higher when standardized patients made brand-specific requests linked to DTCA than when no medication request was made [13].

### **The Future of DTCA**

There have been calls in the U.S. for a moratorium on DTCA to curtail the negative effects of drug advertisements [14], but such a proposal is likely to gain little traction since drug advertising falls under courts’ expanding protection of “commercial free speech” under the First Amendment [15]. Notably, DTCA is relatively rare outside the U.S.; New Zealand is the only other Organisation for Economic Co-operation and Development nation that allows this type of advertising, despite numerous attempts by the pharmaceutical industry and its lobby groups to overturn bans in other regions, including the European Union [16, 17].

While an outright ban on DTCA in the U.S. is unlikely, in 2009 the FDA issued a Notice of Proposed Rulemaking (NPRM) regarding DTCA with the purpose of implementing aspects of the FDA Amendments Act of 2007. The statute called for the major statement of side effects and risks to be “clear, conspicuous and neutral” [18], defining “neutral” as an “unbiased manner” free from “distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement” [18]. The marketing community’s lobbying group, the Advertising Coalition, asserted that FDA’s suggested definition of “neutral” was not grounded in precedent or evidence [19]. In addition, the coalition implied that the NPRM was premature given that it was still in the process of analyzing the results of a recently concluded study looking at the impact of distraction on consumer understanding of risks and benefits [19]. Instead, the Advertising Coalition supported a less restrictive definition that the major statement should “neither underwarn nor overdeter” [19]. Four years later, the FDA has yet to finalize and implement this regulation.

The Internet, too, has served as an increasingly important forum for drug advertising, with recent estimates of online DTCA spending topping \$1 billion annually [20]. The Internet offers substantial patient empowerment through self-directed learning, but online DTCA has been criticized for using seemingly neutral third parties to present biased information about drugs without appropriate sponsorship disclosure [21]. Adding to this concern is the concordant rise of online pharmacies selling counterfeit medications, many of which use the same marketing tactics as the drug manufacturers themselves, leading to increased confusion and potential harm for patients seeking to learn more about their conditions [22].

Early FDA attempts to regulate Internet DTCA have been limited. In 2009, the agency sent out 14 warning letters to pharmaceutical companies informing them that their sponsored links on search engines were considered misbranded since they did not provide any statements about adverse effects. These sponsored links generally contained the brand name, the intended treatment condition, potential benefits, and a link to the product’s website containing risk information. Critics argued that since the product’s website was only “one click” away from the link, the two should be seen as one entity, much like different parts of a television commercial [23, 24]. In response to the FDA’s warnings, drug companies’ sponsored links now include either the name of the drug or treated condition, but not both, which arguably removes the explicit association between drug and disease [25]. At the same time, manufacturers continue to expand their Internet presences, including interacting directly with patients or physicians through online chat rooms and forums [21, 25].

### **Consumerism and DTCA**

DTCA’s relationship to medical consumerism thus remains a conundrum for policymakers. While physicians are the primary source of patients’ information about prescription drugs, the courts have long recognized that print and broadcast DTCA undercuts physicians’ educational role [26]. So-called web 2.0 technology, including YouTube channels, iTunes applications, and social networking sites, can

offer increasingly personalized information to patients, allowing them to play an even more active role in their health. However, this effect is salutary only when the information is true and it is communicated in an accurate and balanced way that takes into account the totality of the evidence.

As a result, we believe that DTCA alone does not adequately support patient autonomy and consumerism. Given the substantial dangers that can arise from use of prescription drugs, and the decades of evidence showing that advertising drives use of medical products, reasonable restrictions are necessary to ensure that DTCA information is presented in a clear, neutral, and patient-accessible manner. The best way to achieve that would be careful prospective assessment by the FDA of all promotional claims for medications and devices, acting on behalf of all the nation's prescribers and consumers. But the FDA's capacity to undertake these reviews is limited, and the delays in rule making show the difficulty in achieving consensus on definitions of even basic terms like "neutral." In the past, medical professional societies like the American Medical Association (AMA) have stepped into this vacuum with their own review processes and provided a third-party seal of approval to advertisements in print media that meet their own evidentiary standards [27]. The AMA eventually stopped this practice in 1955 due to the threat of personal injury lawsuits linked to products carrying the association's seal [28]. Despite the positive effects that DTCA can have in supporting medical consumerism, until regulators or professional societies take a more active role in certifying the reliability of the information, patients have no choice but to remain skeptical about what they read and see about prescription drug and medical devices in print media, on television, and online.

### **Conclusion**

DTCA in the U.S. has evolved along with changing regulations and media outlets. While recent studies of DTCA are mixed, drug advertisements remain pervasive and therefore exert an undeniable influence on the way the public learns about available therapies and how patients and physicians communicate. Because advertisements' primary purpose is to sell products, rather than to inform patients in an unbiased manner, reasonable oversight is essential for the public health. The current rise of highly personalized online DTCA should be a primary focus of this vigilance. Input from all stakeholders is required to ensure that "fair balance" is achieved in all types of drug advertising.

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Bo Wang, PharmD, is a licensed pharmacist and third-year medical student at Harvard Medical School in Boston. His research interests include pharmaceutical regulation and adherence.

Aaron S. Kesselheim, MD, JD, MPH, is an assistant professor of medicine at Harvard Medical School in Boston and a faculty member in the Department of Medicine's Division of Pharmacoepidemiology and Pharmacoeconomics of Brigham and Women's Hospital, where he runs the Program On Regulation, Therapeutics, And Law (PORTAL).

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# Virtual Mentor

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## POLICY FORUM

### Consumerist Responses to Scarcity of Organs for Transplant

Eitan Neidich, Alon B. Neidich, David A. Axelrod, MD, and John P. Roberts, MD

#### Introduction

In March 2009 Steve Jobs, then a northern California resident, flew to Tennessee to receive a liver transplant from a deceased donor [1]. Jobs's choice as a consumer to travel to a distant transplant center to improve his chances of receiving a lifesaving transplant focused national attention on patient choice and allocation of the limited supply of organs. Although Jobs's transplant was performed in compliance with all existing policies and procedures, its success highlighted vast geographic and economic disparities in access to transplantation.

#### The Current Situation: Geographic Disparities

Despite national efforts to increase donation rates, the demand for deceased-donor organs for transplantation continues to vastly exceed the available supply [2]. Because organ allocation systems operate primarily on a "local-first" basis, the impact of the organ shortage is far from uniform.

In general, organs are initially distributed to transplant candidates within the geographic region, called a donor service area (DSA), in which the organ was recovered. These 52 DSAs were defined by the Centers for Medicare and Medicaid Services and include all acute care hospitals in the region. If the organ is not accepted by a transplant center in the DSA, it is offered more broadly to centers within the United Network for Organ Sharing (UNOS) region. There are 11 UNOS regions that generally include several DSAs. If the organ is again declined in the region, it is offered nationally. This pattern of allocation varies by organ type and certain classifications of possible recipients (e.g., liver transplant patients with fulminant hepatic failure).

Under current policy, available liver grafts are allocated within a given region on the basis of disease severity, as assessed by the Model for End-Stage Liver Disease (MELD) score. In densely populated regions, like California, patients must be very ill to receive an organ, while, in regions with fewer waitlisted people per available organ, those with less severe illness (i.e., lower MELD scores) receive transplants, which results in a marked reduction in waitlist mortality and reduced cost at the time of transplantation and beyond [3]. These differences mean that the transplant center at which a patient is listed substantially influences waiting time and chance of death [4, 5]. Jobs chose to be listed at the University of Tennessee because patients at that center receive transplants with substantially lower MELD scores than patients in California.

Similar geographic disparities exist in kidney transplantation, for which waiting times vary from 18 months to more than 8 years depending on where one lives in the U.S. [2, 6]. A 2007 study by Ashby et al. concluded that wait times for kidney transplants in different regions vary from “60 percent lower to 150 percent higher than the national average (RR = 0.40–2.50), after adjusting for patient age, race, ethnicity, gender, ESRD cause, wait-list year, comorbid conditions, insurance type, blood type, PRA and HLA antigens” [6]. Patients with ESRD on long-term dialysis have higher risk of mortality, reduced quality of life, and higher overall health care costs than transplant recipients [5, 7].

A number of factors contribute to these discrepancies, including regional differences in the supply and demand for donor organs [8], centers’ organ acceptance practices [8], the geographical boundaries of UNOS transplant regions and donor service areas (DSA) within them [9, 10], and the size and characteristics of the potential donor populations [8].

In response to these observed discrepancies, the Department of Health and Human Services charged the transplant community in 1998 with ensuring that “allocation of scarce organs will be based on common medical criteria, not accidents of geography” [11]. Despite this guideline, few changes in policy have been implemented to alter the way organs are distributed with the goal of reducing regional disparities.

### **The Consumerist Response to Geographic Disparities: Leveraging Economic Disparities**

This inequality in access has encouraged patient consumers to take their fates into their own hands by acting as domestic transplant tourists. Traditionally, the term “transplant tourism” describes the practice of traveling from a developed country to an economically disadvantaged nation to purchase access to the latter’s supply of organs, generally living-donor kidney and liver transplants. This practice has been widely criticized by the transplant community as economically exploitative [12]. Today, the term is no longer restricted to international travel. There is ample evidence that certain U.S. patients are able to seek services strategically from centers with access to more favorable organ supplies [13]: historically, 5-6 percent of patients awaiting deceased-donor kidney transplantation have elected to be evaluated and placed on more than one waiting list, which is permitted if separate donor services areas serve the centers [9].

Who are these patients? Axelrod et al. demonstrated that it is patients with high socioeconomic status who travel between DSAs [13], resulting in a 74 percent increase in access to transplantation and a 20 percent reduction in mortality after listing [14]. Merion et al. “found that, all other factors held constant, the odds of multiple listing were significantly higher for younger patients, males, whites, and those from higher-income areas, compared with older patients, women, nonwhites (except Asians), and those from low-income areas, respectively” [15].

Transplant transportation companies have sprung up, allowing patients who can access their services to escape the negative effects of discrepancies in waiting time for organ transplantation by selecting distant transplant centers with more favorable organ supplies. Currently, the average transplant candidate selects a secondary center 135 miles from the original listing center or approximately one day's drive [15]. Such companies aim to facilitate distant listing far from the patient's residence, in the vein of Steve Jobs. One such company, OrganJet, educates patients about multiple listing and where they can multiple list, assists patients in deciding whether they should transfer their wait times, and aids in patient transfer via car or commercial or private airplane for less than the price of chartering a private jet [16].

### **Ethical Implications**

Empowering (some) patients to act as consumers and select the most favorable transplant centers does not address foundational problems underlying geographic disparities. A 2004 study by Merion et al., demonstrated increasing multiple or distant listing will not ameliorate geographic inequality in organ allocation.

Median waiting times for kidneys...at OPOs [organ procurement organizations] with the lowest and highest median waiting times demonstrate more than 10-fold and 22-fold differences, respectively [from the overall median waiting time]. The effects of multiple listing, as currently practiced, appear quite modest in comparison. In fact, regional disparities in waiting time would still dwarf the impact of multiple listing even if its use were, for example, to double

from 5.6 percent in 2004 [17]. Thus, one can see that empowering patients to act as consumers and place themselves on multiple lists does not significantly reduce current inequality in access to transplantation. Even after accounting for multiple or distant listing, patients in well-supplied regions (also known as “fly-in” regions) often still have shorter wait times than patients in “fly-out” regions (e.g., California) [18].

Furthermore, multiple listing exacerbates economic disparities. Patients with fewer monetary resources are substantially less able to travel for organs. For patients with ESRD, for example, commercial insurance covers the first 30 months of dialysis, after which Medicare, through the ESRD entitlement, becomes the primary payer. Dialysis costs are estimated to be \$80,000 per year [19]. It is well documented that transplantation is more cost-effective than dialysis [20]. While private insurers may elect to reimburse for travel to available organs, it appears unlikely that Medicare or state-based Medicaid programs will support organ recipient travel. This significantly limits who will be able to act as consumers in the transplant arena. Less affluent patients interested in pursuing this option face significant barriers to multiple or distant listing, including fewer financial resources to devote to travel and less ability to withstand loss of wages and separation from a support system.

Privilege, not just money, may block access to multiple listing. Since 2005 the Organ Procurement and Transplantation Network has mandated that transplant centers inform all patients of their right to multiple list or transfer their care to a different transplant center without loss of accrued waiting time. Additionally, in 2007 the revised CMS conditions of participation required transplant centers to inform patients of their right to be on more than one list [21]. However, the process is logistically complex, which may make it more difficult for those with less health literacy or privilege to navigate.

It is important to note that all travel between DSAs is not a consequence of differences in the organ supply. Patients may travel to distant centers for specific clinical expertise, proximity to family for support, or when directed by their insurance providers. Regardless, all are benefits that accrue to patient consumers with the resources to select any transplant center in the United States.

Ultimately, there is a growing body of evidence to support the conclusion that high socioeconomic status, private insurance coverage, and residence in regions with reduced access to deceased-donor organs are each associated with travel between DSAs and a reduction in mortality [14]. Consequently, while the impact of patient consumerism is immense throughout the U.S. health care delivery system, its impact is perhaps most evident in transplantation, where patient affluence and the choice it affords directly affects patient mortality.

Furthermore, while moving people off an overcrowded transplant list may benefit others on that list by decreasing wait time, it lengthens the wait time of those on the wait list in the “fly-in” region. This means transplant centers in the “fly-out” region that lose low-risk, revenue-generating patients—those who are relatively healthy and covered by commercial insurance—have less revenue to offset the expense of caring for lower-revenue patients (e.g., those with Medicare coverage), possibly jeopardizing those patients’ access to care.

### **Conclusion**

The advent of companies that facilitate multiple listing and travel for organs should alert the transplant community to the expanding ability of a select subset of patients to exploit persistent inequalities in the transplant system. Since the 1998 DHHS final rule, no steps have been taken to alleviate these geographic inequities. A 1999 IOM report recommended that a new, quantitative system of setting priorities based on medical criteria be applied uniformly across geographical areas with populations of roughly nine million, a system that would effectively supersede UNOS’s regional structure, but it has never been adopted [22]. Ultimately, the most equitable solution will require a comprehensive policy that expands the boundaries over which organs are allocated. Patient consumerism in the transplant arena reveals a system rife with disparities in access. In this context, patient choice means that only those candidates with extensive resources are able to escape accidents of geography.

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Eitan Neidich is a medical student at the University of California, San Francisco. He obtained a bachelor's degree with honors in political theory, science, and law from Cornell University. His work has been published in the *Journal of the Royal Society Interface*, *Progress in Transplantation*, and the *American Journal of Transplantation*.

Alon B. Neidich is a medical student at Tufts University School of Medicine in Boston. He obtained a bachelor's degree with honors in law, letters, and society from the University of Chicago, where he was a Howard Hughes Medical Institute Fellow investigating informed consent and women's attitudes toward obstetric and pediatric biobanks. His work has been published in the *American Journal of Transplantation*, *Progress in Transplantation*, the *American Journal of Medical Genetics*, the *Journal of Medical Ethics*, and *The New Physician*.

David A. Axelrod, MD, is chief of transplant surgery at the Geisel School of Medicine at Dartmouth College in Hanover, New Hampshire. Dr. Axelrod chairs the United Network for Organ Sharing's Organ Procurement and Transplantation Network (OPTN/UNOS) pancreas transplantation committee. In addition, he is the chairman of the business practice committee for the American Society of Transplant Surgeons and creator of its Leadership Development Program. He is the author of more than 50 publications in the areas of transplantation economics and outcome research and lectures nationally on these topics.

John P. Roberts, MD, is the chief of the Division of Transplantation at the University of California, San Francisco. He has produced nearly 170 papers on topics including allograft rejection, immunogenicity, immunosuppression, and others. Dr. Roberts has served as the president of the United Network for Organ Sharing's Organ

Procurement and Transplantation Network (OPTN/UNOS) board of directors and its corporate affairs committee, as well as the American Society of Transplant Surgeons.

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# Virtual Mentor

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## POLICY FORUM

### Will the Potential of Personal Health Records Be Realized?

Tara LePage, MPH, and O'Neil Britton, MD

The rapid evolution and advancement of commercially available technology have reshaped the way we do just about everything in our lives. The early days of the personal computer (PC) stimulated the imagination of a generation, but, due to cost considerations, remained inaccessible to many in our society. The introduction of the iPhone by Apple in 2007, followed by the tablet PC, triggered an explosion of widely available and cheap technology with functionality that few could have imagined in prior years [1]. At the same time, traditional brick-and-mortar institutions were pushed by economic forces to embrace the web's revenue-generating and cost-saving potential as a necessary component of a healthy business model, given the rapid migration of consumers to Internet and mobile platforms.

An enormous amount of choice in our lives is being driven by these same technological advancements. Whether we are online shopping through retail sites such as Amazon, selecting meal and leg-room preferences through one of the many online travel agents, or even utilizing online banking to apply for a mortgage without ever having to visit a physical bank, the options appear endless. Thus, it was only a matter of time before this phenomenon started imposing itself on the health care system, where patients and advocates began to clamor for access to, control of, and portability of their personal health information. When these advancements were coupled with policy initiatives promoting patient-centric health care transformation, it was no surprise that the preconditions for creating the first personal health records were set in motion, specifically to engage the individual in the management of his or her own health [2]. Technology has become a major facilitator in the development of this model of care, and its rapid advancements are offering innovative tools that are optimizing patient-clinician connectivity more than ever before. From academic medical centers to rural community hospitals, the sophistication of these information systems is now supporting administrative and clinical decision making; information organization, management, and accessibility; and communication across the care continuum.

### Types of Personal Health Records

An electronic health record (EHR) is a collection of health information that is both gathered and managed by health care professionals [3, 4]. Much attention has been paid to the promotion and adoption of EHRs both in private and public care settings across the country, driven by government incentives for their "meaningful use." In contrast, personal health records (PHRs)—defined as "an electronic application through which individual patients can access, manage, and share their health

information in a private, secure, and confidential environment” [5]—have been developed to address the growing demand of the patient-as-consumer for health information. With far less regulatory attention and incentives, these records currently represent a more niche industry, largely driven by software entrepreneurs and health care institutions attempting to improve their engagement with patients.

There are three general classifications of PHRs:

1. Stand-alone software applications accessible through the Internet or personal storage devices with content solely uploaded by the end user or designee,
2. EHR-based patient portals that directly connect to and are governed by the care providers’ patient information sources, and
3. Complete, patient-controlled records, ideally interoperable with all available information from caregivers across the health care spectrum [3, 5].

In response to the transition towards patient empowerment and patient activism in our health care environment, a number of vendors and institutions have committed to the adoption and implementation of PHRs in order to engage individuals in the management of their health. The common belief is that patients engaged in this manner generally have better health outcomes, but it remains unclear whether this is a result of selection bias, inasmuch as patients who were quick to seek out and adopt PHRs are particularly motivated to take active roles in their health [4].

In 2007, Microsoft released their web-based PHR model, HealthVault, an example of the PHR described in classification 1 above. With Internet accessibility, anyone is able to register with HealthVault to store, organize, and track personal health information, upload relevant data from home health devices, and search for vetted health and wellness resources [6]. These records provide the patient with a centralized repository to track and manage personal and familial health data that can range from over-the-counter medications, special diets, and exercise programs to symptoms of chronic conditions and progress on personal fitness goals [3]. While this classification of PHRs merits complete patient control of data entry and desired mobility, concerns about consistency of reporting and reliability worry those with clinical decision-making roles [4].

The EPIC application My Chart is an example of the second classification: a tethered PHR product that links with the vendor’s enterprise EHR [4, 7]. This model allows patients to view selected pieces of their medical records including diagnoses, medications, immunizations, and, most popularly, test results. Additional features allow the patient to request prescription renewals and office visits and recommend updates to particular fields in the chart as necessary [7]. The opportunity for bidirectional communication between patient and clinicians and the subsequent time saved performing routine tasks electronically are the apparent advantages of this interconnectivity. The patient is now equipped with the most relevant medical records and has the ability to share with the physician pertinent information that may have previously been missing from the chart. Epic’s newest PHR module, Lucy, permits all of the functionality described above, in addition to allowing the patient to

share and store health summaries from other health care organizations. The governance of the information in this module is entirely under the control of the patient with some built-in restrictions to prevent patients from overwriting the EHR. Of all 3 potential models, this one—the PHR tethered to an EHR—appears to be the option with the greatest potential for traction. The EHR vendors’ strengths—resources to invest in software development, ability to meet security and compliance standards, and long-term market presence—would make PHRs attractive.

The third classification speaks to the ideal PHR; a hub-and-spoke model that would capture the entirety of health care services (spokes) encircling each individual patient (hub) [6]. For patients, whose personal health information is scattered across a variety of constituents including many care providers, employers, health plans, insurers, and even family members [8], having the architecture and functionality to import, export, manage, and share relevant information from all sources would yield the greatest value. Successfully achieving this seamless flow of data would require an infrastructure of nationally recognized interoperability standards to regulate the building and maintenance of these technology systems and tools [8].

### **Implementation**

The main barrier to achieving widespread use of PHRs has been achieving interoperability between the EHRs of multiple health systems and other organizations—made more difficult by the fact that EHR vendors are vying for the same customers—but the promulgation of integrated value-based care may reduce these challenges by decreasing the number of health systems from which patients seek care. A secondary barrier to widespread PHR use is varying levels of computer competency and health literacy among patients. Efforts to increase health care understanding among patients will be instrumental in making access widespread and equitable [4, 7, 8].

For patients to adopt any version of PHRs, they must be convinced of the value the technology has for them. Framing that value in a way that actively engages patients as collaborators in their health care management will not only empower the individual but improve patient-clinician relationships overall [9]. For some patients, the value may be control of or immediate access to their information, while others will be most enthusiastic about features such as self-scheduling of exams and social media connections to lifestyle-modification support groups. These concepts of transparency, flexibility, and connectivity reflect the desired participatory model of care, where patients will be welcome to join their clinicians at the table and take ownership of decisions regarding their health [9].

*Benefits.* Working to lower the barriers to adoption and making PHRs available on user-friendly and affordable mobile devices will allow more patients to access PHRs. And, as more engage with the tools, there will be greater opportunities for scholarly evaluation of patient-reported outcomes and patient behaviors, as well as instrumental feedback on desired functionality for future development [7]. Over

time, assessments of robust data sets will more clearly show PHRs' impacts on quality of care, safety, efficiency, and overall patient satisfaction [6].

*Risks.* On the other hand, widespread EHR adoption could compound the effect of threats to information security, leading to unlawful access to patient information and fraud related to misuse of patient accounts, as well as, possibly, to crippling clinician productivity with exponentially increased workloads. The clinician's perception of risk may also be increased if clear rules or policies regarding importation of patient reported information into the "official" medical record are not established. This may be exacerbated by any poor clinical outcome and would be likely to lead to deterioration of the patient-clinician relationship.

### **Conclusion**

It is clear that personal health records represent a significant investment in greater patient engagement—offering unprecedented access to personal health information and encouraging shared patient-clinician decision making to improve clinical outcomes. In a time of broad transformation of the health care system, technologic advances are undeniably providing opportunities to embrace patients as partners in their health care management [8].

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Tara LePage, MPH, is a recent graduate of Boston University School of Public Health with a concentration in health policy management. Her career interests include providing strategies to improve the quality of life of nursing home residents and analyzing the barriers to health information technology adoption in the elderly population.

O'Neil Britton, MD, is the chief health information officer of Partners HealthCare in Boston. He is a senior clinician in the Department of Medicine at Brigham and Women's Hospital and former chief medical officer at Brigham and Women's Faulkner Hospital. His career pursuits have focused on clinical operations, quality improvement and patient safety, and the education and mentoring of trainees and students.

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# Virtual Mentor

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## MEDICINE AND SOCIETY

### The Patient as Consumer Watchdog

Nancy Tomes, PhD

The term “patient consumerism” is, like “managed care,” a notoriously difficult concept to define. While often mentioned in relation to the nobler-sounding “patient empowerment,” it has a far greater capacity to raise physicians’ hackles. In part that response reflects the many and contradictory meanings of the term “consumerism” and the special edge those meanings take on when applied to the practice of medicine. As defined in the *American Heritage Dictionary*, consumerism can mean the belief that a “progressively greater consumption of goods is economically beneficial,” or the deep “attachment to materialistic values or possessions.” But it has also come to connote a more *critical* consumerism, that is, “the movement seeking to protect and inform consumers by requiring such practices as honest packaging and advertising, product guarantees, and improved safety standards” [1].

In medical settings, the term “consumerism” gets invoked in all three of those ways: to describe a market-oriented medicine organized around the provision of more and (we hope) better goods; to criticize patients who “doctor shop” to get goods that they should not have, e.g., addicts in search of narcotic prescriptions; and to articulate the expectation that every patient be a discerning critic of medical care, in the spirit of the old advertising line “an educated consumer is our best customer.” All three versions of patient consumerism present practical and ethical problems, but those posed by the last variant—what I think of as the patient-as-consumer-watchdog—raise perhaps the most difficult issues for today’s patient and doctor.

Consider the very different portraits of the patient-as-consumer presented in these two accounts, one by a patient, one by a doctor. The first account comes from a 2009 blog post written by Carolyn Thomas for *HeartSisters*, a website about women and heart disease. In “What Doctors Really Think about Women Who Are ‘Medical Googlers,’” Thomas describes how she became what she half-jokingly terms the “doctor’s worst nightmare,” namely a patient who reads up on her condition via the Internet and judges her doctor’s advice by what she finds there. Thomas became a critical consumer after an ER physician misdiagnosed her heart attack as acid reflux disease, due to his lack of familiarity with the difference in how cardiac symptoms present in women and men. After her close call, Thomas retired and became “addicted,” in her words, to researching heart disease and sharing that information with other women. Not surprisingly, her experience changed her relationship with her cardiologist. Because of her compulsive Googling, she knew before he did that the FDA had just issued a drug alert advising physicians not to prescribe the drugs Plavix and Wellbutrin together. Fortunately, Thomas noted, she found a caregiver

who did not mind her initiative, but, she noted further, many physicians were not so tolerant of patients like her [2].

In her post, Thomas mentioned an online essay written in 2007 by the orthopedist Scott Haig, titled “When the Patient is a Googler,” that reflected hostility toward the consumerist patient. The subject of Haig’s essay, “Susan,” fit the profile of the “bad” doctor shopper: a sufferer from chronic knee pain, she had already visited several orthopedists before him, had checked out his credentials online, had read a paper he’d written on the subject, and came with a long list of questions to ask him. She was not a good patient, in Haig’s view, because “she brandished her information” and was “too personal and just too rude on our first meeting,” so full of herself that he could hardly get a word in edgewise. He knew from experience that her condition would not respond easily or quickly to available treatments. So Haig decided to “punt,” as he put it: to say politely that he could not help her and send her to another colleague [3]. (Susan must have had good insurance.)

Although they wrote at cross purposes—Thomas to support the value of Internet research, Haig to question it—both highlighted the issues that make the practice of patient consumerism both common and frustrating. On the one hand, the explosion of new information and treatments makes it hard for physicians to stay aware of all they need to know, in Thomas’s case about sex differences in cardiac symptom or the dangers of a particular drug combination. Thomas’s vigilance on her own behalf may well have saved her life. On the other hand, we can also see Scott Haig’s point. Susan was seeking care for a chronic condition that was difficult to treat. If orthopedists who have spent years treating knee pain still differed on its management, how likely was a lay person to arrive at a superior understanding of the subject? Susan’s doctor shopping seemed doomed to fail, in that she expected too much and listened too little to her medical counsel.

As these two vignettes suggest, differentiating between the “good” and the “bad” practice of critical consumerism is no easy task. Many critics decry the tendency to treat medicine as “just another commodity, like breakfast cereal,” as legal theorist George Annas put it [4]. “The relationship between patient and doctor used to be considered something special, something sacred,” economist Paul Krugman wrote in 2011, but is now being undermined by the profit-oriented ideals of “consumer-based medicine” [5]. Yet for better or worse, the expectation that patients think like critical consumers when they visit the doctor is not likely to disappear anytime soon. Simply put, making patients more responsible for their medical choices has been a centerpiece of the “marketization” of American medicine since the 1970s. Assigning the patient the role of consumer watchdog has gone hand in hand with a return to the spirit of “caveat emptor”—let the buyer beware—that allowed health care entrepreneurship to flourish in the late twentieth century [6].

Therein lies the dilemma: the American health care system encourages patients to take more responsibility for their own treatment decisions and expects their doctors to cooperate in that effort. But the guidelines for exercising that responsibility remain

very murky indeed. Patients are told to educate themselves about their medical conditions so they can more fully and rationally participate in their care, and the Internet has made it far easier to do so. But the fact remains that the state of medical opinion on many subjects is not clear, a lack of clarity that does not take a MD or a PhD to appreciate. If doctors disagree, if there is no universal consensus on what constitutes the best treatment, why shouldn't patients be able to “shop” for a clinician whose approach they prefer? To complicate matters, much of the information that patients and doctors have readiest access to comes in the form of advertising: a highly selective, commercialized message designed primarily to sell a product, not to educate the user. One of the great ironies of the 1970s patient-consumer movement is that its leaders' demands for information were used to upend longstanding prohibitions on the advertising of prescription drugs and doctors' services. Finally, the time, money, and literacy levels required to do any kind of “doctor shopping” would seem to make patient consumerism a prerogative only of the relatively educated and affluent [7].

So we are left with more questions than answers. When does patient consumerism shift from sensible to misguided? Is it fair or reasonable to ask people to think like quality control officers when they visit their doctor's office? If not, what are the alternatives? How does patients' duty to be vigilant on their own behalf conflict with the need ultimately to trust their caregivers? Does the patient-as-watchdog ideal disadvantage people who are not literate or affluent? There are no easy solutions, no magic wands to eliminate the complexity of these problems. All we can do is try to raise them for open and honest discussion in a variety of settings, including medical ethics courses, policy forums, and health advocacy groups. “Principles for Engaging Patients in U.S. Health Care and Policy” by Rachel Grob and Mark Schlesinger is a good place to start that discussion [8].

On a more personal level, the proper balance of skepticism and trust has to be addressed patient-by-patient, doctor-by-doctor. In his *Time* essay, Scott Haig concluded that the “good” patient was somewhere in between the “noncompliant Bozo” and the suspicious Susan: a patient who had reasonable expectations of care, asked rational questions, and, after having her questions answered, put her trust in her doctor. For her part, Carolyn Thomas might define a “good” doctor as someone who earned and deserved that trust by (1) being open to their patients' questions, (2) keeping up to date on the latest developments in their areas of expertise (even when brought up by a patient), and (3) being skeptical consumers themselves in their dealings with drug detailers and medical device salesmen. Put those two definitions together and perhaps doctors and patients have more common ground from which to work with each other.

In today's highly fragmented, frequently dysfunctional, deeply politicized health care system, calm and cool discussions of patient consumerism are hard to have. But have them we must. For better and worse, the roles of doctor shopper and patient watchdog will likely remain prominent—and vexing—features of American patienthood for decades to come.

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Nancy Tomes, PhD, is a professor of history at Stony Brook University in New York. She is the author of several books and many articles on the history of American psychiatry, medicine, and public health, a former fellow at the National Humanities Center, and holder of a Robert Wood Johnson Investigator Award. Her latest book, *Shopping for Health: Medicine, Consumer Culture, and the Making of the Modern Patient*, is forthcoming from the University of North Carolina Press in fall 2014. She is president of the American Association for the History of Medicine.

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# Virtual Mentor

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## HISTORY OF MEDICINE

### **Patient Satisfaction: History, Myths, and Misperceptions**

Richard Bolton Siegrist, Jr., MBA, MS, CPA

Patient satisfaction is top of mind today for most health care organizations, from hospitals to physician practices to home health care agencies. Not only do a majority of senior health care executives have compensation tied to patient satisfaction scores, but hospital reimbursement is also being directly affected by inpatient satisfaction ratings as a part of the Center for Medicare and Medicaid Services (CMS) value-based purchasing program and private payer initiatives.

#### **History of Patient Satisfaction in Health Care**

It was certainly not always so. When Notre Dame professors Irwin Press, PhD, a medical anthropologist, and Rod Ganey, PhD, a sociologist and statistician, started Press Ganey in 1985, they essentially created a new market. They brought the science of sound survey design and administration to health care.

Press Ganey started out with just a handful of hospital clients. Each year over the next decade and a half, more and more hospitals saw the value that could be gained from tracking their patients' satisfaction and comparing it with that of other similar organizations. The number of companies providing services correspondingly grew to include such firms as NRC, Gallup, HealthStream, PRC, and Avatar.

During that same period, the survey's subject sites expanded from inpatient units to emergency, outpatient, ambulatory surgery, and medical practice departments, as well as other areas. The sophistication of data collection, analysis, and reporting continued to increase. Survey companies began to offer health care organizations advice on how to improve their satisfaction scores after the surveys had been administered and analyzed.

The federal government first became active in patient satisfaction in 2002 [1]. That year CMS and the Agency for Healthcare Research and Quality (AHRQ) collaborated to research, develop, and test the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. HCAHPS is a standardized 27-question survey administered randomly by approved vendors or the hospital to adult hospital inpatients after discharge.

After an extensive review process that included multiple opportunities for public comment, the HCAHPS survey was approved by the National Quality Forum in October 2005 and implemented by CMS in October 2006. The first public reporting of HCAHPS results occurred in March 2008, with voluntary reporting by hospitals.

As part of the Deficit Reduction Act of 2005, hospitals received a financial incentive (i.e., pay for reporting) for participating in HCAHPS starting in 2007 [1]. Not surprisingly, eligible hospital participation rose to nearly 95 percent that year [2]. These financial incentives were strengthened through the Affordable Care Act of 2010, under which hospital Medicare reimbursement (i.e., pay for performance) was influenced by comparative performance and improvement on HCAHPS [1]. Since HCAHPS results were first made publicly available, hospital scores overall have consistently increased with each new release of HCAHPS data [3-9].

### **Myths and Misperceptions**

With patient satisfaction assuming such a prominent role in health care, a number of myths and misperceptions about it have arisen. The rest of this article explores some of those myths and their implications.

*Myth #1: Very few patients fill out satisfaction surveys.* In most industries, the average response rate to customer satisfaction surveys is relatively low. The response rates in health care are substantially higher, most likely due to the relative importance of the health care experience compared to experiences with non-health-related products or services.

On the HCAHPS national results for hospital inpatient care covering patient surveys for the 12-month period of October 2011 through September 2012 [10], the average hospital response rate was 32 percent. Three-quarters of the hospitals had response rates greater than 27 percent, and one-quarter exceeded a 37 percent response rate.

*Myth #2: Patients who fill out surveys are generally unhappy with their care.* While this may be the case in non-health care industries, it is decidedly not true in health care. In the most recent HCAHPS national results, 70 percent of responding patients rated their hospitals 9 or 10 overall (often referred to as “top box”) on a scale of 0 to 10 [10]. As impressively, 92 percent of responding patients rated their hospitals a 7 or higher [10]. This positive experience led 71 percent of patients nationally to say they would definitely recommend the hospital to friends and family; 95 percent would probably or definitely recommend the hospital to friends and family [10].

Patients are particularly pleased with the communication from nurses and doctors. In the most recent HCAHPS results, 78 percent of patients said their nurses always communicated well, and 81 percent indicated that their doctors always communicated well [2].

While it does vary from one hospital to another, in general, respondents are happy with the care they receive.

*Myth #3: Only very unhappy or happy patients make comments on their surveys.* Patient comments may be one of the most useful aspects of a patient satisfaction survey. While numerical ratings are important, the comments can provide deeper

insights for the hospital into what is leading to high or low ratings. If only very unhappy or very happy patients were to add comments, then the comments could be misleading. However, this is not the case. According to a Press Ganey analysis of client hospital data for 2010, almost half of responding patients took the time to add comments on inpatient surveys, for an average of almost 3 comments per survey. The analysis indicated that 47 percent of patients who gave medium ratings commented (in addition to 59 percent of respondents who gave low ratings and 45 percent of those who gave high ratings). These comments are a rich, often underutilized resource for health care institutions to better understand how they can improve patient satisfaction.

*Myth #4: Patient satisfaction is primarily a popularity contest. Patient satisfaction and quality are not related. Patients can't evaluate the quality of care that is being delivered.* There is a fair amount of controversy about this area of discussion in the health care literature. Some research questions whether patient satisfaction correlates with quality. A 2012 article in the *Archives of Internal Medicine*, for example, reported that higher patient satisfaction was associated with lower emergency room use, but with higher levels of inpatient care, expenditure on drugs, and rates of mortality [11]. Despite this, a number of studies support the idea that, while patients may not understand the technical details of care, their perceptions of quality from what they see, hear, and feel can be remarkably accurate [12, 13]. Patients seem to be able to distinguish reasonably well between friendliness and competence. Is friendliness something that patients' value? Yes, but they see it as only part of the optimal patient experience.

A study reported in *Circulation: Cardiovascular Quality and Outcomes* in 2010 found that higher patient (and patient family) satisfaction was associated with lower risk-adjusted inpatient mortality rates for acute myocardial infarction, even after controlling for hospital performance on the core process measures for treating acute myocardial infarction [14]. The study authors conclude that "higher patient satisfaction is associated with improved [hospital] guideline adherence and lower inpatient mortality rates, suggesting that patients are good discriminators of the type of care they receive" [15]. Similarly, a 2011 article in the *American Journal of Managed Care* reported that higher patient satisfaction was associated with lower 30-day readmission rates for heart failure, heart attack, and pneumonia patients [12]. Additional studies have shown that organizations with higher patient satisfaction ratings tend to have fewer patient lawsuits and stronger financial performance [16, 17].

A 2013 systematic review of 55 studies in *BMJ Open* concludes that "the data presented display that patient experience is positively associated with clinical effectiveness and patient safety, and support the case for the inclusion of patient experience as one of the central pillars of quality in healthcare" [13]. At the end of the day, patients' perception of their care matters from both service and quality perspectives.

*Myth #5: You can't improve patient satisfaction scores significantly in any reasonable timeframe.* It is clearly not easy to improve patient satisfaction scores dramatically over a relatively short period of time. It requires a true commitment throughout the organization, constant attention to results, and usually a big change in the organization's culture. Yet, organizations have demonstrated that it can be done.

The Cleveland Clinic is a prime example. As a major academic medical center, it has a long-standing reputation for clinical excellence, consistently being ranked at the top of such surveys as that of the *U.S. News and World Report*. But until recently, it had not distinguished itself in patient satisfaction. In fact, when HCAHPS results were first publicly released, covering the 12 months ending June 2007, only 63 percent of Cleveland Clinic's patients gave it a top box score of 9 or 10 overall, putting it around the 55th percentile [3]. Six years later, that is up to 82 percent of patients or the 92nd percentile. Similarly, ratings of nurses' communication improved from 63 percent always communicated well to 81 percent, and doctor communication ratings improved from 72 percent to 82 percent [10, 3].

*Myth #6: If we build a nice new building, patient satisfaction scores will go up.* It is easy to attribute low satisfaction scores to overutilized capacity or a lack of recent capital investment in newer facilities. While these may contribute somewhat in certain circumstances, spending more money does not necessarily increase patient satisfaction. Surprisingly, it can lower satisfaction scores in the short term while staff gets used to working in the new facilities or as bottlenecks are moved from one location to another. For example, constructing a new emergency department with more capacity can result in increased overcrowding on the nursing floors as more patients are admitted, which can lead to a decline in patient satisfaction scores.

### **Improving Patient Satisfaction**

If the solution is not more bricks and mortar, what is it? It is relatively simple in concept, albeit difficult to implement.

As mentioned earlier, going beyond the numerical rankings to analyzing the comments—especially those about staff interaction—can be key to identifying meaningful change. Sentiment analysis is a new scientific approach to comment interpretation that is starting to be applied in health care to gain deeper insights into what patients are saying. It categorizes verbatim comments into meaningful groups and measures how strongly the patient feels using “natural language processing” to complement the numerical ratings.

In general, it is about the people—nurses, doctors, and staff. Patients consistently rank interaction with the health care staff as paramount in how they evaluate their health care experience, either positively or negatively. It is more specifically about communication and explanation from the clinical and nonclinical staff. If nurse and doctors communicate well with patients and explain what is happening and what to expect, patients react quite favorably and tend to overlook less important aspects of their experiences that may not be as positive. Expressed another way, the care

process needs to be patient-centered rather than clinician-centered, and that means effective communication.

Finally, it is about culture. The May 2013 *Harvard Business Review* article “Health Care’s Service Fanatics: How the Cleveland Clinic Leaped to the Top of Patient-Satisfaction Surveys” provides important insights into how Cleveland Clinic was able to transform itself from a patient experience perspective [18]. Not surprisingly, it started with CEO Toby Cosgrove, MD, making it a strategic priority, but it ultimately involved a culture change throughout all levels of the organization. As illustrated by the experience of Cleveland Clinic and other health care organizations, patient satisfaction can be dramatically improved if one looks beyond the myths and misperceptions to the reality of what can and should to be done to enhance the patient experience.

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Richard Bolton Siegrist, Jr., MBA, MS, CPA, is director of innovation and entrepreneurship, associate academic director of the master's in health care management program, and adjunct lecturer on management at the Harvard School of Public Health in Boston. He was previously the CEO of Press Ganey Associates and the co-founder and CEO of several health care software companies dealing with cost accounting, comparative analysis, and patient flow.

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## OP-ED

### **Consumerism in Health Care: Challenges and Opportunities**

Richard Zeckhauser, PhD, and Benjamin Sommers, MD, PhD

The era of consumerism in health care has arrived. Direct-to-consumer advertising of pharmaceuticals, health newsletters from leading hospitals and medical schools, and, most importantly, the near-ubiquity of the Internet have made it easy for consumers to obtain information about their medical conditions and possible treatments. This presents health care providers and patients with both challenges and opportunities.

#### **Challenges of Consumerism in Patient Care**

Some studies suggest that patients' consumerism can negatively affect the quality of patient-doctor communications [1, 2]. Physicians are constrained by schedules that limit the typical office visit to 17 minutes [3]. In this context, spending a considerable portion of appointment time trying to correct misperceptions held by consumerist patients who may hold strong opinions with little medical or scientific background is inefficient and impractical. In addition, consumerism among patients may engender negative feelings among doctors. Physicians may feel that consumerism erodes the respect accorded to their profession [4], and many physicians have mixed feelings about discussing web-based medical information during the clinical encounter [5].

Difficulties can arise when the patient's preconceptions clash with the doctor's assessment. Perhaps less information gets effectively exchanged. Even when more information is in fact exchanged, the patient may discount what he or she hears from the doctor. Consider a patient who arrives at the doctor's office, having already settled in his or her own mind on a diagnosis and preferred treatment. To simplify the problem, assume the patient and doctor agree on the diagnosis. However, the doctor differs strongly as to the treatment, perhaps telling the patient to keep off an injured leg rather than strengthen it by exercise, the patient's selected therapy. The field of behavioral psychology tells us that people often anchor on the first guess, opinion, or option presented to them [6]. The patient, having anchored on therapeutic exercise, is now told that rest is required. The conflicting beliefs are likely to lead to poor adherence. This is a relatively trivial example. Far more consequential examples arise when patients forgo well-established treatments, say, for cancer, for what is essentially evidence-free medicine [7].

Overall, consumerism may raise the possibility of disagreement and worsening communication between patients and providers, mutual frustration, and inefficient use of patient-clinician visit time. Of course, this is only part of the story.

## **Opportunities for Consumerism to Improve Care**

This is not to say that patient empowerment and participation in decision making are neither necessary nor valuable. It is usually the case that patients, even those who lack technical knowledge, have valuable insights into their health that can improve the quality of care [8]. Moreover, studies have demonstrated that playing a role in medical decision making is important to patients, although results vary based on patient demographics and on the complexity of the medical decisions [9, 10]. Surely, most patients have a much greater personal investment in their own well-being and treatments than their clinicians do and are therefore willing to devote much more time to proper determinations of diagnosis and treatment.

This situation is typical of what economists refer to as a principal-agent problem. The patient is the principal, the individual whose interests are to be served. The doctor is the agent, called upon to contribute his or her superior knowledge. Here, the principal's and the agent's interests are well aligned with respect to outcomes: both want the patient to be in good health. However, their interests diverge strongly when it comes to the amount of effort the agent should expend. Most patients would be delighted (and surprised) if their doctors spent an hour assessing their particular conditions, examining the relevant literature, and prescribing treatments. The agent, a busy doctor, is constrained by the amount of time he or she can realistically spend with each patient.

Furthermore, as Jerome Groopman [11] has described, the typical physician's approach under such time pressures can lead to errors. Here is where we start to see some of the advantages of consumerism. Physicians think in patterns and are at risk of leaping to conclusions too early, often ignoring or minimizing subtleties that do not fit their preconceived patterns. They subject patients to rule-of-thumb choices and what have been labeled "ready-to-wear" treatments, when treatments customized to the patient would be far superior [12].

We suspect that patients are often consulted far too little about their symptoms and preferences and that treatments are, therefore, suboptimal. The physician may not carefully listen when patients provide information he or she otherwise could not possibly know, such as information about their preferences or symptoms that diverge strongly from those usually associated with the suspected condition. In many medical contexts, patients are consulted too little [13]. That is, some physicians fail to base treatment decisions on patient preferences when those preferences are critical for choosing the most appropriate treatment [14] or when the patient's symptoms have changed significantly [12, 15].

Take prostate cancer, for example. The most prominent treatments for this disease pose different risks for side effects and long-term outcomes. A physician can easily tailor a treatment to a patient's age and tumor risk profile. Without asking the patient directly, however, the physician cannot know how the patient would fare psychologically with watchful waiting or what tradeoff he would make between the risks of erectile dysfunction and of metastatic disease.

Several years ago, we helped lead a study that employed a questionnaire to inquire of prostate cancer patients their preferences for various outcomes of treatments, as indicated by quality-adjusted-life-year (QALY) equivalents. The questionnaires were distributed at two urology clinics and two radiation oncology clinics. We followed up by looking at the patients' eventual treatments. The results were disappointing. Though patient preferences should factor prominently in appropriate treatment choices, the respondents' ultimate treatments bore little relation to the preferences they described. The treatment a patient received was most strongly correlated with the specialty of the consulted physician. This result persisted even though the physicians prescribing the treatments knew that we were conducting this study [16].

It is equally disturbing that, for some chronic conditions, physicians fail to adjust their treatment plans as a result of realized outcomes. For instance, two studies of care for patients with depression show that the likelihood of a physician's changing a treatment regimen is essentially independent of whether the patient's symptoms improve or worsen [12, 15]. In many cases, physicians pick a treatment and stick to it, even if evidence emerges that the treatment is not working.

All these problems may impel patients to become "consumerists," devoting substantial time to investigating their own conditions, looking into available treatments, and, as Groopman recommends, asking their clinicians to reconsider whether there is anything about their cases that does not fit the patterns the clinicians have identified. In this context, consumerism can be a boon.

### **A Prescription for Better Care Through Consumerism**

Taking these potential advantages and disadvantages of medical consumerism into consideration, we suggest the following prescription for the patient: (1) Undertake substantial knowledge gathering on your own, with the intention that you will impart it to your physician without getting too attached to your own view. (2) Ideally, your assessment should not differ dramatically from that of your doctor or of established medical evidence—or else (and sometimes this is essential) you should find another doctor.

Our prescription for clinicians is the following: (1) When you are struggling with a difficult diagnosis or find that your initial treatment plan is not succeeding, stop and ask that patient directly for insights about what might be going on and for any suggestions for improving your management. (2) When approaching decisions involving complicated tradeoffs among different outcomes, explore with your patients what they most value or fear; there is simply no way to make some medical decisions properly without that knowledge. (3) When you encounter a patient who seems overly assertive, argumentative, or opinionated, make sure you are not ignoring items 1 and 2 above—your approach may well have motivated his or her consumerism.

The proliferation of easily available information (of varying quality) related to health conditions, testing options, and treatments means that patients are likely to be

increasingly involved, alongside their clinicians, in medical decision making. Consumerism in medicine is here to stay. While this may cause inefficiencies—and sometimes headaches—that need to be managed appropriately, consumerism has the potential to improve communication between patients and clinicians and to facilitate better shared decision making. How well patients and clinicians strike this balance will be one of the emerging challenges of practicing medicine in the decades to come.

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14. While we accept the notion that patient preferences are always important in the context of respecting patient autonomy, they are not always *determinative*

because the consensus across all individuals may be broad and easy to assume. For instance, in deciding whether to treat a life-threatening infection that would be easily cured with 3 days of oral antibiotics, most clinicians would assume (probably correctly) that any patient pursuing medical care—if well informed—would want to take the antibiotic. In these cases, given that the vast majority, if not 100 percent, of patients would prefer the same outcome, it would make little sense for a clinician to engage in a long, thoughtful conversation with the patient about his or her preferences in this scenario. This contrasts with our prostate cancer example, in which the “right” answer about treatment varies considerably from person to person, depending strongly on preferences.

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Richard Zeckhauser, PhD, is the Frank P. Ramsey Professor of Political Economy at the John F. Kennedy School of Government at Harvard University in Cambridge, Massachusetts. He is an economist and decision scientist whose research frequently examines the ways decisions are made, both well and poorly, by individuals and groups. Medical and health care examples often illustrate his studies.

Benjamin Sommers, MD, PhD, is an assistant professor of health policy and economics at the Harvard School of Public Health and an assistant professor of medicine at Harvard Medical School and Brigham and Women’s Hospital in Boston. He is a health economist and a practicing primary care physician whose research focuses include Medicaid, health insurance reform, and medical decision making.

### **Related in VM**

[The Patient as Consumer Watchdog](#), November 2013

[Responding to Patients’ Requests for Nontraditional or Unproven Treatments](#), November 2013

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## Virtual Mentor

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### Suggested Readings and Resources

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# Virtual Mentor

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## About the Contributors

### Theme Issue Editor

Ravi B. Parikh is a fourth-year student at Harvard Medical School in Boston and a Knowles Fellow at the John F. Kennedy School of Government at Harvard University in Cambridge, Massachusetts. Ravi is the administrative chair of the Crimson Care Collaborative, a network of student-run clinics in Boston that serves patients who have limited access to primary care. His opinion pieces have been published in the *Washington Post*, *Huffington Post*, the *Philadelphia Inquirer*, the *Boston Herald*, and the *Tampa Bay Times*, and he is an editor of *Medgadget*, a blog about medical technology and innovation.

### Contributors

David A. Axelrod, MD, is chief of transplant surgery at the Geisel School of Medicine at Dartmouth College in Hanover, New Hampshire. Dr. Axelrod chairs the United Network for Organ Sharing's Organ Procurement and Transplantation Network (OPTN/UNOS) pancreas transplantation committee. In addition, he is the chairman of the business practice committee for the American Society of Transplant Surgeons and creator of its Leadership Development Program. He is the author of more than 50 publications in the area of transplantation economics and outcome research and lectures nationally on these topics.

Michael A. Batista is a second-year doctoral student in the Center for Bioengineering Innovation and Design at Johns Hopkins University in Baltimore, where his work focuses on the translational development of new medical technologies and tools. He was a founding team member of the Smartphone Physical exhibit, which has been featured at conferences and events across the country to promote mobile-based health care technologies.

O'Neil Britton, MD, is the chief health information officer of Partners HealthCare in Boston. He is a senior clinician in the Department of Medicine at Brigham and Women's Hospital and former chief medical officer at Brigham and Women's Faulkner Hospital. His career pursuits have focused on clinical operations, quality improvement and patient safety, and the education and mentoring of trainees and students.

T. Forcht Dagi, MD, DMedSc, MPH, is distinguished scholar and professor at the School of Medicine, Dentistry and Biomedical Sciences at Queen's University Belfast and holds an appointment in the Division of Medical Ethics in the Department of Global Health and Social Medicine at Harvard Medical School in Boston. Dr. Dagi is an editor of *Neurosurgery* and of the *Journal of Clinical Ethics*.

He is a neurosurgeon, medical educator, and medical ethicist with particular interests in the ethics of uncertainty, diversity, and international disaster assistance.

Shiv M. Gaglani is a second-year MD/MBA student at the Johns Hopkins School of Medicine in Baltimore and Harvard Business School in Boston. He is the co-founder and CEO of the medical education technology company Osmosis and an editor of the medical technology blog *Medgadget*. Shiv curated the Smartphone Physical exhibit that was featured at TEDMED 2013.

Aaron S. Kesselheim, MD, JD, MPH, is an assistant professor of medicine at Harvard Medical School in Boston and a faculty member in the Department of Medicine's Division of Pharmacoepidemiology and Pharmacoeconomics of Brigham and Women's Hospital, where he runs the Program On Regulation, Therapeutics, And Law (PORTAL).

Tara LePage, MPH, is a recent graduate of Boston University School of Public Health with a concentration in health policy management. Her career interests include providing strategies to improve the quality of life of nursing home residents and analyzing the barriers to health information technology adoption in the elderly population.

Ateev Mehrotra, MD, MPH, is an associate professor in the Department of Health Care Policy at Harvard Medical School in Boston. Dr. Mehrotra's research focuses on the impact of innovations in delivery on the costs and quality of health care.

Alon B. Neidich is a medical student at Tufts University School of Medicine in Boston. He obtained a bachelor's degree with honors in law, letters, and society from the University of Chicago, where he was a Howard Hughes Medical Institute Fellow investigating informed consent and women's attitudes toward obstetric and pediatric biobanks. His work has been published in the *American Journal of Transplantation*, *Progress in Transplantation*, the *American Journal of Medical Genetics*, the *Journal of Medical Ethics*, and *The New Physician*.

Eitan Neidich is a medical student at the University of California, San Francisco. He obtained a bachelor's degree with honors in political theory, science, and law from Cornell University. His work has been published in the *Journal of the Royal Society Interface*, *Progress in Transplantation*, and the *American Journal of Transplantation*.

Susan P. Pauker, MD, is an associate professor at Harvard Medical School, chief of medical genetics at Harvard Vanguard Medical Associates (formerly HCHP), and a member of the Genetics Unit at Massachusetts General Hospital, where she trained as a genetics fellow. She is a founding fellow of the American College of Medical Genetics and has served on its board. Dr. Pauker specializes in individual decision support for prenatal and preconception prevention of birth anomalies.

Rachel O. Reid, MD, MS, is a resident physician in the Department of Medicine at Brigham and Women's Hospital and a clinical fellow in medicine at Harvard Medical School in Boston. Dr. Reid's research interests encompass the primary care delivery system and how cost and quality data relate to decisions in health care.

John P. Roberts, MD, is the chief of the Division of Transplantation at the University of California, San Francisco. He has produced nearly 170 papers on topics including allograft rejection, immunogenicity, immunosuppression, and others. Dr. Roberts has served as the president of the United Network for Organ Sharing's Organ Procurement and Transplantation Network (OPTN/UNOS) board of directors and its corporate affairs committee, as well as the American Society of Transplant Surgeons.

James E. Sabin, MD, is a clinical professor in the Departments of Population Medicine and Psychiatry at Harvard Medical School in Boston, a member of the American Medical Association Council on Ethical and Judicial Affairs, and the director of the ethics program at Harvard Pilgrim Health Care, a not-for-profit health plan. His research interests include the ethics of health care resource allocation. Dr. Sabin blogs on ethics at [healthcareorganizationalethics.blogspot.com](http://healthcareorganizationalethics.blogspot.com) and on aging issues at [www.over65.thehastingscenter.org](http://www.over65.thehastingscenter.org).

Richard Bolton Siegrist, Jr., MBA, MS, CPA, is director of innovation and entrepreneurship, associate academic director of the master's in health care management program, and adjunct lecturer on management at the Harvard School of Public Health in Boston. He was previously the CEO of Press Ganey Associates and the co-founder and CEO of several health care software companies dealing with cost accounting, comparative analysis, and patient flow.

Benjamin Sommers, MD, PhD, is an assistant professor of health policy and economics at the Harvard School of Public Health and an assistant professor of medicine at Harvard Medical School and Brigham and Women's Hospital in Boston. He is a health economist and a practicing primary care physician whose research focuses include Medicaid, health insurance reform, and medical decision making.

Nancy Tomes, PhD, is a professor of history at Stony Brook University in New York. She is the author of several books and many articles on the history of American psychiatry, medicine, and public health, a former fellow at the National Humanities Center, and holder of a Robert Wood Johnson Investigator Award. Her latest book, *Shopping for Health: Medicine, Consumer Culture, and the Making of the Modern Patient*, is forthcoming from the University of North Carolina Press in fall 2014. She is president of the American Association for the History of Medicine.

Bo Wang, PharmD, is a licensed pharmacist and third-year medical student at Harvard Medical School in Boston. His research interests include pharmaceutical regulation and adherence.

Richard Weinmeyer, JD, MPhil, is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs. Mr. Weinmeyer received his law degree from the University of Minnesota, where he completed a concentration in health law and bioethics and served as editor in chief for volume 31 of the law journal *Law and Inequality: A Journal of Theory and Practice*. He obtained his master's degree in sociology from Cambridge University and is completing a second master's in bioethics from the University of Minnesota Center for Bioethics. Previously, Mr. Weinmeyer served as a project coordinator at the University of Minnesota Division of Epidemiology and Community Health. His research interests are in public health law, bioethics, and biomedical research regulation.

Richard Zeckhauser, PhD, is the Frank P. Ramsey Professor of Political Economy at the John F. Kennedy School of Government at Harvard University in Cambridge, Massachusetts. He is an economist and decision scientist whose research frequently examines the ways decisions are made, both well and poorly, by individuals and groups. Medical and health care examples often illustrate his studies.

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