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When Patients Can't Afford Drugs

Viewpoint

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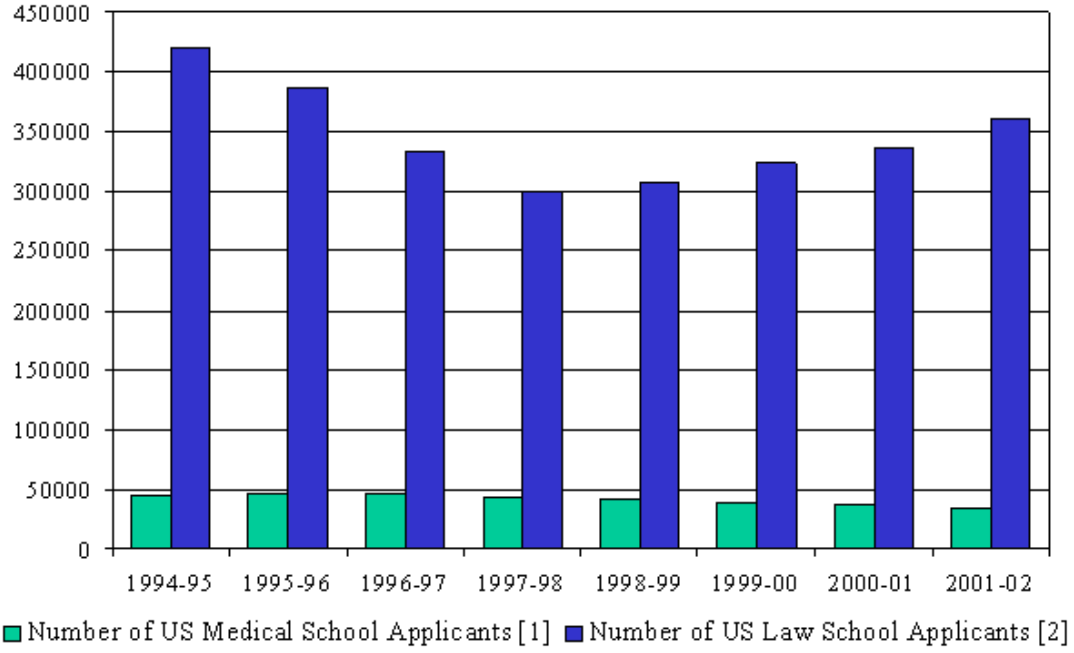
FROM THE EDITOR
What's Wrong With This Picture?
Audiey Kao, MD, PhD

Figure. Bar chart of law vs. medicine



[1] Source: Association of American Medical Colleges
[2] Source: American Bar Association; law school applicants for full-time or part-time programs

Audiey Kao, MD, PhD is the editor in chief of *Virtual Mentor*.

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CASE AND COMMENTARY
Patients Who Can't Afford Drugs, Commentary 1
Commentary by Amy Haddad, PhD, RN

Case
Mrs. Michaels has been under treatment for hypertension for several years. She started with a well known, brand-name drug, which effectively reduced her blood pressure. She has a steady full-time job and some employer-sponsored health insurance that includes a prescription benefit. The prescription co-payments, however, have increased dramatically, especially on brand-name drugs. On several visits, when her blood pressure was high, Mrs. Michaels told Dr. Bennett, her physician, that she had postponed getting her prescription filled for several weeks because she didn't have the money at the time. Her salary barely covers her urban living expenses, food, and transportation to her job.

Because Mrs. Michaels cannot afford to take the brand-name drug all the time, Dr. Bennett has prescribed several generic versions, as each came on the market. Unfortunately, none reduced her hypertension effectively, so she is again using the brand-name drug. One day, after another increase in her blood pressure, Mrs. Michaels told Dr. Bennett that a co-worker of hers takes the same brand-name hypertension drug. The co-worker gets a month's supply of 40-mg pills for the same co-pay that Mrs. Michaels is charged for her one-month's supply of 20-mg tablets under the same prescription benefit policy. Mrs. Michaels asks Dr. Bennett whether he will prescribe the 40-mg tablets under the pretense that it is a one-month's supply. She will split the tablets in half, so that she gets her prescribed 20 mg a day and the prescription lasts for 2 months. "You and I will know that I only take ½ tablet a day," Mrs. Michaels says to Dr. Bennett. "But the pharmacy will think that I am taking one tablet a day and getting a one-month supply." She adds, "That's the only way I can take this medicine every day, all year long. Otherwise, I have to skip it about half the time."

What should Dr. Bennett do? When trying Mrs. Michaels on generic drugs, he was able to offer her samples, but, of course, he cannot continually supplement Mrs. Michaels' prescription with drug company samples.

Commentary 1
The moral life, for health professionals and everyone else, comprises multiple and competing duties. It is not the case of deciding between wrong and right, but between or among numerous conflicting obligations all demanding our moral attention. Our days are filled with choices, largely unconscious, that indicate which

obligations or duties should, for the moment, receive priority. The case in question presents several duties in conflict, the most obvious being the duty of Dr. Bennett to Mrs. Michaels. But the physician also has obligations to his colleagues in whatever practice setting he works, the values of the medical profession, the third-party payer, and the pharmacy benefit manager. Taken further, the physician as health professional and citizen in the larger society has obligations to promote the common good. Clearly, the costs of prescription drugs is of great concern to many individuals especially those who do not have the benefit of drug coverage as part of their health insurance. As the case indicates, even those with drug coverage may have difficulty in affording the co-pays that are part of the health plan. So, the case includes much more than the basic problem of whether or not to comply with the patient's request to commit fraud (for that is basically what the patient is asking Dr. Bennett to do). Rather, imbedded in this problem of an individual patient who cannot afford a brand name drug that works best for her are institutional and societal ethical concerns.

In *The Three Realms of Ethics*, John W. Glaser proposes a model that views ethics in 3 realms: individual, institutional, and societal.[1] Most work in contemporary ethics focuses on the individual realm, so much so that the tools we use to resolve ethical problems at the individual level are, Glaser contends, inappropriately applied to concerns at the institutional and societal levels. It is worthwhile to think about Mrs. Michaels' case from the broader perspectives of institutional and societal levels because decisions in the areas of policy development, benefit design, drug detailing, and drug pricing have profound effects on structuring the particular situation in which Dr. Bennett and Mrs. Michaels find themselves.

Societal ethics deals with the common good of society. Attending to the common good requires balancing the many conflicting goods realized at this level—education, housing, recreation, health care, defense, etc. Within health care, there is also the need to balance acute and chronic care needs, administration and direct care services, and research and technology development. Although drug therapy provides great good to many people, its benefits and burdens must be weighed against other goods in health care. From a societal perspective, the growth in costs of prescription drugs must be recognized as having a significant impact on clinical outcomes. One area that should be questioned is the drug manufacturers' high expenditures on physician marketing and direct-to-consumer advertising. These costs significantly surpass the cost of research and development and are folded into the price of the products, thus creating a greater problem of drug affordability than the research and development alone. The argument made by the industry is that the education of health care professionals and patients is in their best interest. However, a counter argument can be made that this is really the responsibility of basic professional education and continuing education, not the job of a manufacturer or distributor.

It would be interesting to see a case that included the actual cost of the brand-name drug along with a break-out of 3 categories of costs allocated to each pill as a

percentage of the total cost per pill as follows: (1) the cost associated with the annual manufacturing and distribution of the drug; (2) the cost associated with recovery of the research and development investment over the life of the drug patent; and (3) the cost associated with annual professional marketing and direct-to-consumer advertising for the drug. This would give us some idea why the brand-name drug that Mrs. Michaels needs is so expensive. Since Dr. Bennett, Mrs. Michaels, the commentators, and the readers do not have access to this information, this aspect of the case and the associated societal issues cannot be fairly evaluated.

Institutional ethics deals with the good and thriving of the individuals within the institution as well as the institution as a whole within the larger community. Institutions can be as small as a family or group practice and as large as a health plan with hundreds of thousands of people. In this case, the example of a fixed co-payment per prescription that is part of the "institution" of the health plan seems to put the patient in an impossible situation. The logical way out of this impossible situation is for Mrs. Michaels to ask Dr. Bennett for an incorrect prescription to be written to achieve affordability. This kind of action is not safe for the patient, and must also involve the pharmacist in the conspiracy. It also adds to the potential risk of medication errors. The fixed dollar co-payment amount was generally designed to benefit the consumer. In this case it is working against Mrs. Michaels' benefit. Perhaps a percentage co-payment would be a more fair approach for rational distribution of the health care premium dollar. It is possible that, if enough physicians were to suggest such a change, that there might be a shift in the way the benefits are designed in the health plan. Nevertheless, the cost of the drug remains an issue for the patient regardless of whether it is at the point-of-sale or in the monthly health care premium.

Individual ethical concerns cover familiar ground in bioethics. This realm is concerned with the well-being and thriving of individuals. In this case, we would focus on the potential benefits and harms to Mrs. Michaels if she does or does not receive the drug that is presently identified as being the drug of choice for her. The facts presented in this case present a troubling assumption. The case states that the physician "has prescribed several generic versions, each as they came on the market. Unfortunately, none reduced her hypertension effectively . . . ." Presented this way, it appears that it is common for patients to have difficulty achieving the same therapeutic effect from the "generic versions" of brand name drugs. However, the opposite is true. Based on the thoroughness of the FDA approval process, the reality is that it is unusual for a patient not to be able to take one of the generic versions of a brand name drug and achieve the same clinical effect. If Mrs. Michaels is one of the rare patients who cannot control her blood pressure on one of the many generic drugs on the market, then her case should be treated differently. This sort of "discrimination" is appropriate when other avenues have been exhausted and the patient stands the chance of suffering long-term harms that are the result of hypertension.

Furthermore, we would look at the harms and benefits that would occur should Dr. Bennett agree to write a fraudulent prescription. Although in the short run Mrs. Michaels may benefit from this ruse, the very act of resolving the problem so myopically diminishes not only the physician's integrity but also ignores the larger issues that created the problem in the first place. If a particular patient's case represents larger inadequacies within the health care system, and Mrs. Michaels' case certainly does, then the physician is obligated to be an advocate for changing the system for all of the physician's patients, present, and future.

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CASE AND COMMENTARY
Patients Who Can't Afford Drugs, Commentary 2
Commentary by Audiey Kao, MD, PhD

Case
Mrs. Michaels has been under treatment for hypertension for several years. She started with a well-known, brand-name drug, which effectively reduced her blood pressure. She has a steady full-time job and some employer-sponsored health insurance that includes a prescription benefit. The prescription co-payments, however, have increased dramatically, especially on brand-name drugs. On several visits, when her blood pressure was high, Mrs. Michaels told Dr. Bennett, her physician, that she had postponed getting her prescription filled for several weeks because she didn't have the money at the time. Her salary barely covers her urban living expenses, food, and transportation to her job.

Because Mrs. Michaels cannot afford to take the brand-name drug all the time, Dr. Bennett has prescribed several generic versions, as each came on the market. Unfortunately, none reduced her hypertension effectively, so she is again using the brand-name drug. One day, after another increase in her blood pressure, Mrs. Michaels told Dr. Bennett that a co-worker of hers takes the same brand-name hypertension drug. The co-worker gets a month's supply of 40-mg pills for the same co-pay that Mrs. Michaels is charged for her one-month's supply of 20-mg tablets under the same prescription benefit policy. Mrs. Michaels asks Dr. Bennett whether he will prescribe the 40-mg tablets under the pretense that it is a one-month's supply. She will split the tablets in half, so that she gets her prescribed 20 mg a day and the prescription lasts for 2 months. "You and I will know that I only take ½ tablet a day," Mrs. Michaels says to Dr. Bennett. "But the pharmacy will think that I am taking one tablet a day and getting a one-month supply." She adds, "That's the only way I can take this medicine every day, all year long. Otherwise, I have to skip it about half the time."

What should Dr. Bennett do? When trying Mrs. Michaels on generic drugs, he was able to offer her samples, but, of course, he cannot continually supplement Mrs. Michaels' prescription with drug company samples.

Commentary 2
This clinical case presents physicians with one of the most difficult challenges of patient care—how to ensure your patients' access to needed medical services and treatment. In this specific circumstance, an insured patient with prescription drug reimbursement coverage comes to a physician asking for assistance in paying for

her prescription medication. The patient's "solution" is for the physician to write a prescription for double her prescribed dose, thus allowing her to pay for a two-month supply on a single co-payment.

Paying for high-priced prescription drugs is an increasing problem in the United States. According to a recent national survey, almost 3 in 10 people say they have not filled a prescription because of the cost; one-quarter say they have given up other things to buy prescription drugs for themselves or their families; and 1 in 10 report having to curtail basic necessities, cutting down on food, for example, to pay for prescription drugs.[1] The circumstances of this case are certain to become more common for physicians and their patients.

As with most challenging clinical ethics cases, it is oftentimes easier to say what you shouldn't do, and more difficult to map out a course you would follow in addressing the pressing need at hand. First, a physician should not write an erroneous prescription purposely, even if his or her intentions are good. Beyond the potential legal consequences of such actions, a physician undermines key foundational ideals that define the medical profession—honesty and truth telling. Even if one considers such actions to be an immediate remedy to this specific problem, it cannot serve as a long-term solution because the patient is likely to require other costly medical treatments. The physician may well be in a similar situation in the future, when the patient suggests less "benign" solutions—falsely coding a diagnosis, perhaps, to get coverage on a medical test. If the ethical prescription in this case is to not write an erroneous prescription, then what should Dr. Bennett do?

Based on the information provided, all other therapeutic options seem to have been exhausted. Assuming this to be so, resolving this case revolves around who will pay for the expensive but needed medication. According to the pharmaceutical industry, more than 3.5 million patients received prescription medications through patient assistance programs in 2001.[2] These programs, which are administered by individual drug companies, offer eligible patients, typically low income individuals who do not have health insurance, free access to prescription drugs. Mrs. Michaels is unlikely to be eligible for such programs because she has health insurance that includes prescription drug benefits. Despite that, it is clear that Mrs. Michaels is better off than most people who have no health insurance at all, and herein may lie the solution to this case.

First, Dr. Bennett must be confident that Mrs. Michaels understands the importance of treating her hypertension and the health consequences of not managing it adequately. Oftentimes, patients fail to understand the necessity of controlling their high blood pressure because it is a disease that typically has no symptoms. Second, all of us make tradeoffs in how we spend our financial resources. There are certain things we must have, such as food, shelter, and medical care, and other things that we would like to have. This is typically not a topic of discussion between patients and their physicians, but I believe that it is important in this specific case. If Mrs.

Michaels understands the medical necessity of treating her hypertension, then it is rational for her to pay for certain needs by forgoing certain "wants" that she could live without. This solution is based on the assumption that Mrs. Michaels, who is employed and has medical insurance, can make such financial tradeoffs. If, indeed, she cannot, she may be eligible for drug company patient assistant programs. The solution has broader implications, though. We should all take greater personal responsibility for our health and health care, regularly assessing what life changes and sacrifices we are willing to make to prevent illness and treat it when it occurs.

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Audiey Kao, MD, PhD is the editor in chief of *Virtual Mentor*.

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IN THE LITERATURE
If Role Models Do Model Roles
Faith Lagay, PhD

Medicine has traditionally relied on senior physicians to impart values and attitudes to the upcoming generation of physicians through their actions and behavior. In a recent issue of the *British Medical Journal*, three investigators reviewed existing research on the traits medical students and clinicians look for in senior physician role models, whether they find the traits they seek, and whether they, in fact, adopt the traits they claim to seek.[1]

Authors Elisabeth Paice, Shelley Heard, and Fiona Moss explain that role models are people "we can identify with, who have qualities we would like to have, and are in positions we would like to reach."[2] The authors found much overlap in the qualities that student and clinician participants in various studies listed as traits they looked for in role models. All lists included compassion for patients and respect for colleagues, clinical reasoning skill and competence, enthusiasm for their subjects and for teaching, integrity, and interest in psychosocial aspects of patient illnesses.

Such results would lead to the conclusion that medical students and doctors-in-training value patient care, respect for peers, and concern for the education of new physicians, and that they seek role models who support them in developing these attitudes and values in practice. But the journal authors sought answers to 2 more questions: do students *find* role models for the qualities they seek and do they actually *emulate* the behaviors they claim to value? The latter inquiry led them to the work of psychiatrist-anthropologist Simon Sinclair. Sinclair found that "students were drawn to and emulated senior doctors who had responsibility and status . . . . He also observed the students learning an aversion to investigating patients' social and psychological problems."[3]

Studies of the former question—do students find role models for the qualities they seek—produced interesting results also. The *BMJ* authors cite surveys in which (1) students considered their teachers to be insensitive toward them and toward patients, (2) clinical teachers rated themselves "wanting" as role models and expected better patient-physician relationships from their students, and (3) students reported witnessing unethical behavior among their teachers.[4]

In light of the findings they summarize, authors Paice, Heard, and Moss question the wisdom of relying on role models to hand down professional values. In counting on senior physicians to model behavior for junior physicians, we may have "created

a built-in resistance to change," they say.[5] In other words, role-modeling may perpetuate the older paternalistic mode of medical interaction rather than the patient-centered alternative that society has been urging on medicine since the 1970s. The authors suggest a less serendipitous, more formalized method for transfer of professional values: mentorship. In mentorship, students are matched one-on-one with individuals who become actively engaged with them. The mentor role is consciously chosen and voluntary. Students can be matched with mentors whose attitudes coincide with professional ideals and society's changing expectations. The medical profession will not change from "one that is paternalistic to one that is self-aware and quickly responsive to society's expectations . . . through emulating our predecessors," the authors conclude.[5]

Questions for Discussion

1. Survey findings cited by the authors suggest that medical students and junior physicians claim to admire one set of traits in senior physicians but emulate other traits. Why do you think surveyed students and others misrepresent the traits they value or, conversely, emulate traits they do not value?
2. Role modeling will not disappear. In all walks of life, people emulate what "succeeds." Should the medical profession attempt to change its definition of "a successful physician"? If so, how?
3. Is there something inherent in the health care system that makes it difficult to be both a compassionate, sensitive, and medically competent doctor and one with responsibility and status?
4. To what degree should "responding to society's expectations" be part of the definition of professional success?

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AMA CODE SAYS
AMA Code of Medical Ethics Serves as "Gold Standard"
Audiey Kao, MD, PhD

Paul Glader's *Wall Street Journal* article (11/12/02), "Doctors Question Use of Dead or Dying Patients for Training" begins with a provocative statement: "Unbeknownst to the vast majority of family members, after a patient dies in the emergency room of many hospitals, a senior physician draws a curtain and supervises young doctors practicing several rounds of emergency medical techniques on the deceased." Glader quickly acknowledges that the AMA's Council on Ethical and Judicial Affairs adopted a report in June 2001 that no training be performed on newly dead patients unless the patient or family members had given prior consent.

That report became Opinion 8.181 in the 2002-2003 *Code of Medical Ethics*.[1] But the AMA *Code* is non-binding, and there is no way to know how many hospitals enforce the "with-consent-only" guideline. Some physicians think the AMA position hinders the training of medical students and residents, arguing that emergency room physicians must know how to perform difficult procedures such as intubation. If they don't, some say, future patients will die.

Supporters of the *Code's* position, like Paul Wolpe at the Center of Bioethics at the University of Pennsylvania whom Glader quotes in the *WSJ* article, believe that the AMA policy "will serve as a gold standard for hospital ethics boards."

Glader mentions that the *Code* opinion, entitled "Performing Procedures on the Newly Deceased for Training Purposes", does not address the practice followed in some hospitals of allowing training on *nearly* dead patients. While that statement is correct as it applies to this particular opinion, other *Code* opinions specifically prohibit performing procedures on living patients without their consent, that of their family members, or that of their designated decision makers.

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STATE OF THE ART AND SCIENCE

Adopting the Unborn

Swathi Arekapudi

In vitro fertilization has helped to produce tens of thousands of children since the procedure became widespread in the mid-1980s.[1] As with any new medical technology, several unexpected problems developed, such as what to do with the more than 200,000 excess frozen embryos stored in fertility clinics around the country.[2] While many countries have national policies governing how long such embryos can be stored, the US does not. Entrenched in the debate over what to do with unwanted embryos is the uncertain legal and moral status of the embryos themselves.

A US couple faced with the question of what to do with their excess embryos currently has 3 options: (1) discard the embryos, (2) donate the embryos to a non-federally funded lab for research purposes, including embryonic stem cell research, or (3) donate the embryos so that other infertile women may use them.

In late August, the Bush administration announced its plan to publicize what it refers to as "embryo adoption" by offering individual grants ranging from $200,000 to $250,000 and totaling approximately $1 million.[3] Like embryo donation where couples give their unused embryos for research, couples may also give extra embryos to another infertile couple for "adoption." Babies born by this process are considered the children of the recipient couple. Organizations may apply for the federal grant dollars to fund public awareness campaigns promoting donation of embryos.

The term "embryo adoption" was originally coined by Nightlight Christian Adoptions.[4] The director for Snowflakes, the agency's embryo program, explained that "we use the adoption language and materials with the hopes of setting a precedent that someday the court will say embryos need to be handled like any other child."[5] Knowledge of the origin of the term embryo adoption has fueled sharp criticism of the Bush administration by abortion rights groups.

One pressing question about this program is why embryo adoption is deemed to need governmental support. Critics argue that the administration is using the embryo adoption program to confer upon the embryo the rights of a fully developed person, as if it were a baby. Much of this argument stems from the use of the term "adoption." How, critics argue, can one "adopt" a 6-celled embryo as if it were the equivalent of a child? Certainly a private laboratory that uses donated embryos for

research purposes does not adopt them but merely accepts a donation. Nor does a person who donates blood or a kidney give these tissues up for adoption.

Senator Arlen Specter (R-Pa) inserted the grant program into a Health and Human Services spending bill. Although Sen. Specter supports both abortion rights and embryonic stem cell research, he also supports the grant program because "if any of those embryos could produce life, I think they ought to produce life."[4] Specter is of the opinion that while couples are free to discard or donate their embryos for research, it should be a last resort option. If the goal of the federal government were to develop a workable solution, than more than one of the available options would be examined. Promoting 1 out of 3 possible options demonstrates a clear bias on the part of the Bush administration.

Although the current administration supports and has offered financial assistance to promote embryo adoption, only 5 states have any legal protection for the recipients of donated embryos, and embryo adoption is not legally recognized.[4] The federal government may face some difficulty promoting a course of action that has such little legal support.

With an ever-growing number of people seeking in vitro fertilization treatment, the problems of excess frozen embryos and disagreements about what to do with them will only increase in number and complexity. Who should address these issues? Some have called for additional regulation of the industry, either at the state or federal level. Others think that such regulation should come from within the profession—from the specialty organizations, fertility clinics, and physicians. It will certainly take the cooperation of all these parties to establish comprehensive procedures. In the absence of legislation and regulation, disagreements will end up in the courts, which will lead to case by case decisions that fail to address the broad underlying problems.

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MEDICAL EDUCATION

Medical Professionalism in the Digital Age

Jeremy Spevick

The information revolution of the last decade has transformed many aspects of our lives. The Internet, e-mail, and a host of other technologies spew volumes of information with just a click of the mouse or a peek at a personal organizer. Buried in the millions upon millions of Web sites are, according to 1 search engine, approximately 19,000 sites dedicated to the dissemination of health knowledge. With so much health information so readily available, one has to wonder: How reliable is the data? Will the information exchanged by e-mail remain confidential? What policies are needed to ensure user safety?

The information revolution has not only offered us a wealth of medical information, but it has also initiated changes in the patient-physician relationship and in the notion of what it means to be a medical professional. Today, many physicians are reluctant about introducing new forms of connection into medicine. Of particular concern is many patients' desires to contact their doctors by e-mail. While this would be a great convenience to patients seeking routine requests such as appointments or test results, many doctors worry that they will be bombarded by patients around the clock with incessant and often unreasonable requests. Other doctors fear that patients may rely on e-mail in situations that warrant an immediate response or even a visit to the ER or doctor's office. Some have begun to add disclaimers to their own emails, informing patients not to rely on e-mail communications if their message is urgent or sensitive.

Ironically, similar reservations were expressed upon the introduction of the telephone in the late 19th century. Many doctors, "believed that practicing medicine over the telephone compromised the moral integrity of the profession."[1] Doctors were able to adjust to the telephone by using answering machines and hiring secretaries. In the recent issue of the *Milbank Quarterly*, physician David Blumenthal argues that doctors will be able to make the necessary changes to adapt to e-mail. He goes on to say that, "if physicians are willing to accept some basic changes in their training, attitudes, and practices," then the information revolution will create opportunities to not only preserve professionalism, but "enhance it."[2]

The concept of professionalism is something that most people are aware of, but it is difficult to define. Paul Starr identifies 3 attributes of professionalism in *The Social Transformation of American Medicine*.[3] The first is cognitive knowledge, the scientific knowledge and technical dexterity doctors possess that enables them to

diagnose and treat patients. Secondly, there is a moral component of professionalism, which requires that the needs of patients come before the needs of the doctor. Finally there is a collegial responsibility for doctors to monitor one another and to ensure competence in the profession. Collegial monitoring is peer-review and is necessary because the layperson does not know enough to evaluate the medical profession accurately.

Traditionally, the relationship between the physician and the patient was asymmetrical; that is to say, doctors had significantly more information about medical conditions than their patients. This unequal distribution of knowledge makes trust an integral part of a successful patient-doctor relationship. Blumenthal notes that the medical profession's claim has been to offer "something that society cannot find elsewhere."[4] The availability of health information on the Internet severely weakens this claim by giving patients alternative sources for health advice. The question now is whether the information revolution will provide the layperson with enough knowledge to make decisions that were previously reserved for doctors.

Blumenthal talks about the information revolution as a series of possibilities for increased connectivity between members of the health care system. The various connections could include superior communication between individual patients, between patients and their doctors, and among doctors, patients, and health care organizations. This increased connectivity in the health care system will affect each of the 3 attributes that define professionalism.

Patients with access to the Internet can search the Web for vast amounts of information on a particular condition, whether it be through Web sites, or chatrooms with other patients. Before visiting the doctor, a patient may have looked up possible diagnoses for his or her symptoms and may be aware of different treatment options. By assuming part of the physician's role, the patient effectively reduces the knowledge asymmetry in the patient-doctor relationship.

The multi-way communications may strengthen patient appreciation for the physician's moral commitment to putting patients first. Among the welter of patient-to-patient communication and of advertising on the Web and elsewhere, patients will find that it is only in the personal relation with their own physicians that the information becomes specific to them and their needs. This can occur only within the patient-physician relationship.

With increased connectivity, patients will likely enter into the current system of self-governance that ensures competence in the medical profession. They will be able to contact one another more easily to compare and evaluate their visits to a particular doctor. Perhaps more significantly, Web sites already exist which focus on evaluating specific hospitals on specific procedures, such as coronary bypass surgery, or back and neck surgery. See for example http://www.healthgrades.com.

Blumenthal contends that in the new information age physicians must recognize a new role, that of a consultant. Patients will still need doctors to prescribe medications and to perform physical exams and diagnostic and therapeutic procedures. Patients, bombarded by the media with health information, will depend on doctors, with years of rigorous training, to transform health data into medical knowledge and appropriate treatment decisions. Patients will begin to look at doctors more as partners with whom they can consult to make informed decisions under uncertain circumstances. As a physician who uses the Internet, Blumenthal believes that patients will not doubt their doctor's knowledge if the doctor consults the Web during a visit; in fact he believes that most patients will expect this from their doctors. And there are still millions in the country who do not have access to the Internet. For these people, the doctor's role will remain unchanged.

If history is any indication, a doctor's professional status is rooted in something deeper than knowledge itself. In the 14th century doctors had little valid knowledge, yet they were still highly regarded and "compensated generously."[5] Blumenthal discusses the possibility of humans having a "primal urge to project onto some group the power to heal."[6] The argument is that people desire a healing class that can offer hope in times of suffering. This desire goes beyond the knowledge-based asymmetry that distinguishes medicine today.

There is no way to predict the precise way that the information revolution will continue to unfold. More knowledgeable patients should not decrease the importance of the medical profession, but rather force the profession to adapt to a new role. Doctors will still be needed to perform medical procedures, but now patients will ask medical professionals to help them sort through the vast amount of data available on the Internet. Perhaps the information revolution will bring us closer to Robert Veatch's collegial model of the patient-physician relationship, wherein doctors and patients work together to reach a common goal in a relationship that seeks input from both the doctor and the patient.[7] With the Internet's help, patients may become more equal partners with their physicians in caring for their health.

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MEDICAL EDUCATION

Cost-Effective Prescribing

Susanna Smith

We live in lean times. Coupon cutting and frugal living may pare down spending in many parts of the budget, but it's hard to get discount health care. When you get an ear infection you can't call around to the local medical practices for a price comparison. You cannot be a 30-day trial patient or get a free sample visit. So how can you, as a patient, be sure that you are getting the most for your money when it comes to health care? And how can physicians best offer their patients cost-effective care? The key to cutting spending on health care may be cost-effective prescription medications.

There is an endless stream of direct-to-consumer advertisements for everything from Allegra to Zantac, but what you don't often see advertised are the prices of these medicines. The average American uses about 10 prescriptions a year, accounting for 8 percent of the nation's health expenditures; a percentage which is expected to rise in the coming decade.[1] Some estimates put the percent of health expenditures on prescription medication at 20 to 25 percent for working-age adults.[2] Many patients, such as those who are uninsured and those who are dependent on Medicare, pay the full cost of their prescription medications out-of-pocket. Doctors report that a major reason for non-compliance is a patient's inability to pay for a medication, which may be exacerbated by physicians' lack of knowledge about drug prices.[3]

Left to their own devices, some patients have turned to potentially dangerous practices such as taking a lower dose than prescribed, sharing old prescriptions with family members, and splitting pills to save on prescription drug costs. More savvy consumers have started ordering prescription drugs from Internet sources that can provide lower-price medications from overseas. The message doctors should be receiving is that some patients do just about anything to cut drug costs. What are physicians doing on their part to offer their patients the safest and most affordable treatments?

One of the primary ways physicians can practice cost-effective prescribing is by offering patients a generic medication when one is available. For example, a year's worth of the same daily dosage of the anti-depressant Desyrel would cost an out-of-pocket payer about $1,080, whereas a year's supply of the generic form costs $35.10.[4] One study published in the *Archives of Family Medicine* suggested that these shocking differences in price might come as a surprise to many physicians. Its

survey of 178 physicians found that when asked to price commonly prescribed medications to the nearest $10, doctors underestimate the cost of brand-name drugs about 89 percent of the time and overestimate the cost of generic drugs about 90 percent of the time.[5] More than 60 percent of physicians in the survey felt they receive inadequate information on drug costs.[5]

A similar study published in the *Archives of Internal Medicine* underscored the fact of physician ignorance about drug costs, finding that 80 percent of the 134 physician respondents stated they were unaware of drug prices. In this study only 33 percent of the respondents thought they had easy access to drug price information, and only 13 percent said they had been formally educated about cost-effective treatments.[3] The knowledge deficits, which were found to be especially prevalent among residents, support the claim of physicians that they do not receive formal training on cost-effective prescribing methods.[3] Considering how drug cost can influence patient compliance with the recommended treatment, residency programs should include sessions about cost-effective prescribing.

Doctors are not blind to the need for cost-effective prescribing, but many may not know enough about drug costs or a patient's prescription drug insurance plan to offer the patient the most in drug efficacy and financial savings. For example, the authors of 1 survey stated they were "struck by the fact that nearly a third of physicians did not appear to understand that Medicare does not pay for medications."[6] Doctors are aware, however, that not having prescription drug insurance places a heavy financial burden on patients. More than 70 percent of doctors in the *Archives of Internal Medicine Survey* reported their choice of medication was influenced by whether or not a patient had prescription drug insurance. But these physicians forgot to ask about the patient's prescription drug insurance more than half the time when actually writing the prescription.[5]

When a patient's health insurance includes a prescription drug plan, part of the cost of expensive drugs may be borne by the patient anyway through a higher co-payment. With tiered drug insurance plans, the consumer pays a lower co-payment for generic medications than for brand-name drugs. Some insurance plans even distinguish between "preferred" brand-name drugs and "non-preferred" brand-name drugs, charging consumers more for a non-preferred brand.[7] Many employers and health insurance companies have used the tiered system as a strategy to encourage patients and physicians to use fewer and less expensive drugs.[7] But are most physicians aware of these types of plans? And do they have easy access to find out how much a particular patient with a specific insurance plan will pay for a chosen prescription?

With all the other demands on a doctor, is it reasonable to hold him or her responsible for offering cost-effective medications? Doctors are in a unique position to direct their patients drug purchases,[5] since a patients cannot obtain prescription drugs without a physician's recommendation. The patient's dependence on the physician suggests that the doctor should be conscious of helping patients receive

cost-effective drugs by prescribing generic medications when they are available. Tools like the palm-held organizer, now required in many medical schools, which offer programs like ePocrates Rx TM, can aid doctors in quickly finding the prices of medications. But a doctor cannot be expected to know how a patient's prescription drug plan will charge for a particular drug. For physicians to be well informed about cost-effective medication they need more tools. One of the best resources for a doctor is an informed patient. Patients should also be held accountable for understanding how their own insurance plan charges for prescription drugs and making inquiries to the doctor about cost-effective medications.

A drug price resource can be can be found at:
1. International Drug Price Indicator Guide. Available at: http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=Dmp&language=English

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VIEWPOINT

Cultural Differences Intensify End-of-life Care Challenges

Linda MacDonald Glenn, LLM and Faith Lagay, PhD

Evonne, an intelligent and appropriately mature 16-year-old, is suffering from systemic scleroderma, a chronic, autoimmune disease of the connective tissue, generally classified as one of the rheumatic diseases. She has extensive gastrointestinal and myocardial involvement and has been admitted to the pediatric intensive care unit (PICU) because of fluid build-up around her heart. Evonne is malnourished because her bowels are not functioning properly due to scarring from the disease. She has been treated with methotrexate and prednisone over the last 6 years. Her primary care physician describes her condition as "pre-terminal" because Evonne is at imminent risk of heart failure.

Evonne's parents, Mr. and Mrs. B, immigrated to the United States from West Africa, and Evonne and her younger sister were born and raised in the southern US. Evonne's mother suffered cognitive impairment following head trauma from a motor vehicle accident several years ago and is unable to participate meaningfully in discussion of her daughter's care. Mr. B holds to his cultural/religious belief that to talk about death is to invite it. He has adamantly refused to discuss the inevitable course of Evonne's disease and has suggested treatments such as heart/lung transplant. Evonne's physicians respond that her chronic systemic disease would soon reproduce the current damage to those organs. Moreover, the heart/lung transplant would not mitigate Evonne's mal-absorption problems. Her father insists that "everything possible" be done and has refused to discuss a DNR order.

Evonne is a socially active, happy teenager and an A+ student despite her disease. She tells her primary care physician, Dr. T, a pediatric rheumatologist, that she has researched her disease extensively on the Internet's Juvenile Scleroderma Network [www.jsdn.org/]. She has learned about the treatment and is aware of her prognosis. Evonne's father is by her side continuously so that the doctors or nurses cannot speak with Evonne alone. In the presence of Dr. T and her father, Evonne asks, "Am I going to die?" Mr. B quickly intervenes with "Don't be silly—you are not going to die, Tell her, doctor." The doctor somewhat caught off guard, replies, "I don't want to lie to you—it's certainly possible." Upset by this response, Evonne's father has told everyone involved with Evonne's care that they are not to speak about death in front of him or Evonne and that by doing so, they are "inviting the Devil."

Evonne's primary care physician would like to talk to Evonne alone and determine her wishes. He believes Evonne is mature enough to exercise decision-making capacity and would like to know how much she wants to talk about her present situation, her prognosis, and her future treatment. At the same time, Dr. T is aware that Evonne does not want to distress her father. Dr. T believes that intubation and resuscitation would be inappropriate in Evonne's case. His colleagues agree; the pediatric surgeon points out that normal intubation is impossible, due to the narrowing of airways, caused by the disease. Dr. T consults the ethicist about approaching Evonne alone.

Discussion

The serious medical, ethical, and cultural challenges in this case are complicated by the fact that the patient, 16-year-old Evonne, is "pre-terminal," ie, expected to die soon, and apparently discussion of truth-telling and end-of-life medical treatment has not been broached with Evonne's father. Her father does not want Evonne to know of her prognosis, he wants no mention of death in her, or his own, presence, and he wants "everything done" to save her life. The cards seem so stacked against a "good" outcome in this case that Evonne's medical care givers may have to be satisfied with good process rather than good outcome, that is, proceeding on a medical and ethical course that avoids "worst" outcomes.

The outcomes to be avoided include (1) causing Evonne pain by subjecting her to medical interventions that will neither lengthen her life nor make her remaining life more comfortable and satisfying; (2) angering her father and giving him no "face-saving" choice but to remove Evonne from the current clinical setting; (3) setting Evonne and her father at odds with each other so that her last days (and his last days with his beloved daughter) are filled with pain and strife.

The challenges in Evonne's case can be broadly separated into treatment issues on the one hand, and issues of cultural difference in information-sharing, truth-telling, and autonomy, on the other, although these, of course, overlap and affect each other. The cultural/communication/ truth-telling issues highlight the differences between the culture of Western biomedicine and Mr. B's West African American culture. They infuse the treatment dilemmas and need to be resolved, or at least addressed, first.

Mr. B fears that if he, or Evonne, or Evonne's medical care givers discuss death, they will be inviting it or, worse, inviting the Devil, a view that most Western biomedical theory dismisses as unscientific and superstitious. Evonne's best interest will not be served, however, by attempts on the part of her care givers or ethicists to overturn her father's belief system overnight or to ignore it completely, so that they can approach Evonne and talk to her about death. Enrolling the help of hospital chaplains or other spiritual advisors could be effective if a representative familiar with Mr. B's religious tradition can be summoned. If such a person is found, his views must be expected to conform more closely with those of Mr. B than with those of Western medicine.

The fact that Evonne is an unemancipated teenager, that is, one who is still living with her parents and subject to their authority, limits the choices available to those who wish to improve end-of-life care for Evonne without her father's cooperation. The course that may produce greatest peace and comfort during Evonne's final hospitalization may be to honor her father's ban on discussion of death. When Mr. B trusts that no one will talk to Evonne about death, he may allow them to discuss other matters with her, probably in his presence.

There is much to talk to Evonne about besides death. Dr. T can ask her how she is feeling, what causes her pain or relieves it, who she would like to visit with, how she would like to spend her time while in the hospital. Though this course denies Evonne the opportunity to talk about death outright, it may be the only way to avoid contentious division between Evonne and her father or Mr. B and Evonne's care givers and may prevent more severe curtailments of her autonomy. Some cultures approach end-of-life discussions metaphorically[1] and, although this is frowned upon by recent thinking about truth-telling in US bioethics, the approach should not be overlooked. (Recall that the trend to tell patients the truth about their prognosis and "how long they have left" *is* recent, and many US patients, particularly the elderly, do not want to know the specifics of their prognoses.) Evonne is intelligent and mature. Discussion of what "you would like to happen while you are here in the hospital" may well be understood by Evonne, who has researched her disease and knows she how sick she feels, to mean exactly what it is intended to mean—while you are still *here*. This level of interchange between Evonne and her medical care givers would amount to a not-so-bad outcome, given her father's strongly held beliefs, even though frank discussion of death is absent.

With the cultural impasse banning any discussion between Evonne and her caregivers sidestepped, talk can focus on treatment. In this area, physicians at least have the right to exercise medical judgment in a way that they could not exercise overriding cultural judgment. A surgeon can say, "I will not perform surgery on Evonne because of her current compromised physical condition and because her chronic disease will quickly attack the transplanted organs." Mr. B's refusal of a DNR order is more difficult to manage, although no physician can be coerced to commit what he or she considers to be torture on a patient. Here again, what care givers want to avoid at all costs is causing Mr. B to move Evonne from place to place in search of medical staff who will agree to resuscitate her under all circumstances. Ultimately, medical staff may have to continue dialogue with Mr. B, hoping to convince him to sign a DNR order and hoping that Evonne does not code before they succeed in persuading him. Other treatment questions—eg, intubation—have arisen, and others are likely to arise. Mr. B may ask that an enteral feed tube be placed, for example. Again, physicians must proceed along a medically and ethically justifiable course, attempting to convince Mr. B that these interventions will not buy Evonne time and explaining why they will not.

In sum, then, the least worst outcome that can be expected in Evonne's case is good medical and ethical *process*—open dialogue with Evonne and her father and non-

abandonment of either of them by Evonne's medical care givers. At best, the opportunity may open to talk metaphorically with Evonne about her eventual death and allow her to express her wishes about her time "while she is in the hospital."

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VIEWPOINT

Weighing the Risks of Weight-Loss Aids

Colleen Danz

- The herbal alkaloid ephedra is a central nervous system (CNS) stimulant that acts on the appetite control center of the brain, the hypothalmus, suppressing the desire to eat. Like all CNS stimulants, ephedrine causes the heart and blood vessels to constrict, increasing blood pressure and heart rate.
- Sixty percent of deaths reported from dietary supplements between January 1993-February 2001 have been linked to the ephedrine alkaloids (EA).[1]
- An FDA study from January 1993-February 2001 shows the EA dietary supplements are associated with more deaths, myocardial infarctions, cardiac arrhythmias, hypertension, stroke, and seizure events than all other dietary supplements combined.[1]
- EA is contained in more than 200 hundred dietary supplements used by an estimated 12 million people last year.[2]
- Some appetite suppressants can create psychological dependence because they contain phentermine, which is chemically similar to amphetamines. Others can cause insomnia, drowsiness, irritability or depression.
- Drugs that prevent fat absorption can cause cramping, diarrhea, flatulence, and intestinal discomfort.
- Dietary supplements are classified as foods under federal law and they are assumed to be safe. They are subjected to limited regulatory oversight.
- Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):[3]
    - The dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product only after it reaches the market.
    - Manufacturers do not need to register with FDA nor get FDA approval before producing or selling dietary supplements.
- Unlike dietary supplements, all prescription and over-the-counter drugs must be proved effective and safe before the FDA approves the them for marketing. A drug is deemed safe when the benefits outweigh the risks.[4]

Dietary supplements like the ones that suppress the appetite may be widely used in the US because obesity is a serious health concern.

- Results from the 1999-2000 National Health and Nutrition Examination Survey (NHANES) indicate that an estimated 64 percent of US adults are either overweight or obese.[5]
- Among children and teens ages 6-19, 15 percent (almost 9 million) are overweight according to the 1999-2000 data.[6]

Those seeking to lose weight should consult a physician before taking weight-loss pills or appetite suppressants.

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VIEWPOINT

Fetal Photos and Body Scans in Parking Lots: The Implications of Bypassing Physicians in the Medical Marketplace

Michelle Lim

Pharmaceutical advertisements have become commonplace in print and on television. Now medical device companies and test makers are following the lead of pharmaceutical firms in marketing directly to consumers rather than to physicians. Direct-to-consumer (DTC) marketing is spurring debate, however, because the practice bypasses an important gatekeeper—the physician. The medical community is concerned that this marketing strategy will weaken the patient-physician relationship.

DTC Companies

HealthcheckUSA offers "health awareness" blood and genetic tests through its Web site. These tests check cholesterol levels and screen for diabetes, sexually transmitted diseases, and hereditary cancers. Another company, CATscan 2000, delivers body scan services to church parking lots. CATscan 2000 makes its convenient computerized tomography (CT) scans for heart diease and lung cancer available to people who, until recently, couldn't get them—those without symptoms or doctor referrals.[1] Other "medical" services hot on the market are 3D and 4D fetal sonograms. These new ultrasound images show fetal movements in close-to-real time. Companies like Fetal Fotos, Inc. and Before the Stork offer pregnant women the opportunity to get their first snapshots of the baby, complete with keepsake videos and souvenir pictures, often in the convenience of a local shopping mall.[2]

A Brief History of DTC Advertising

The Food and Drug Administration (FDA) may have inadvertently facilitated the increase in DTC marketing. This marketing strategy has been technically legal since the early 1970s, as long as companies disclosed major risks and made "adequate provisions" for information relating to the "side effects, contraindications and effectiveness."[3] But the phrase "adequate provision" caused much confusion, so in 1997 the FDA issued a "draft guidance" for broadcast advertising. The 1997 guidelines clarified that "adequate provision" for television advertising could be met by referring consumers to a toll-free number, their doctor or pharmacist, a print advertisement containing a summary of risk information, and a Web site.[4] Many companies took this as a go-signal for marketing their goods to consumers. After the promulgation of the 1997 guidelines, pharmaceutical companies shifted focus from print to television advertising. Annual spending on DTC advertisements for prescription drugs tripled between 1996 and 2000, reaching nearly $2.4 billion.[3]

While the 1997 FDA guidelines pertain specifically to pharmaceutical companies, medical device companies and test makers are also vying for the same consumer attention. Aside from the changes in the regulatory environment, the spread of managed care, advances in information technology, and the changes in consumer attitudes and behavior may have also contributed to the increase in DTC marketing.[3]

The Pros and Cons of DTC Advertising

Proponents of DTC marketing contend that the advertisements empower consumers and allow them to be active participants in decisions about their health. They argue that DTC marketing informs the consumer of alternative therapies and diagnostic approaches.[5] Making tests and services available directly to consumers also eliminates hospital and doctor fees that are usually added to the cost for obtaining the services.

In addition to financial savings, consumers save time, not having to wait weeks to see the physician to order the test and days or weeks to receive results. For instance, a consumer can view blood test results online from HealthCheckUSA within 48 hours of having blood drawn. Convenience is the key. As Holt Vaugh, vice president of HealthCheckUSA points out, "Utilizing a service like ours, [consumers] can simply log on to our Web site [and] pick the location that is closest to them. [W]e send them the paperwork, and they can walk into a lab at their convenience. [They] have the blood work done, and they're in and out in 10 minutes."[5] Supporters of DTC marketing reason that eliminating the extensive waiting period between taking the test and obtaining the result gives consumers reassurance and peace of mind.[6]

Critics, however, charge that DTC marketing by medical device companies and test makers bypasses physicians who normally serve as important gatekeepers in the exchange of medical goods and services. Pharmaceutical companies can defend their DTC marketing by emphasizing that their advertisements refer consumers to doctors, thus strengthening the patient-physician relationship.[7] Medical device companies and test makers, on the other hand, completely eliminate the need for physician consultation, an omission which may endanger the patient. Consumers may not have a good understanding of what the tests and services mean and how they will relate to the consumer's condition. DTC advertising by these companies can thus weaken the connection between patients and their physicians.

The DTC-marketed tests and services do not always take into account medical history and do not use other tests simultaneously to ensure accuracy when reporting the results. False-positive findings are also common and may create the need for more invasive procedures to ensure certainty in the findings. The financial and other costs of these follow-up interventions can negate initial savings of DTC-marketed tests. False-negative findings are also hazardous because they give the consumer an unwarranted sense of well-being.[6]

In a recent *New England Journal of Medicine* article, Dr. Sidney Wolfe points out that patients have dangerous misconceptions about DTC advertising, believing, for example, that only the safest and most effective drugs and medical services can be advertised directly to consumers. They believe that the FDA requires these advertisements to be under strict review and scrutiny before being published or aired on television.[8] On the contrary, the FDA has not approved and, in fact, opposes some services directly offered to consumers such as the CT scan services marketed by CATScan 2000. The FDA and the American College of Radiology oppose the use of CT scans for preventive screening among asymptomatic individuals on several grounds, one being the danger associated with exposure to high doses of radiation.[9] Another professional organization, the American Institute for Ultrasound in Medicine strongly discourages non-medical use of ultrasounds, such as 4D sonograms for psychosocial and entertainment purposes.[10]

Partners in Care

Ultimately, the effects of DTC marketing depend most on the consumer—"how the consumer perceives and acts on the information made available through advertising."[3] While consumers have every right to be in control of decisions that affect their health, they must also understand the importance of consulting the physician before and after obtaining DTC-marketed services and tests. Many physicians encourage patient involvement in their health decisions, but completely eliminating physicians from the decision-making process concerns them because of the possible harm to misinformed consumers. An important step, then, is to extend regulation of DTC marketing from the pharmaceutical industry to medical device companies and test makers to ensure accurate and balanced information. Furthermore, companies employing DTC marketing strategies should encourage consumers to consult with and obtain referrals from their physician. In turn, the medical community must renew the bond of trust that strengthens the patient-physician relationship by creating mechanisms that facilitate effective exchanges of information between physicians and their patients.

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