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Ethical Challenges in Modern Cardiovascular Medicine

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FROM THE EDITOR
New Clinical Powers, New Ethical Questions

In putting together an issue of a medical ethics journal, there are two starting points from which one can work: ethical principles and clinical situations. In the first approach, one chooses an ethical idea and then identifies clinical situations in which that principle plays a central role; those situations can be the jumping-off points for case discussions and other articles. This approach, one could posit, might be preferred by ethicists with backgrounds in philosophy or some other nonclinical field, who have a primary interest in principles and view the clinical world as a realm in which those principles are applied. An example of this approach is the August 2009 issue of *Virtual Mentor* on the theme of Problematizing the Principle of Autonomy: autonomy, the bioethics concept, was taken as central and its clinical implications examined from there.

The alternative is to begin in the clinical realm, either an area of practice (e.g., surgery) or a situation (e.g., the end of life), and then seek to identify ethical challenges inherent in the practice or situation. A well-executed example of this approach is the *Virtual Mentor* issue from February 2010 on Ethics and Innovation in Surgery, edited by Catherine Frenkel, a medical student at Albany Medical College (and, coincidentally, a former classmate of mine). This alternative is particularly attractive to clinicians, who encounter ethical dilemmas in practice and seek concepts to help resolve them.

As a future clinician in, with luck, the field of internal medicine, I was attracted to the latter approach when developing this issue of *Virtual Mentor*. Cardiovascular medicine, a specialty area within internal medicine, is the focus of the issue, and the ethics topics it confronts within the field range considerably—another benefit of the clinical lens. Cardiovascular medicine offers particularly fertile ground, from a clinical standpoint, on which to have an ethics discussion because we are currently contending with the results of what many consider to be a revolution in the field. While specialties like neurology and genetics (another research interest of mine) are still waiting for the big collective breakthroughs in their modern incarnations, cardiology has just recently undertaken a massive leap forward. The data we have about cardiovascular conditions like hypertension, heart failure, and arrhythmias and the corresponding pharmacologic, interventional, and device-based diagnostic and treatment modalities—statins, beta-blockers, anti-arrhythmics, cardiac catheterization, prosthetic valves, cardiac ablation, pacemakers, implantable cardioverter-defibrillators, echocardiography, stress testing, and so on—have exploded in recent decades.

This onslaught of new techniques and related clinical data has put us in the position of feeling as if we have fantastic capabilities, and it is in such a situation that ethics is most important. Indeed, as a matter of historical fact and philosophical axiom, new ethical challenges arise precisely when either our intellectual understanding of or our ability to intervene in a given situation takes a big step forward. This is exactly where the field of cardiovascular medicine stands today.

In this issue of *Virtual Mentor*—Ethical Challenges in Modern Cardiovascular Medicine—we first examine three dilemmas facing practicing cardiologists today through clinical case commentaries. James N. Kirkpatrick, MD, a clinician and ethicist at the University of Pennsylvania School of Medicine, discusses a case of recurrent infective endocarditis in an intravenous drug user, taking us beyond the knee-jerk feelings many physicians have when they encounter a patient who appears wholly responsible for his or her own medical problems. Dr. Kirkpatrick also considers the widespread concern about inefficient use of medical resources in an American system burdened with astonishing high costs. The clinical pearl, on infective endocarditis, is contributed by Arash Aghel, MD, a fellow in cardiovascular medicine, and Sri Madan Mohan, MD, a cardiologist and assistant professor of medicine, both at University Hospitals Case Medical Center.

Karen Uhlenhuth, a journalist and scientific writer at Children's Mercy Hospital Bioethics Center, Angira Patel, MD, a fellow in pediatric cardiology at Children's Memorial Hospital and a clinical medical ethics fellow at the University of Chicago, and John Lantos, MD, a pediatrician and director of the Children's Mercy Bioethics Center in Kansas City, weigh the costs and benefits of aggressive interventions—specifically statins—to control cardiac risk factors in the pediatric population and the effects interventions like these may have on incentives for less aggressive treatment such as lifestyle modifications.

David Brush, MD, a pulmonary medicine fellow and trained ethicist, and Crystal E. Brown, MD, an internal medicine resident, both at the University of Chicago, discuss the ever-important topic of defensive medicine, specifically with respect to the hot-button issue of possible acute coronary syndrome and cardiac catheterization. On a related topic, the health law section—by Ryan Bailey and Kristin E. Schleiter, JD, LLM, under the auspices of the AMA's ethics group—recounts the facts and court decision in *Riegel v. Medtronic, Inc.*, a case brought against device-maker Medtronic when one of its cardiac catheters burst during use.

We then turn from individual practice issues to topics concerning the field and its relationship to government, industry, and public health. The journal discussion, by Katherine R. Schlosser, a fourth-year medical student at Case Western Reserve University School of Medicine, and me, analyzes a recent article from *Circulation* documenting health disparities in cardiology consultation rates between different patient cohorts.

Jeremy A. Greene, MD, PhD, an internist and assistant professor in the Department of the History of Science of Harvard University, chronicles the evolution of the marketing strategy and subsequent scandals of the blockbuster statin Lipitor.

A pair of articles look at the health behaviors of individuals and what interventions from clinicians and government, if any, are appropriate. Mark E. Votruba, PhD, an associate professor of economics and medicine at Case Western Reserve University, provides an economic take on public health measures aimed at altering American dietary choices, using the controversial New York City ban on trans fat as a case study. Jane S. Jue, MD, MSc, an internist who is currently a Robert Wood Johnson Foundation Clinical Scholar at the University of Pennsylvania, identifies the multiplicity of socioeconomic and individual contributors to heart health and disease and the changes that could help reverse the trend toward disease in the United States.

Finally, Stephanie King, a student at The Cleveland Institute of Art, and Sarah Cross, MD, a resident physician in obstetrics and gynecology at Yale-New Haven Hospital, provide art and poetry on the iconography of the heart.

In the end, the goal of this issue is to serve both clinicians—cardiologists in particular—and nonclinician ethicists. For physicians, it can function as a manual of sorts—a guide to a more nuanced understanding of the ethical principles at stake in situations that arise in their practice and in their field. For ethicists trained in philosophy, the law, and other nonmedical fields, the issue can illustrate how ethical questions emerge in practice as our research and clinical capabilities expand. Perhaps in no specialty is this more necessary than in cardiovascular medicine.

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CLINICAL CASE
Infective Endocarditis in the Intravenous Drug User
Commentary by James N. Kirkpatrick, MD

Looking at the chart on the way to visit a new patient in the cardiac intensive care unit, Dr. Collins saw that Mr. Addison had been admitted from the emergency department with a diagnosis of presumed infective endocarditis. When he walked into the room, Dr. Collins recognized Mr. Addison. He had cared for him 5 years earlier, when Mr. Addison had had a mitral valve replacement.

At that time, Mr. Addison had been 40 years old and had a history of intravenous drug use. After the surgery, he had entered a drug rehabilitation program and had remained drug-free (confirmed by urine toxicology screening).

When Dr. Collins began interviewing Mr. Addison, the patient admitted having relapsed into drug use, and, Dr. Collins noted, there were fresh tracks on Mr. Addison's arms. The echocardiogram from the emergency department showed vegetations on the mitral valve consistent with recurrent infective endocarditis.

The typical clinical management approach would be to examine the patient and recommend that a surgeon be consulted to discuss emergency valve replacement, but Dr. Collins paused. Mr. Addison's relapse was almost certainly a direct result of his renewed drug use. Dr. Collins could just turf the case to the cardiac surgeon and leave the decision up to him or her, but he wondered whether he had some responsibility to intervene at this point and ask some serious questions about the use of medical resources and money to keep patching up people who abused their bodies, in this instance, unlawfully.

Commentary
This case bears some resemblance to a consult I recall from my ethics fellowship training. A drug user was admitted through the emergency department one week after he had been discharged. During the previous hospitalization, he had been verbally abusive to all staff members and had eventually left against medical advice. The consult question from the beleaguered medicine team was, "Do we have to take care of this patient?" My knee-jerk answer was: "Of course you have to take care of him. You are medical professionals with a duty to care for your patients." The AMA *Code of Ethics* clearly states that "the relationship between patient and physician…gives rise to physicians' ethical obligations to place patients' welfare above their own self-interest and above obligations to other groups, and to advocate for their patients' welfare" [1]. Perhaps a similarly reflexive answer to Dr. Collins is that he should not put the interests of taxpayers, or Mr. Addison's insurance

company, or society (the "other group") above those of his difficult patient. Instead of worrying about other people's money, he needs to buckle down and care for his patient.

But before we upbraid either the good Dr. Collins or the medicine team, we must realize that they are us. At some point in all of our careers, frustration at the follies and noncompliance of patients compromises our humanism. For many, it rears its head in the middle of the night after a long day. I recall dragging myself to the elevator one night during internal medicine residency to see yet another demented nursing home patient in the emergency department, bound for a lengthy stay on the general medicine ward. I was wishing, hoping, even yearning that the patient would die before I reached the ground floor. I really, sincerely felt that way.

Later, after sleeping, I was shocked at my own callousness. Then I ran into a colleague, a perpetually upbeat and always ethically appropriate future chief resident who confided, "I have to tell you, I hate my patients." I think both of us were tired to the point of being brutally honest. But I can remember other times when frustration with patients was sublimated into musings about the waste in medical care. At our lowest points, we can become very philosophical about limited resources. Now, to be clear, there is nothing wrong with feeling frustrated, but we should guard against disguising our personal feelings as generalized conclusions about whether we should or should not treat patients. As James Groves eloquently expressed, "when this ideal of the perfect physician collides with the quotidian realities of caring for sick and troubled patients...there may be a desperate attempt to avoid or to extrude the patient from the care-giving system" [2]. This "attempt to avoid or to extrude" can be subconscious, with a thin veneer of rationalization covering deep frustration.

Assume that Dr. Collins was clearly and objectively evaluating the situation, without any personal disappointment or prejudice. Would an expensive valve replacement for Mr. Addison be a waste of resources? There are at least two ways of looking at this question. I think we can quickly dispense with the first: that Mr. Addison is not worth a valve replacement. Except in moments of extreme frustration, there are few physicians who would deny a patient needed care because of the patient's moral failings or perceived lack of social worth. The days of the "God committee"—when a small group at Swedish Hospital in Seattle decided who would receive access to the first kidney dialysis machines on the basis of a complicated algorithm which included social worth—are mostly behind us [3]. We do consider behavioral factors such as active drug use to be contraindications to receiving limited resources, like transplants, not because drug use lessens the intrinsic worth of the patient but because the patient is unlikely to be able to care for the organ as well as someone who is not addicted to drugs.

This behavioral consideration is related to the second view of the question: futility. Replacing Mr. Addison's valve is a useless endeavor, this argument goes, because he will simply infect it again. He cannot keep getting the valve replaced indefinitely. Each time the chest is opened for cardiac surgery, adhesions form, making the next

surgery more difficulty and risky. In essence, the idea is that there is no way to keep an artificial valve free from infection in Mr. Addison because of his behavior, and, eventually, it will not even be possible to replace the infected valve. Valve replacements are not limited resources in the same way that organs are, but they are expensive. Why waste the money?

There is another way to think about Mr. Addison. His addiction to drugs is a medical condition that precludes the success of standard therapy. It is similar to the traditional thinking about performing a heart transplant on patients with cardiac amyloidosis—the amyloid will eventually affect the new heart; or the traditional thinking about stenting left main coronary artery lesions—they are better left for coronary bypass surgery. But recently heart transplants have been found to have survival benefit in some cardiac amyloid patients, and some left main coronary artery lesions have been successfully stented. The point is that the definition of when a given therapy is futile is not set in stone. Just as thinking about transplant in cases of cardiac amyloidosis and stenting left main lesions is changing, the inability of Mr. Addison to keep his valve free of vegetations is not a foregone conclusion. Nor is his addiction to drugs untreatable (newer pharmacological and psychological interventions may substantially improve long-term abstinence). Of course, not every cardiac amyloid patient receives a transplant, and not every patient with a left main coronary artery lesion is appropriate for stenting. And there definitely are clinical situations in which given therapies are truly futile.

There is no guarantee that Mr. Addison will stay off drugs (or free of endocarditis even if he does). The question of whether a valve replacement for Mr. Addison is a waste of resources or a good investment hinges, to some extent, on probabilities. Perhaps there are ways to risk-stratify Mr. Addison in this regard, to perform a psychological pre-operative risk assessment. We know that he successfully completed a drug rehabilitation program (favorable risk predictor), but we are not told other important details about how long he remained sober before his relapse, whether he has a stable social situation, how severe his drug habit is, whether he has a separate mental illness diagnosis, and so on. Mr. Addison did keep his first valve for 5 years, about half of the average lifespan of a valve (assuming he had a biological valve, rather than the more durable mechanical valve). Was this a good investment? If not, how long must a valve last to make it a good investment?

Even if our assessment suggests that Mr. Addison is a high risk for relapse, his situation is no more futile than that of the person with diabetes and coronary artery disease who smokes and frequents all-you-can-eat buffets. Such an individual certainly uses more medical resources than the person with well-controlled diabetes. These resources may, over time, exceed the cost of valve replacement. There are legal and moral aspects of Mr. Addison's drug use, but arguments about futility and cost-effectiveness probably cannot distinguish between the drug user and the profligate diabetic. The unwillingness or inability to change behavior on the part of either patient costs money. In fact, it is difficult to think of a medical condition in which perfect adherence to medicine, diet and exercise recommendations, and

follow-up care would not end up saving at least some money (except that they keep people alive longer—after burial or cremation, death is cheap). Few clinicians would consider it ethically justified to deny therapy to the person with poorly controlled diabetes. And, at this point at least, those whose money is being spent, whether the insurance company or society, have not decided to ration care based on behavior. It is not really Dr. Collins's place to make such decisions on behalf of these entities.

Thus, Dr. Collins has an ethical duty to intervene, but not to circumvent a medically indicated treatment in order to protect society's resources. It is difficult to define what futility means in this case, much less to assign it in a single clinical encounter. Dr. Collins should not just "turf" the decision to the surgeon, but should take an active part in the medical decision-making process. If Mr. Addison reenters a treatment program and successfully deals with his addiction, the resource of a new valve would definitely be well used. Even if he does not, and even though it is frustrating, Dr. Collins should continue to treat him as he would his other patients, many of whom probably also exhibit costly, resource-intense behaviors.

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CLINICAL CASE

Pediatric Obesity, Statin Use, and the Goals of Medicine

Commentary by Karen Uhlenhuth, Angira Patel, MD, and John Lantos, MD

When Jessica was 8 years old, her pediatrician, Dr. Rosen, recommended that she undergo comprehensive nutrition and exercise counseling to reduce her risk of future morbidity and mortality. She was overweight for her age, and there was family history of high blood pressure and coronary artery disease. Jessica's parents took Dr. Rosen's warnings seriously; they were both overweight and dealing with high blood pressure and diabetes, and saw their daughter heading down the same path. As a family, they attended classes and made some nutritional and behavioral changes, but with no real clinical success; Jessica's weight gain was still above the normal curve. Two years later, Jessica and her parents returned to Dr. Rosen's office. Her parents explained that it was difficult for the family to maintain the diet all the time or to exercise on schedule. Dr. Rosen agreed the task was difficult, but reemphasized its importance. He also told them that Jessica now had high cholesterol.

Worried that, with as little progress as she had made, Jessica would end up just like her parents and grandparents—overweight and struggling with high cholesterol, high blood pressure, diabetes, and coronary artery disease—her parents asked Dr. Rosen if Jessica could start on a medication like prevastatin to try to lower her cholesterol. They had seen advertisements for it that said the medications—known as statins (such as Lipitor)—could now be used in children. They said they also planned to speak to other doctors about aggressive interventions such as bariatric surgery.

Commentary

Jessica's case is a frustrating one for pediatricians. She is overweight and faces the potential health problems that arise from her obesity. The best way to treat those problems would be for her to change her habits—to eat less, exercise more, and subsequently lose weight. These lifestyle changes could lower her cholesterol, help control her blood pressure, and cure her diabetes. She and her family have tried those, however, and not succeeded. Now, she has a complication that can be treated—albeit less successfully—with medication. The pediatrician is thus being asked to provide a less effective treatment because the patient is, in essence, unable or unwilling to comply with the more effective treatment.

Over the last two decades, there have been many arguments about whether statins are truly effective for a youngster like Jessica. We will assume that they are. That is, we assume that a lifetime of statin therapy will lower Jessica's cholesterol and risk of coronary artery disease and myocardial infarction.

But would giving her a statin make her healthy? Would it set her on course for a healthy adulthood? Or would it be, essentially, labeling her as a child with a treatable but incurable chronic disease? And, if the latter, are we, as pediatricians, doing her a service or a disservice?

Overweight and obese children and adolescents are turning up in pediatricians' offices with ever greater frequency. Most pediatricians find the treatment of obesity and its associated problems to be one of the more frustrating clinical problems that they face, in part because many of the sequelae of obesity, such as hypercholesterolemia, hypertension, and diabetes, are treatable. But treatments administered over decades often introduce complications of their own.
The physician in this case must address two issues: the rising cholesterol level and the persistently unhealthy body weight that is its root cause. To that end, Dr. Rosen should consider a few questions:

- Does a statin prescription imply to the family that cholesterol is the primary problem here?
- Will a statin prescription possibly make it even harder for the family to follow through with changes in eating and exercise habits?
- If so, could statin treatment be postponed without causing irreversible damage?
- Is bariatric surgery a feasible option, now or later?
- Most importantly, what is the best way to help Jessica get healthy and stay that way?

Health is much more than a set of normal biochemical measures or the absence of disease. A healthy 10-year-old should have a high level of energy, a desire and ability to run and jump on the playground, the freedom to interact with his or her peers without fear of being bullied, and a generally happy outlook on life. Obesity could interfere with these goals. A statin drug will not help Jessica achieve any of these goals, nor will it improve her day-to-day functioning.

But it is not as if she hasn't tried. Jessica has attempted nutrition changes and increased physical activity. Yet she still has multiple fasting lipid levels that are above goals. In light of these facts and her strong family history, it would be appropriate to treat Jessica with statin therapy. Such therapy would likely decrease her risk of cardiovascular disease in the future [1], and thus would improve her long-term health prospects. Even if nothing else changes, Jessica will likely live longer on a statin than she would without it. Nothing else is likely to work better. Bariatric surgery should not be considered at this time, given its invasive nature and undetermined therapeutic profile in a young adolescent. If her obesity persists, in spite of ongoing attempts at behavioral modification, Jessica may become a candidate for bariatric surgery in the future.

Statins won't solve all her problems. With a continually escalating body mass index, Dr. Rosen's young patient would still be at increased risk for premature puberty, social difficulties, depression and other psychological problems, diabetes,

hypertension, asthma, sleep apnea, various cancers, gallbladder disease, heart disease, fatty-liver disease, carpal-tunnel syndrome, fertility difficulties, and pregnancy complications. In addition to this litany of conditions that statin use will not affect, there may be other, as yet unknown, problems from long-term statin therapy. We do not know the safety profile of a lifetime of statin therapy.

Nothing is without risks, however. Even in the short-term, a statin prescription might worsen Jessica's problems by taking the immediate pressure off her and her parents to solve the underlying problems that plague them all. In time, the statin prescription will be followed by prescriptions for diabetes and hypertension. When these drugs normalize her numbers, Jessica and her parents might have the impression that her disease has been treated and her problem solved. Dr. Rosen will have perpetuated the myth that pills alone can solve obesity.

What is the alternative? Dr. Rosen could use Jessica's rising cholesterol level to press the case with this family that they need to take a more serious shot at diet and exercise. He could refer them to a dietician, a psychologist, and a physical therapist to devise a new behavioral program. In this way, he would be helping to identify the real problem and the most effective solution.

Or, he could do both. Ongoing attention to Jessica's diet and exercise does not require him to withhold the statin. This is not an either/or choice. But the prescription drug is the easier option for both doctor and patient. Both may view prescription as the end of the story. Dr. Rosen must make sure that Jessica and her family understand the limitations of drugs, the risks of her current condition, and the preferred approach to minimize those risks. He must advocate for Jessica's health, not just for the treatment of one of her physiologic conditions. He must walk a fine line between his obligation to provide medical treatments that are recommended and effective and his obligation to make sure that his patients understand the limits of medical therapy.

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CLINICAL CASE
Cardiac Catheterization and Defensive Medicine
Commentary by Crystal E. Brown, MD, and David R. Brush, MD

Mr. Damon, a 62-year-old man with known coronary artery disease and a long history of angina, came to see his cardiologist, Dr. Ross, with chest pain—again. Such complaints had been typical during Mr. Damon's clinic visits over the last two years. Each episode was brought on by physical exertion and, just as predictably, was relieved with rest and a nitroglycerin tablet. Previous stress tests and cardiac catheterizations had shown the presence of stable angina without major blockages or areas of ischemia. Dr. Ross did his usual evaluation of Mr. Damon and concluded that Mr. Damon was having his typical angina, needed no changes to his medications, and did not need invasive cardiovascular testing.

As he was about to send Mr. Damon home, he remembered a fellow cardiologist who, in a similar clinical situation, sent a patient home without a cardiac catheterization. That patient died shortly thereafter of a heart attack, and the patient's family attempted to sue the physician for malpractice. Dr. Ross's clinical judgment told him that further testing was unnecessary, but he was concerned that such judgment alone might not hold up in court. While he knew that many of his colleagues would agree with his clinical assessment, he also knew that others would order a catheterization to protect themselves from potential litigation. Dr. Ross was worried about the complication risk of feeding a catheter up through the femoral artery into the heart and injecting dye into the coronary arteries, and he also wondered about the added strain on Mr. Damon's finances.

Commentary
Physicians are said to practice defensive medicine when they pursue unnecessary diagnostic modalities, prescribe unneeded pharmacologic therapies, avoid high-risk procedures, or refuse to care for complicated patients in an attempt to avoid malpractice litigation [1]. Such practices are not uncommon [2, 3]. In a 2005 survey of Pennsylvania physicians practicing in specialties such as emergency medicine, surgery, radiology, and obstetrics, 93 percent of physicians stated that they "sometimes or often" practiced defensive medicine [4]. Approximately 59 percent reported ordering unnecessary diagnostic tests and one-third reported recommending clinically unwarranted invasive procedures. In a more recent national survey of medical and surgical physicians, 91 percent of respondents stated that they believed that physicians order more procedures and tests than indicated due to fear of litigation [1]. Surprisingly, physicians' individual litigation experiences do not appear to increase their likelihood of practicing defensive medicine; instead, a physician's behavior appears to be spurred by collective anxiety over malpractice

litigation in general [5, 6]. The financial burden of such practices is not inconsequential. It has been estimated that defensive medicine practices account for tens of billions of dollars a year in diagnostic and treatment expenditures and 5-9 percent of Medicare costs [6].

The practice of medicine requires that physicians distill a clinical decision from a complicated assortment of potential risks and benefits to the patient. While a physician ideally favors a decision that minimizes risks and maximizes benefits for the *patient*, sometimes potential risks and benefits to the *physician* can shift decision making towards the physician's personal aims. Such acts can warp a clinician's selection of treatment options, poison the process of informed consent, and harm patients.

Our vignette presents a physician, Dr. Ross, who is considering ordering an invasive study despite his clinical judgment that the procedure will not benefit the patient, Mr. Damon. Should Dr. Ross proceed, he would do so in violation of one of the core principles of medicine: physicians' moral obligation not to inflict harm upon others. The Hippocratic Oath is clear when it states: "I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them" [7]. This responsibility of nonmaleficence encompasses obligations to neither directly inflict harm nor impose risk [8]. To avoid negligence, the physician must ensure that any harms and risks are necessary and reasonable because they stand to substantially benefit the patient. Dr. Ross predicts that catheterization will not change Mr. Damon's current medical management or long-term outcome. While the proposed procedure may shield Dr. Ross from legal vulnerability and possibly provide financial compensation, this does not warrant subjecting the patient to bodily discomfort, possible emotional duress, financial responsibility for related costs, and the remote possibility of life-threatening complications. While this vignette focuses on an invasive procedure, noninvasive testing such as echocardiograms and computed tomography—and even blood tests—carry with them burdens and risks that must be justified by a corresponding direct or potential benefit to the patient.

Next, consider the impact of defensive medicine on informed consent. If Dr. Ross decides to order the catheterization, how will he explain his reasoning to Mr. Damon? Informed consent requires that the consenting person understand the potential risks and benefits of the proposed action. If the physician inaccurately plays up the benefit of the procedure, deceives the patient into believing that it is necessary, or inappropriately minimizes the potential risks, the patient's consent is invalid [8]. Such behavior on the part of the physician denies the patient his or her legal and moral rights to self-determination.

Not all defensive practices are wrong, however. In 1998, Kenneth de Ville observed that increased communication and interaction between the physician and patient are risk-free and of minimal cost to the physician and may enhance the patient-physician relationship [9] Clearly documenting the patient's involvement in the decision-making process, the physician's clinical reasoning, and the risks and benefits

communicated to the patient can provide additional legal protection for the physician. Physicians who emphasize patient education and involve the patient to a greater extent in the decision-making process can both improve the patient-physician relationship and, simultaneously, provide themselves better legal standing.

While this case features a scenario in which the physician has judged the procedure to be of no benefit to the patient, real-world clinicians confront substantially more complicated cases, in which medical decision making involves more uncertainty. When the balance of risks and benefits is more uncertain, consultation with other physicians is wise. Ultimately, if uncertainty cannot be resolved, physicians must disclose not only risks and benefits, but also their concerns, and work with the patient to come to a joint decision. Just as physicians have different levels of risk tolerance, patients are similarly varied. In these cases, it is the patient's view of the risk and benefits and his or her personal values that ultimately guide management, sometimes despite the clinician's preference.

The welfare and health of the patient should outweigh any financial, political, or legal concerns of the physician. Defensive medicine impinges upon a physician's duty to do no harm by placing the physician's self-preservation before the patient's well-being. The pervasive and palpable anxiety in the medical community leads one to expect that defensive practices will remain commonplace [4, 5]—but that does not make it right.

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Disclosure
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THE CODE SAYS
AMA *Code of Medical Ethics*' Opinion on Disparities in Health Care

Opinion 9.121 - Racial and Ethnic Health Care Disparities

Differences in treatment that are not directly attributable to variances in clinical needs or patient preferences constitute disparities in health care. Among racial and ethnic minority populations, such disparities may contribute to health outcomes that are considerably worse than those of majority populations. This represents a significant challenge for physicians who ethically are called upon to serve patients without regard to medically irrelevant personal characteristics. The following guidelines are intended to help reduce racial and ethnic disparities in health care.

1. Physicians must strive to offer the same quality of care to all their patients irrespective of personal characteristics such as race or ethnicity. The provision of care should be customized to meet patient needs and preferences.
2. Physicians must learn to recognize racial and ethnic health care disparities and should examine their own practices to ensure that inappropriate considerations do not affect clinical judgment.
3. Physicians should work to eliminate biased behavior toward patients by other health care professionals and staff who come into contact with patients. Inappropriate discrimination toward any patient or group of patients must not be permitted.
4. Participatory decision making should be encouraged with all patients. This requires trust, which in turn requires effective communication. Physicians should seek to gain greater understanding of cultural or ethnic characteristics that can influence patients' health care decisions. Physicians should not rely upon stereotypes; they should customize care to meet the needs and preferences of individual patients.
5. Physicians should recognize and take into account linguistic factors that affect patients' understanding of medical information. In particular, language barriers should be minimized so that information is exchanged in a manner that both parties can understand.
6. Increasing the diversity of the physician workforce may be an important step in reducing racial and ethnic health care disparities. Physicians should therefore participate in efforts to encourage diversity in the profession.
7. Physicians should help increase awareness of health care disparities by engaging in open and broad discussions about the issue in medical school curricula, in medical journals, at professional conferences, and as part of professional peer review activities. Research should continue to investigate health care disparities, including the development of quality measures.

Issued March 1992 based on the report "Black-White Disparities in Health Care," adopted December 1989. Updated June 1994 and November 2005 based on the report "Racial and Ethnic Health Care Disparities," adopted June 2005.

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JOURNAL DISCUSSION
Dissecting Health Disparities in Cardiology Patients
Katherine R. Schlosser and George L. Anesi

Cook NL, Ayanian JZ, Orav EJ, Hicks LS. Differences in specialist consultations for cardiovascular disease by race, ethnicity, gender, insurance status, and site of primary care. *Circulation*. 2009;119(18):2463-2470.

Introduction

Heart disease is the most common cause of death in the United States [1]. Cardiovascular outcomes, however, differ significantly when examined by gender and race, among other patient characteristics [2]. As the amount of attention paid to health disparities grows, so have efforts at exploring the underlying reasons for their existence and potential steps toward removing them [3].

"Health inequality" and "health inequity" are complex terms often used in the context of discussions about "health disparities," itself a catch-all term for differences in health outcomes between different patient groups. Health *inequalities* are defined as "differences in health status or in the distribution of health determinants among different population groups"; in contrast, a health *inequity* is an inequality that is "attributable to the external environment and conditions mainly outside the control of the individuals concerned" [4]. When *inequalities* are unnecessary, avoidable, unjust, or unfair, we define them as *inequities*.

In "Differences in Specialist Consultations for Cardiovascular Disease by Race, Ethnicity, Gender, Insurance Status, and Site of Primary Care," Cook et al. address one particular health inequality: the varying rates of referral from a primary care setting to a cardiology specialist based on various patient characteristics [5]. The authors find that referral to a cardiologist improves cardiovascular outcomes and that referral rates differ significantly based on nonclinical patient characteristics, and they therefore deem this inequality an inequity—and one worth further investigation.

Study Design and Limitations

This retrospective cohort study examined electronic medical records for patients seen in two academic health care centers between 2000 and 2005. Criteria for inclusion in the study were racial/ethnic categorization as non-Hispanic white, non-Hispanic black, or Hispanic; two visits to a primary care office in the 12 months preceding the study period; and a diagnosis of coronary artery disease (CAD) or congestive heart failure (CHF). Their three main outcome measures were: (1) time to first cardiology consultation, (2) frequency of follow-up consultations, and (3) each patient's yearly health performance as measured by number of clinic visits.

An examination of the study design and cohort yields a few weaknesses worth noting. The retrospective design does not account for cardiology consultations prior to the index study visit or consultation at time of diagnosis, so the results are limited to continuing care received during the study period by previously diagnosed patients. Furthermore, the authors defined "disease severity" as the number of visits in the primary care clinic in the 12-month interval before the index study visit. It is well documented that racial and ethnic minorities have less access to health care, especially cardiac care [6]. It follows that using visit number as the measure of disease severity may underrepresent the severity of disease in ethnic minorities and introduce bias into the study.

Finally, the study sample was more than 75 percent non-Hispanic white for both CAD and CHF. Low representation of minorities in the sample may limit the ability to draw conclusions for these populations, which is particularly troublesome in a study examining inequities in health outcomes among patient groups. Underrepresentation of minority groups in clinical trials is well documented [7]. It is problematic to exclude certain populations from studies because conclusions generalized from a population with particular illness behaviors and life circumstances are applied to other groups which may or may not share them.

One particular strength of this study is the authors' ability to draw conclusions about women, who represented 48 percent of their study population. Women are traditionally underrepresented in clinical trials and studies [8]; this paper did not suffer that fate.

Study Results and Epidemiologic Implications

The authors found that, for both CAD and CHF, women were less likely than men, and community health center patients were less likely than hospital practice patients, to receive primary and follow-up cardiology consultation. They noted additionally that women experienced greater health benefits than men when they did receive a cardiology consultation.

The authors unsurprisingly found that whites were more likely than blacks, and—perhaps surprisingly—that Medicare/Medicaid patients were more likely than privately insured patients, to receive primary consultation for CAD. The well-known and long-standing disparities in health outcomes between patients who are in minority groups and those who are not persisted. Patients with consultation status, men, whites, and privately insured patients had better outcomes than those without consultation, women, blacks, Hispanics, and Medicaid recipients.

Research supports the hypothesis that members of racial minorities are less likely to receive intervention for acute coronary syndrome (ACS) than whites [9]. This evidence also suggests that cardiology consultation may be an important factor in bridging the gap in the rate of intervention, and Cook et al's conclusion that minorities receive fewer consultations may indeed account for at least part of that gap.

Ethical Considerations

Health inequities—what people tend to mean when they say "health disparities"—are of significant ethical concern due to the confluence of two findings: (1) when all else is corrected for, some groups—in this study, women and members of minority racial and ethnic groups in particular—receive worse health care and have poorer health outcomes than others, and (2) this seems to be explained by nonclinical factors (e.g., gender and race/ethnicity) or, put another way, factors that should not matter. The latter of those findings is an important one that defines the difference between inequality and inequity introduced at the beginning of this article. Inequalities are everywhere in our world, and only a true utopian (or dystopian, depending on the point of view) would believe it possible to eliminate all of them.

The same is true in health care: there is most certainly an inequality in the rates of cancer between the young and the old, for instance, and, while we certainly have an enduring goal of reducing cancer in the elderly, we do not see this inequality as an injustice, because age is a factor that matters in the acquisition of genetic mutations and the development of tumors—indeed on some level, it *should* matter. Inequities, on the other hand, are unjust inequalities; those made by factors—race, gender, socioeconomic status—that we believe should not matter.

The bioethical principle that underlies our moral objection to inequities, such as those illustrated by Cook and colleagues, is justice. Rooted in the Aristotelian notion that "equals must be treated equally, and unequals must be treated unequally" [10], justice can be thought of, though it is indeed more complicated, as a measure of fairness and of what is "due" to an individual. It follows that our objection to health inequities derives from our view that these situations can be described as the unequal treatment of those who, for the purposes of the issue at stake, are equal. That is to say, there is no inherent reason why blacks and whites and women and men should have unequal access to specialty cardiology consultation, and yet they do.

Objection to unequal access, characterized rightly as an injustice, also carries with it a moral and ethical imperative to reduce or remove the inequity. What makes such a task so difficult is that inequities—different rates of cardiology consultation, for instance—are systemic and come about less from overt discrimination than from subtle patterns unnoticeable in individual patient interactions. It takes statistical analyses of the sort that Cook and colleagues executed to even identify the inequities, and it is vitally important that such research is done to find, as precisely as possible, where inequities exist and to give us a chance to address them.

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CLINICAL PEARL

Diagnosing and Treating Acute Infective Endocarditis

Arash Aghel, MD, and Sri Madan Mohan, MD

Infective endocarditis (IE) is broadly defined as a microbial infection involving the endocardium, or inner chamber lining, of the heart. The process is termed "acute" if it progresses over days to weeks or "sub-acute" if it has a more protracted course. The incidence of infective endocarditis in population studies is estimated to be between 3.6 and 7 cases per 100,000 patient years [1]. Infective endocarditis occurs predominantly in the context of structural heart disease and conditions or procedures that increase the risk of bloodstream infections, such as indwelling intravenous catheters, hemodialysis, prolonged hospitalization, pacemaker or ICD placement, and intravenous drug abuse. Despite advances in modern medicine, infective endocarditis remains a major cause of death from an infectious process, with an overall mortality approaching 20 percent.

Infective endocarditis occurs when platelet-fibrin deposition takes place in an area of endothelial injury caused by a high-velocity jet from a dysfunctional valve. This process results in small sterile vegetations. During episodes of bacteremia, these deposits can become secondarily infected; if untreated, the infection can progress to valve destruction and distal embolization. The most common organisms causing bacterial endocarditis are staphylococci, streptococci, and enterococci species.

Diagnosis

Fever is by far the most common sign or symptom of acute infective endocarditis. Other constitutional symptoms include chills, sweats, loss of appetite, and malaise [2]. Although a new or changed regurgitant murmur is the most common cardiac finding on physical examination, this may be absent in right-sided endocarditis. Classic peripheral manifestations of infective endocarditis include petechiae, splinter hemorrhages, Osler nodes, Janeway lesions, and Roth spots. These are immunologic or embolic phenomena.

Echocardiography is central to the diagnosis of endocarditis. Transthoracic echocardiogram (TTE) should be the initial study of choice in most cases, though transesophageal echocardiogram (TEE) has a higher sensitivity for detecting vegetations. This makes TEE useful for patients with suboptimal images on TTE, a high likelihood of IE, or prosthetic valves.

The Modified Duke Criteria [3] is a well-validated set of clinical, microbiological, and echocardiographic criteria for diagnosing infective endocarditis. The major criteria are two positive blood cultures with a typical microorganism for infective

endocarditis and evidence of endocardial involvement on echocardiogram. The minor criteria include fever, a predisposing condition for IE (such as intravenous drug use), vascular phenomena, immunologic phenomena, and microbiological evidence not included in the major criteria. A classification of definite IE requires the presence of 2 major criteria, or 1 major and 3 minor criteria, or 5 minor criteria. The presence of 1 major criterion and 1 minor criterion, or 3 minor criteria, indicates a possible case of IE.

Treatment

It is of the utmost importance to have blood cultures drawn before initiating therapy. Physicians often infer the diagnosis from symptoms and begin treatment before the causative organism and its sensitivities have been determined. However, if the patient's clinical condition is stable, antibiotics can wait until microbiological confirmation is obtained. If treatment is started before then, it should be aimed at the common pathogens; a combination of nafcillin (or vancomycin, if the patient is allergic to penicillin or in an area with high prevalence of methicillin-resistant *Staphylococcus aureus* [MRSA]) and gentamicin is an acceptable combination. Further tailoring of the antibiotic regimen should occur once the organism is identified. Most patients with uncomplicated IE become afebrile in 3 to 5 days with appropriate antibiotic treatment. Surveillance cultures should be obtained 48 to 72 hours after treatment begins to ensure eradication of the organism.

The most common treatment regimens for specific organisms are as follows [4]:

- Methicillin-sensitive *Staphylococcus aureus* (MSSA): nafcillin or oxacillin for 6 weeks, plus optional gentamicin for 3-5 days;
- Methicillin-resistant *Staphylococcus aureus* (MRSA): vancomycin for 6 weeks
- Staphylococcus with prosthetic valve: nafcillin or oxacillin plus rifampin for at least 6 weeks, with gentamicin given for 2 weeks; for methicillin-resistant strains, use vancomycin in place of nafcillin or oxacillin;
- Penicillin-susceptible Streptococcus: penicillin G or ceftriaxone for 4 weeks; vancomycin for 4 weeks if penicillin allergy is present;
- Penicillin-resistant Streptococcus: ceftriaxone for 4 weeks plus gentamicin for 2 weeks, or vanomycin for 4 weeks;
- Enterococci: penicillin G or ampicillin plus gentamicin for 4-6 weeks, or vancomicin plus gentamicin for 6 weeks;
- HACEK microorganisms: ceftriaxone for 4 weeks, ampicillin-sulbactam for 4 weeks, or ciprofloxacin for 4 weeks.

Indications for surgery

In one-third of patients with IE, antibiotic therapy alone is not sufficient, and surgical intervention is necessary to debride the infected source and restore valve competence. Repair of the valve is preferable, if feasible. A good understanding of the indications for surgery allows for early risk stratification of patients who will benefit from it. Patients who require surgical intervention during the acute phase of

endocarditis are usually ill, and although mortality is high in this setting, survival is still significantly better than with medical therapy alone.

Some of the most common indications for surgery are as follows [5]:
Clear indications

- Acute severe valvular dysfunction or valvular dysfunction resulting in heart failure;
- Persistent infection despite 7-10 days of antibiotic treatment;
- Structural complications such as valve abscess or fistula formation;
- Endocarditis caused by fungi or other resistant organisms.

Relative indications

- Recurrent embolic events despite antibiotic therapy; native or prosthetic valve;
- Mobile vegetation larger than 10 mm;
- IE due to virulent organisms such as *Staphylococcus aureus*, making valve repair preferable to delayed valve replacement.

IE in IV Drug Users

There is a higher incidence of IE among intravenous drug users (IVDUs) than in the general population. The majority of right-sided IE occurs in IVDUs, with septic pulmonary emboli present in 75 percent of such patients. *Staphylococcus aureus* is the most frequent pathogen. As for non-IVDUs, antibiotic therapy is guided by culture results. The prognosis for drug-using patients with right-sided IE is generally good with medical therapy, but problems often arise when these patients have recurrent bouts of IE in the setting of continued IV drug abuse. While indications for surgery are similar whether the patient is an intravenous drug user or not, ethical considerations regarding the indications, timing, and choice of valve are paramount.

Final Points

Treatment of infective endocarditis requires a multidisciplinary approach. It is generally advisable to involve a cardiologist, an infectious disease specialist, and a cardiac surgeon early on in the course of the disease. Prompt antibiotic therapy geared toward the causative organism and careful timing of surgical intervention, if indicated, are essential to ensuring a good outcome.

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HEALTH LAW

Testing Manufacturer Liability in FDA-Approved Device Malfunction

Ryan Bailey and Kristin E. Schleiter, JD, LLM

In 1996, an Evergreen Balloon Catheter, marketed by Medtronic, Inc., burst during Charles Riegel's angioplasty [1]. The catheter had been granted premarket approval (PMA) from the Food and Drug Administration (FDA) in 1994. While the manufacturer's instructions recommended that physicians inflate the catheter to only 8 atmospheres, the treating physician in Riegel's case inflated the catheter to 10 atmospheres before it burst. As a result, Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypass surgery.

Riegel and his wife filed a product liability complaint against Medtronic. A federal district court dismissed the complaint, holding that federal legislation—the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act [2] preempted the state negligence and liability claims the Riegels cited in their case against Medtronic. The case eventually made its way to the U.S. Supreme Court.

Riegel v. Medtronic, Inc. brings to light a conflict between manufacturers who have obtained FDA approval and injured patients who want to retain the option of seeking restitution for damages resulting from defective medical devices [3]. Patients who believe defective devices caused their injuries take little comfort in knowing that the devices had FDA approval. Conversely, device manufacturers who received FDA approval after extensive review want to avoid repeating the review process in the courts. In *Riegel*, the Supreme Court addressed whether the preemption clause of the Medical Device Amendments bars state law claims that challenge the safety and effectiveness of a medical device given premarket approval by the FDA.

Summary of the Medical Device Amendments of 1976

The Medical Device Amendments (MDA) of 1976 established three regulatory classes of medical devices. Class I medical devices, which include elastic bandages and examination gloves, are subject to "general controls," such as labeling requirements [4]. Class II medical devices, which include powered wheelchairs and surgical drapes, are subject to "special controls," such as performance standards [4].

The most regulated medical devices are those in Class III, which the amendments define as devices that support or sustain human life, are "of substantial importance in preventing impairment of human health" or "present a potential, unreasonable risk of illness or injury" [4]. Class III medical devices include replacement heart valves and the catheter used on Charles Riegel. These devices are subject to a rigorous premarket approval (PMA) process that includes:

- full reports of all studies and investigations of the device's safety;
- a complete statement of the device's components, ingredients, and properties;

- a detailed description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device;
- samples of device components required by the FDA; and
- a specimen of the proposed labeling [1].

The FDA grants premarket approval to Class III devices only after determining that there is reasonable assurance of their safety and effectiveness [5]. In making this determination, the FDA weighs any probable benefit to health from the use of the device against any probable risk of injury in light of available alternatives. For example, a ventricular assist device for children with heart failure was approved, despite a survival rate of less than 50 percent in children using the device, because no other device had a higher survival rate [1]. However, a Class III device that fails to meet PMA requirements is considered unmarketable [4].

At issue in *Riegel* was the Medical Device Amendments' preemption clause. In general, preemption clauses provide that federal laws that conflict with state laws will trump, or "preempt" them [6]. The preemption clause in the Medical Device Amendments prohibits states from establishing a requirement with regard to any device intended for human use that is different from, or in addition to, any federal requirement applicable to the device [5]. The preemption clause also forbids states from establishing any requirement that relates to the safety or effectiveness of a device intended for human use [5].

How Safe is Safe Enough?

The dispute in *Riegel* centered on the amount of regulation necessary to ensure the safety and effectiveness of medical devices. Medtronic argued that letting state claims proceed against devices that had passed the premarket approval process would usurp the power of the FDA, because the PMA process was designed to assure the safety and effectiveness of medical devices [7]. The Riegels countered that Congress never intended the FDA's power to regulate medical devices to negate the right of private citizens to sue negligent manufacturers [8].

The Riegels also contended that FDA regulations alone were not enough to protect consumers, since no amount of rigor in the premarket approval process could predict all possible outcomes or problems with a device and its use. Without the threat of litigation, the Riegels argued, manufacturers could attempt to hide safety flaws from the FDA [9].

Medtronic challenged the plaintiffs' assertion that the threat of litigation would improve product safety. Instead, it argued, state restrictions would reduce innovation in the development and availability of beneficial medical devices [7]. Moreover, Medtronic argued, because manufacturers factor the cost of potential litigation into product prices, increasing the threat of litigation would increase the cost of health insurance and put some devices out of reach of potential consumers [10].

Interpreting the Medical Device Amendments and Applicable Precedent

To settle this dispute, the Supreme Court turned to judicial precedent and the plain text of the Medical Device Amendments' preemption clause. In particular, the Court relied on its 1996 decision in *Medtronic v. Lohr*. In *Lohr*, the Supreme Court had ruled that the Medical Device Amendments preempt state requirements only when the FDA has established "specific counterpart regulations or there are specific requirements applicable to a particular device" [11]—in other words, only when the FDA has a regulation that covers the same safety aspect or the same device that the state requirement covers. The Court rejected the Medtronic contention that general labeling requirements for all medical devices fall under this "specific counterpart" description [10].

Unlike general labeling requirements, premarket approval entails an in-depth review of a specific medical device. Writing for the majority, Justice Scalia stressed that the premarket approval process for medical devices is one that is rigorous and highly individualized [1]. The Court held that because "premarket approval is specific to individual devices" it constitutes "federal safety review" which, under the Medical Device Amendments, preempts state law [1]. Because the Medtronic catheter that burst during Charles Riegel's angioplasty had premarket approval from the FDA, state claims against its manufacturer were invalid under the Medical Device Amendment and *Lohr* [1]. In support of this holding, Justice Kennedy emphasized during oral arguments that, if state law damage claims were not preempted by federal regulations, state juries would be asked to repeat the demanding review process already completed by the FDA for any potentially hazardous device [3].

The Effect of the Ruling

By ruling against the Riegels, the Supreme Court refused to allow injured patients to sue device manufacturers whose products pass the FDA's findings of adequate safety. This ruling prevents courts from enforcing state regulations on medical devices with premarket approval unless those restrictions are identical to corresponding FDA restrictions. Going forward, this may prevent consumers injured by such devices from receiving adequate compensation [8]. Though consumers are not completely without legal recourse—they can still bring suit against negligent manufacturers under state laws identical to FDA requirements or against negligent physicians—the Supreme Court has immunized PMA medical devices from many product liability suits founded in state law, leaving some injured consumers without a common source of judicial remedy [1, 10].

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POLICY FORUM

Trans Fats, the Rational Consumer, and the Role of Government

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In 2006, a new federal regulation was implemented requiring packaged foods to include trans fat content on their nutrition labels [1]. Restaurant foods were not covered by the labeling requirement, but a more stringent "trans fat ban" for restaurants (servings cannot exceed 0.5 grams) was passed later that year in New York City [2, 3]. Similar restaurant-specific "bans" have since been enacted in dozens of local and state jurisdictions [4, 5] but remain highly controversial.

It is no surprise that policymakers have taken an increased interest in trans fat consumption. A large and growing medical literature links consumption of trans fats to cardiovascular disease [6]. According to the American Medical Association, replacing artificial trans fats with healthier oils could save 30,000 to 100,000 lives annually in the U.S. [7]. Should the government not try to reduce the amount of trans fat Americans consume to help improve the population's health and longevity? More generally, what role (if any) should public policy play in moving the population towards healthier diets?

The purpose of this commentary is to discuss the leading economic arguments for government intervention in food consumption decisions: negative externalities, imperfect information, and self-control problems. Each is ultimately an argument for some deficiency in how individuals make dietary choices—that individuals ignore the costs imposed on *others* (negative externalities) or misjudge or undervalue the *personal* health costs (imperfect information or self-control problems). While proponents of trans fat regulation often base their arguments on negative externalities, evidence of their existence is lacking, and the empirical justification for government intervention lies in the other two arguments.

A Benchmark Model: The Rational, Well-Informed Consumer

In modeling consumption behavior, economists commonly assume that individuals make rational, well-informed decisions to maximize their own well-being. These assumptions lead to a predisposition against government interference with free choice, including interventions to reduce consumption of unhealthy foods. When rational consumers choose particular diets, they presumably do so because the benefits they derive from those diets—taking into account concerns for food price, taste, and healthfulness—are greater than they would obtain from any other diet. Interfering with free choice, therefore, can only serve to reduce people's welfare and should be avoided.

Importantly, rationality does not preclude the consumption of unhealthy foods. As Tomas Philipson and Richard Posner put it, "rational persons constantly trade off health for competing goods, such as pleasure, income, time and alternative consumption possibilities" [8]. In the case of trans fats, an individual could be informed about the health implications of a high-trans fat diet and still "rationally" choose such a diet because, for him or her, the expected health gains from eating more healthfully are insufficient to justify paying higher prices or consuming less-flavorful foods. If people choose unhealthy diets or lifestyles, so be it: they are theoretically choosing what maximizes their own well-being—if they are rational and well-informed.

In traditional economic analysis, food producers play only a secondary role in the determination of people's diets. Economists consider food production to be a competitive industry; producers compete by developing foods with price, taste, and health attributes that consumers find most desirable. To most economists, blaming food producers for consumers' diets is akin to blaming the tail for wagging the dog. What the market produces is presumably what consumers demand.

Negative Externalities

Even if consumers are rational and well-informed, an economic case for government intervention exists if negative externalities are present—that is, if the costs associated with trans fat consumption extend to others. It is easy to imagine this is true. Poor health leads to higher medical spending, the cost of which is mostly paid "by society" through higher premiums and taxes. Poor health can lead to work disabilities, reducing a worker's productivity (a cost partly borne by his or her employer) and can potentially qualify a person for disability-related benefits (a cost borne by taxpayers).

Rational, self-interested consumers have no reason to consider these "external" costs when they make food choices, and, as a result, the choices individuals make to maximize their *own* well-being may not maximize *aggregate* well-being. In effect, self-interested consumers overconsume unhealthy foods because the cost of doing so falls partly on others.

The traditional economic solution to the problem of negative externalities is to raise the price of the personal choice through "corrective taxation"; the price of eating foods with trans fats is "too low" because it fails to capture the external costs associated with trans fat consumption [9]. If a gram of trans fat consumption imposes an $X cost on society, a tax of $X should be set per gram of trans fat in each food item. If the social costs associated with trans fat consumption were sufficiently high, this could even justify a ban on trans fats.

Whether a trans fat tax (or ban) is *empirically* justified by negative externalities therefore rests on the magnitude of social costs associated with trans fat consumption. Unfortunately, no empirical evidence exists that speaks to the social

cost of trans fat consumption, but evidence from the contexts of obesity and smoking is revealing.

While policymakers commonly assume that obesity and smoking impose large economic burdens on society, the evidence base for negative externalities is quite poor [8, 10, 11]. Cost estimates for obesity and smoking rarely distinguish between costs to the individual and costs to society. Moreover, these estimates generally rely on *contemporaneous* comparisons of health care consumption and other costs, not costs over the lifetime of individuals. This has the predictable effect of exaggerating the social costs associated with smoking and obesity, since decreased life expectancy translates into reduced social spending on elderly benefit programs like Medicare and Social Security [12, 13]. A recent Dutch study estimating the lifetime medical costs for different cohorts of individuals—an obese cohort, a smoker cohort, and a "healthy" cohort (nonsmokers with body mass index between 18.5 and 25)—found that lifetime costs were 12 percent higher among the healthy individuals than among the obese and 27 percent higher than among smokers [14]. While more research in this vein is needed, it raises the suspicion that the social costs associated with poor diets may be small or even negative, in which case it would be difficult to support government intervention on those grounds.

Do Consumers Maximize Their Own Welfare in Trans Fat Consumption?

The logic of negative externalities is that consumers undervalue the healthfulness of their food choices because the health costs of a poor diet fall partly on others. An alternative and more controversial possibility is that consumers undervalue the healthfulness of their food choices to the detriment of their *own* well-being. Assessing the truth of this is difficult since the optimal decision for a particular consumer depends on personal preferences that we cannot observe.

To demonstrate, consider the costs and benefits to American consumers if they voluntarily eliminated artificial trans fats from their diets. If consumers were currently maximizing their own well-being, the personal costs of eliminating trans fats would have to exceed the benefits. If the AMA is correct, the elimination of trans fats would save 30,000 to 100,000 lives annually. Economic evidence suggests that $7 million represents a reasonable estimate for the value Americans place on a "statistical life" (i.e. the elimination of one mortality through the reduction in some mortality risk) based on how much workers need to be paid to accept more dangerous jobs [15]. In monetary terms, then, the annual health benefit consumers would enjoy is roughly estimated at $210 to $700 billion in aggregate, or, when spread over 308 million citizens, $680 to $2,270 for the average consumer.

The financial costs are seemingly trivial in comparison. There is some suggestion in the literature that the trans fat ban in Denmark has not affected food production costs [16], but no meaningful empirical evidence supports this claim. More likely, replacing trans fats with healthier oils would increase food production costs but only by a small amount—almost certainly by less than 1 percent [17]. We should expect consumers to ultimately bear this cost by paying higher food prices. In light of

current aggregate spending on food in the U.S. ($1.2 trillion annually), the aggregate annual financial cost imposed on consumers is likely less than $12 billion, or less than $40 for the average consumer [18].

If the only costs were financial, then it seems impossible that *current* diets are optimal since eliminating trans fats would apparently leave the average consumer better off. Only if the "taste costs" (i.e., loss of flavor) of eliminating trans fats were very large could we defend the notion that trans fat consumption levels are well-informed and rational. Based on the estimated financial costs (less than $40 per person) and estimated health benefits (at least $680 per person), taste costs would have to exceed $640 annually for the average consumer to be worse off under a self-imposed trans fat ban.

The question of whether individuals are rational, well-informed consumers of trans fats therefore rests heavily on whether the taste costs associated with reducing trans fats are large or not. Certainly, advocates for trans fat regulation believe the taste costs are small. There is some survey evidence from Denmark indicating that consumers did not notice a taste difference after artificial trans fats were banned in that country [19]. To my mind, it seems unlikely that the taste costs incurred by trans fat reduction are generally very high, though I am willing to believe taste costs could be high for some food products or for some individuals. We can also probably expect these costs to decline over time as producers innovate with healthier oils.

Imperfect Information

One reason consumers might overconsume unhealthy foods to their own detriment is that they have imperfect information: consumers could be unaware of the amount of trans fat in their food options or ill-informed about the health risks associated with trans fat consumption. Lack of information on either front could lead consumers to choose diets that are higher in trans fat than those they would choose if they were well-informed.

Economists are generally comfortable with the government playing a role to ensure that consumers have adequate information to make informed choices, for instance, through nutritional labeling requirements. Such a role may be especially important in food markets, because there is strong intuitive reason to believe the market underprovides information about the healthfulness of different food products. (McDonald's commercials emphasize the deliciousness of a Big Mac, not its 34 fat grams.) Moreover, studies document that "humans have a weak innate ability to recognize foods with a high energy density" [20], a deficiency which likely applies to other nutritional aspects of food as well.

Labeling requirements and public awareness campaigns therefore seem eminently reasonable, but their *value* depends on whether the provision of better information actually leads individuals to consume healthier diets (and must, of course, be weighed against the associated costs). The trans fat example is encouraging in this regard. Federal labeling requirements and growing awareness about the risks of trans

fats have spurred many major food producers to reformulate their products to reduce or eliminate artificial trans fats [1, 21], presumably to meet the evolving demands of better-informed consumers. Perhaps then, as public awareness increases, the provision of trans fat content information is sufficient to combat trans fat overconsumption.

Evidence from calorie labeling suggests otherwise. By now, the relationship between caloric intake and obesity is well-known, as are the risks posed by obesity. However, the limited scientific evidence on calorie labeling in restaurant settings finds inconsistent and weak effects on caloric intake. Following implementation of calorie labeling in New York City fast-food restaurants, for instance, only 28 percent of survey respondents reported seeing the new calorie labels, and labeling had no detectable effect on caloric intake [22]. In a public health sense, this speaks to the inefficacy of caloric labels to combat obesity. In an economic sense, it also undermines the notion that imperfect information about calorie content is a significant cause of high-calorie diets.

Evidence pertaining to the perceived risks of smoking casts further doubt on the usefulness of policies based on the notion that poor health behaviors stem primarily from imperfect information. Kip Viscusi finds that the perceived risks of smoking significantly reduce an individual's likelihood of smoking, but that smokers and nonsmokers alike *overestimate* the health risks associated with smoking [23]. More accurate information on the health risks of smoking might be expected to *increase* smoking rates, an implication most public health experts would find troubling.

Self-Control Problems

Since the pioneering work of Daniel Kahneman and Amos Tversky [24], economists have become increasingly cognizant of the ways people fail to act rationally. Of special import to the issue of trans fat consumption, people commonly exhibit self-control problems, valuing future outcomes far less than immediate outcomes [25, 26]. This could lead to excessive consumption of trans fats because price and taste are immediate considerations for consumers, while health considerations come to bear much later. If consumers excessively consume trans fats because they irrationally undervalue the health consequences of so doing, government interventions that increase the immediate cost of consuming trans fat can improve well-being.

Imposing a trans fat tax is one means of accomplishing this. In the case of negative externalities, we think of the tax as correcting the price of unhealthy foods to incorporate the social costs. Here, a trans fat tax corrects for individuals' tendency to underweigh the *personal* health costs of consuming unhealthy foods. Because it is predicated on the notion that people, in some decisions, fail to maximize their own welfare, such a tax could be labeled "paternalistic."

Determining the optimal tax to combat self-control problems would be very difficult. In some sense, the optimal tax depends on how much the average individual

underweighs the health consequences of trans fat consumption, which I do not presume to know. That said, a modest tax—one large enough to reverse the cost advantage trans fat holds over alternatives—would likely have a dramatic effect, especially if the taste advantage of trans fats is small. Banning trans fats is plausibly justified (if the taste costs are universally small) but possibly overreaches if there are specific foods for which trans fats contribute substantial taste value.

Conclusion

The mere fact that dietary choices affect individuals' health does not justify government's interfering in those choices. The full costs of doing so must be considered, including "taste costs" that are inherently personal and exceedingly difficult to measure. On the issue of regulating diets, economists are predisposed to favor consumer sovereignty because individuals presumably seek to maximize their own well-being. That disposition is strengthened by the recognition that political interest groups sometimes exploit regulatory regimes to their own benefit [27] and by concerns of unintended consequences, such as the replacement of one unhealthy food additive with another [28].

But these considerations do not justify a dogmatic opposition towards diet-related interventions. In the case of trans fats, it is difficult to argue that consumers are making welfare-maximizing choices unless the taste costs associated with reducing trans fats are very high—improbably high, in my opinion. More likely, individuals overconsume trans fats to their own detriment, so that interventions to reduce trans fat consumption can improve aggregate welfare. Proponents of trans fat regulation often couch the issue in terms of negative externalities [8], but the existence of negative externalities in dietary decisions is highly suspect and certainly lacks any meaningful empirical support.

Information-related interventions, such as labeling requirements and public awareness campaigns, are probably justified. Growing public awareness about trans fat risks has led many producers to dramatically reduce trans fat content in their products. Still, the evidence from calorie labeling suggests a limit to how much poor diets can be attributed to poor information.

More dramatic interventions may be warranted. Given the uncertainty regarding the taste costs of reducing trans fat, one pragmatic option would be to impose a modest tax based on the trans fat content of foods. A tax large enough to offset the current cost advantage of trans fat over healthier oils could have a dramatic effect, especially if (as advocates believe) the taste costs of reducing the trans fat content are low.

Aside from intervening in dietary choice in these ways, the government can also play a positive role in another fundamental way. By sponsoring research to improve the relative taste of trans fat alternatives, the government could promote trans fat reduction without interfering with consumer sovereignty. If the taste costs were known to be small, government interventions to reduce trans fat consumption would be more easily justified—and, perhaps, no longer necessary.

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into an annual cost of $490 million, which is less than 0.1 percent of total restaurant sales. The percentage increase in the price of home-prepared foods is likely smaller, given that restaurant foods are generally higher in trans fat.
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The Personal, Social, and Economic Determinants of Cardiovascular Disease

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Ms. Simpson is a 58-year-old woman who has hypertension, is overweight, and has smoked a pack a day for the last 40 years. She recently suffered a heart attack.

As an internist I know this case is all too common and comes in many variations. Though we can see the role of Ms. Simpson's personal choices in her heart attack, there are outside influences of which she and others like her may be unaware. No one forced her to make the individual choices she has made over the last few decades, but there were indeed forces working against her making healthier decisions. Let us look more closely at her life and the context of her choices and health behaviors to discern who else may have played a role. We will examine what could have been and still can be done to ameliorate her situation, and, more generally, reverse the cardiovascular disease (CVD) trend in our country.

Ms. Simpson's Surroundings

Ms. Simpson lives with her 35-year-old daughter and two grandchildren, whom she helps look after. Since her heart attack, Ms. Simpson has been on disability from her job at the post office. Her daughter is a single mother who works as a phlebotomist. The Simpsons live in an area that would be considered a "food desert" for its lack of supermarkets that supply fresh produce and other healthy food items.

Living in a food desert equals poor access to healthy foods, which has been associated with worse cardiovascular health [1]. The process by which particular areas become food deserts is complex, with socioeconomic, geographic, and market force contributors [2]. Supermarket chains argue that it is difficult to make a profit in low-income neighborhoods. There is growing recognition of this and other types of environmental and local factors that play a critical role in the health of individuals and communities. Recent, innovative work by the Food Trust has created models for sustainable partnerships for transforming food deserts in low-income areas [3].

Ms. Simpson knows that she and her family should exercise, but there are no sidewalks where they live and few outdoor spaces for physical activity. In the evening it is not safe to be outside. The absence of sidewalks, outdoor green space, and safe streets compounds her situation [4, 5], but they are unable to move, so what can she do about it? She cannot afford a gym membership, and, on top of it all, she finds it difficult to make time to exercise.

Ms. Simpson would benefit from education on the importance of physical activity and also from some practical guidance on easy, inexpensive, and safe ways to increase daily activity that are specific to her situation. Where should she get this information? Should she have learned it in school in physical education class or from her doctor's office? Should she have received the information from her employer or health insurer, both of whom have a vested interest in her health?

Generally families with fewer resources make up communities with fewer resources. Yet communities can and should advocate for green spaces and recreation centers in their neighborhoods, as well as supermarkets that carry fresh produce [6]. Similarly, city planners should consider community health when they design and redesign neighborhoods [7]. And communities must be able to count on support from their local government in meeting these needs. Making communities safe should be a priority, not just to bring down violence, but also to improve the overall health of community members by enabling them to engage in more outdoor physical activities.

In part because of the lack of a local supermarket, as well as her daughter's busy work schedule, Ms. Simpson's family tends to eat out a lot, frequenting the local fast food joint where Ms. Simpson's dollar can stretch and she can feed her entire family for $20, especially when she gets the value meals with extra large fries and soda. When Ms. Simpson does get to the nearest supermarket, she finds that a bag of chips and a soda are less expensive than fruits and vegetables for a snack. She knows the fruits are a better health choice, but she feels she just can't afford it. She also finds that processed foods like instant mac and cheese are cheaper and more convenient than other items.

Unfortunately, that convenience and apparent value-for-dollar are not really the good deal they seem to be, when the future health consequences of these conveniences are calculated, since increased fast food intake is associated with increased weight [8]. That processed foods are less expensive than fresh produce seems a paradox, but is another complex issue. Some point to government subsidies, on corn, for example [9], as a major culprit, while others dispute that [10]. Given the unintended consequences, perhaps the government should reconsider its agricultural policies [11]. Others also point to the food industry and corporate America and their ruthless pursuit of a profit.

Role of the Food Industry

Though she has a general sense of what foods are good for you, Ms. Simpson doesn't understand the nutrition and calorie information on labels. She looks for items that say "fat free" or imply that they're "healthy" on the package. We know that nutrition information is not easily interpretable by consumers [12]. More must be done to arm individuals with the knowledge they need to pick health-promoting foods and make other healthy choices. Once again, whose job is this, the public education system in health education class; the health care system (physicians or nurses); or employers and insurers? Perhaps we need to invent a simplified way of deciphering the nutritional content of foods. We also need to find better ways to

counterbalance the existing disincentives for choosing nutritious foods, whether through effective messaging, product placement, discounts or taxes, or other innovative methods.

Furthermore, though diet soda, which Ms. Simpson hears is better for her family, is the same price as the regular, high-calorie soda, it just doesn't taste the same to her and her grandkids. On top of that, her grandkids know exactly what they want from watching TV, and it's always the junk food. Resisting the children's pleas for the latest hero-shaped cookie, colorful sugary cereal, or soda often takes more time and energy than Ms. Simpson has.

The food industry's prowess and success in marketing to children is undeniable [13]. While I doubt there could be significant regulation of food marketing directed at children on TV, there is increasing interest in regulation of fast food advertising in the vicinities of schools, similar to restriction of alcohol and tobacco advertising in many cities and states [14]. The food industry may, like the tobacco industry, cry "foul," citing their constitutional right to free speech. Instead, industry leaders ought to reflect on the consequences their marketing machine has on the health of the nation and consider self-regulating and limiting their advertising aimed at children. An association has been demonstrated between TV viewing and increased consumption of foods advertised, so parents should also consider the hours their children (and they, themselves) are exposed to commercial advertisements. [15].

Years ago, long-term corporate growth was the expectation. Today's corporate shareholders expect companies to post a profit every quarter. This desire for quick profit often results in decisions that don't consider the long view or the larger effect on the health of society [13]. Will corporate America reflect and reign itself in, or will government have to step in to regulate and protect the public as it has in trans fat bans and sugar taxes? Finding the right balance in the tension between the free marketplace and government regulation is the challenge.

A college friend, who is a senior marketing executive at a major beverage company, shared with me that his company's extensive marketing research finds that Americans just don't like diet or zero-calorie beverages as much as they do the regular stuff. According to him, though the company continues to invest in research to make identical tasting, zero-calorie versions of their beverages, they have not been successful. I doubt they spend as much on this as they do on advertising. They and others in the food industry must try harder to create affordable, appealing healthier products.

The Role of Health Care

While there's much funding for research on treatment of CVD, more is needed in the realm of CVD prevention, particularly on health behaviors and incentives. A year prior to her heart attack, Ms. Simpson had seen her primary care provider (PCP) because of a cold. At that visit her PCP treated the cold, but also found her blood pressure elevated and told her she needed to lose weight and quit smoking. He

scheduled her for a follow-up in 3 months and to talk with the nurse about tobacco cessation and weight management, but she never came back. Taking public transportation for an hour and waiting another hour to see her PCP for 15 minutes to talk about her weight and smoking did not seem worth it. The next time she saw him was a year later, when she was in the hospital with her heart attack.

The lack of effective resources devoted to prevention of chronic diseases such as CVD in primary care [16] undoubtedly plays a role in the state we are in. The average physician's training in nutrition, weight management, and tobacco cessation counseling is fair at best [17]. Not only that, but the limited amount of time PCPs have during a visit is a barrier to effective counseling on such important, individual, lifestyle-specific topics as diet and daily activity [18]. Given these limitations on physician time and training, maybe other members of the health care team, such as health behaviorists or nurses, should take on that education role. New models of care that integrate health promotion and disease prevention in a multidisciplinary manner are needed, and everyone is hoping the patient-centered medical home will be it.

The shortage of primary care physicians does not help the situation. Medical students are discouraged from going into primary care fields by current reimbursement structures that favor procedurally oriented specialties [19]. And it is difficult to obtain payment for prevention services such as educating and counseling about nutrition, physical activity, or cardiovascular risk [20]. How do we realign incentives to aid PCPs in focusing on prevention? More governmental investment in prevention and primary care is a start, including reevaluating reimbursement structures. The new health care financing reform act affords some hope that greater investment will be made in prevention and primary care.

Conclusion

By considering Ms. Simpson's situation, we can see that the problem of CVD in America is a complex one influenced by many sectors of our society, some of which are not obvious contributors at first blush. I touch upon some of the larger players, but there are others that I did not have space to mention. Everyone is affected by the prevalence of CVD, whether or not you or someone you know has the disease. At a minimum, we all bear the cost through elevated insurance premiums and taxes that pay for the publicly insured [21]. But there are other reasons we should all care about CVD in America. Perhaps we, too, should reflect on how we may be silent accomplices to the epidemic.

First Lady Michelle Obama has called the country to action, specifically challenging industries to realign some of their incentives and the forces that work against a heart-healthy America. Though her focus is children and obesity, the issues are relevant to our society as a whole. Like the problem, the solution is not simple and will require the participation and commitment of many sectors of our society. It is up to us. Will we heed the call to reverse the trend of CVD in the U.S.?

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MEDICINE AND SOCIETY

"For Me There Is No Substitute"—Authenticity, Uniqueness, and the Lessons of Lipitor

Jeremy A. Greene, MD, PhD

Analysts of the pharmaceutical industry have questioned what will happen in 2011 when Lipitor—Pfizer's sales leader for more than a decade and the world's best-selling prescription drug, ever—loses its patent exclusivity and faces generic competition [1]. When it was first approved for marketing by the U.S. Food and Drug Administration (FDA) in January 1997, Lipitor (atorvastatin) was a "me-too" drug, the fifth entry into the therapeutic class of HMG-CoA-reductase inhibitors, or statins. Entering this already-crowded field alongside Merck's Mevacor (lovastatin) and Zocor (simvastatin), Novartis' Lescol (fluvastatin) and Bristol-Myers Squibb's Pravachol (pravastatin), Lipitor stood out for its claims of superior cholesterol-lowering ability, which—along with a massive marketing campaign—led to its swift and lasting dominance of the statin market, even as other agents became available in generic forms at far lower prices. Indeed, for most of the past decade, Pfizer's promotion of Lipitor has centered on convincing consumers (and their physicians) that no generic could compare to Lipitor.

The phrase "I take Lipitor instead of a generic" was embedded in the public consciousness through an advertising campaign that featured Robert Jarvik, the medical investigator-cum-entrepreneur credited with the invention of the Jarvik artificial heart. The Jarvik Lipitor campaign, first aired in early 2006, coincided with the market entry of generic simvastatin. Many readers will remember images of his silver-haired visage on bus-stops and billboards, and video sequences of a calm, confident Dr. Jarvik rowing across a mountain lake while discussing the central role of Lipitor in the maintenance of his own cardiovascular vigor. These advertisements taught patients to be wary of pharmacists, insurers, or physicians who might try to substitute a generic statin for Lipitor. "For me," Dr. Jarvik voiced, looking straight into the camera, "there is no substitute."

The campaign revolved around authenticity and the perils of imitation. Dr. Jarvik, as many would soon point out, was not an actor playing a doctor, but a "real" doctor—the first well-known case of a physician serving as a celebrity sponsor for pharmaceutical promotion. By analogy, Lipitor was the authentic center of cholesterol therapy—the market leader and strongest statin available (until the launch of Astra-Zeneca's Crestor [rosuvastatin] and now Kowa's Livalo [pitavastatin]). While the forces of cost containment might attempt to foist cheap generic "substitutes" upon patients and prescribers, the ads seemed to imply, none of these could boast the same results as Lipitor.

These claims of superior efficacy were based partly on pharmacological principles of potency—milligram per milligram, Lipitor reduced the biomarker of low-density lipoprotein (LDL)-cholesterol more than any generic statin, an abstract concept cleverly rendered graphic in the form of the curve traced by Jarvik's boat. Beyond biomarkers, by the time of the Jarvik ad campaign Pfizer could point to more than 400 trials of Lipitor, involving over 80,000 patients, which allowed for claims of clinical efficacy simply not studied in other statins. For example, one year into the Jarvik campaign, Lipitor became the first cholesterol-reducing drug approved by the FDA to lower the risk of hospitalization in patients with heart failure [2]. In other, select cases, Lipitor had been compared to the now-generically available statins in, for example, the PROVE-IT trial, which revealed better cardiovascular outcomes for patients treated with Lipitor at high doses than for those treated with pravastatin at conventional doses following myocardial infarction [3]. The implication was clear: what other drug could claim to be the same as Lipitor?

Pfizer's narrative of authenticity would soon backfire. In a popular and political environment increasingly skeptical of direct-to-consumer (DTC) pharmaceutical advertising, this broadly visible campaign was a lighting rod for criticism. Katie Watson, a bioethicist at Northwestern University, claimed that it was an ethical lapse for someone who appeared to be a practicing physician—who had direct responsibilities to patients—to accept funds to promote a prescription pharmaceutical [4]. As Jarvik became a topic of conversation for pharmaceutical industry bloggers both sympathetic to and critical of DTC advertising, publicly available sources of information were scoured to flesh out the story of this controversial spokesperson.

Jarvik had received poor grades as an undergraduate at Syracuse University. He had difficulty getting into medical school and had ultimately received his MD from an offshore medical school, after having been rejected for admission by American schools. Then came the most surprising detail: not only had Jarvik attended a suspect school—he was not a cardiologist [5]. Not only was he not a cardiologist, he was not currently licensed to practice medicine. Not only was he not currently licensed, but he had never had a license to prescribe drugs in the United States. Indeed, through the work of a loose collective of bloggers, it soon became apparent that Robert Jarvik—though an accomplished researcher who had received a full undergraduate medical education—had never completed a residency or internship and had no clinical experience in internal medicine beyond the few months afforded by his undergraduate clerkships. As the story grew, competitors in the field of cardiovascular engineering came forward and announced that Jarvik had falsely claimed credit for inventing the artificial heart, arguing that the concept and technique had predated his own work.

These critiques of Jarvik as professional were soon joined by critiques of Jarvik as patient. By mid-2006, a middle-aged rower in Seattle named Dennis Williams, whose receding silver hairline bore close similarity to Jarvik's own, announced that he had served as a body double for Jarvik's solo-rowing craft during a 3-day commercial shoot at Lake Crescent, Washington [6]. Jarvik, who had rowed when

younger but had not been an active rower for several years, was filmed with oars in hand on a rowing platform by the side of the lake, and the frames had been superimposed to give the appearance that Jarvik himself was navigating the mountain waters. A subsequent admission by Jarvik that his own use of Lipitor did not begin until after he had been hired as a Pfizer spokesperson rendered the implied depiction of Lipitor as responsible for Jarvik's cardiovascular health still more troubling [7].

Jarvik's authenticity as both physician and patient spokesperson was visibly frayed. Taken claim by claim, the Jarvik Lipitor advertisements contained no outright lies, but constituted an assemblage of partial truths that, taken together, gave viewers the wrong impression. For a marketing campaign based on the importance of authenticity, these revelations of dissimulation were intensely damaging. The rowing ad was replaced by an ad showing a person unequivocally identifiable as Jarvik jogging with his son. But substituting one form of cardiovascular performance (jogging) for another (rowing) was not sufficient to quell the growing unrest over the campaign. By late 2007, it had been taken up by Congressman John Dingell's (D-MI) Committee on Energy and Commerce as a signature example of duplicity in DTC marketing. Pfizer received letters of investigation and a subpoena in January of 2008, and a Pfizer executive appeared in congressional hearings to testify about the campaign in May of 2008 [8]. Concerns about Jarvik's authenticity as clinician, prescriber, patient, and athlete seemed to threaten Lipitor's authenticity as a singular form of therapy. The portrayal of Jarvik as spokesperson and the positioning of Lipitor as superior to generic statins were explicitly linked in the congressional cross-examination of Pfizer's representative. If, for Jarvik, there clearly *was* a substitute (Dennis Williams), then quite possibly there was a substitute for Lipitor as well (generic simvastatin).

By the time of the congressional hearings, Pfizer had already announced the termination of the Jarvik ads. The executive responsible for marketing Lipitor, James Sage, apologized and said that, while Pfizer regretted that "the way in which we presented Dr. Jarvik in these ads has, unfortunately, led to mis-impressions and distractions" [9], Pfizer and Jarvik could nonetheless maintain that every individual statement made in these advertisements was based in a defensible claim. Real physicians and patients were left to wonder how much of Lipitor's reputation was likewise based on a string of facts each of which may have been technically correct, but which taken together may have created an impression that was misleading. After the Congressional hearings, the matter was soon forgotten: no fines or penalties were issued, no aspect of DTC advertising regulations was changed, and Pfizer moved on to another, less controversial Lipitor campaign involving "everyman" patients in place of experts.

The artful negotiation of similarity and difference continues, however, to be central to Lipitor's marketing success as the company girds for the imminent appearance of generic atorvastatin products. This is perhaps most explicit in the current Lipitor campaign, which claims with deliberate (and, for now, easy to defend) tautology that

"only Lipitor is Lipitor" [10]. Absent Jarvik, the underlying promotional message of inimitableness is still in place. Also in place is a delicate fabric of implication in which individually verifiable claims are woven together to suggest a broader untruth: that *for most patients* Lipitor is a drug incommensurate with all other statins.

Although Lipitor is more potent than generically available statins, the utility of taking a more potent drug at a higher price —when equivalent LDL-lowering capacity for most patients can simply be found at a higher dosage of the generic—remains irrelevant for most statin consumers other than those with stubbornly high initial LDL levels, or patients who require extreme lipid lowering. While clinical trials support claims of Lipitor's superior efficacy in preventing coronary events in specific sub-populations (i.e., those who have just had a myocardial infarction or been diagnosed with heart failure), these populations do not represent the lion's share of Lipitor consumers, many of whom take it at low doses, at which it is basically interchangeable with other statins.

For the majority of Lipitor consumers—who take Lipitor for primary prevention—there is no clear evidence that the higher potency of this statin translates into more favorable outcomes. There is, however, evidence that patients who take brand-name drugs are significantly *less* likely to be consistently adherent with their treatment regimens than those who take generic drugs [11], and high cost is a clear predictor of poorer adherence—a very real cause of adverse clinical outcomes. Moreover, while it is true in late 2010 that there is no generic equivalent of Lipitor, this will no longer be true in 6 months. The concept that "only Lipitor is Lipitor" seems intended to last long after atorvastatin is generically available.

Conclusion

As pharmaceutical scandals go, the Jarvik/Lipitor story was a minor affair. But the importance of scandals lies not so much in the extraordinary circumstances that give rise to their publicity, but in the vantage they provide on the political, economic, and moral structures governing ordinary activity. For decades the substitution of brand-name drugs with chemically equivalent generic versions—which provide vital cost savings for the increasingly unaffordable American health system—has been undercut by the marketing efforts of brand-name pharmaceutical manufacturers.

Although suspicion of therapeutic equivalence is occasionally grounded by specific demonstrations of well-demarcated, clinically important differences between putative equivalents (as in the case of high-dose Lipitor's superiority over moderate-dose pravastatin in post-MI patients), the history of generic drugs is a chronicle of the repeated magnification of small and specific differences into widespread popular and professional skepticism of generic drugs as a category [12]. Indeed, only in recent years has a consensus emerged that generic drugs—at least within the field of cardiovascular medicine—can be equivalent and cost-effective replacements for brand-name versions [13]. Within other fields of medicine, such as neurology, antigeneric sentiment continues apace and has led to efforts in recent years to undo state laws governing generic substitution [14]. As the economic crisis of American

health care continues to intensify, the need to reconcile our aversion to substitution in medicine has only become more urgent.

For the practicing physician, the ethics of therapeutic substitution must navigate between two comparable potential harms. On the one hand, to substitute a drug that is therapeutically different—under the pretext of assumed similarity—risks harming the patient through adverse effects, allergic responses, or decreased efficacy. On the other hand, to prescribe an expensive, brand-name drug when an inexpensive generic form is therapeutically equivalent is to cause another form of harm to the individual patient's chances for long-term therapeutic adherence—not to mention his or her pocketbook.

More perilous still is the paucity of data available to distinguish between these two risks. Indeed, the continued promotion of Lipitor's singularity in the face of impending generic competition reminds us how heavily our system for generating, circulating, and acting on medical knowledge relies upon industry-funded and industry-promoted studies meant to differentiate products rather than to provide meaningful clinical comparisons of therapies. Recent enhanced federal support for the field of comparative effectiveness research and the founding of a new Patient-Centered Outcomes Research Institute under the Patient Protection and Affordable Care Act of 2010 offer some promise for patching up these gaps in our collective knowledge base. For the present, however, resolving the everyday yet urgent problems of therapeutic equivalence—or knowing when a medicine is good enough—remains elusive for real and imitation doctors alike.

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IMAGES OF HEALING AND LEARNING

One Millimeter

Sarah Cross, MD

Eyes pull across glass
landscapes of hematoxylin & eosin:
hollow corridor of vessel within
foreign sea of blood,
horizon of starry lymph node sky.
Just one cell with its small
blue nuclear heart may
go awry.

What glimpse did van Leeuwenhoek
have with his golden glass eye?
We cannot pretend we saw the usual
three-layered curve of the cerebellum
folding over itself—a clean cloth.
Deeper the brave Purkinje cells
with their pink eyes and long lashes
are lost.

At day's end the sky is understated,
but familiar: Castor & Pollux at right,
Auriga—invisible, but always there.
The dark holds the already gone
and the yet to come.
Even Pleiades will fall into itself,
the burning cell with its cytoplasm
falling apart.

I once held a flask of cardiac myocytes,
small stars in their wet pink plastic galaxy.
I used to think of the heart as one.
But that's the thing: *each one* of these cells
was beating.

Sarah Cross, MD, is a resident physician in obstetrics and gynecology at Yale-New Haven Hospital in Connecticut. She is the winner of Northeastern Ohio Universities College of Medicine and Pharmacy's William Carlos Williams Poetry Competition, among other awards, and is a member of the editorial board for the *Journal of Medical Humanities*. Her work has appeared in *Chest*, the *Journal of Medical Humanities*, *The Pharos*, and a number of other journals.

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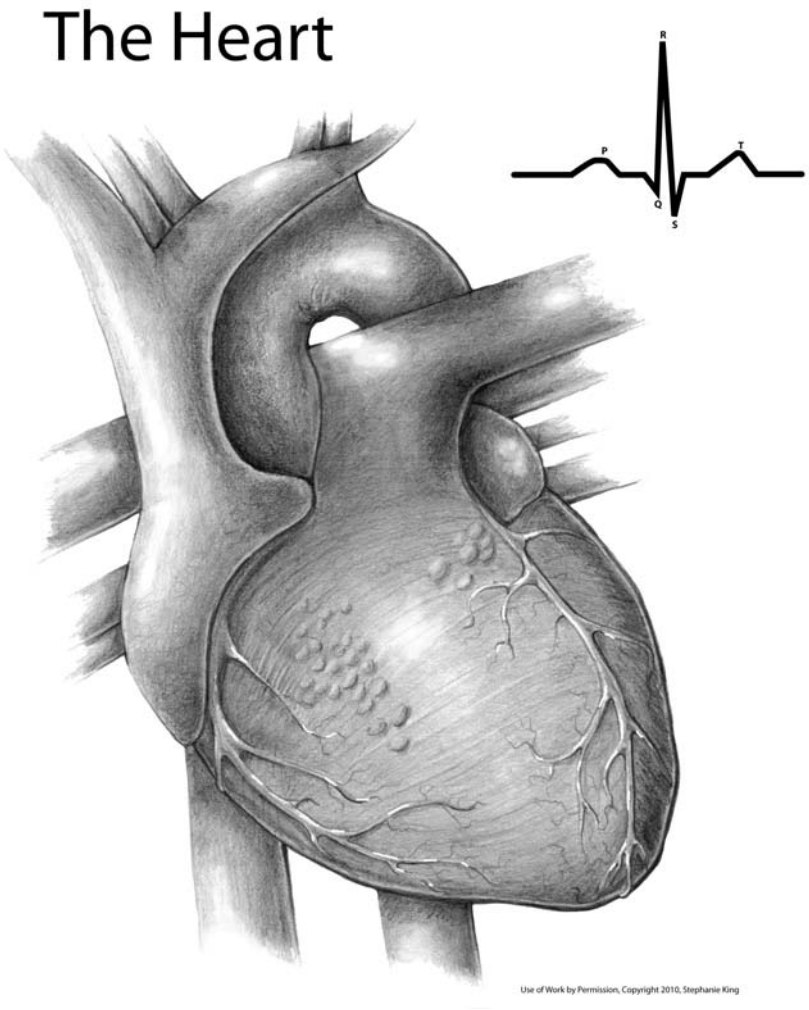
IMAGES OF HEALING AND LEARNING
The Heart
Stephanie King



Graphite on paper, 2010.

Stephanie King is a student at The Cleveland Institute of Art in Ohio, class of 2012. As a biomedical illustration major, she creates highly realistic scientific illustrations for use as learning tools. She works in colored pencil, graphite, computer rendering, photography, and paint. She started to draw at an early age and enjoys learning through science about the world around her.

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