

# CROSSROADS

VOLUME III

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Essays on  
Health Care in  
Modern America

*by*

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# Preface

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**T**en years ago, when I became president of The Johns Hopkins University, I thought the toughest challenge to the job would be managing the tremendous changes taking place in education and medicine at the start of the twenty-first century.



Since then, I've come to the conclusion you don't so much *manage* change as accommodate it; the trick is to get everyone focused on the same challenges and working toward the same solutions. And that, as any executive will attest, is easier said than done.

One tool I've found to be especially effective is a regular column I write for *Change*, the aptly-named publication that is sent twice a month to all Johns Hopkins medical faculty. In these "Crossroads" columns I've been able to talk candidly—and directly—to the employees who can make a real difference in issues ranging from infection rates to insurance premiums, research protocols to patient satisfaction results. A lot of candor and a little humor, I have found, can make a real difference in how we perceive and respond to daily challenges in medical education, patient safety, and ever-increasing cost of medical care.

The columns in this volume of essays are culled from the past several years of *Change* and represent my thinking and prognosticating about the endlessly fascinating, and oftentimes frustrating, frontiers of modern medicine. It is not without warrant to say that where Johns Hopkins goes, there too will go most of American medicine. These columns offer a good look at our thoughts, deeds and dreams as we try to make medicine more effective, and more accessible, for all.

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P.S. This discussion is ongoing. Please let me know what you think.

# Table of Contents

## **MAKING HOSPITALS SAFER**

4. **I'VE BEEN FIRED!**  
And thanks for the pink slip.
5. **BOMBS VERSUS BANDAIDS**  
Fixing only one step in flawed process doomed to fail.
6. **PERFECT IS THE ENEMY OF THE GOOD**  
Innovation stifled when bureaucracy bogs down ideas.
7. **WHERE'S THE CHECKLIST?**  
Taking a lesson from airlines makes a big difference.
8. **WHO'S ON FIRST?**  
Poorly designed systems allow human errors to cascade to a disastrous end.
9. **THE ONE PERCENT SOLUTION**  
Zero errors *is* an achievable goal.
10. **THE IMPOSSIBLE DREAM**  
Buy-in to transformative idea made all the difference.
11. **THIS REVOLUTION SHOULD NOT BE TELEVISED**  
Prenatal photo shops may hold health hazard.

## **USING OUR COMMON SENSE**

12. **YOU DESERVE A BREAK TODAY**  
There's an obesity crisis but don't blame it on McD's.
13. **THE UNFAIRNESS OF IT ALL**  
"Medical justice" is oxymoron of the year.
14. **PAPER OR PLASTIC?**  
Even in the coffee shop, our tort system has run amok.
15. **HIP! HIPAA! HOORAY!**  
Implementation of this worthy goal just plain dumb.
16. **THE END OF MEDICAL MALPRACTICE**  
Here's bigger fish for trial lawyers to fry.
17. **FOOLED BY RANDOMNESS**  
Big pharmas are setting themselves up to fail.
18. **YINNED IF YOU DO, YANGED IF YOU DON'T**  
Our absurd expectations put drug companies in a bind

## **HEALING THE HEALTH CARE SYSTEM**

19. **HEALTH CARE—THREE BIG ISSUES (AND THREE LITTLE IDEAS)**  
But do we have the political will to try new solutions?
20. **ADVERTISING'S BLACK EYE**  
DTC ads are bad for health of the health care system.

21. **NO CARDS PLEASE**  
It's "cover the uninsured week."
22. **HMO-HOPPING**  
Short-term focus equals long-term problems.
23. **IS MEDICARE COST EFFECTIVE?**  
Lessons from its success would help other sectors.
24. **DEMOGRAPHICS 102: THE GOOD, THE BAD AND THE UGLY**  
Predicting ultimate life expectancy may hold surprises.
25. **SEX, DRUGS AND MONEY**  
How to really understand Medicare Part D.
26. **DRUG ADDICTION**  
We've become a society hooked on legal meds.
27. **THE DYNAMIC HOCKEY STICK**  
What are the consequences of reducing early deaths?
28. **CHANGING THE EQUATION**  
Let's improve health, not just treat disease.

## **REFORMING ACADEMIC MEDICINE**

29. **LOST IN THE TRANSLATION**  
The public expects faster results from research.
30. **CONTRARIANS DIVERGE!**  
Applying fresh reasoning takes courage—and mentors.
31. **MEDICAL EDUCATION, POST FLEXNER**  
It's time for a serious remake.
32. **TRAINING FOR 21ST CENTURY MEDICINE**  
To cut costs, replace apprenticeship with scenarios.
33. **YOU GOTTA HAVE CONNECTIONS**  
Research workers of the world, connect up! Scientific progress depends on it.
34. **THE UNCENSORED IDEA**  
Open source network could speed new drug development.
35. **IN THE BLINK OF AN EYE**  
Clinical moxie: out of favor but never out of fashion.
36. **NO CONFLICT, NO INTEREST**  
Moving from bench to marketplace entails risk.
37. **DOCTOR BEWARE: A NEW CONFLICT OF INTEREST**  
Casual conversation can have serious consequences.
38. **WHOSE INTEREST?**  
The public holds us to a higher standard.
39. **INSTITUTIONAL CONFLICT OF INTEREST**  
At risk: our reputation and the public's interest.
40. **USE OF THE NAME**  
Determining guidelines for our seal of approval.

# I've Been Fired!

AND THANKS FOR THE PINK SLIP.

If you pick up the business section of the newspaper, hardly a day goes by that you don't read about some CEO of a Fortune 100 company who has resigned to pursue other business interests. Translation: The CEO was fired, but to avoid a lawsuit they paid the guy (or gal) off and sugar-coated the press release.

Don't you wish sometime they would tell it like it is? Well, you can read it here first: I've been fired! Bill Brody has been canned. Laid off. Booted. You can fill in whatever descriptors you would like to use. No sugar-coating it, just the unvarnished truth.

How'd it happen, you ask? Well, for several years I had been assigned to the cardiac surgery intensive care unit (CSICU) to make biweekly patient safety rounds. My job was to probe, prod, engage, indulge and lead the physicians, nurses, pharmacists, information gurus and other staff to greater heights of excellence to make the CSICU a safer and better place for patients. And during that period I wrote about a number of my experiences on the unit. We had some excellent first results and I thought I was helping in the process.

Until one day a year ago or so, after one of our meetings, the group fired me. They told me to take a hike and they would run the process themselves. My services were no longer required, or perhaps even desired. So, I hit the

road and was afraid I would never hear from them again. That is until one day a few weeks ago, when the CSICU patient safety team invited me to a safety summit. For about two hours I listened in awe as different members of the group described and demonstrated what they had been up to for the past 12 months or so. They even presented posters with their results.

Infections from central lines had fallen to almost zero. Surgical-site wound infections, down 50 percent or more. Better communication, tight glucose control, reduced time on ventilator assist, automated medication dosage distribution to reduce medication errors, etc., all leading to markedly improved patient outcomes. There were presentations by doctors, nurses, pharmacists and others—a true multidisciplinary team effort.

I see now why I was work-furloughed. As long as I was in the room, the team would never completely own the task of patient safety. With me out of the loop, everyone was willing and empowered to step up and do their part as members of a team whose focus was to do no harm and to improve patient care. Each and every team member assumed responsibility for the safety of the patient.

I am truly proud to see the power of bright, energetic caregivers and support staff giving their all for quality and safety in patient care.

Congratulations, CSICU. And thanks for the pink slip. ■



# Bombs versus Band-Aids

FIXING ONLY ONE STEP IN FLAWED PROCESS DOOMED TO FAIL.

When I was in medical school I purchased a dilapidated old car. Discovering that it lacked sufficient power to climb a modest hill, I decided that a rebuild of the engine was called for. After completing the task (over several months), I proudly took the buggy out for a spin. Lo and behold, it still couldn't make it up the hill, because whenever I applied power from the newly renovated engine, the clutch would slip. So it was back to the garage for many more weekends to rebuild the clutch. Out again for a drive, I tooted quickly and effortlessly up the hill—only to encounter sheer terror as I crested the top.

During my periodic patient safety rounds at the hospital, I have observed a tendency toward the same kind of incremental approach to problem solving. Teams are reluctant to think big. Goal-setting is conservative, and implementation strategies are designed to fix deficiencies within existing processes rather than starting over and redesigning an entirely new process.

The old curse “may you get what you wish” suggests that in our situation, if we set modest goals for safety, the best we will achieve under optimum conditions are modest gains. Conservative goals only bring about rel-

atively minor modifications to existing processes. This approach ignores the key fact that the processes are inherently flawed to begin with.

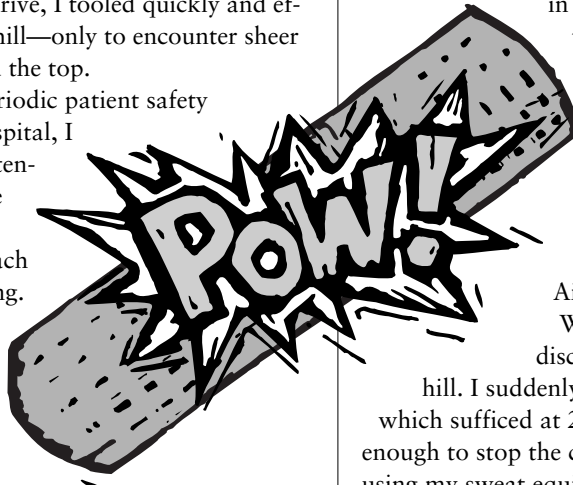
If, on the other hand, we set outrageously challenging goals, we are obligated to literally “blow up” the existing procedures and take a radically new approach. That is the only hope of achieving an audacious goal. Rather than reducing medication errors by 50 percent, we should adopt the goal of zero medication errors. Currently, we have more than 100 steps

in our existing chain between the doctor's Rx and the delivery of that medication at the bedside. It is simply not possible to have a low enough error rate per step in order to achieve a low enough overall error rate. Band-Aid fixes won't suffice.

Which is precisely what I discovered as I crested that

hill. I suddenly realized that brakes which sufficed at 25 m.p.h. were not good enough to stop the car at 50 m.p.h. Instead of using my sweat equity to fix defects, I should have taken a part-time job and used the money to purchase a newer car with properly functioning systems already in place.

Fixing one defective step in a flawed process will only highlight other defects in the system. Blow up the process and start over, with a goal of zero tolerance for errors and complications! ■



# Perfect Is the Enemy of the Good

INNOVATION STIFLED WHEN BUREAUCRACY BOGS DOWN IDEAS.

In one of my former incarnations, I was CEO of a medical imaging company. We designed and built a system for magnetic resonance imaging based around a novel magnet design—an MRI machine with the world’s most powerful non-superconducting magnet. Systems like the one we had designed are today known as “open-MRI” systems because of the much wider bore in which the patient is placed during image acquisition.

But this column is not about MRI systems. Rather, it is about an important lesson I learned from that entrepreneurial exposure. You see, to create this novel MRI system, we recruited a superbly talented engineering team and turned them loose to design a magnet that many “experts” had deemed impossible to build. And design it they did. The only problem was, this engineering group of racing thoroughbreds could never quite reach the finish line. Despite deadlines and our best intentions to get into production, there were always aspects of the magnet that could be improved. And engineers being engineers, they engineer. Never ask an engineer if something can be made better, unless you have some time to find out. At some point, however, someone has to say, “Enough is enough—let’s get on with it!”

It turns out that Hopkins doctors and nurses, though they might not know or appreciate the analogy, are “clinical engineers” at heart. They want to do the very best for our patients. And when redesigning systems for clinical care delivery, they want to be sure that they have optimized every step of the process.

The problem is when perfect, being the

enemy of the good, freezes us into inaction. A decision to change preprinted orders in the cardiac surgery intensive care unit was made by our patient innovations team, only to get bogged down in nine separate steps of review to be sure there wasn’t an uncrossed t or undotted i. More than a month’s delay ensued before we could call off the engineers and implement the newer, safer orders. Similarly, a decision by our intensivists to use antibiotic catheters in certain high-risk patients has been held up for nine months in an intellectual debate about whether such a move will actually provide a cost-effective reduction in serious blood-borne infections in open-heart surgical patients. This

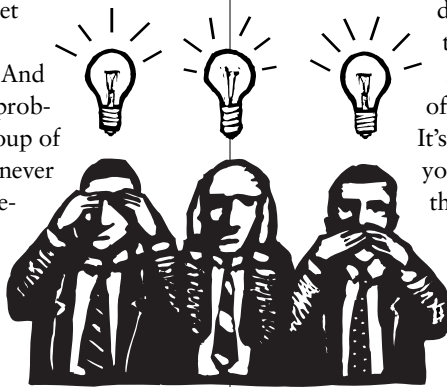
debate is somewhat akin to trying to predict whether the light in the refrigerator goes off when the door is closed.

It’s so much faster to put on your longjohns and climb into the fridge to see for yourself!

Quality improvement is not about a single, billion-dollar fix. It is about a billion one-dollar changes. Think of them as

micro-experiments in patient care, done in rapid succession with very short cycle times.

The importance of speed is that the shorter the time between idea generation and implementation, the more innovation is encouraged. Long cycle times allow ideas to get bogged down in the bureaucracy, either by over-engineering the change in a futile attempt to get to perfection, or by excessive mental gymnastics attempting to predict the outcome in advance of doing the experiment. In this case, a little less perfection can bring a whole lot more good. ■



# Where's the Checklist?

TAKING A LESSON FROM AIRLINES MAKES A BIG DIFFERENCE.

I was talking to the visionary CEO of a successful Fortune 500 company the other day and she (yes guys, wake up, it is the 21st century!) asked me the following question: “Bill, how come when I fly across country, the pilot—who has been fully certified in the proper procedures required to operate that specific aircraft—still must use a checklist, whereas my doctor may perform a procedure with no specific certification and no checklist?”

“Duh, I dunno!” replied I, unable to come up with a really good explanation. Previously, I would have told her that medicine is not like flying an airplane. It’s much more complex and varied, and things like checklists are not applicable. To implement specific certifications for individual procedures would be too complicated, costly and time consuming, I would have said.

But that was before I became a pilot. Recently, I have begun to suspect that the real reason physicians don’t have checklists and procedure certification has more to do with differences between the FAA and FDA—and to whom each agency feels it must be ready to answer. As a pilot, I have undergone intensive training, not unlike a medical residency (except the hours are better and the use of simulators for pilot training have really improved the quality, efficiency and safety of the training). Written tests and oral exams for each level of competence (private pilot, instrument rating, commercial pilot, multi-engine, flight instructor, etc.) might correspond to the written medical boards.

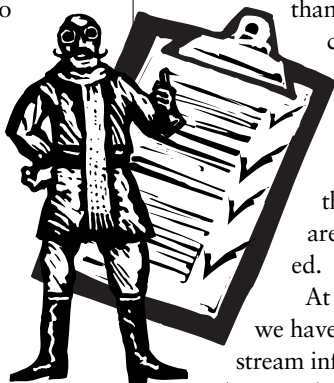
But there, the similarity ends. As a potential private pilot, or flight instructor, I must also undergo a practical test in which an FAA-authorized examiner rides in the right seat of the airplane and tries to determine my competence to

actually fly the airplane to a well-defined set of standards. Not quite the same as the “see one, do one, teach one” method in medical training.

Finally, once certified, I am required to use checklists in operating the airplane. The amazing thing to me is that although I have flown the same airplane for 500 hours, there are times when I find that I may have omitted an item (and only discover my error upon checking the checklist). This occurs even though the checklist for takeoff is very simple—consisting of fewer than 10 steps! Distraction, complacency and maybe boredom all contribute to failing to follow the prescribed procedures. But in an airplane, I am forced to cross-check using the list, so these potential errors are quickly identified and corrected.

At The Johns Hopkins Hospital, we have virtually eliminated bloodstream infections (BSIs) in ICU patients due to indwelling central venous catheters through the implementation of checklists. Doctors placing central lines are required to use the checklist. If they miss a step or fail to follow the checklist procedure properly, the nurse asks the doctor to stop the procedure and correct the error and/or restart the procedure. This change has allowed us to achieve unprecedented results: In the medical ICU, we have gone nine months without a single identifiable BSI attributable to central line contamination!

This transformation was not achieved without pushing the envelope of the medical hierarchy. I still occasionally get reports that nurses are rebuffed by doctors who fail to follow the checklist. My CEO colleague was right when she asked the question. I am convinced that procedure certification and checklists are an important vehicle for improving patient safety—a goal we should all embrace. ■



# Who's on First?

POORLY DESIGNED SYSTEMS ALLOW HUMAN ERRORS TO CASCADE TO A DISASTROUS END.

**M**any errors in complex organizations, especially hospitals, occur when we fail to clearly define lines of responsibility. Like the gang that couldn't shoot straight, the culprit in disastrous events often proves to be poorly designed systems that allow human errors (or equipment malfunctions) to cascade to a disastrous end. Recently, I came across an evaluation of a maritime disaster involving a car ferry, the *Herald of Free Enterprise*, which sank in calm seas off the coast of Belgium in 1987. On this occasion, system failures led to the 90-second capsizing of a 433-foot ship, numerous injuries and the loss of 188 lives.

The *Herald of Free Enterprise* was one of those car ferries where the bow opens up like a clamshell, allowing cars to drive on and drive off quickly and easily. On this unfortunate day, the ship left port with the clamshell bow mistakenly left in the open position. The ferry was heavily laden with cars and trucks as well as over 400 passengers. Only minutes out of the harbor it took on water, sank and almost immediately capsized. Most of the fatalities were people caught below decks as the ship dove to the bottom.

How could this happen? How could such a fundamental mistake be allowed to occur? A cascade of errors was allowed to propagate due to two factors: incomplete or non-existent communication among the crew with fuzzy lines of authority and a poor definition of responsibilities, coupled with the absence of adequate warning systems.

The sinking began when the person direct-

ly responsible for closing the doors—the assistant bosun—fell asleep in his cabin after completing his maintenance and cleaning duties. That error cascaded when the assistant bosun's supervisor noticed that the bow doors were still open, but did not close them: He did not see that as part of his duties.

The captain of the vessel assumed the doors would be safely closed unless told otherwise; even though no one was specifically assigned the duty to tell him. The chief officer, responsible for ensuring door closure, thought he saw the assistant bosun going to close the door, but did not verify that such was the case and that the doors were actually closed.

Further, the ship had a serious design flaw:

From the bridge, it was impossible to see if the doors were open, and

there was no information display (not even a single

warning light) to tell the captain if the bow

doors were open. Yet

after a similar situation two years earlier

(that resulted in a near-miss discovered before

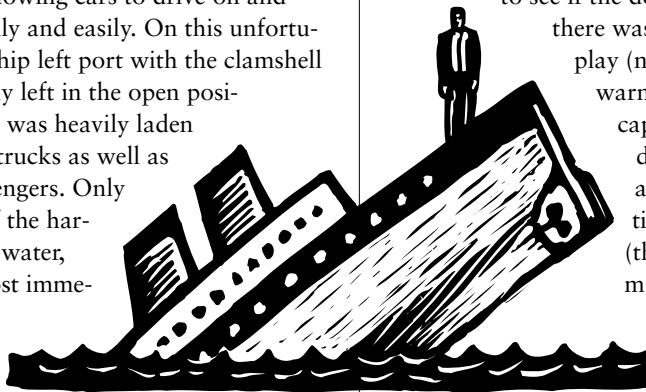
disaster occurred),

a captain had requested a warning light be installed.

But no action was ever taken to do so, nor were other captains warned of the deficiency.

The result: Numerous opportunities were missed to correct a single error caused by neglect of one person's duties. There was no redundancy, no checklist, no definition of duties, no personal assumption of responsibility for safety, no knowledge of requests for safety improvements made two years earlier.

Is this any way to run an airline, er... ferry? ■



# The One Percent Solution

ZERO ERRORS IS AN ACHIEVABLE GOAL.

Over the summer, I received an e-mail from a friend of mine who has a successful construction business. He and his family have been patients at The Johns Hopkins Hospital and are great fans of what we do here. His e-mail recounted the unfortunate situation of the 3 year-old son of one of his subcontractors—a tree removal specialist—who was being treated for leukemia at the Hospital.

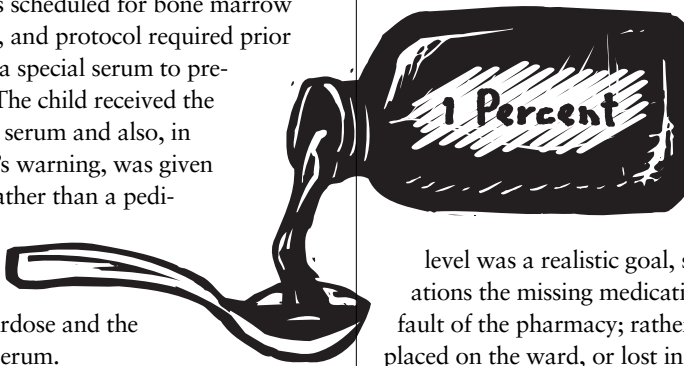
The boy was scheduled for bone marrow transplantation, and protocol required prior treatment with a special serum to prevent rejection. The child received the wrong batch of serum and also, in spite of a nurse's warning, was given an adult dose rather than a pediatric dose. Fortunately, the child survived the massive overdose and the wrong type of serum.

The father, obviously quite distraught, spoke with the attending physician, who explained that medication errors do occur at Johns Hopkins, and that, in fact, "we try to keep the error rate down to about 1 percent." Hearing this, the father of the child went ballistic. "If I had a 1 percent error rate in my business, I would kill or maim one of my employees every month!" Recounting this incident to my friend, the father said, "I took my precious son to Johns Hopkins. They are supposed to be the best in the

world. Where can I take him if not Hopkins?"

You might think this was an isolated incident involving an uninformed Hopkins doctor. But I think this type of thinking is endemic to our Hospital. A few months earlier, while I was making executive rounds, I met with a representative from pharmacy to discuss missing medications. I asked her what level of missing medications she was striving for. Her answer: "4

percent." This time, I went ballistic. "How can you tolerate a 4 percent missing medication rate?" I retorted. She said the 4 percent



level was a realistic goal, since in many situations the missing medication was not the fault of the pharmacy; rather it might be misplaced on the ward, or lost in transit, etc. "Does the patient care," I asked, "whose fault it is when the proper medication fails to show up and be administered at the bedside?"

It appears that we continue to have a disconnect between the public's expectation of our level of performance and what we ourselves are willing to accept. When we all can agree that zero errors is an achievable goal, and when we each take full responsibility for patient safety, we shall actually make The Johns Hopkins Hospital the best and safest hospital in the world. ■

# The Impossible Dream

BUY-IN TO TRANSFORMATIVE IDEA MADE ALL THE DIFFERENCE.

A recent publication of catheter-borne bloodstream infections showed that the rates of infection for the various intensive care units in The Johns Hopkins Hospital are at, or very close to, zero! That is truly amazing. Congratulations to everyone who has partnered in this extraordinary effort to do what many said was impossible.

Zero tolerance for “defects” is truly a transformative idea. When such an audacious goal was proposed, it took a while for people to buy into the concept that it might actually be feasible to eliminate almost all bloodstream infections arising from indwelling venous catheters. But once people accepted the challenge, the creativity and energy that was brought to bear was overwhelming.

Visitors coming to see what we are doing at Hopkins to promote patient safety may ask the question: “What was the single most important factor in getting to zero catheter-borne infections?” There are two answers to this question:

- a) Everything
- b) Getting everyone to accept responsibility for patient safety

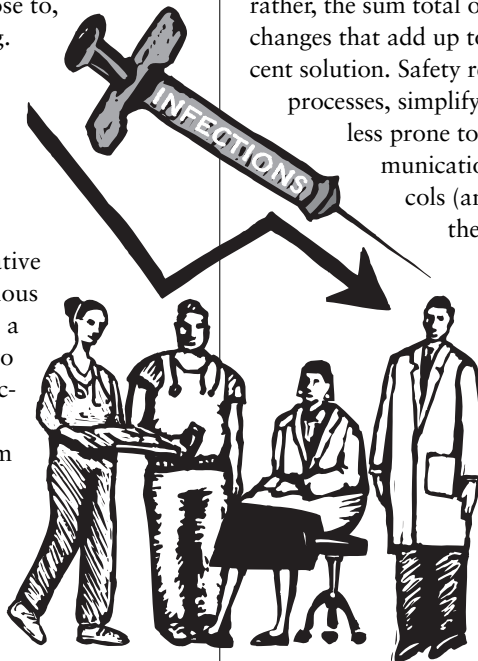
Either response is correct. Let’s briefly consider each one.

First, reducing errors to zero requires a series of steps and changes—often no one of which is, by itself, that significant. It is, rather, the sum total of a hundred 1 percent changes that add up to achieve the 100 percent solution. Safety results from redesigning processes, simplifying them, making them less prone to error, improving communication, establishing protocols (and following them)—all the result of teams of caregivers getting together to try to meet a seemingly unreachable goal.

And second, unless everyone in the Hospital assumes personal responsibility for improving patient safety, none of the above-mentioned changes will occur.

This personal commitment to patient safety is a necessary ingredient to change an unsafe system.

So, again, hats off to those who have achieved the unachievable. You have pointed the way for all of us to continue these efforts throughout The Johns Hopkins Hospital, not only for bloodstream infections, but in many other areas of patient safety as well. I dream of a Hopkins Hospital free from medical errors. ■



# This Revolution Should *Not* Be Televised

PRENATAL PHOTO SHOPS MAY HOLD HEALTH HAZARD.

I grew up with the revolution in ultrasonic medical imaging. In 1968, I began work on my doctoral dissertation, using ultrasound for measuring blood flow. Back then, ultrasound images were fuzzy and offered very little diagnostic information. A physician at the National Institutes of Health was conducting an experimental study using ultrasound to predict the sex of the fetus. The day before the birth of my daughter in 1974, he hooked my wife up to his machine, took a look and proudly announced that she was going to deliver a baby boy!

Over the next 30 years, however, the quality of the images improved. The techniques for measuring blood flow that I could barely imagine ever having practical applications in 1968 are now routine.

In fact, ultrasound imaging has become so good that it has given birth to a fledgling new industry: the prenatal photoshop. The new three- and four-dimensional ultrasound technology means you can take a strikingly lifelike photo or video of your little bundle of joy weeks before delivery. Perhaps not surprisingly, fetal portrait studios are springing up across the land, some conveniently located in your local shopping mall. The newspapers report that there are at least 120 of these shops open now—and more are on the way.

It reminds me of another cottage industry, one from my youth. Many in my generation can recall going to the shoe store, trying on a new pair of shoes, and then putting their feet into an X-ray fluoroscope so that the salesperson—but more importantly their mother—could see that the shoe was large enough that they wouldn't be back in two months buying another pair. However, these machines quickly disappeared after studies documented the risk of radiation exposure.

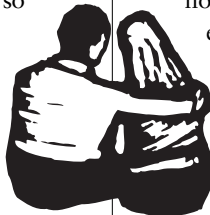
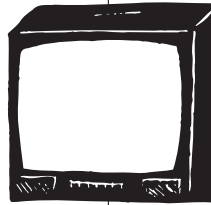
Dazzling pictures can blind us to important issues of safety and radiation exposure. Physicians trained in the art and science of diagnostic imaging have long employed a standard to use the minimum

dose practicable in order to solve a diagnostic problem. This is true whether the exam is using X-rays, gamma rays, magnetic resonance imaging or ultrasound for prenatal evaluation.

Unfortunately, the dose of high-frequency sound waves used to create the beautiful pictures of a mother's fetus require considerably more energy than the simpler but less pretty photos you'll get in your obstetrician's office. And although many studies have failed to document any risk to the mother or fetus by exposure to ultrasound, we do know from animal studies that, at some higher levels of exposure, ultrasound can cause tissue or chromosomal damage. Many of the critical fetal organs are being formed during the time that ultrasound exams are being performed, which is why prudent physicians restrict their use to diagnostic purposes only and perform the minimal exam necessary.

Parents expect perfect babies. Often, when a child is born with a deformity, they are inclined to sue their obstetrician for the imperfect outcome, even when it is uncertain what caused the problem in the first place. As a result, malpractice rates for obstetricians amount to several thousand dollars per baby delivered. But many factors influence the outcome of pregnancy, from the health of the mother to diet and nutrition, genetic factors, infections and yes, exposure to radiation. When a problem develops, it is very difficult to know which among the many factors might have caused the problem. Therefore, however minimal the risk, we should not tolerate any intervention that has the potential to harm the fetus unless there is a clear medical benefit.

Unfortunately, the FDA cannot regulate these new fetal photoshops. By law, the FDA is not allowed to regulate so-called off-label uses of medical devices and pharmaceuticals. Therefore, we must educate mothers, fathers and grandparents not to get shutter happy before the birth of their precious arrival. This is a revolution that should *not* be televised. ■



# You Deserve a Break Today

THERE'S AN OBESITY CRISIS BUT DON'T BLAME IT ON McD'S.

Last month, fast food giant McDonald's achieved a major victory when a judge dismissed a lawsuit alleging it was responsible for causing obesity. The judge, appropriately named Sweet, ruled against the plaintiffs, parents who claimed that by failing to properly disclose the ingredients of its food, Mickey D's had caused severe health problems—including diabetes, hypertension and obesity—for their two teenage daughters. Three cheers for Judge Sweet!

The next health crisis is not HIV/AIDS, heart disease or cancer, but rather obesity. Over the past two decades, overweight Americans have become the majority. They are literally gaining on us every day. Is it because there is too much fat in the Big Mac? Not exactly.

Americans are becoming overweight consuming far too many carbohydrates, mostly in the form of simple sugars obtained from things like soft drinks, low-fat foods and breakfast cereals, as well as the thick shakes and tasty fries served at the fast food palaces. Super-sizing gives you an extra-large soft drink and more fries to stoke even more fat cell production.

Recently, researchers from the Harvard School of Public Health conducted the first long-term study to examine sugar-sweetened beverage consumption and its impact on children's body weight. Their findings, published in *Lancet*, show that for each additional daily serving of a sugar-sweetened soft drink, the incidence of obesity is significantly increased. Adolescent women average 36.2 grams of sugar per day from soft drinks and adolescent men average 57.7 grams per day. David Ludwig, co-author of the study, said, "It's not uncommon for teenagers to receive 500 to 1,000 calories per day from sugar-sweet-

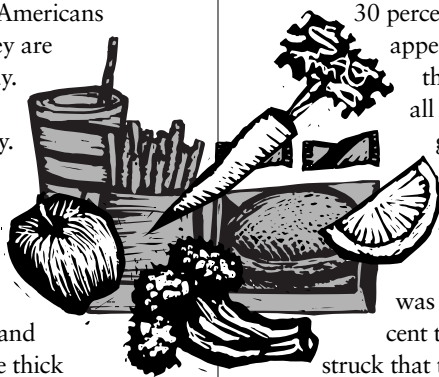
ened drinks."

According to the USDA, people consuming 2,000 calories a day shouldn't eat more than about 10 teaspoons of added sugar, yet their surveys show that the average American is consuming about 20 teaspoons of sugar per day. "Sugar consumption is off the charts," said Michael F. Jacobson, executive director of the Center for Science in the Public Interest. "Added sugars—found largely in junk foods such as soft drinks, cakes and cookies—squeeze healthier foods out of the diet." USDA data indicate that sugar consumption in 1999 was 158 pounds per person—

30 percent higher than in 1983! Sugar appears to be a better investment than the stock market. "With all the focus on fat, we've forgotten about sugar. It's time to rethink our national infatuation with sweets," concluded Jacobson.

Our addiction to sugars was driven home to me on a recent trip to the grocery store. I was struck that the food lining the periphery of the store is mostly fresh food: fruits, vegetables, meat, fish and dairy products. On the other hand, the majority of foodstuffs in the inner aisles, where shoppers spend most of their time, consists of high-carbohydrate, high-sugar prepared foods, low-fat "diet" foods often full of sugar, soft drinks, chips, crackers and breakfast cereals that are sometimes literally candy when you stop to read the labels. One lap around the store and you begin to get a very clear picture of why we have this public health crisis.

So, let's hope Judge Sweet is not indulging in sweets: His wisdom in dismissing the McDonalds case strikes a blow against judicial mediocrity, and I wish him a long and successful tenure on the bench. As for myself, I'm going on a diet. ■



# The Unfairness of It All

“MEDICAL JUSTICE” IS OXYMORON OF THE YEAR.

A year or so ago I wrote about the dramatic inflation in the cost of malpractice insurance. As we have seen in various media reports, that inflation has continued unabated. The tangle we’ve created between law and medicine in this country is unjust, unworkable and unfair.

Most of the media focus has been on the outsized jury verdicts in malpractice cases and the inability of many physicians to continue practicing high-risk specialties due to the cost of malpractice insurance. It makes for eye-catching headlines. In Florida, for example, obstetricians may pay as much as \$200,000 annually for malpractice insurance, which adds costs of about \$2,000 for every delivery in the state.

In Arkansas, a 93-year-old woman in the advanced stages of Alzheimer’s is alleged to have died due to nursing home negligence. Rather than shutting down the nursing home, which might have been the appropriate action in this instance, the family sued for cash.

They—and their lawyers—were awarded \$78 million.

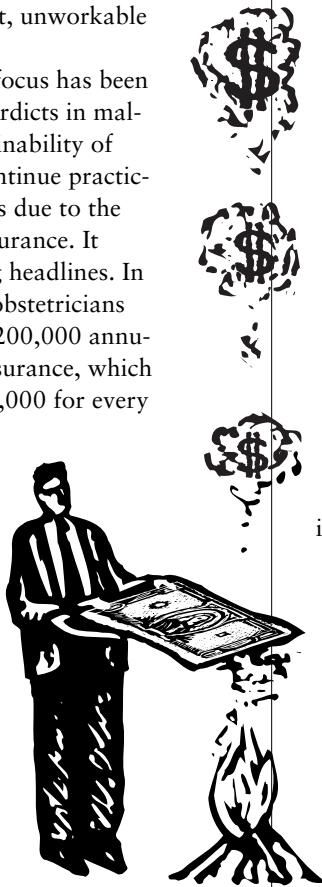
What I’ve learned recently is that our system of legal justice is not only unjust for physicians, nursing homes and hospitals. It is especially unfair to the patients. This is a bit surprising, because patient advocacy groups are generally the ones who are fighting tooth

and nail to preserve the status quo. In fact, hardly anyone seems to know about this, although the specifics are a matter of public record.

The Department of Health and Human Services published a report in July 2002 (<http://aspe.hhs.gov/daltcp/reports/litrefm.pdf>) detailing how malpractice litigation doesn’t help the vast majority of people harmed by the medical system. That’s right: Overwhelmingly, people harmed through medical mishaps are *not* compensated through the current tort system. Moreover, that same system does nothing to promote a better, safer system of health care.

The New York State Insurance Department studied the current system of malpractice litigation and found that nine out of 10 malpractice victims ultimately go uncompensated. It further found that the system expends more than half its income in overhead and transaction costs, and it produces widely differing monetary awards for comparable victims. The federal study done last year essentially confirmed these findings and went on to conclude that our current system is unpredictable, slow, doesn’t deter bad conduct and doesn’t provide justice. One wonders, can we even refer to it as a system of justice when 90 percent of those aggrieved find no recourse?

In fact, it is probably more appropriate to refer to our medical malpractice system as the medical/legal lottery, where a precious few patients who have endured unwanted or unanticipated outcomes receive outsized awards while the majority receive no compensation whatsoever. Which is why my nominee for *oxymoron of the year* is “medical justice.” ■



# Paper or Plastic?

EVEN IN THE COFFEE SHOP, OUR TORT SYSTEM HAS RUN AMOK.

The other day as I was about to pick up my “tall cappuccino” drink order at Starbucks, I asked the barista creating this concoction if she would mind not putting the plastic lid on top of the paper cup. “It’s company policy,” she told me, “I have to serve you your cup of coffee with the plastic lid on top.” I replied, “I don’t really want one, and as soon as you give it to me, I will just take it off and throw it into the trash can anyway.”

There began a nuanced series of negotiations that nearly eclipsed in complexity the recent U.S. attempt to get the United Nations to pass a second resolution on Iraq. However, using my best negotiation skills, we were able to reach détente: The barista agreed that she wouldn’t put a plastic top on the cup, and as she was forbidden by company policy to serve it to me without one, I was permitted to reach over the counter and grab the topless cup myself. Victory! Now the wonderful foam in the cappuccino stays in the cup and doesn’t get plastered up against the inner surface of the plastic lid.

These plastic lids—I’m sure you know what they are: the ones that force you to drink through a slit that reduces the fragrance of a freshly brewed cup of java, while supposedly preventing accidental spillage of hot coffee upon one’s corpus. They have apparently become de rigeur since a notorious lawsuit

against a well-known fast-food restaurant wherein a patron was burned after spilling a cup of hot coffee. Since apparently nobody can be trusted to have sense enough to understand that a hot cup of coffee in the wrong hands is a potentially dangerous weapon, we are now forced to receive our coffee covered in despicable and environmentally unsound plastic tops.

The jury that ruled against the restaurant in that infamous case no doubt failed to consider the millions of dollars that would thereafter be wasted in needless and probably not-very-effective plastic lids, let alone the environmental damage resulting from their disposal. If you stop to consider that McDonald’s alone serves a billion cups of coffee a year, the number of plastic disks needlessly incinerated each year begins to boggle the mind. Talk about a weapon of mass destruction—we have again met the enemy, and shame on us!

OK, so the only thing this issue has in common with health care is the deleterious effect of a legal-tort system run amok. At least Starbucks didn’t make me sign a release indicating that I understand and accept the dangers of ordering a hot cup of coffee. Informed consent at fast food restaurants? What’s to be next: drive-thru HIPAA (Health Insurance Portability and Accountability Act)? More about HIPAA to come. ■



# Hip! HIPAA! Hooray!

IMPLEMENTATION OF THIS WORTHY GOAL JUST PLAIN DUMB.

Last week, I visited an old friend and former business colleague. In the past several years, we've occasionally discussed a medical condition with which he is afflicted, and he has asked if perhaps one day he could meet an expert from Hopkins, with the thought of providing a charitable contribution to support research related to this disease. It so happened that last week we could align three hectic schedules to finally enable me to introduce him to the Hopkins physician doing research in this area.

So we all get together and sit down for a visit, but before I can get two words out of my mouth about how opportune it was to have this meeting, the Hopkins faculty member pulls out a one-page, single-spaced, small typeset form and asks my friend to sign it. "What the [censored] is this?" my friend demands. "A HIPAA authorization form," sayeth the doctor of Hopkins. "Before we can talk about your illness I need permission from you to hold this discussion about what might be sensitive personal medical information."

Can this be happening? Few things are more sacred or important to us than preserving the privacy of our medical records. We all want that. But because there were some egregious violations of this trust in the past, the feds jumped on their white horses and rode down Pennsylvania Avenue, papering it with a mile of privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA). Presumably these new regs will save us all from the evil-doing snoops out there who would abscond with our sensitive medical records without our knowledge.

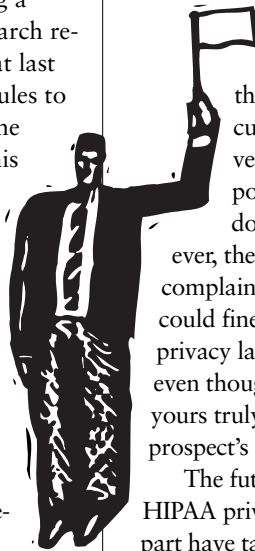
Well intentioned? "You betcha!" as they say in Minnesota. But even the reticent denizens of Lake Wobegone would shout: The implemen-

tation of this worthy goal is just plain dumb. Now, even casual conversations about medical conditions become a potential use or disclosure of sensitive medical data, and are therefore covered by HIPAA.

These regulations have the potential to expand medical malpractice suits to a level never previously imagined. A casual conversation like the one we held might lead to a discussion with the medical school development staff in order to put a proposal together for the prospective donor. Without HIPAA consent, however, the prospect could turn around and complain to the federal government (which could fine us), or could sue us under state privacy laws for inappropriate disclosure, even though, as in this case, the doctor (and yours truly) were never involved in the prospect's care.

The future costs of implementing the HIPAA privacy regulations, which for the most part have taken effect only recently, represent a huge unfunded mandate. Certainly, the direct costs of heightened security to protect unauthorized access to your medical records are reasonable and especially necessary in this day of easy electronic access. We expect to pay them and do so. But the indirect costs involved—tracking every conversation and every form of encounter with patients and patient data and maintaining an audit trail—have yet to be calculated. They are going to be enormous. And no doubt the prospect of HIPAA-related fines and litigation will lead to new layers of defensive administrative practices that will even further raise the cost of medicine.

And they ask me why I drink—it's to numb the pain! But don't tell anyone, because if you do, I might have to sue you for unauthorized release of my personal medical information. ■



# The End of Medical Malpractice

HERE'S BIGGER FISH FOR TRIAL LAWYERS TO FRY.

For years, physicians and hospitals had been preaching to deaf ears about the deleterious effects of medical malpractice suits. With so many members of Congress and the executive branch trained as lawyers, our cries brought little sympathy and even less action. Plus, there was also the not-insignificant financial support the trial lawyers guild provided to so many elected officials.

But then the tide changed rapidly. Suddenly, the government seemed sympathetic to our plight. The number of frivolous medical malpractice suits dropped precipitously. I couldn't believe it. It seemed too good to be true. So I went to see my close friend Hale Goodfellow, president of the American Trial Lawyers Guild, for an explanation.

"It's simple," he told me, looking like I didn't have a brain in my head. "If your business is suing for malpractice, the key to achieving a multimillion dollar net worth is finding situations where decision-making is based largely on judgment and intuition, yet the decisions themselves run the risk of producing an undesired outcome. Even though prudent judgment may have been exercised, we believe that in America, the mere fact of an unsuccessful or unwanted outcome is sufficient grounds for a large settlement."

"So are you telling me you found bigger fish to fry?" I asked.

"Exactly!" said Goodfellow with a huge oleaginous grin. "You know, you're not as dumb as you seem." The genesis of their new approach, he told me, was the realization that elected officials in government are forced to

make thousands of decisions daily in the face of insufficient information. "It's impossible for them to assure faultless outcomes," he continued gleefully, "so we started suing members of Congress and the executive branch. But rather than middling little million dollar malpractice lawsuits, we determined that nearly every governmental malpractice case is worth a cool billion dollars—or more."

"But don't you need to show they were remiss?" I ventured.

"That's the beauty of it," Goodfellow exclaimed. "Who makes more mistakes than the government? Can't find weapons of mass destruction in Iraq? Too bad for President Bush. We'll nail him with a

multibillion dollar lawsuit alleging

lack of informed consent by the American people. Didn't like the way the war in Iraq went? Sue Donald Rumsfeld."

"So if my Professor of Near Eastern Studies is disgruntled about the looting of antiquities from the Iraqi National Museum, we should file a billion dollar lawsuit alleging malpractice by the defense secretary?," I asked. "Now you're getting it," beamed Goodfellow.

I left our meeting with a new spring in my step. So what about those pesky new HIPAA regulations? The Secretary of Health and Human Services will be hearing from our lawyers. And as for myself, I am preparing to file a class action suit against the members of Congress who passed the Paperwork Reduction Act. Based on the exponentially increasing size of my federal tax return, I think I have an open-and-shut case. Even if I might not be able to retire after a successful settlement, I am sure my attorney will. ■



# Fooled by Randomness

BIG PHARMAS ARE SETTING THEMSELVES UP TO FAIL.

How many go to Las Vegas or Atlantic City and play the roulette wheel? While it may be fun to go once or twice, I doubt that any of us would resign our faculty positions to make a career playing roulette. Why? Well for one thing, the payoff is too low to compensate for the risk involved. The expected value of playing roulette is negative, not positive—over time, it costs more than it returns.

Now consider for a moment that the success rate for drug development is about 1 in 200. Not great odds, unless the payoff is considerably greater than 200 to 1, right? In general, the payoff for drug development thus far has more than compensated pharmaceutical companies for their investments. Okay, but following the mergers of smaller pharmaceutical companies into bigger ones, consider that the emphasis has shifted to the development of so-called blockbuster drugs—ones that bring in more than \$1 billion in annual sales. Such drugs include statins, antihypertensive medications, analgesics and antidepressants—drugs that not only have a large market, but also that are taken chronically. Now the rewards are much higher—but so are the stakes. The odds of success go down way below 1 in 200, while the payoff increases far beyond 200 to 1 as well. But by emphasizing blockbuster drugs, the big pharmaceuticals set themselves up to fail in two ways.

The first is related to the so-called St. Petersburg paradox first posed in 1713 by Swiss mathematician Nicholas Bernoulli. The paradox considers games of chance with a positive expected value in which the probability of winning is low but the payoff is huge. Each play produces a small loss, but in an extraordinarily rare event, the payoff is enormous. Even though the expected payoff for this game is ultimately positive, most gamblers will go bank-

rupt before they hit the jackpot because they don't have enough cash reserves.

Similar forces are at work with blockbuster drugs. The payoff is huge, but the losses incurred to get there, though less than the payoff, are quite large—some companies may not have the financial stamina to stay in the game.

Vioxx, on the other hand, was already a successful blockbuster drug, so Merck—the drug's manufacturer—can be said to have beat the St. Petersburg paradox.

But Merck stumbled into another pitfall that blockbuster drugs engender—fooled by randomness. If you develop a drug used chronically by large populations, you are going to experience measurable numbers of adverse outcomes (irrespective of the safety of the drug) as the size of the population on which the drug is used increases. The more patients using the drug, the more likely adverse events will appear. Moreover, while these adverse events may occur as random fluctuations, they will appear to many to have a causal correlation with the use of the drug. If you do enough studies on a large enough sample, you can expect to find serendipitous correlations that may, or may not, be causally related.

The difficulty is in proving the null hypothesis—namely, that the correlation between the drug and an adverse outcome is not causally linked.

He who lives by the sword, dies by the sword. To promote Vioxx to blockbuster status, Merck used direct-to-consumer advertising to boost sales. Increasing usage increased the likelihood that adverse effects would appear that might be correlated with use of the drug. Even if there is absolutely no causal relationship, there can be the appearance of one, especially when presented by a sophisticated legal team to a jury of nonstatisticians. Fooled by randomness. ■



# Yinned if You Do, Yanged if You Don't

OUR ABSURD EXPECTATIONS PUT DRUG COMPANIES IN A BIND.

One of the most difficult tasks we face is balancing the needs of the individual versus those of society when the two are in direct conflict and no perfect resolution exists.

We applaud the use of a drug, device or clinical procedure when the beneficial effects clearly outweigh the risks. Sometimes a drug, test or treatment might, in fact, be beneficial to the individual but still not be efficacious overall. Debates over screening tests like the PSA for prostate cancer or the mammogram for breast cancer fall into this category. Here, it is not a question of whether the test works, but if its use in a selected population promotes a better outcome than not performing the test or using some alternative method.

But what happens when a drug has some benefits but also appears to have some risks? The withdrawal of Vioxx from the market is instructive.

The problem was not the drug's efficacy but rather the ethics of its use by patients for whom the specific advantages of a Cox-2 inhibitor needed to be weighed against additional risk of adverse reaction, such as increased heart attacks. This balancing act suggests more stringent guidelines are needed for its prescription. The outrage (and, of course, lawsuits) following the withdrawal of Vioxx represented one side of the coin—patients who expect zero side effects from drugs and have no tolerance for adverse reactions, wanting to hold someone accountable for the down side of beneficial drugs.

Now comes the flip side—this time involving the drug GDNF, which was being tested by Amgen Corporation to treat Parkinson's disease.

After initial studies of the drug in about four dozen patients, Amgen said they were stopping the trials and would not make GDNF available, even to those patients who had participated in the study, believing the drug carried unnecessary risks. Amgen CEO Kevin W. Sharer told *The New York Times*, "We're trying to do the right thing for the most people."

Amgen concluded that GDNF, which initially was given to 15 patients who knew they were receiving the drug, produced results that were attributable to the placebo effect. In fact, of the 34 patients in the subsequent blinded trial, the four who showed some of the greatest response to treatment were receiving the placebo. Amgen, knowing that high doses of GDNF induced brain damage in monkeys, decided it was better to come down on the side of conservatism.

Despite support for the move from medical ethicists and some neurologists, the Parkinson's patients, especially those in the trial, were extraordinarily vociferous and unrelenting in their criticism of Amgen: "How dare they take away such an effective drug?" Yet, we have to ask, how many of these same patients, if they were later to suffer brain damage from taking the drug, might line up to sue Amgen, holding them responsible for the ill effects of this new agent?

I conclude you can't win. The yin and yang of public opinion promotes absurd expectations. Companies are damned for not taking an effective drug off the market soon enough, but also denounced for not leaving an ineffective drug on the market. It's another example showing that human beings are particularly inept at acting coherently in evaluating risk. ■



# Health Care—Three Big Issues (and three little ideas)

BUT DO WE HAVE THE POLITICAL WILL TO TRY NEW SOLUTIONS?

**H**ealth care costs are growing rapidly, now approaching 15 percent of GDP. Meanwhile, the numbers of uninsured are rising even faster. Hospitals are operating on razor thin margins, and doctors are working faster just to stay in place as reimbursements for professional services decline.

I'd like to outline three big issues on my top-ten list of health care challenges and propose three simple 'little' ideas that might have a big impact.

**Big Issue #1:** Rapidly rising numbers of uninsured. Between large corporations reducing coverage and small employers not able to provide insurance, there are now over 44 million Americans without health insurance.

**Little idea #1:** Require everyone to have health insurance, like we require everyone who drives a car to purchase automobile insurance. Auto insurance is no longer a luxury; why should health insurance be any different? Massachusetts must have obtained a draft of this article, because it recently passed a bill that will require its citizens to be covered by health insurance. For those below a certain income level, tax subsidies will be provided. By putting everyone in a large risk pool, denial of coverage by individual risk profiling will be eliminated, so everyone can access affordable coverage.

**Big Issue #2:** Doctors are working faster and faster just to stay in place with declining professional-fee reimbursement, while health care costs escalate.

**Little idea #2:** Uncap physician reimbursement to lower health care costs. Yes, you heard me: if doctors were paid more, health care costs would not escalate as fast, and, in fact, might go down. Why is that, you ask? Well, paying primary care doctors to spend more time with patients will allow them to better counsel patients on optimal

therapies and also allow them to treat simple conditions for which they now refer to specialists because they can't get reimbursed.

For specialists, higher reimbursements lead to lower utilization because of perverse incentives created by the notion of 'targeted incomes.' This is best described by a discussion I had with a classmate who is a plastic surgeon.

In this field, most procedures are not covered by insurance, so doctors set their own fees. After

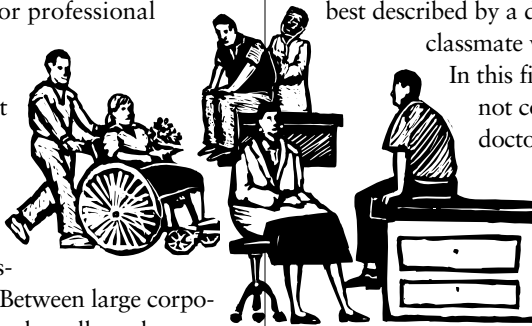
my friend opened his practice, I saw him nine months later and asked, "Jim, how is your practice going?" He replied, "Bill, business is so

good, I reduced my fees." Yes, targeted income is a well-documented concept. If the target isn't met, and lacking the ability to raise fees due to fixed fee schedules, the surgeon will endeavor to generate more demand for her services (with a resultant rise in income). Eliminating standard fees would allow the market to work positively in this unusual variant of supply-side economics.

**Big Issue #3:** Quality of medical services is highly variable. Health care variability may be the number one disease in America—resulting in patients who are sub-optimally treated, many injuries and deaths, and utilization that is higher than necessary. All of these factors lead to higher costs as well as poorer outcomes.

**Little Idea #3:** Require all providers to publish statistics on quality, safety, and outcomes. Yes, this may be another unfunded mandate, but in this case, promoting safety and transparency is in the patients' best interest and will help slow the rise in costs.

These three little ideas could bring a major transformation in our health care system. The question is: Do we have the political will to discuss the big issues, let alone try new solutions? ■



# Advertising's Black Eye

DTC ADS ARE BAD FOR HEALTH OF THE HEALTH CARE SYSTEM.

One of my recent pet peeves is the proliferation of consumer advertising run by the pharmaceutical companies. Disarmingly called direct-to-consumer, or DTC, ads, they usually go something like this: "If you have allergies, baldness, impotence or arthritis, our product is just for you. Go see your doctor and ask for osteosynthesase-A."

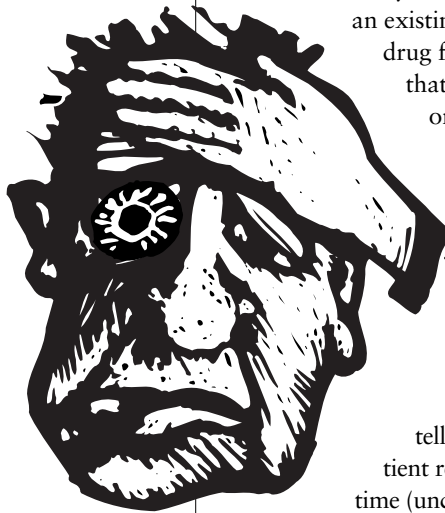
I figured these ads must be effective because of how expensive television and glossy magazine advertising can be. Pharmaceutical companies are not likely to throw that kind of money around without some demonstration of success. How successful, I only recently learned: 75 percent of the time when patients ask their doctors for a specific medication, the doctor prescribes that medicine.

Wow! Think of the implications for getting new and wonderful products into use faster than ever—regardless of cost or need. There are certainly benefits to an informed consumer, but in my view the DTC ads are ultimately deleterious to the health care system. They typically promote new products that are meant to compete with existing products from rival companies or, more importantly, with off-patent generic drugs that are considerably cheaper.

In some cases, I will admit, there is good reason to prescribe one of these new wonder drugs. But oftentimes there is no compelling reason to prescribe. With DTC ads, we see COX2 anti-inflammatory drugs being pushed over much lower cost generics when there are no clear medical indications for doing so. In other cases, the new drug is merely a slow release formulation of an existing drug. If you are taking a drug for gastric reflux, is it really that important to move from a once-a-day to a once-a-week dosage? In some cases yes, in many cases no. But the subtleties of indications are lost in the DTC medium.

Doctors are trapped in this new onslaught between the patient and the advertisements. They tell me that saying no to a patient requires spending significant time (uncompensated by the health plans, of course) explaining the reasons why the DTC-advertised drug is unnecessary. Even so, they still may alienate the patient who believes he or she needs access to this new wonder drug. And since the higher costs of the newer drug are in almost all cases not borne by the doctor or the patient, it is simply more efficient to prescribe rather than put up a fight.

This is a case where too many of us would rather switch than fight. ■



# No Cards, Please

IT'S "COVER THE UNINSURED WEEK."

**T**alk about inflation: After Thanksgiving, Christmas, Valentine's Day, Easter, Secretaries Day, Bosses Day, Labor Day, Memorial Day, Independence Day and more, I thought I would have to declare Chapter 11 if I had to buy another greeting card. I remember when those cute little Hallmark ditties were 25 cents; now it'll cost you 10 times that to get an entry-level (read cheap-looking) card for your friend, relative or colleague at work.

Well here's one of the few special occasions that doesn't require a trip to the greeting card rack: It's "*Cover the Uninsured Week*." Sponsored by the Robert Wood Johnson Foundation and a number of diverse for-profit and not-for-profit organizations, "*Cover the Uninsured Week*" will focus national attention on this enormous problem. The U.S. Census Bureau reports that more than 14 percent of our population is medically uninsured, and that number is growing at an annual rate of 3 percent to 4 percent. Former Presidents Gerald Ford and Jimmy Carter have signed on as honorary co-chairs of this event, underscoring the seriousness of the problem.

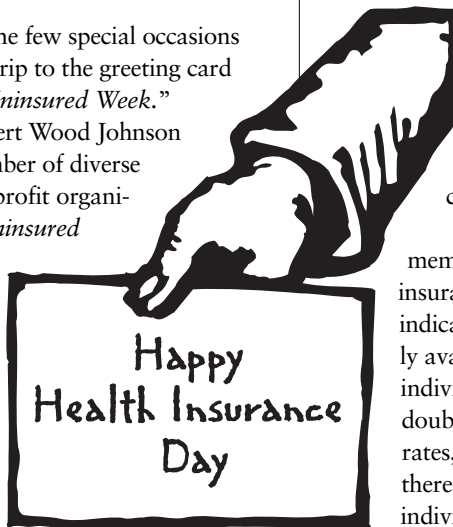
While many of the medically uninsured may lack the financial resources to obtain insurance or may have existing medical conditions that make it difficult to find any coverage at all, a sizable number of those not covered are not purchasing insur-

ance for other reasons. Some are young and assume they will never get sick; others believe incorrectly that individual insurance is priced beyond their ability to pay for it; or they simply don't know how to go about purchasing a cost-effective health insurance policy or where to look for one. I can relate to this latter predicament. Every year, I have more and more difficulty choosing among even the limited number of

options that Hopkins offers its employees. Can you imagine with no human resources department to evaluate various plans and pick the most cost-effective, how much more difficult it would be to pick a health insurance policy?

Recent data from a survey of 30,000 members of eHealthInsurance, a health insurance information and online retailer, indicate that individual insurance is readily available at a reasonable cost for many individuals and families. And unlike the double-digit run-up in group insurance rates, according to their information, there hasn't been significant inflation in individual health insurance premiums.

Louisiana Senator John Breaux has proposed mandatory coverage—like if you want to drive a car you have to have automobile insurance, so if you want to breathe, you gotta have health insurance. Maybe it's time. The eHealthInsurance study found the average premium for a single person (at average age 32) is about \$155.90 per month. When I think about what I'm spending on greeting cards nowadays, that seems like a pretty good deal. ■



# HMO-Hopping

SHORT-TERM FOCUS EQUALS LONG-TERM PROBLEMS.

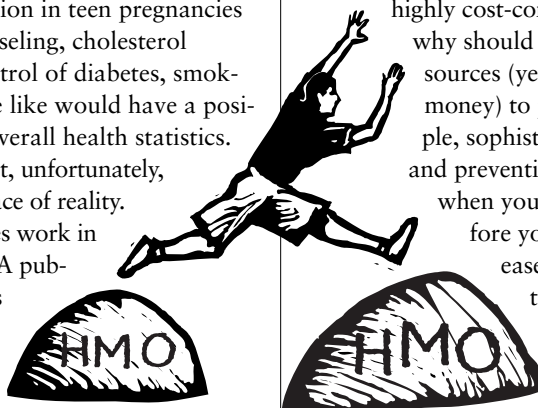
One of the most compelling arguments in favor of the health maintenance organization model of health care delivery is that these organizations are able to focus on disease prevention through effective implementation of public health strategies for their enrollees. Given the fact that Americans suffer in comparison to other developed nations on most public health statistics (such as infant mortality, life expectancy, etc.) it was reasoned that HMOs would do a better job by providing a longer-term focus on health care issues pertinent to individual patients. Better prenatal care, reduction in teen pregnancies through family counseling, cholesterol screening, better control of diabetes, smoking cessation and the like would have a positive impact on our overall health statistics.

It's a great idea but, unfortunately, one that flies in the face of reality. You see, the incentives work in the wrong direction. A public health focus, by its very nature, looks at the long-range impact of today's decisions regarding health and lifestyle. Yet you can understand why it is difficult for HMOs to focus on the long-term welfare of their enrollees when you consider this statistic: *The average duration of enrollment for subscribers in a health plan is only two years.* In other words, patients are changing health plans frequently, and often for valid reasons: A marriage may provide a spouse access to better coverage, or a move to a new location or change of employer may necessitate a different health plan.

However, many people change health plans from one year to the next simply because of relative costs: the price of Kaiser versus Blue Cross/Blue Shield, for example, may change by a few dollars per month. If an employer provides more than one coverage option, families are often all too willing and ready to shift to competing health plans. Loyalty to a particular HMO is apparently only skin deep—for literally \$10 a month, patients will pack up and move. And therein lies the dilemma.

If your HMO can only count on your being enrolled for a couple of years, given the highly cost-competitive environment, why should it spend the extra resources (yes, it does cost them real money) to provide you, for example, sophisticated lipid screening and preventive health counseling when you will be long gone before you develop heart disease? So in reality, although health plans do provide some focus on public health (by which we mean long-term health issues), the more they do in this area, the more they are likely to penalize their competitive position in the marketplace.

A few states have mandated coverage of certain public health initiatives within health plans. But those states are in the minority. Wall Street's focus on quarterly earnings has driven American corporations to focus on the short term. Unfortunately, HMOs are not exempt from this trend, and the health of Americans suffers because of it. ■



# Is Medicare Cost Effective?

LESSONS FROM ITS SUCCESS WOULD HELP OTHER SECTORS.

I recently spent a half-day in a meeting discussing a number of issues regarding Medicare. Most of us on the provider side of the street view Medicare as this multiheaded bureaucracy with more pages of regulations than the Internal Revenue Service's tax code. However, I came away from the meeting with some (to me at least) shocking revelations:

- Medicare beneficiaries are overwhelmingly satisfied with their Medicare coverage, except for the absence of prescription drug benefits;
- The administrative costs of Medicare are lower than any other large health plan. In fact, Medicare is very efficient by any objective means: According to the Urban Institute's Marilyn Moon, who testified before the Senate Committee on Aging, Medicare expenditures between 1970 and 2000 grew more slowly than those of the private sector. Initially, from 1965 through the 1980s, Medicare and private insurance costs doubled in tandem. Then Medicare tightened up, and per capita expenditures grew more slowly than private insurance, creating a significant gap. In the 1990s, private insurers got more serious about controlling their costs, and the gap narrowed. But by 2000, Medicare per capita expenditures remained significantly lower than the private sector.
- The average income of Medicare beneficiaries is closer to the poverty line than many of us working folks would like to believe: According to government statistics Moon cites, more than 90 percent of retirees covered by Medicare earn less than \$32,000 per year for individuals or \$40,000 for couples. In 2003,

Medicare beneficiaries will spend an average of 23 percent of their income on health care!

Moon argues somewhat convincingly that Medicare has been a success. While not necessarily denying that certain reforms might be needed, she stresses the importance of preserving three essential tenets of the program:

1. Its universal coverage nature creates the ability to redistribute benefits to those who are neediest.
2. It pools risk in order to share the burdens of health care among the healthy and the sick.
3. Through Medicare, the government protects the rights of all beneficiaries to essential health care.

It has been argued that, in part, Medicare's cost effectiveness arises from the fact that it does not need to expend funds on marketing and sales—functions that are obligatory for the success of competitive, private-sector health plans. Moreover, some argue that the competitive model for health insurance has not been successful. In a mar-

ket-driven economy, the healthy can and will change health plans for savings of only a few dollars a month, while the sick must remain in their existing plan in order to retain their physicians. Such behaviors lead to asymmetric risk pools and cost inequities.

This was all sobering news to a market-driven entrepreneur such as yours truly. However, given the perverse incentives that frequently drive behavior in health care, my take-home lesson is that there are examples in the success of Medicare we can apply to other sectors of our population. ■



# Demographics 102: “The Good, the Bad and the Ugly ...”

PREDICTING ULTIMATE LIFE EXPECTANCY MAY HOLD SURPRISES.

**OK**, here is what I know you’ve all been waiting for: the second installment of our course on demographics. Everything you need to know for the final exam can be found in an article published in the May 10, 2002 issue of *Science*: “The Broken Limits to Life Expectancy.”

First, the good news in the article: We are all going to be living longer than we thought, even taking into account that we expect to live longer. Consider this quote from the *Science* article: “Female life expectancy in the record-holding country has risen for 160 years at a steady pace of almost 3 months per year.” Longest life expectancy has gone from 45 years for women in Sweden in 1840, to about 85 years for women in Japan today, and it has increased linearly over the 160-year period (with a correlation coefficient of 0.992!). Even for men, the news is pretty good: Life expectancy for males is also growing linearly, though slightly more slowly. Guys, we’re living longer, but we’re falling behind. Before 1950, much of the gain in life expectancy resulted from reducing death rates among the younger age groups. Since then, it has been improvements in survival of the over-65 cohort that have driven life expectancy upwards.

The bad news is that policy makers haven’t been very good at anticipating the expansion of life expectancy. I often preach against the dangers of extrapolation, which typically leads to overly optimistic future projections. In the case of life expectancy, however, extrapolation has proven to

be overly conservative. In 1928, a statistician named Louis Dublin used U.S. life tables to estimate what he thought was the lowest level to which the death rate could go for each age group, and then used those numbers to predict the ultimate “hypothetical” life expectancy—a figure he calculated to be 64.75 years. One has to wonder how Dublin’s predictions influenced Social Security’s choosing 65 as the appropriate retirement age.

Adding to the confusion, of course, is the growing knowledge about replication in biological systems—since programmed cell death exists, it must have implications for the life expectancy of the organism as a whole. In other words, we think we know that there is a ceiling on ultimate life expectancy under the most optimal circumstances. But how high is that ceiling? No one can say for sure.

There is an ugliness to all this as well: When we forecast future needs for Social Security, Medicare, nursing homes and so forth, even small increases in life expectancy can have a large effect on the number of elderly and thus the financial burden of social services. According to the *Science* article, “officials responsible for making projections have recalcitrantly assumed that life expectancy will increase slowly and not much further. They give politicians license to postpone painful adjustments to Social Security and medical care systems.”

Class dismissed. ■



# Sex, Drugs *and* Money

## HOW TO REALLY UNDERSTAND MEDICARE PART D.

**B**y a serendipitous juxtaposition of events, I happened to spend a Saturday with a CEO of a major pharmaceutical company last winter, and on the very next day I had a chance meeting with a noted health care economist (not from Johns Hopkins, by way of disclaimer). To each I posed this identical question: “What do you think of the recently enacted Medicare drug benefit legislation?”

From the pharma CEO came the reply (paraphrased slightly): “It’s a terrific piece of legislation. It will give our seniors access to the drugs they need to ensure their health.”

And from the health care economist: “A very bad piece of legislation. Seniors will have a hard time figuring out how to avail themselves of the benefits by way of the drug discount cards, and the costs of implementation haven’t been fully acknowledged by the administration.”

I quickly surmised that the pharmaceutical companies must have scored a major victory. I must admit I was nonplussed by the CEO’s gleeful response initially, since I knew that the pharmaceutical industry had long been opposed to government-backed drug benefits, as they believed that price controls would inevitably follow. Of course, as we know, the Medicare legislation specifically forbids the government from negotiating prices for drugs with the pharmaceutical manufacturers and opts instead to allow a secondary private market to offer the so-called drug discount cards. Still, I wondered why the drug compa-

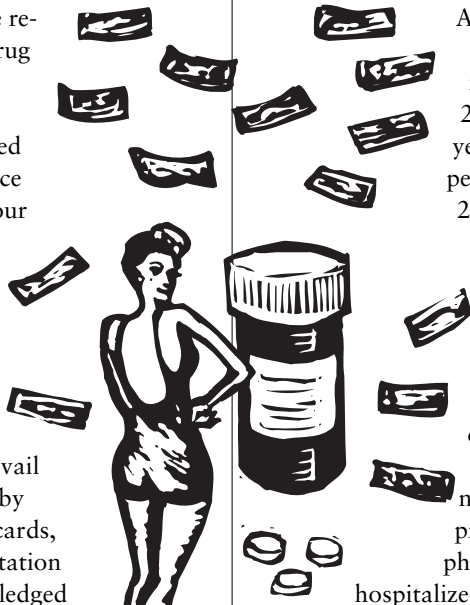
nies would be pleased with any program that provided an option for discounting.

Wondered that is, until recently, when I came across an article in *USA Today*, which quoted two studies documenting significant increases in drug prices in the four years prior to enactment of the Medicare drug legislation.

One study, commissioned by AARP, looked at 155 brand-name drugs and found a price increase of 27.6 percent over four years compared with a 10.4 percent inflation rate. In 2003 alone, prices for these drugs increased 6.9 percent, more than triple the 2.2 percent inflation rate. The second study, by Families USA, documented similar increases.

Of course, this is hardly news to health care providers, who have seen pharmaceutical costs for hospitalized patients rising often by double digits annually, driven both by expensive new drugs as well as inflationary pricing.

I teach an undergraduate class called “Uncommon Sense” that focuses on reasoning and problem solving applied to real-life situations. One of the things I talk about is interpreting human behavior. I advise my students that when they can’t understand why someone behaves in an unpredictable way, they should look for “sex, drugs or money” as a possible causative factor. In the case of an industry acting seemingly against its stated interests, and including Viagra in the equation, maybe what we should be looking at is sex, drugs *and* money. ■



# Drug Addiction

WE'VE BECOME A SOCIETY HOOKED ON LEGAL MEDS.

In my last column I talked about the new Medicare drug benefit and the fact that inflation in drug prices may have eroded any of the potential discounts available under the new plan. Of course, finding a way that seniors can get reimbursed, at least partially, for their prescription medications is a good idea.

One of the challenges of providing a drug benefit for Medicare recipients is to try to estimate the cost of such a benefit. I decided to take a look at what Johns Hopkins pays its employees who have health insurance coverage under one of our plans, and I was absolutely shocked at the results.

We are all aware that the costs of health care have been rising over the past decade. Many of us surmised this escalation was due to rising costs of hospitalization and, in particular, to new technologies such as drug-coated stents and the like. So what, in fact, is happening to health care costs for Johns Hopkins University employees? The envelope, please.

The numbers are nothing less than staggering. From 1999 to 2003 (the past four years for which data have been compiled), total health care costs per enrollee have risen 64 percent. During that same period, per capita prescription drug costs went up 167 percent (yes, that is one-hundred sixty seven!). Comparatively speaking, all other enrollee health care costs

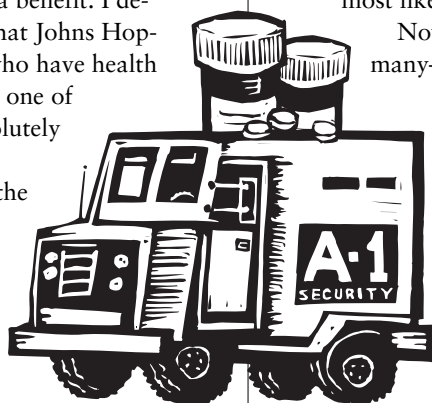
have been a bargain, rising only 45 percent in the same period.

Per capita prescription drugs cost Johns Hopkins health plans \$1,768 per enrolled employee in 2003 compared with \$661 in 1999. What is driving this increase? Certainly some of it may represent inflation in individual drug costs, as I described in my last column. But the advent of newer and more costly drugs, coupled with the tendency to prescribe them, are most likely driving up costs the most.

Now in some—and perhaps in many—cases, these new drugs are providing superior results. Witness, for example, the recent study linking certain statin drugs with improved morbidity and mortality from coronary heart disease, not to mention other potential benefits of these lipid-lowering drugs.

On the other hand, the overuse of antibiotics, or the substitution of a newly introduced branded drug when a generic will suffice, no doubt is contributing to the hyper-escalation of drug costs. Prescription pharmaceuticals represent about 25 percent of the total of all health care costs covered under the Johns Hopkins University health benefit plans.

We used to worry about drug addiction in the context of cocaine, heroin and the like. No more: We have become a society addicted to legal, prescription pharmaceuticals. Is there any way we can kick the habit? ■



# The Dynamic Hockey Stick

## WHAT ARE THE CONSEQUENCES OF REDUCING EARLY DEATHS?

Recently, I heard someone exclaim that the predicted Social Security crisis will never actually occur. The reason, goes this armchair analysis, is simple: The epidemic of obesity, combined with the resurgence of smoking among our youth, will preclude many from ever reaching retirement age.

This brings a curious question to mind. We have heard time and again that more than 50 percent of an individual's lifetime health care costs occur during the last six months of life. Will the budget bureaucrats in the health care establishment someday conclude we're better off allowing people to smoke and overeat so that the young die faster? After all, when health care decisions are made purely on the basis of cost efficiency, it is best for individuals to be healthy most of their life and then to have a single, fatal heart attack. The alternative to sudden cardiac death is to help someone during the initial acute ischemic event, but then the person develops a chronic disease—congestive heart failure—which is one of the most costly diseases among Medicare recipients.

Another way of stating the question: Are all of the things we're doing with medicine and public health to reduce premature mortality actually going to increase lifetime health care costs by converting acute illnesses into chronic diseases?

I recently met with distinguished Hopkins medical alum James Fries, currently professor of medicine at Stanford. He has demonstrated that the most efficient interventions are those that delay the onset of morbidity of chronic diseases. In other words, allowing people to smoke and contract lung cancer with a likely premature death is more costly than spending money to reduce smoking and letting these individuals die at a later age from some other causative factor.

Most medical and public health interventions, according to a landmark article published by Fries in 1980, don't prolong maximum life expectancy, they advance the age at which chronic illness occurs and/or they prevent premature death. And in so doing, they reduce overall health care costs.

The age of onset of chronic illness can be significantly influenced by a number of factors, including lifestyle choices or therapies, and hence onset of senescence may be delayed, even if lifespan is not increased appreciably.

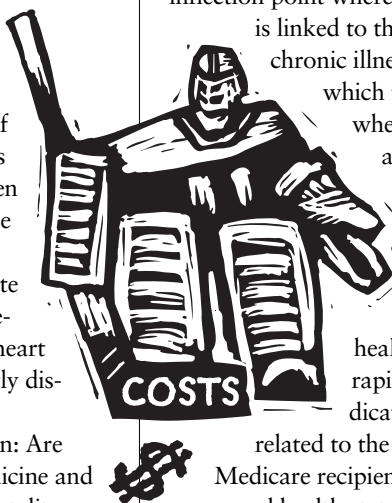
Think of the graph of health care costs over time as a "dynamic hockey stick" in which the inflection point where costs begin to rise rapidly is linked to the onset of some acute or chronic illness. By delaying the time at which that inflection point occurs, when life expectancy remains approximately the same, the area under the curve is minimized, and so are costs.

Medicare costs (along with total U.S. health care costs) are rising rapidly. Some analysts have indicated that the rise is primarily

related to the increased number of Medicare recipients, not necessarily to their age and health status. Such an observation, if correct, would be in concert with Fries' hypothesis that delaying onset of chronic illness is an effective means to controlling health care costs.

This way of looking at health care costs is a new construct for me, and I find it worthwhile to think about its implications, as we are going to be faced over the next half-century with questions about how to allocate efficiently the funds for providing health care to an aging population.

And since the NHL is no longer playing hockey, maybe we can use our new dynamic hockey stick to shoot the puck into the goal of lowering health care costs. ■



# Changing the Equation

LET'S IMPROVE HEALTH, NOT JUST TREAT DISEASE.

**A**re you part of the problem or part of the solution?" How often have you heard that question asked? Well, I thought about this question after a brief tête-à-tête with one of our very best Hopkins-trained internists concerning a previous column about rising health care costs. In my article, I had indicated that while the United States spends somewhere between 50 percent and 100 percent more on health care per capita than other developed nations, we were nonetheless close to the bottom of the ladder in our public health statistics, such as infant mortality, life expectancy and other common measures. The physician rightly pointed out to me that patients travel from all over the world to take advantage of our medical care, a statement with which I certainly agree. "And," he continued, "problems of infant mortality, substance abuse and so on have more to do with broader societal issues than they do with medical care." Again, I couldn't disagree.

However, where the rubber meets the road, in my view, is in the inescapable conclusion that our medical care system is driving our country into bankruptcy (in part because we have to treat diseases that are the result of inadequate investments in public health). So, I still must ask, "Are we physicians part of the problem or part of the solution?"

And what is the problem, exactly? John C. Nelson, president of the American Medical Association, very specifically pointed out the problem in a commencement address to the School of Public Health at the University of

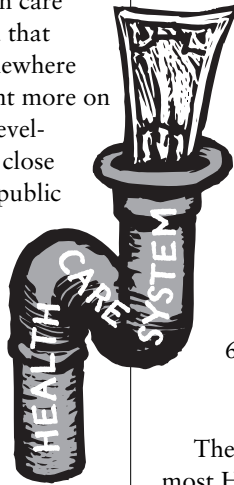
Utah last year. He said our nation continues to be ravaged by eight preventable conditions. The eight scourges are:

1. Alcohol and drug abuse that one study claims costs society upwards of \$240 billion a year.
2. Violence that another study claims adds \$300 billion to our health care costs.
3. Accidents, another \$275 billion.
4. Tobacco addiction, \$75 billion in medical costs and \$80 billion in lost productivity every year.
5. Obesity, from \$50 billion to \$75 billion, according to yet other studies.
6. Youth suicide, sexually transmitted disease and teen pregnancy, \$12 billion.

These numbers are approximate, but most Hopkins doctors could recite this list from memory because of the impact on their medical practice, especially so because of our location in the inner city. Because we are "benefiting" from these scourges by having a steady stream of patients requiring treatment, we de facto have become part of the problem.

I believe there are actions that physicians can take to highlight these problems if we are really serious about improving health, not simply treating disease. The AMA, for example, could take on obesity by running a national ad campaign and lobbying corporations that contribute to the obesity problem to change their ways. Difficult? Yes. Impossible? No.

We can make a difference. Let's be part of the solution. ■



# Lost in the Translation

THE PUBLIC EXPECTS FASTER RESULTS FROM RESEARCH.

About six weeks ago I had lunch with the chairman of a major technology company, someone who, because of an illness affecting a family member, has become a serious student of medical research. Not just a student, I should add, but a significant donor to a distinguished academic medical center in support of medical research. To put it in proper perspective, when I see him I am reluctant to discuss specific research results on this disease because my knowledge of the science would be considered trivial compared to his depth of understanding.

“Bill,” he said, between bites of chicken Caesar salad, “why is it that medical research is dominated by basic scientists?”

“Whoa, there!” I responded in surprise, almost choking on my crouton, “what do you mean by that?”

He said the medical establishment is fixated on basic molecular biology and its applications to fruit flies, worms and perhaps to mice and rats. But, he said, when it comes to true translational research applied to human clinical trials, academic medicine is in the Dark Ages. To add credence to his point of view, he directed me to an April 25, 2003 article in, of all places, *The Wall Street Journal*, amplifying his perspective and seriously challenging our emphasis on basic science.

I have always disliked the term “translational research,” but my friend and the WSJ article do raise valid questions. What progress has and is being made toward actual treatments for different diseases like cancer,

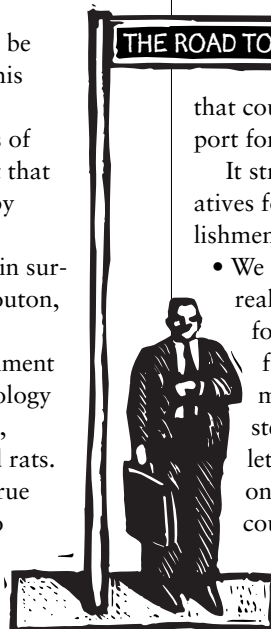
stroke and Alzheimer’s, and how does it compare with advances in our basic science understanding of the pathogenesis of these diseases? Furthermore, how well (or poorly) have we communicated these results?

We take it on faith—and perhaps more than a little dogma—that improved understanding of the mechanisms of action of disease will ultimately lead to new and improved treatment. But the long delays in new treatments for at least some diseases may be creating a potential public perception crisis in medical research: one that could challenge the long-standing support for NIH research in Congress.

It strikes me that there are several imperatives for us in the medical research establishment:

- We must make sure we are not setting unrealistic expectations about the time lines for advances in improved treatments for morbid diseases—nowhere is this more true than in the application of stem cells, where some researchers have let it be known that if only restrictions on stem cell research were lifted, we could cure many diseases.
- We should evaluate the portfolio of research being done on various diseases to determine if the mix of basic versus translational research is, in fact, appropriate.
- We need to stimulate the training of additional clinical scientists who would focus their academic research on clinical trials.

If academic medicine doesn’t take a proactive role in undertaking these imperatives, we may find that our mission of advanced medical therapy through discovery gets lost in the translation. ■



# Contrarians, Diverge!

APPLYING FRESH REASONING TAKES COURAGE—AND MENTORS.

Two roads diverged in a wood, and I—  
I took the one less traveled by,  
And that has made all the difference.

—Robert Frost, *The Road Not Taken*

Addressing a group of faculty recently, I asked them to define contrarian. Some thought contrarians were “oddballs.” Others said “curmudgeons,” or people who “go against the flow.” I like to think of contrarians as finding opportunities that everyone else has passed by. Contrarians take the road less traveled, and that, as the poet said, makes all the difference.

I recall my own experience as a young faculty member, circa 1978, presenting results on digital radiography to an international radiology meeting. As with most meetings of this type, there were multiple scientific presentations going on in parallel. For my presentation there were more than 200 people in the audience. All the seats were filled, and scores were being turned away at the door. My topic—about using computers to acquire radiographic images, process and distribute them throughout the hospital—had a number of important potential applications, including moving to a totally “filmless” radiology department. There was a lot of excitement about this new technology, and we were able to demonstrate some striking clinical results.

Next door, in a lecture hall identical to mine, was a presentation on another new imaging technology. The results were rather dismal, the images quite crude, and attendance in the audience numbered about eight people. Perhaps four of the eight were members of the presenter’s research group, and the fifth may well have been the presenter’s spouse. It was not exactly a hot topic.

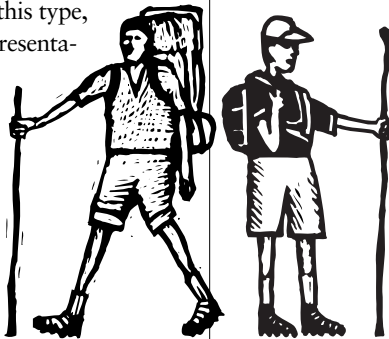
If you were a newly minted Ph.D. in imaging science, or a young academic radiologist fresh out of training, which session would you attend? In fact, most would likely try to get into the presentation on digital radiography—a “hot” area with a lot of exciting initial results. Few would venture into the other room. While we don’t like to admit it, the herd instinct—so prevalent in fashion and on Wall Street—also dominates scientific research.

But if all the bright people are working on one particular problem, what chance does a young scientist have to compete to get her or his ideas heard above the noise of the crowd? Better to find a forgotten or ignored area and see if you can apply fresh reasoning to unsolved problems. However, this takes courage and support from mentors. Encouraging contrarian behavior in our students is perhaps one of the most important attributes we can foster. But how?

I highly recommend *Moneyball*, an entertaining and informative view of how one contrarian transformed a poorly funded major-league franchise, the Oakland Athletics, into a consistent winner. This despite having to compete against teams like the Yankees, which have substantially greater financial resources. The application of logic and statistics—and a little bit of contrarian thinking—often yields surprising results.

Oh, as for the title of the unattended presentation in the room next to mine: “An Introduction to Magnetic Resonance Imaging.” Nobel prize-winning material, indeed. And digital radiography? Like the paperless office, the filmless radiology department is something we’re still dreaming about. One day it may yet come true.

As Yogi Berra said, “If you come to a fork in the road, take it!” ■



# Medical Education, Post Flexner

IT'S TIME FOR A SERIOUS REMAKE.

**M**edical education is in need of a serious remake. And, in the spirit of audacious abandon, I thought I would proffer a few recommendations for change.

We must, first of all, agree on the major problems needing to be addressed. Simply stated, I think they are:

1. The medical training period is too long.
2. The finished product is not suited for 21st century medicine.
3. The costs are too high (for student and for medical school alike).

This time out, I want to suggest how we might make the training period shorter. There! I've said it! But now how do we make it happen?

Fundamentally, the solution requires recognition that medical school curricula are often dictated by a group of department chairs who each believe his or her department's existence is threatened if a significant chunk of that discipline is not a required part of the curriculum. So we insist our medical students take courses that may not be fundamentally necessary to the task at hand, or may be redundant. Not crediting college biochemistry, for example, leads to considerable duplication in medical school.

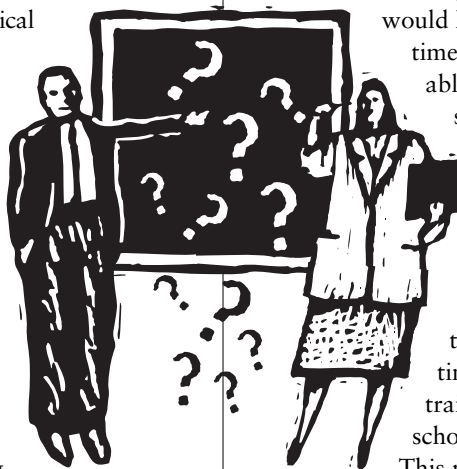
And how much basic science is enough? I am all for the advancement of basic biomedical science, but we must open the curriculum to other courses—on patient safety, bioethics and other pressing concerns. What we can't do is simply keep adding more courses. Maybe we are teaching too much basic science, or perhaps not enough. One way or the other, a critical rethinking of curriculum content is in order.

One obvious and relatively easy time-saving change would be to reduce and try to eliminate teaching and training redundancies. We have this tremendous proliferation of pre-meds taking biological science courses. Why can't we offer medical school courses to undergraduates? If we devote some of the undergraduate pre-med time to relevant courses, we can shorten the overall time between high school and completion of residency—which should be our goal. I am not suggesting we tell our pre-meds to avoid undergraduate courses in literature, philosophy, languages and so on—far from it. But by substituting medical school preclinical courses for some undergraduate science courses, we could potentially realize two gains. First, it

would help shorten the training time. And second, it would enable us to focus the medical school curriculum on important courses that are not presently being taught.

There are really two parts to the medical training time equation, the second part being the time required for clinical training (both in medical school as well as in residency).

This part of the medical education is predicated on the student acquiring enough experiential training, i.e., seeing lots of patients with different diseases in the clinical setting. Here again, we confront the force of tradition, but in this case the opportunities for real improvements are especially compelling. Next time, I will focus on ways to make clinical training more efficient and effective, both to reduce training times and to improve the overall finished product—the practicing physician. ■



# Training for 21st Century Medicine

TO CUT COSTS, REPLACE APPRENTICESHIP WITH SCENARIOS.

Most readers are familiar with the use of flight simulators for pilot training. But did you know that when Boeing or Airbus comes out with a new aircraft, the pilot trains and is certified in a flight simulator and is qualified to fly the plane and carry passengers only after 25 hours of actual flight time? The use of simulators guarantees that each pilot has been exposed to a standard set of experiences that she might encounter in real life. In fact, the simulator allows the pilot to be put in situations that would otherwise be too costly, too risky (even life-threatening) to do in an actual aircraft.

Harvard Business School is famous for scenario-based training using their case study method. Can this be done in medical education? Certainly.

It might not be simple, but one can imagine a variety of techniques used to develop and refine clinical skills using multimedia, actors posing as patients, automatic simulation and the like. Important issues not receiving enough attention in the current training system, such as medical ethics, can be introduced and explored in depth in this manner.

Scenario-based training would not only reduce training time and assure a standard level of clinical skills, it could also readily be employed for continuing medical education and recertification, potentially bringing a much more efficient use of faculty time and thereby reducing the overall costs of medical education.

Ultimately, it is not just the teaching technique that must be changed, but the focus of medical education as well. We need to train doctors to work in teams—with other physicians, with nurses and physician's assistants, with pharmacists, social workers and so forth. Underpinning

this new approach must be a laserlike focus on evidence-based medicine. Future physicians should develop and practice their art based on protocols and performance standards. These skills are vitally important for improving quality and reducing the costs of health care, yet currently, they are mostly absent from medical school curricula.



My mentor in cardiac surgery, in reference to the long training periods for cardiac surgical residencies, used to quip, “The hardest part of surgery is getting to operate.” With scenario-based training, one could get to the operating table much earlier and at the same time be better prepared and more competent. Rather than requiring medical students and resident physicians to spend years acquiring enough experience

through on-the-job training, I believe we should be taking this different approach—one utilized successfully in many different highly skilled professions. Our current model is essentially an apprenticeship; I hope we can create a structured learning environment that ensures each student is exposed to all elements of a discipline before certification of competence.

Readers expecting a third column on reducing the costs of medical education are to be disappointed—all the important means of slashing costs are contained in this and the prior column. It all comes down to reducing training periods by making the acquisition of skills more efficient. Do this, and we will dramatically reduce costs for the student and, at the same time, reduce the burden of clinical education on our faculty. It may, however, throw a monkey wrench into the machinery of how we staff our teaching hospitals, but that’s another idea for another column. ■

# You Gotta Have Connections

RESEARCH WORKERS OF THE WORLD, CONNECT UP! SCIENTIFIC PROGRESS DEPENDS ON IT.

When I wrote a column about open-source research networks, I was sure that I would receive a lot of negative feedback—something to the effect that, Bill, you've absolutely lost your mind; no one would share their intermediate results in an open forum.

Now, it is probably true that I have lost my mind, but what is even more surprising is that many of you not only agreed with the concept, but sent me concrete examples where open-source research is already alive and well.

Of course, when I wrote the column, I already had a couple of aces up my sleeve, in case I needed them. Open-source research has actually been in use for many decades. The high-energy physics community has been conducting its research entirely in the sunshine (well, more explicitly in lead- or concrete-lined corridors) since the 1950s and 60s. Teams of scientists from around the world would collaborate at the site of one of the powerful particle accelerators in order to conduct state-of-the-art research. Results were immediately known.

Some say the Web was developed to serve the need for these teams to work across large geographic areas when they weren't together at the accelerator.

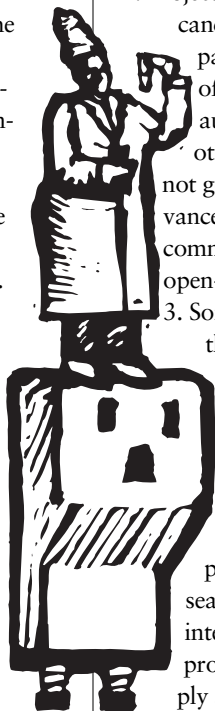
In the life sciences, there is an exquisite example: The human genome database has demonstrated the power of thousands of investigators sequencing different loci on the genome and placing that sequence data on a shared database for broad access. Perhaps the fact that the genome sequencing was completed on budget and ahead of schedule is a tribute to the open access to data and results.

Many e-mails I received have documented a number of other open-source projects, from clinical trials databases to software for analyzing gene sequences to research on autism. While there are likely to be thousands of different examples of open-source biomedical research, it seems to me that certain projects are particularly amenable to this approach:

1. Projects that generate large amounts of data, such as the human genome database, that can and should be accessed by multiple investigators. The larger the scale of the project, the more open-source collaborative networks will be the norm.
2. Projects that study rare diseases. While lung cancer has tens of thousands of affected patients and therefore many thousands of investigators studying the disease, autism, amyotrophic lateral sclerosis and other diseases with lower prevalence are not going to undergo rapid scientific advances unless the relatively small global community of scientists can team up, via open-source networking, to collaborate.
3. Software-intensive projects. For example, the Bioconductor project

(<http://www.bioconductor.org/>) develops open-source software for the analysis and comprehension of genomic data.

Scientific progress depends, in no small measure, on the number of people working in a particular area of research. The more people the greater the interaction, and this interactivity drives productivity. Networked research is simply another way of enlarging the size of the research community. So, I leave you with this manifesto: Research workers of the world, don't rise up—connect up. ■



# The Uncensored Idea

OPEN SOURCE NETWORK COULD SPEED NEW DRUG DEVELOPMENT.

I seem to be getting stuck on a single theme these days. However, I was recently in a meeting of presidents of U.S. and European universities and the topic of open-source research and education again came up in several presentations, including, of course, my own. After the third paper mentioned open-source applications, I decided I should raise with the readers of *Change* an idea I discussed in the hallway with one of the meeting participants. So here it is, in pretty much uncensored form.

One of the problems in drug development is that the costs associated with bringing a drug to market—especially costs incurred in Phase I, II and III testing—are high. Thus, pharmaceutical companies increasingly are focusing primarily on drugs that have a very large target population and/or that can be priced at a level which will allow them to recoup their development costs. Drugs that target diseases affecting small numbers of the population are not likely to interest the major pharmaceutical companies—and ditto for drugs that target diseases affecting the poor of the world.

Why not create a large open-source network, to both develop and test drugs, that could be used, for example, to treat HIV/AIDS patients in the poor nations of the world? Could we create a new compound through the interaction of hundreds of pharmaceutical scientists, who would assign the license for the compound to a worldwide open-source network? Similarly, an even larger network of clinical investigators could test the drug in various patient populations, funded by research agencies like the NIH, foundations and private philanthropy. The open-source consortium would hold the license for the intellectual property, create a database of shared information, and so forth.

The goal would be to create effective drugs against AIDS (or malaria and other infectious diseases) at a price that could be afforded by developing nations. The consortium would grant a royalty-free license to a pharmaceutical manufacturing house that would agree, as part of the license, to make and distribute the drug for a fraction of the cost that a normal proprietary new drug would command.

Some of these steps are already in process. For example, the NIH has funded studies that examine the efficacy of lower-cost alternative therapies for AIDS. The Gates Foundation has funded consortia of multiple research organizations for vaccine development. Expanding the concept to a completely open-source network could multiply the effectiveness of these current funding sources several times over. Once the infrastructure for data collection, analysis and storage is created, the costs of conducting incremental studies and adding to the database becomes much lower than might otherwise be the case.

Imagine assembling a network of 2,000 clinical testing sites in hospitals around the world. If each studied a new drug in 50 patients, one could rapidly and inexpensively acquire data from 100,000 patients. The NIH or a large foundation might fund the consortium and its infrastructure, with each of the clinical sites taking ownership for the trial on its patient population, absorbing the costs locally.

An advantage of this open-source approach is that once a new drug is approved, postmarket surveillance data could be collected and analyzed as well, leading to the early identification of new side effects and additional data on the efficacy of the drug when used more broadly. ■



# In the Blink of an Eye

CLINICAL MOXIE: OUT OF FAVOR BUT NEVER OUT OF FASHION.

When I was a resident in radiology at UCSF, we had several rotations at San Francisco General Hospital, where we took frequent calls at the Mission Emergency Room, definitely an interesting and exciting learning experience. After the radiology resident would read the films, she or he would hang them on a mechanical alternating viewer (this was in the good ol' days before digital radiology), and in the early morning, one of the attending radiologists would come in to check the films.

A colleague of mine told me about reviewing the films one morning with Hideyo Minagi, who had one of the best “eyes” of any radiologist I had ever seen. Minagi’s style was to keep the films continuously rolling down the alternator. Then he would stop the conveyor to query the resident whenever he saw something abnormal.

As the films were moving down, there was a chest X-ray on a 3-year-old child. “Well, that’s interesting,” said Dr. Minagi, as he perused the image for no more than probably half a second or so. My resident colleague’s palms began to sweat, as he had interpreted the film as “normal.”

“No, not correct,” Dr. Minagi blurted out, “that child has Down syndrome.”

“How could that be?” said the resident.

“Because the patient only has 11 ribs,” the attending replied.

Now, I can guarantee you that it’s simply impossible for anyone to count the number of ribs visualized on a chest X-ray in less than five to 10 seconds. Obviously, Dr. Minagi had the subconscious ability to recognize an abnormal number of ribs without explicitly counting them.

Sound supernatural? I suggest not, and to bolster my case, I recommend that you read *Blink: The Power of Thinking Without Thinking* by Malcom Gladwell (of *The Tipping Point* fame).

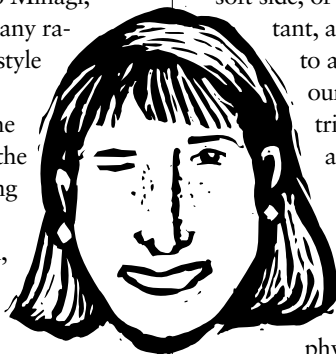
In his latest book, Gladwell will regale you with tales of people who make these kinds of subconscious decisions accurately without having to compile lots of data. For example, he tells of the psychologist who can view a few minutes of a taped segment of a husband and wife, then predict whether they will remain married. Or the art historian who could spot a fraudulent sculpture in 10 seconds after expert testing had indicated otherwise.

*Blink* is highly relevant in this day of high-tech medicine and even more highly sophisticated diagnostic tests. It highlighted to me, anyway, that the soft side, or the art of medicine, is still as important, and perhaps even more so. Listening to and observing the patient with all of our innate powers has as much to contribute to the diagnosis and treatment as do all the expensive tests we are able to order.

Let me close with a story told to me 10 years ago: A man had been hospitalized at another hospital under the care of a non-Hopkins physician. He knew one of Hopkins’ finest, Wilmot Ball, but was not under his care. According to the story, Ball showed up at the hospital around midnight to see his friend. He took one look at the man and announced, “Sam, you’re going to die. We have to get you to Johns Hopkins immediately!” And that is exactly what Ball did.

After the man was admitted to the ICU, the attending made the diagnosis of acute pulmonary embolism. A thoracotomy and successful pulmonary embolectomy were performed. The man is in great health today.

Clinical moxie may be out of favor, but it shouldn’t be out of fashion. Our medical students and residents need to be ever diligent to sharpen their powers of observation and reasoning in clinical situations. Intuitive reasoning can be very powerful and very accurate. Whoever said that first impressions are inaccurate hasn’t read *Blink*. ■



# No Conflict, No Interest

MOVING FROM BENCH TO MARKETPLACE ENTAILS RISK.

**F**ormer Hopkins faculty member Elias Zerhouni has his hands full at the National Institutes of Health (NIH) trying to manage a conflict-of-interest scandal that arose from decisions made long before he assumed his role as director. Faced with disclosures that NIH scientists and administrators were receiving payments from the private sector for consulting, honoraria for speeches, and cash prizes for awards, Zerhouni put together a blue-ribbon panel chaired by Hopkins trustee and former Lockheed-Martin CEO Norman Augustine that recommended adopting a policy not unlike those in place at leading universities.

Continuing stories about serious conflicts of interest involving NIH members drove the federal government to go beyond the Augustine Commission recommendations and adopt more severe restrictions, leading to a cloistering of NIH scientists and administrators within the confines of their government duties and compensation. Now, I read that NIH scientists are threatening to rebel against these more draconian measures.

This issue, I should add, will not stop at the gates of the NIH. A number of people in Congress and the media are calling for the adoption of similar restrictions for anyone who is receiving NIH grants. Conflict of interest is a battle between maintaining our pristine “trusted agent” status for society and the pressures to move discovery from the bench to the marketplace. There are many issues involved, among them:

- Protecting the integrity of scientific research
- Making sure that technology developments and scientific discoveries move quickly from the university to industry
- Making sure that student training is not subverted to the priorities of outside corporations
- Ensuring open communication among physicians

and scientists, unencumbered by consulting arrangements

- Assuring the reputational integrity of the university
- Maintaining the dedication of the faculty to the aims of the university

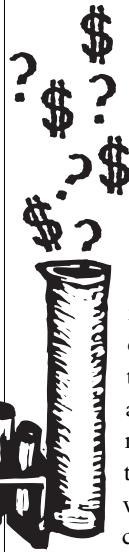
There are no easy answers to these challenges. We have debated them in the past and developed guidelines that have for the most part served Hopkins well. Whenever conflict-of-interest issues arise, rarely do both sides get

heard. The media and general public tend to gravitate toward the belief that the “negative” pressures of outside financial interests will trump any other societal gains that might accrue from university/industry collaborations.

In my mind, conflict of interest begins the day a scientist has an idea. Even receiving NIH grant support drives a certain mode of behavior that could conflict the objectivity of that scientist. And licensing the idea to outside interests adds additional conflicts. A surgeon who develops a new clinical procedure will want to pursue the development of that procedure—even without the involvement of an outside company. If she invents a surgical device that enables the operation and licenses that

technology to an outside company, the conflict becomes more apparent, even though the conflict was no less real before any agreement was signed. But it is probably impossible to erect a firewall between the scientist and the supposed source of conflict. I know of few surgeons who would use a device invented by someone else if that colleague, even for reasons of conflict of interest, did not use that device herself. As a venture capitalist once told me, “No conflict, no interest.”

In light of changing expectations and heightened public concern over conflict of interest, it is time to review the Hopkins experience to evaluate the effectiveness of our current policies and procedures. ■



# Doctor Beware: A New Conflict of Interest

CASUAL CONVERSATION CAN HAVE SERIOUS CONSEQUENCES.

I love reading the kinds of spy novels where a Russian KGB agent gets on a train, spots a man in a heavy wool suit and white socks in the middle of summer, and then uses convoluted analysis to deduce correctly all of the details of a complex plot to overthrow the government of Bulgaria. It's fun reading about superb detective work. Today, the spirit of spying lives on in the work of some stock-market analysts. Their relevance to academic medicine is the subject of my column.

It has long been the practice of Wall Street firms to hire high-profile physicians involved in the development and application of cutting-edge therapies to provide advice so that investors can determine where to place their future bets. This is a bona fide way for investment professionals to get current and generally accurate information about market and industry trends.

However, there's an important distinction between providing general market and scientific advice and revealing specific knowledge that has not been publicly disclosed regarding the progress (or lack thereof) of a clinical trial or critical research experiment. An article in the Aug. 10, 2005, *Washington Post* indicates that the Securities and Exchange Commission is taking more than a passing interest in this latter phenomenon, probing physicians' dealings with stock-market analysts and investors. *The Seattle Times* reports that "some doctors involved in running corporate-sponsored drug tests are taking payments from stock analysts for violating confidentiality agreements and revealing secret information."

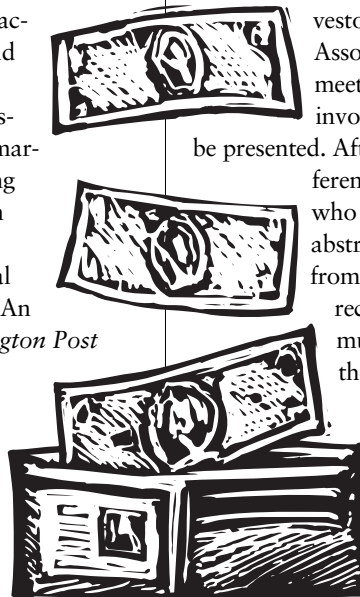
One reason the SEC is suspicious is the financial equivalent of the wool suit in summer: the all-

too-telling bump (or drop) in the stock price of a publicly traded company just before good (or bad) news regarding a clinical trial or FDA ruling is about to be announced. At issue is, where does this information come from that predicts impending significant events, and how was it obtained?

Since the Martha Stewart case, we are all quite familiar with insider *trading* and the serious ramifications thereof. But we should also be aware that trafficking in insider *information*—even if you don't participate in buying or selling stock, or benefit financially in any way—can be a serious breach of confidentiality. Careless talkers may find themselves behind bars, paying a substantial fine or wearing those now-fashionable ankle locks.

Even a casual conversation can have serious consequences. I was told about an investor who called the American Heart Association just before the annual meeting to see if a particular abstract involving a clinical trial was going to be presented. After placing multiple calls to different offices, he spoke to a secretary who innocently informed him that the abstract in question had been pulled from the meeting. The investor correctly surmised that the results must have been positive and that the researchers were submitting a manuscript for publication instead of presenting an abstract. The investor went ahead and purchased stock in the company involved and made a handsome profit.

Confidential information is just that. If you are involved in a clinical trial that requires confidentiality, you (and your secretary and other staff) cannot divulge *any* information to your colleagues, let alone to outsiders, without breaching your ethical obligations and exposing yourself to potential legal scrutiny. ■



# Whose Interest?

THE PUBLIC HOLDS US TO A HIGHER STANDARD.

I just finished a book that should be required reading for all physicians, and maybe for all medical scientists as well. It does not paint a pretty picture of how outside organizations, particularly the pharmaceutical industry, can influence the behavior of doctors and medical researchers.

*On the Take*, written by academic physician Jerome Kassirer, former editor of *The New England Journal of Medicine*, outlines the many forms of conflict of interest that confront and confound doctors, medical scientists and medical organizations ranging from hospitals to specialty groups like the Heart Association.

In response to the defensive cries of “I can’t be bought,” Kassirer presents considerable evidence to the contrary. Despite their protestations, many in our profession have placed themselves in positions where their judgment is questionable. Even if there is no explicit or implicit bias in their behavior, the mere presence of significant financial incentives casts a pall over their work. And numerous studies have, indeed, documented that outside influence in the form of financial compensation does (in many cases) bias the outcome of treatment, clinical research and even basic science studies. Psychological research studies document this “rule of reciprocity.”

After reading Kassirer’s book, I reviewed some investigative reporting about consulting activities of NIH senior scientists. I was truly ashamed of the behavior of key people in our profession. Granted, as paid consultants for medical companies, they may have acted in perfectly good faith. Lack of sufficient disclosure and other safeguards, however, failed to protect the integrity of their work. At best, there was the appearance of bias in their actions. At worst, the financial compensation significantly swayed their opinions.

Even perfectly ethical and totally forthright behavior can create the appearance of conflict. A senior cardiologist from UCSF wrote an opinion piece endorsing a product made by a startup company.

His article was published in promotional material distributed by the company. Kassirer concluded that the doctor had been paid to write this opinion and contacted him inquiring as to why a senior academic leader would allow a company to use him in this way. Much to his surprise, he learned that the doctor had refused any compensation and had no financial interest in the company. He was simply so impressed with the improved clinical outcomes of patients using the device that he felt it was important to help support the startup company.

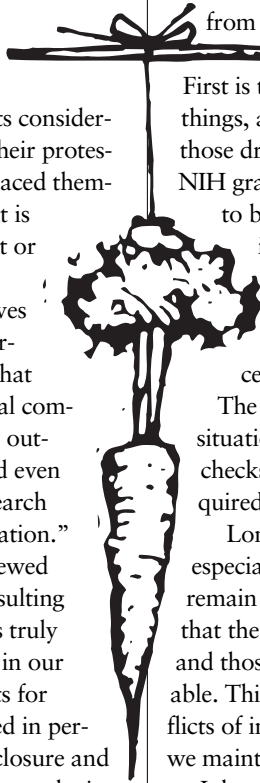
There are many important lessons to learn from Kassirer’s book. I cite only a couple here.

First is that opinions can be influenced by many things, and financial incentives are clearly one of those drivers. Fame, promotion, getting the next NIH grant, winning the Nobel can also contribute to biased results. But in the case of financial incentives, the conflict is both readily identifiable and quantifiable. Most importantly, the conflict of financial incentives is often avoidable. One can simply proceed without taking outside compensation.

The second lesson is that conflict-of-interest situations always require disclosure. Additional checks, balances or prohibitions may be required, but full disclosure is the vital first step.

Long gone are the days when academicians, especially those involved in clinical research, can remain in the ivory tower. We want to help assure that the best drugs and devices get tested properly, and those that pass muster become widely available. This objective involves the assumption of conflicts of interest—and a higher degree of risk than if we maintained a completely cloistered environment.

Johns Hopkins Medicine is a revered and honored name—we are what I call a trusted agent of medical science and clinical care. The public holds us to a higher standard than other hospitals and academic medical centers. In order to carry out our mission of discovery through innovation, we need to be sure that we comport ourselves to the absolute highest ethical standards possible. ■



# Institutional Conflict of Interest

AT RISK: OUR REPUTATION AND THE PUBLIC'S INTEREST.

Much has been written about financial conflict of interest involving an individual faculty member who receives remuneration in one form or another from a commercial entity like a pharmaceutical company. Little notice has been given, however, to the conflicted positions in which universities and hospitals may possibly find themselves. Institutional conflict of interest is a relatively new but growing subject of concern, one worthy of further study.

A couple of months ago, I had a conversation with the president of a major research university, which had licensed a new drug to Pfizer. The drug was about to receive FDA approval, and the expected royalties from the drug might run into the hundreds of millions of dollars per year. Not long after that, I read about a report detailing a couple of cases in which a rare form of blindness occurred in patients who were taking either Viagra or a similar drug. These two unrelated occurrences got me to thinking.

Consider the following hypothetical case: Suppose you were the chair of the board of trustees of DuPont University (with apologies to Tom Wolfe and the main character of his latest book, *Charlotte Simmons*). Suppose also that DuPont U. is receiving \$200 million a year in royalties from Big Drug Inc. for a particular drug and that one of the young DuPont faculty members has just written an article indicating that taking this drug in some very small number of cases can cause blindness. One day, in your role as board of trustees chairman, you get a call from Big Drug Inc.'s CEO, who threatens to stop all payments unless the untenured faculty member is convinced to print a retraction or a mitigat-

ing follow-up paper. You know (as does Big Drug's CEO) that without those royalties, the university's expansion program will be halted and serious deficits will be incurred. So you call the DuPont University president to ask her to throttle the offending young physician.

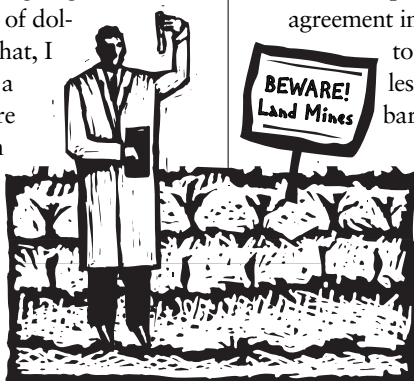
Ah, you say, this could never happen!

But consider the real-life case of Nancy Oliveri from the University of Toronto Hospital for Sick Children. Oliveri was conducting a study of a drug sponsored by Apotex, the manufacturer of the drug and the largest pharmaceutical company in Canada. After an initial publication providing positive results, she began noting liver toxicity in patients and wanted to notify the IRB about these side effects. Apotex, citing a clause in the research agreement in which the investigators agreed

to keep all results confidential unless approved by the company, barred her from disclosing these complications.

Oliveri decided to go to the IRB anyway. Apotex terminated the study and removed her from the steering committee. The University of Toronto and the Hospital for Sick Children, instead of coming to her defense, removed her as hemoglobinopathies program director at the hospital and refused to defend her against lawsuits from Apotex. She was ultimately vindicated in a detailed investigation. Only later was it revealed that the University of Toronto had been negotiating with Apotex for a \$20 million donation to the university for a biomedical research center.

Institutional conflict of interest presents a new minefield that must be carefully navigated to protect the interests of the public and the reputation of the institution. Expect more to be heard on this topic in the lay press and medical journals in coming months. ■



# Use of the Name

## DETERMINING GUIDELINES FOR OUR SEAL OF APPROVAL.

The recent announcement that Johns Hopkins Medicine collaborated with a cosmetics company marketing a new line of skin treatment products under the name Cosmedicines triggered a public outcry. People asked how a venerable and respected organization like Johns Hopkins could choose to work in an industry that has traditionally sold its products more on image than on substance.

Rather than dwell on the specifics of this relationship, I would like to ask readers to step back and consider what the guidelines should be for determining when the institution should enter into a relationship with for-profit corporations in any industry. And when, in particular, should we allow companies to cite Hopkins in any of their promotional literature?

This particular relationship made headline news. But there are other companies that have touted relationships with Hopkins—and it isn't clear if in all these situations our name was used in a way that was officially sanctioned by us. Nor can we expect to exert control in all situations. Even when the University doesn't allow the use of its name, many of our faculty may nevertheless have consulting relationships with companies. Occasionally a company will cite the Hopkins faculty member's participation as a sort of Good Housekeeping Seal of Approval, even though our participation is neither a seal of approval nor an endorsement of any kind.

There are serious issues here worthy of discussion and debate within the Hopkins community. First among them is how to deal with institutional conflicts of interest. We have developed a pretty effective system to identify and work through conflicts of interest that involve individ-

uals. But, as I wrote in a previous column, mechanisms for identifying and resolving conflicts that involve the University in a relationship with an outside entity are still poorly defined.

In what situations is it proper to allow outside groups to use the Hopkins brand? While this might seem easily decided, closer examination reveals that short of a 100 percent prohibition, any other approach involves a lot of subtleties. If our faculty members conduct a study sponsored by the NIH and report findings in a peer-reviewed journal, a pharmaceutical company is free to cite the report (and the Hopkins connection) without any prior approval from the University. On the other hand, if the research is sponsored by a pharmaceutical company, in what circumstances would we allow the company to cite the research, even if the results themselves are not published?

Derek Bok, in his book *Universities in the Marketplace*, describes the increasing trend toward commercialization of university activities, from Nike endorsements for athletic teams to technology licensing. He believes that the shift in emphasis calls into question the essential purpose of the university and wonders if our historic mission of education, research

and service is likely to be compromised by the newer focus on commercial relationships. Having recently attended the NCAA Final Four in Indianapolis, I can attest to how significantly commercial interests have altered the face of Division I basketball.

Over the next few months, the board of trustees and I will be discussing commercialization, institutional conflicts and the use of the Johns Hopkins name. If you have thoughts about any of these important issues, I would appreciate hearing from you. ■



**W**illiam R. Brody became the 13th president of The Johns Hopkins University on September 1, 1996. Previously, he had been provost of the Academic Health Center at the University of Minnesota and, from 1987 to 1994, director of the Department of Radiology at Johns Hopkins and radiologist-in-chief of The Johns Hopkins Hospital.

A native of Stockton, California, Dr. Brody received his B.S. and M.S. degrees in electrical engineering from the Massachusetts Institute of Technology, and his M.D. and Ph.D., also in electrical engineering, from Stanford University. Following post-graduate training in cardiovascular surgery and radiology at Stanford, the National Institutes of Health and the University of California, San Francisco, Dr. Brody was professor of radiology and electrical engineering at Stanford University (1977-1986). He has been a co-founder of three medical device companies, and has made contributions in medical acoustics, computed tomography, digital radiography and magnetic resonance imaging.

Dr. Brody is a member of the Institute of Medicine and a fellow of the Institute of Electrical and Electronic Engineers, the American College of Cardiology, the American Institute of Biomedical Engineering, and the American Academy of Arts and Sciences.

Co-chair of the National Innovation Initiative of the Council on Competitiveness, he also is a classical pianist and counts “flight instructor” as his most recent certification.

Dr. Brody and his wife, Wendy, have two grown children and reside at Nichols House on the Johns Hopkins Homewood campus.

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