Maryland Medicine
The Maryland Medical Journal
Volume 12, Issue 1

Medical Controversies:
the great divides

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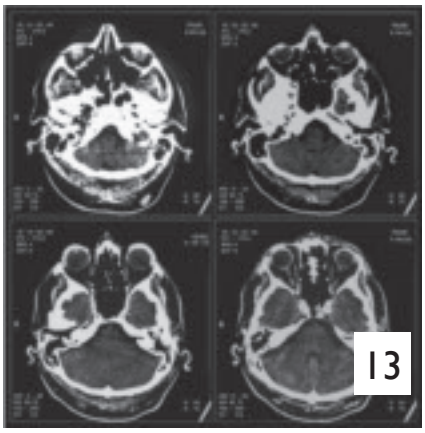
Volume 12 Issue 1

INSIDE



Currently, concussions in athletes are an important focus in the news. Doctors Crutchfield and Ferrell address this issue head-on.

Features

Departments

Wannabes

PRESIDENT'S MESSAGE

David Hexter, M.D.

Maryland has a long and rich history as the leader for developing standards for the practice of medicine. According to its charter passed by the Maryland General Assembly in 1799, MedChi was established to prevent the citizens of Maryland "from risking their lives in the hands of ignorant practitioners or pretenders to the healing art." The Flexner report on medical education in 1910 cited Johns Hopkins School of Medicine as the ideal model for medical education and recommended its adoption nationwide, a model that exists to this day.

Over the years, dizzying arrays of allied healthcare professions have been established. There are perfusionists, radiation therapists, paramedics, audiologists, dieticians, and many more. The ranks of these professions have grown to the point where they now make up an estimated 60 percent of the healthcare workforce. The support services they provide are critical to the delivery of high-quality and effective health care. Most of us work closely with one or more of the allied health professions.

The development of allied professions is not unique to the medical field. Attorneys have paralegals, dentists have dental hygienists, accountants have bookkeepers, veterinarians have animal health technicians, etc. Each of these allied professionals provides services under the supervision of a licensed professional, and assist that professional in providing high-quality services to more people.

In the pre-industrial era, a professional learned the trade and passed it on through an apprenticeship. No doubt some allied professionals become so skilled over time that they could perform their tasks better than the professional who trained them. For example, a dental hygienist may be able to clean teeth and recognize cavities better than the dentist who supervises him/her.

Some, feeling empowered by the skills they have acquired, may "wannabe" the professional they work with. If they "wannabe" the professional badly enough, they may decide to apply to the professional school in their field, acquire the necessary competency that makes them a professional, and take the certifying examination(s). Many of our MedChi members were nurses, physician assistants, or paramedics in their earlier lives, and later made the personal and professional sacrifices necessary to attain their ultimate career goals.

"...there are those who prefer not take the entrance exams, pay the tuition, and commit the time and energy necessary to become a professional. In their limited universe, they feel they have all the training and experience they need to perform the service independent of professional supervision. For them, the pathway to independent practice is political, through the state's General Assembly..."

However, for various reasons, there are those who prefer not take the entrance exams, pay the tuition, and commit the time and energy necessary to become a professional. In their limited universe, they feel they have all the training and experience they need to perform the service independent of professional supervision. For them, the pathway to independent practice is political, through the state's General Assembly.

The recipe for a "wannabe" is simple. Convince legislators that you can indeed perform the tasks of the profession as well as your supervising professional. Bring citizens along who are pleased with the services you have provided, as well as, perhaps, a few patients who were dissatisfied with your supervising professional. And soon you may be granted an expansion of your scope of practice, perhaps to the point of complete independent practice, especially if you say you will do it for less money.

Each year, several groups of allied professionals implore the legislature to expand their scope of practice. The dental hygienists request to open offices where a patients can have their teeth cleaned without any supervision by a dentist. Paralegals ask for the authority to write wills, but they don't get very far in a legislature with so many lawyers! And, of course, optometrists want to perform surgery and nurse practitioners want independent practice.

This year, the "wannabes" are more energized than ever. Budgets for government-sponsored insurance are tighter than ever. At the same time, these taxpayer-funded programs are expanding. The Patient Protection and Affordable Care Act passed last year promised to insure an additional 32 million people over the next eight years, over half of whom will be covered by Medicaid. Medicaid enrollees already face significant barriers to access to care, primarily due to below-market reimbursements that do not cover the cost of providing the care. There will not be enough physicians to meet this demand. At the same time, the aging of our general population is increasing demand for healthcare services.

Certain allied health professionals believe they have the answer—relieve them of the burden of physician oversight and grant them an increased scope of practice. They claim to be ready and eager to address the physician shortfall by providing a cheaper, **more cost-effective** alternative, but certainly not a **more medically effective** alternative.

Allied health professionals should carefully consider what they are asking for.

They will face higher liability premiums and accept liability risks that could bankrupt their practices, their livelihoods and even their homes. They will also learn the ruthlessness of the insurance monopsony. Employers of healthcare professionals, particularly hospitals, may be eager to expand scope of practice for allied health professionals so that they can replace their employed physicians at a lower cost. However, allied health professionals may not be so eager to accept lower wages. According to one recent survey, certain advanced practice nurses have averaged higher salaries than physicians for the past four years.

It is essential that we be true to the mission of MedChi, as espoused in its 1799 charter. We must uphold standards for training and experience of the medical profession, despite strong forces that seek to denigrate our profession and lower that standard of healthcare for Maryland's citizens. While allied health professionals have become an increasingly essential part of the healthcare team, they must continue to work as a part of the team under the direction of a physician. Rather than to the legislature, the "wannabes" should be directed to medical school, with a kind letter of reference.

Medicine-Lite

EDITOR'S CORNER

Bruce M. Smoller, M.D.

"*Electronic health records don't improve outpatient healthcare, even when paired with software that provides treatment tips", according to an analysis released online by the Archives of Internal Medicine(as reported in AMA morning Rounds, Jan 25, 2011).*

Every day brings new joy to our daily medical practices in the form of all manner of people who think they know what it means to practice medicine.

Electronic health records experts, Institute of Medicine experts, consultants, politicians, and talking head experts, physician extenders who feel they can do the same job as primary care physicians experts ,politicians mouthing absurdities about the "broken health care system"experts, lawyers, insurers, procurers, professors, promoters, producers, predictors, phew!... all rather impatiently boarding the health system express. We know that the value received from any of these folks will be transitory, expensive, redundant, and probably ineffective. Yet the experts keep coming, heaven bless them, and the nonsense keeps piling up. Well, not all nonsense. But medical system nonsense is like pornography…we may not be able to define it, but we know it when we see it. Or smell it.

I have written in these pages before that what is often couched as needed reforms based on some study or other, is in reality a "follow the money" game. Whether embedded in scope-of-practice issues or based on ephemeral studies, or even on solid ground, there is no dearth of hangers on and wonks willing to winnow money out of the health care coffer. What struck me, though, is that many, if not all of the suggestions for change, and many, if not all the players in the system have bought into a piece of the medicine-lite pie. It's the philosophy that electronic records will improve patient care. It's the attitude that less well trained occupations can provide more than rudimentary triage services. It's the approach that prevention can take the place of a huge medical knowledge base learned over many years and the great deductive and inductive skills of the physician. It's the poppycock that waste and fraud are rampant among physicians, and, if we could only root that out, the system would be funded and fixed. It's the philosophy of medicine-lite. It's an abstract phenomenon that finds a hole to crawl in when the same people who propose this claptrap become seriously ill. It's all contained in the book called *Medicine for Dummies*…and it will become a bestseller unless we scream out the real message. The real message is… yes, prevention can help…yes, electronic health records can be a supplemental help, yes there is some small amount of fraud… yes, no one should go without medical care because of poverty...yes physician extenders can do a wonderful job under some form of supervision. The big lie, though, as we should proclaim from any rooftop allowing us a perch, is first that these will make a difference at the core and second, if this philosophy of the dumbing down of medicine is allowed to ensue, the cost will remain…it'll just get shifted into the medicine-lite industry… where "prevention" is king, the elimination of all forms of waste and abuse will rule, the physician is to be infantilized, and never will be heard a discouraging word, 'cause what can the moribund say!

I've been entreated to write about positive changes to be brought about by the vast network of Medicine "improvers." During the same week, a physician of some note and some power carped about doctors always coming to the well for more money. Well, I can't find much good to write about in the land of medicine-lite. And in answer to the usually perspicacious gentlemen who mentioned the venality of doctors, I would just say that in hockey, it's usually the responder to the first foul that gets caught and put in the box.

This gives me a headache. I think I'll go exorcise a fraud. I certainly won't bother my doctor…he's too busy trying to survive and I just haven't figured out yet how to prevent that migraine.

"It's the approach that prevention can take the place of a huge medical knowledge base learned over many years and the great deductive and inductive skills of the physician."

Introduction

Mark G. Jameson, M.D., M.P.H. & Sallie. Rixey, M.D., M.Ed.

In 1797, two years before the founding of the Maryland Medical and Chirurgical Faculty (MedChi), a physician named John Davidge wrote in a Baltimore newspaper, The *Federal Gazette of Baltimore*, the startling claim that yellow fever was not contagious but instead transmitted by mosquitoes.[1] He was ignored. The controversial issue wasn't settled until 1830 when the Medical and Chirurgical Faculty and Baltimore Board of Health convinced the Baltimore City Council to cease yellow fever quarantines.[2] Clinical controversies preceded the commencement of MedChi and will persist past all of our careers. The specific controversies change with time but not the intensity of debate nor our desire to improve the care of patients.

> *Controversy* (according to Merriam-Webster Dictionary) is "a discussion marked especially by the expression of opposing views; …opinion or judgment colored by feeling or bias." Synonym: Imbroglios - a confused mass
> Antonym: Consensus

This issue of *Maryland Medicine* explores several contemporary health care controversies. Starting with the MedChi president's message, Dr. David Hexter takes on the controversy of who is qualified to practice clinical medicine, under what circumstances they may be permitted to do so, and who makes that decision. Dr. Hexter articulates his opinion concerning the value and effectiveness of non-physician clinical practices, an opinion held by many but not all of our membership, and at a time when evidence is still in the eye of the beholder.

In his letter to the editor, Maryland Delegate Dan Morhaim, M.D. reacts to Doctor's Retzky and Dr. Baker's commentary on the medical marijuana bill in the autumn 2010 issue of the journal, which is being reintroduced in this session (2011) of the Maryland legislature. Doctor Morhaim reminds us of both the necessary role and the limits of legislation as it relates to the regulation of (as well as the interference with) medical practice.

Doctors Crutchfield, Ferrell and Smoller update us on the ramifications of traumatic brain injury, the nuances of signs, symptoms, and their thoughts on what state of the art evaluation and treatment should be. The controversy: who is qualified to evaluate and treat the growing at-risk population—from soldiers to athletes? This question is especially important when access to and the cost of such care is prohibitive for many citizens and communities.

From the technologic advances in head trauma to the technologic advances in health care reform, Dan Kazzaz brings to

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LETTERS

Maryland Legislator Agrees with the Legalization of Medical Marijuana

The article titled, "Maryland's Medical Marijuana Bills" (*Maryland Medicine*, autumn 2010) concludes by stating, "Maryland can and should legalize medical marijuana…."

As one of the bill's many bi-partisan sponsors, and as the only physician in the Maryland General Assembly for the next four years, I agree.

However, other parts of the article deserve comment.

First, it is suggested that the Departments of Health and Agriculture need "direction" on quality control. This reflects the authors' lack of familiarity with the legislative and regulatory process. Many, if not most bills, allow for regulation by appropriate departments. This insures a more careful analysis, does not lock in detailed policy in law, and permits full participation by the public with legislative overview. If this "direction" was in law, then any changes, no matter how minor that might come about as new science or data became known, would require a change in the law, an expensive, slow, and laborious process.

Second, the article states that the "fiscal note" assumes only one grower. This is irrelevant. The fiscal note is not legislation and is not policy. The original draft of the legislation does not limit the number of growers, but it does spell out that each potential grower must meet stringent controls and qualifications.

Third, the authors add "registration and educational requirements" for physicians "are a must." While this may seem like a nice idea, it should be noted that this would be the only medicine (with the possible exception of *buprenorphine*) where legislative requirements would be specified before a physician could recommend use of a medicine. Doing this would start down a slippery of slope eventually leading to legislative action defining which physicians could prescribe what medicines under what circumstances. This is a dangerous precedent. The legislation has numerous safeguards, including tracking all recommendations, requiring use only in "bona fide physician-patient relationship" for conditions "severe and resistant to conventional medicine" and including documentation of the "medical condition," discussion of the "potential benefits" that "would likely outweigh the health risks for the patient." This would have to be written in the medical record and in a "written certification" and failure to do so would put the physician at risk of violation of the law, disciplinary action, and possible lawsuit.

The reality is that only certain physicians in appropriate specialties (e.g. oncology, neurology) would be recommending medical marijuana use. These physicians would do what any of us physicians do when a new medication or therapy becomes available: we study and review its indications, adverse effects, and contraindications, and we discuss this with our patients. These actions do not require legislative interference.

Many medicines come from plants. In the final analysis, cannabis is just another plant with medical risks and benefits. What is most important is the context of its use. Morphine for pain is appropriate; heroin addiction is not. The cannabis phobia that has dominated our perspective is out-dated, out of touch, and un-scientific. Let's take advantage of what cannabis offers as we do for other medicines.

Last, the article suggests that Congress amend the CDS act to move marijuana to Schedule 2 status. That would put cannabis in the same posture as other useful but potentially dangerous drugs, and this would allow proper research and safe channels for distribution and use. I agree, and I urge physicians and patients to write their federal legislators and the President to make this change. Until that happens, it's up to the states to act. In fact, it's common in U.S. legislative history that the federal government changes policy only after a significant number of states have done so. Recently, New Jersey and Washington, D.C. enacted prudent medical marijuana laws, so it is likely that Marylanders who desperately seek compassionate care for intractable symptoms will travel to other states, putting otherwise law-abiding citizens at risk for criminal punishment. This is unfortunate, and all the more reason why Maryland should pass a carefully crafted, judicious, and responsible medical marijuana law now.

Delegate Dan Morhaim, M.D.
Deputy Majority Leader
Maryland House of Delegates and
Associate Professor, Department of
Health Policy and Management, Johns
Hopkins Bloomberg School of Public Health

End-of-Life Issues

The articles in the last two issues of *Maryland Medicine* regarding advance directives and 50 years of cardiopulmonary resuscitation, while very nicely presented, leave one hoping that they are part of a series that will cover the deficiencies of durable powers of attorney once the subject is presumed dead, and the abysmal salvage rate for resuscitation attempts in the field.

First, the most important advance directive that went unmentioned in the first issue is the do not resuscitate (DNR) order. Maryland is one of a handful of states that provides for the wearing of a Medic Alert bracelet or necklace if the paper DNR form is not immediately available. Once a citizen goes into cardiopulmonary arrest, the durable power of attorney is no longer legally valid because the victim is presumed dead. An emergency medical service (EMS) team must initiate resuscitation efforts

despite the objections of the holder of the power of attorney and any advance directive other than the state authorized DNR form. Actually, although it depends somewhat on the judgment of the EMS team leader, if the body is warm and supple or if there is an occasional heartbeat or respiratory gasp, resuscitation will be attempted even in the most terminally ill. This is why 911 calls for the terminally ill should be the exception, not the rule. Such patients are best put into the care of a hospice team, which can greatly facilitate a smooth, pain-free demise for the struggling patient and his/her family.

Second, regarding "The Beat Goes On," there are several articles in the literature that compare the better than 75 percent salvage rate achieved on television in fictional medical series with the 10-45 percent success rates in the hospital setting and the single-digit salvage rates achieved by EMS teams in the field. Of those successes, only a fraction achieve complete recovery.

These problems are where the rubber meets the road and cover end-of-life issues that many physicians ignore or find too distressing to discuss with their patients.

This letter is intended to call the editor's attention to readers' need to face the sad underside of all of the marvelous progress that is being witnessed.

(In 1958 Jim and I were working in the Lab on esophageal reconstruction when we observed Dr. Kouwenhoven at the adjacent table resuscitating an anesthetized dog several times after his electrocution studies. The keel shape of the canine chest is perfect for closed chest cardiac massage by lateral chest compression. It was that experience that got Dr. Jude started on his work with Knickerbocker and Safar on closed chest massage.)

Frederik C. Hansen, M.D.
Baltimore, Maryland

Author's Response to Delegate Morhaim's Letter

We appreciate the work Delegate Dan Morhaim, M.D., has done on the important issue of medical marijuana. We address points raised in his letter with which our views vary or to provide further clarity for readers.

Setting Legislative Expectations, for Quality Control and Safety

If Maryland votes to enable the compassionate use of medical marijuana, it should also provide safeguards to protect both patients and workers who process and manufacture marijuana plant materials. It is imperative that lawmakers not assume that state regulatory agencies can or will handle this.

Medical marijuana is a botanical drug. Providing marijuana will be a unique challenge for state governmental agencies. For safe, quality plant substance, we believe medical marijuana must be greenhouse grown and the plant strain must be selected with care. Contamination with coliforms, pesticides, heavy metals and/or molds can occur with botanicals. Medical marijuana is no exception.

Safe botanicals have controls for potency. It does not take much Internet searching to see how greatly potency varies among medical marijuana products. In our research, we found THC levels advertised in medical marijuana products from 12 percent-35 percent[1], many fold higher than the THC content in marijuana from the 1960s (1.5 percent) or 1980s (3 percent).[1] Physicians are not accustomed to prescribing a drug without knowing potency. Minimally, the state must be able to assay marijuana products for the concentration of Δ9-tetrahydrocannabinol (THC), the principal psychoactive component. Since medical marijuana has multiple active constituents, there is an argument to be made for determining their relative amounts as well. Batch-to-batch consistency is another aspect of potency to consider.

There are also the issues of product stability, storage conditions, labeling and container choice. THC interacts with plastic, glass, and light. Container closure is also a concern. Though rare, there have been reports of toddlers ingesting their parent's marijuana with disastrous consequences.[2]

FDA approved drugs have a mechanism in place for adverse event reporting. This is critical to detecting safety problems at the population level. No state with medical marijuana currently does this for its citizens and providers. Maryland's laws should contain sufficient detail to provide clear direction and intent to the regulators who will ultimately implement and oversee the law.

Fiscal Policy Note

Since providing drug product is not routine for state agencies, they will need to hire experts and acquire appropriate infrastructure. None of this was anticipated in the fiscal policy note accompanying Maryland's earlier medical marijuana bills. In an era of tight budgetary constraints, fiscal policy is relevant. Beyond providing safe product, states must be able to sustain drug supply. This aspect should not be underestimated. In an ideal situation, sustaining drug supply is accomplished with back-ups, redundancies and demand forecasting.

Registration and Educational Requirements

Physicians should have registration requirements similar to those for prescrip-

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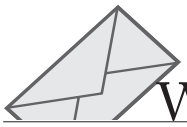
1 THC is expressed as a percent of dry weight marijuana. A typical marijuana cigarette or "joint" weighs approximately 1 gram. A marijuana cigarette from the 1960s would have contained 15mg of THC. In contract, the same cigarette today may contain as much as 120mg-350mg of THC.

Letters to the Editor are each the opinion of the author and may not reflect the opinion of the Maryland Medicine *Editorial Board or MedChi, The Maryland State Medical Society.*



WRITE TO US

The Editorial Board of *Maryland Medicine* welcomes your letters, comments, and opinions. Readers may respond to the authors or the editors by e-mail at sraskin@montgomerymedicine.org or by mail to Editor, *Maryland Medicine,* c/o Montgomery County Medical Society, 15855 Crabbs Branch Way, Rockville, MD 20855.

Controversies in Treatment

The Quality of Medical Care: A Commentary

Barton J. Gershen, M.D.

In 2000, the Institute of Medicine (IOM) released a publication titled *To Err is Human: Building a Safer Health System*. In this monograph the authors concluded that in the United States 44,000 to 98,000 hospital deaths per year are due to medical error. Within days of the release of that publication, those conclusions had become canonical. Their validity was unquestioned and their supporting statistics were sanctioned as legitimate and authoritative.

As a consequence, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) mandated procedures designed to increase patient safety, the Agency for Healthcare Research and Quality (AHRQ) developed new safety guidelines, hospitals dutifully complied, state and federal legislators expressed their concern, television and print news sources iterated their shock and alarm, patients expressed their increasing fear of hospitalization, and the issue of quality health care had become an overnight concern.

Gradually, however, there began to appear doubts regarding the validity of the IOM publication. It became evident, and the authors acknowledged, that their conclusions had been based largely on **only two papers** that had previously been published by the Harvard Medical Practice Study. Indeed, the principal author of both those papers, Troyen Brennan, subsequently wrote an editorial in *The New England Journal of Medicine*[1] in which he clearly **rejected the IOM inferences** that were based on his original work. Dr. Brennan wrote:

> *Two studies of injuries due to medical care are the source of the headline-grabbing numbers in the IOM report: a 1984 study of New York hospitals that my colleagues and I reported in 1991 and a 1992 study of Colorado and Utah hospitals that my colleagues and I reported this year. In both studies, we used an approach pioneered by the California Medical Association in 1976: physicians reviewed hospital medical records for evidence of adverse events caused by medical care, not by the disease process. We further classified a subgroup of adverse events as the result of negligent care, meaning that the care fell short of the expected standard.*
>
> *In both studies, two investigators subsequently reviewed the data and reclassified the events as preventable or not preventable.… In both studies, we agreed among ourselves about whether events should be classified as preventable or not preventable, but these decisions do not necessarily reflect the views of the average physician and certainly* ***do not mean that all preventable adverse events were blunders.****

Dr. Brennan then discussed whether the adverse events found in the chart reviews were caused by medical **errors**:

> *Perhaps more to the point, neither study……involved judgments by the physicians reviewing medical records about whether the injuries were caused by errors.* ***Indeed, there is no evidence that such judgments can be made reliably.****

Dr. Brennan concluded:

> *All these points might be considered hairsplitting over definitions if it were not for four important aspects of the IOM report. First, the report and the accounts of it in the media give the impression that doctors and hospitals are doing very little about the problem of injuries caused by medical care. Yet the data that the report cites give a different impression. In the three studies cited, the rate of injury due to medical care was 4.6 percent in California in 1976, 3.7 percent in New York in 1984, and 2.9 percent in Colorado and Utah in 1992. Moreover, if one*

extrapolates from our studies in New York and in Colorado and Utah in order to calculate the number of deaths nationwide due to substandard care, the total ***decreases*** *from 92,000 deaths in 1984 (on the basis of the data in New York) to 25,000 in 1992 (on the basis of the data in Colorado and Utah)…and although my colleagues and I have cautioned against drawing conclusions about the numbers of deaths in these studies,* ***the evidence suggests that safety has improved, not deteriorated.****

In 2000, McDonald, Weiner and Hui published another critique of the IOM report.[2] The authors wrote:

The Harvard study includes no information about the ***baseline risk of death*** *in these patients or information about deaths in any comparison group. Therefore, it cannot be determined whether adverse events are correlated with, let alone whether they cause, death. Indeed, an assertion that adverse events caused death in 13.6 percent of the patients who experienced adverse events is tantamount to the assertion* ***that there would be no deaths in a group with similar baseline risks who avoided all adverse events.*** *Clinical experience tells us that this is not true…. The Harvard study acknowledged that eliminating the adverse event (and even the negligence) would have* ***little effect on the life expectancy of many terminally ill patients****…. The 30-day post-hospital admission mortality rate of 11.6 percent and the 30-day death risk up to 40 percent for some categories of Medicare patients suggest that* ***an important proportion of hospitalized patients are at, or near, the end of their lives****….Given these facts, using available data and some reasonable assumptions, we believe that the increment in the published death rate due to adverse events above the baseline death rate could be very small. We also assert that the available data* ***do not support IOM's claim of large numbers of deaths caused by adverse events (preventable or otherwise)….*** *The IOM uses elaborate controls to ensure a careful balance of interests in the parties on the committees that produce reports and it uses extensive review to avoid errors in its reports. However, the reliance on* ***studies without controls to make headline claims about huge numbers of preventable deaths*** *was one error that it did not catch….**

> "The definition and appropriate measurement of "quality health care" is currently uncertain and debatable.."

Despite these flaws, the IOM report triggered a renewed focus on the quality of medical care. One of the outgrowths has been the concept of "evidence-based medicine"—the proposal that physicians should base therapy on authoritative information, rather than on anecdotal and personal experience. Presumably the physician would acquire this wisdom through reading peer-reviewed journals, attending educational forums, and carefully studying practice guidelines developed by expert authorities. However, there lies the rub. Peer-reviewed journals—as valuable as they are—have some problems. In one appraisal, 30-50 percent of articles published in peer-reviewed journals were considered to be invalid within five years of their publication date.[3] Furthermore, editorial biases do exist and often influence which articles are approved for publication. Also, journals rarely publish studies with negative results. These factors leave the physician loath to have full confidence in any given article.

For years physicians have recognized that coronary artery disease in women was uncommon until the onset of menopause. The general consensus was that estrogen somehow conferred protection. This appeared to be substantiated by numerous articles in the peer-reviewed literature. As a result, it became common practice to treat post-menopausal women at high risk for coronary disease with estrogen or estrogen plus progestin. However, the Women's Health Initiative, begun in 1991,[4] put an abrupt end to that practice by discovering that hormone therapy actually increased myocardial infarctions, strokes, and peripheral blood clots. This immediately resulted in a paradigmatic shift in our understanding of the heart disease/estrogen-progestin relationship. What had been thought to be standard, mainstream medicine was in fact found to be wrong.

From the early years of the 20th century, peptic ulcers were believed to be caused by emotional stress, abetted by smoking, alcohol use and caffeine. Customary therapy involved placing the patient on a bland ("Sippy") diet, restricting alcohol and coffee and placing the patient on abundant antacid therapy, including the more recent addition of H_2 and proton pump inhibitors. This was conventional wisdom until 1982, when Nobel Prize winners Barry Marshall and Robin Warren proved conclusively that the bacterium *Helicocenter pylori* was the actual cause of 90 percent of peptic ulcerations.[5] Once again a paradigm shift had occurred in medical therapeutics.

Even thoughtful and reasoned practice parameters established by elite academic panels have occasionally been found to be flawed or erroneous. Based upon new data, conventional standards of cardiopulmonary resuscitation (CPR) have recently been changed, the lowest desirable blood sugar level in diabetic patients has been altered, the optimal blood pressure level in hypertensive patients has undergone a revision, the standard and recommended practice of removing sentinel and axillary lymph nodes in breast cancer victims has been questioned, and a recent study has confirmed that more than 50 percent of the recommendations from the Infectious Disease Society of America are based on poor evidence[6].These and other revisions of long-established protocols illustrate the reason why physicians must occasionally disregard conventional wisdom and exercise their personal experience and judgment in treating patients.

With respect to measuring quality of care, the first problem we encounter is the definition of "quality." Unfortunately, there appears to be no consensus regarding which parameters to measure in order to best define that characteristic. Most frequently, epidemiologists have judged quality of care as measured against hospital death rates, assuming that hospitals with the higher rates offered inferior care. These assessments often reach the public through television, newspapers and magazines, with the caption "Best Hospitals"—or the more ominous heading "Hospitals to Avoid."

David Shahian, Robert Wolf, et al, from Harvard Medical School and the Harvard School of Public Health, recently published a paper titled *Variability in the measurement of Hospital-wide Mortality Rates*[7]. These authors wrote:

> *The Massachusetts Division of Health Care Finance and Policy provided four vendors with identical information on 2,528,624 discharges from Massachusetts acute care hospitals from October 1, 2004, through September 30, 2007. Vendors applied their risk-adjustment algorithms and provided predicted probabilities of in-hospital death for each discharge and for hospital-level observed and expected mortality rates. We compared the numbers and characteristics of discharges and hospitals included by each of the four methods. We also compared hospitals' standardized mortality ratios and classification of hospitals with mortality rates that were higher or lower than expected, according to each method.*

The authors concluded:

> *Four common methods for calculating hospital-wide mortality produced* ***substantially different results.*** *This may have resulted from a lack of standardized national eligibility and exclusion criteria, different statistical methods, or* ***fundamental flaws in the hypothesized association between hospital-wide mortality and quality of care.****

Let me summarize what I've presented above:

1. The document *To Err is Human*, published by the IOM, reached flawed conclusions based on ambiguous and uncontrolled data.

2. Journal articles and practice parameters have a brief lifespan and are frequently modified as new scientific data become available.

3. The definition and appropriate measurement of "quality health care" is currently uncertain and debatable.

Physicians have long understood that evidenced-based therapy is often tenuous, vague and evanescent. Proper management of any given illness may change with publication of the next article. Nonetheless, the physician must make his decision at the moment. Illness will not often wait for the definitive answer. Furthermore, it is imperative that we develop competent and indisputable standards to evaluate the quality of medical care. Without such acceptable benchmarks, judging the value of patient management will remain nebulous, uncertain, and subject to the prejudice of each investigator.

These thoughts do not invalidate our obligation to provide competent, thoughtful and sensitive care for our patients, nor should they mitigate our efforts to ensure patient safety. And certainly we must acknowledge that, despite the many exciting and revolutionary advances in medical knowledge, we continue to have vast lacunae of ignorance. Physicians are compelled to live with these uncertainties, yet continue their conscientious and rigorous care of patients.

Within the past several years, insurance companies, federal and state governments, and the JCAHO have each created new regulations and restrictions designed to control the practice of medicine. The principles underlying these directives are varied and have been largely based on uncertain data obtained in an uncontrolled manner. At a minimum, most of these policies have not been rigorously tested and their effect on quality of care is questionable. Nonetheless, as a consequence of these numerous proclamations, physicians have lost much of their professional autonomy, which has been gradually usurped by an unenlightened, imperious bureaucracy.

In this Kafkaesque universe, physicians have stepped through a looking glass, the White Rabbit has fled down the hole, the Mad Hatter is serving tea, and the Red Queen is roaring "Off with their heads."

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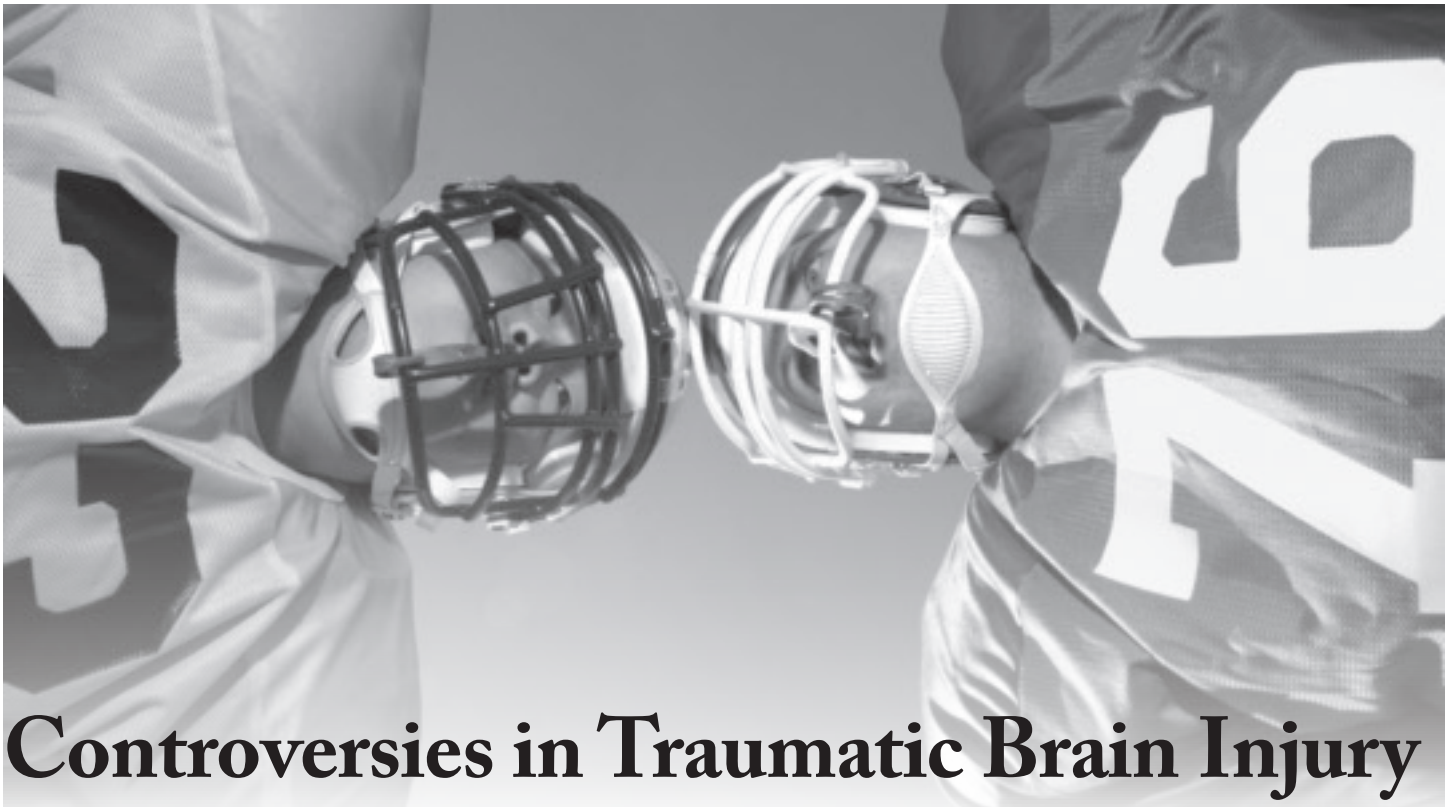

Controversies in Traumatic Brain Injury

Bruce M. Smoller, M.D.

The subject of traumatic brain injury (TBI) has received a great deal of public press recently in two areas of combat: the war in Afghanistan and the war in the National Football League. There has been increased recognition of the neuropsychiatric consequences of shelling and proximity to non-lethal improvised explosive devises on the battlefield, and the consequences of repeated trauma to the head in sports, particularly football and hockey. In fact, hockey players are being kept out of the action far longer than in the past because of an increased understanding of the additive susceptibility of the brain to repeated injury. Returning troops are being screened in increasing numbers for post-concussive injury.

Yet the field of traumatic brain injury remains shrouded in half-truths, suppositions, and inferential errors because of a lack of standardization in diagnosis and treatment. It is under-diagnosed in some circumstances, such as sports and the military, and over-diagnosed in others, such as civilian trauma. The definition of concussion and traumatic brain injury is made more difficult by a lack of consistency among various stake-holding organizations. The diagnostic criteria are far from consistent and depend too much on factors such as secondary gain, the sponsoring organization of one's definition, and the philosophy of the treating organization. There is often significant difficulty in coming to conclusions regarding diagnostic and treatment criteria on a scientific basis. For instance, a simple concussion is defined by the Centers for Disease Control and Prevention as usually involving no loss of consciousness and constituting a brain injury. The Academy of Neurology tends to see concussion as a temporary alteration in electrical activity, while professionals involved in physical medicine and rehabilitation often view concussion in three clinical stages without defining the pathophysiology.

Everyone recognizes concussions, but few agree on the parenchymal changes that take place. The syndrome that may ensue secondary to a concussion—a post-concussive syndrome, usually consisting of prolonged headaches, difficulty in concentrating, and some emotional changes—is so nebulous in definition and imprecise in pathophysiology that it has become somewhat of a "wastebasket" diagnosis. In fact, these symptoms may follow a concussion, but may also be extraneously generated. Concussions heal about 98 percent of the time, so why are there so many cases diagnosed that seem prolonged. The answers lie in a complex diagnostic scheme that is not consistent across facilities. And this doesn't even begin to elaborate on the question of TBI.

The vast majority of cases diagnosed as traumatic brain injury are usually staged as mild (the vast majority), moderate and severe. However, the diagnosis, taxonomy, and subsequent treatment of traumatic brain injury is, frankly, a mess. Depending on whose definition one accepts, (even more byzantine than that of concussion) pathologic changes may show on an MRI or may not. Loss of consciousness is a diagnostic and prognostic sign of great importance, or it is not. The Glasgow coma scale is important as a diagnostic criterion…or it is not. The list goes on and on.

One explanation given for the clinical signs and the pathophysiologic changes that account for those clinical signs in brain injury is that of the "axonal shearing." It has been proffered that not only direct trauma to the brain but rotational and acceleratory forces as well can produce injury. That is, not only can brain injury be caused by a direct blow by the helmet of an opposing tackler, but sudden stops and starts, by striking the brain's anterior and posterior poles against the braincase, can cause brain injury by shearing the axonal sheaths, producing, presumably, hemorrhaging, electrical disruption, and axonal death. The problem is that most of this damage should be visible on computerized axial tomography (CAT scan) or on an MRI, but many of the cases diagnosed

as head injuries have normal imaging. The concept of "micro axonal shearing" has thus been invoked as an explanation…and, in fact, post-mortem studies have demonstrated this phenomenon. The problem is that this phenomenon is also quite evident in decedents who have *never* experienced head trauma, and of the population properly diagnosed with demonstrable axonal shearing, *60 percent die*! This does not comport at all with the mortality statistics associated with mild or moderate TBI where, in the case of mild TBI, 98.8 percent recover without residua. Both the medical and popular literature are replete with claims for a taxonomy of TBI. One can find multiple examples of competing and contradictory case reports and clinical research, as well as many that do not meet the muster of scientific inquiry. This has more than passing importance for the physician, but not least of all for the patient who is not adequately diagnosed and denied needed treatment, or, conversely, is over-diagnosed and subject to unnecessary treatment.

Despite this somber appraisal of the current status of the field of traumatic brain injury, research has redoubled itself in recent years. Treatment of the accurately diagnosed patient as having sustained a brain injury has generally been both symptomatic and "education"-based. That is, the persistent headache of the post-concussive syndrome has been treated with the usual array of opioid and non-opioid agonists, triptans, and anti-epileptics used for migraine. Patients often come to the office of a psychiatrist because of changes in cognition and, more often, emotional changes. The use of antidepressants often helps patients not only to alleviate symptoms of sadness and hopelessness but also to increase processing speed, improve attentional lapses, and foster better working memory. This is not surprising, given the fact that symptoms of depression without head trauma include decreased processing speed, attentional lapses, and difficulty laying down new memories and retrieving old ones. Patients taking antidepressants for either depression or head injury often seem to "get smarter" because the external expression of these neurochemicals changes.

Educational tasks—the repetition of cognitive problems with coaching to help re-establish efficient mentation—sometimes works and often does not. We do not fully understand the reasons for this. The results, however, seem to comport with research emerging recently regarding Alzheimer's and other dementias. This research indicates that the working out of complex problems repetitively only helps a small proportion of patients. Since we have no predictors as to who will benefit, we will often prescribe this for all patients with a cognitive deficit.

The vast majority of opinion in the medical field suggests that over 98 percent of patients with uncomplicated head trauma—single episode, with or without loss of consciousness—will heal in, at most, three months without sequelae. Yet the field remains replete with controversy in diagnosis and treatment. Much of this controversy is simply a product of our place in time. Research has been done, but is slow to be integrated into a reasonable diagnostic and treatment algorithm. Other factors have muddied and continue to muddy the waters, including secondary gain, stakeholder claims, social stigma, and budgetary concerns. Literature is contradictory and anyone can find anything they are looking for to support a particular point of view regarding definition, criteria for diagnosis, and cost-effective treatments. Anyone who seeks to diagnose and treat patients with head trauma needs to recognize the indistinct borders of the field before embarking on a treatment program.

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Introduction...

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light health information technology for "increasing cash flow and reducing the length of time it takes for doctors to get paid." Who would argue with that? And who would argue with Doctors Retzky and Baker's plea to PhRMA on behalf of women. They ask PhRMA to emerge from the security of designing knock-off drugs and instead to address women's unmet health needs such as preterm labor, preeclampsia, endometriosis, incontinence and interstitial cystitis. Until these health concerns are met, it is perhaps understandable that skeptical women often reject physician recommendations for coronary interventions, even though those recommendations may be evidence-based.

Finally, in addition to another wonderful Word Rounds, Dr. Gershen reviews and re-evaluates the ultimate controversy of the decade, the Institute of Medicine's (IOM) publication *To Err is Human: Building a Safer Health System*. Doctor Gershen not only disputes this report, he summarizes the problems concerning who defines (and profits from) the definition of "quality care"—a question that has plagued us since release of that IOM report. We hope you will enjoy this edition as much as we enjoyed putting it together for you. For now, however, each robust controversy ultimately devolves to *one* individual physician caring for *one* specific patient. We must understand, as theologian and mathematician Thomas Bayes (1702-1761) theorized, that *beliefs depend on evidence to which one is exposed and on one's prior experiences.* We must cautiously contemplate all of the controversial components of an issue, and conscientiously work to broaden our reference frames, in order to prudently promote the best interests of the patient and our society. At its core, this is the art of medicine.

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(The views expressed in this article are strictly those of the authors and do not represent the views of the Washington County Health Department or the Maryland Department of Health and Mental Hygiene.)

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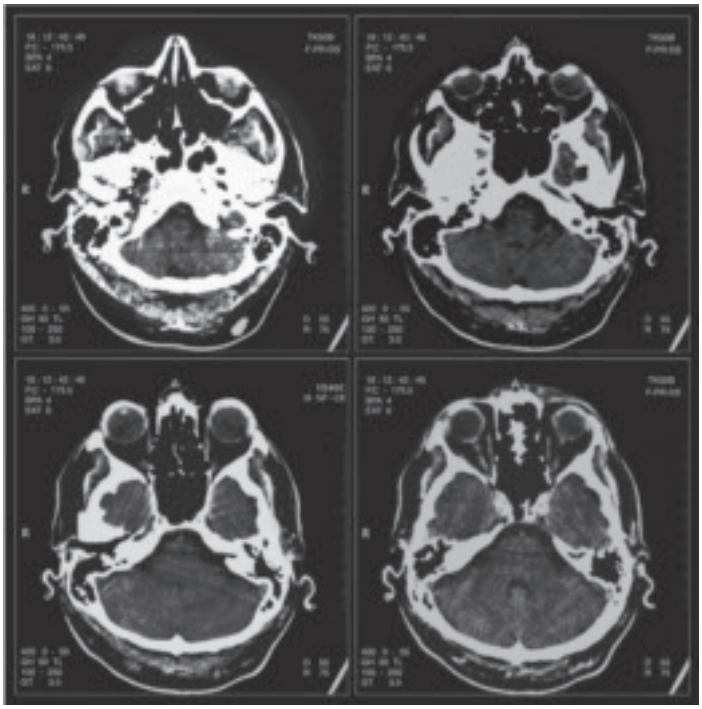

Controversies in Concussion Management:

Who Should Clear the Athlete to Return to Play?

Kevin E. Crutchfield, M.D., and John L. Ferrell, M.D.

Concussion is an injury to the brain occurring as the result of biomechanical forces. More properly termed mild traumatic brain injury (MTBI), it is characterized by the rapid onset of a constellation of symptoms or cognitive impairment, which typically resolves spontaneously. A significant number of people are at risk for concussions; the number of concussions per year in the United States is estimated to be between 1.6 and 3.8 million.[1]

An estimated 7.2 million high school students play sports each year, and surveys of athletes have repeatedly revealed marked under-reporting of concussions, making estimates of incidence and prevalence grossly underestimated. However, the number of sports-reported and other concussions is increasing on a yearly basis. Concussion is a clinical issue that affects millions of Americans.

The following are excerpts from a recently released statement by the American Academy of Neurology about concussions:

1. Any athlete who is suspected to have suffered a concussion should be removed from participation until he or she is evaluated by a physician with training in the evaluation and management of sports concussions.

2. No athlete should be allowed to participate in sports if he or she is still experiencing symptoms from a concussion.

3. Following a concussion, a neurologist or physician with proper training should be consulted prior to clearing the athlete for return to participation.

4. A certified athletic trainer should be present at all sporting events, including practices, whereathletes are at risk for concussion.

5. Education efforts should be maximized to improve the understanding of concussion, by all athletes, parents, and coaches.

This is the first time that guidelines and recommendations have been made that specifically state that a concussed athlete be cleared by a neurologist or a physician trained in sports concussion.

People have been getting concussions for years. Why is it so important to have them cleared by a physician now?

Concussions can lead to a number of symptoms, including the following; blurred vision, dizziness, drowsiness, excessive sleep, easy distractibility, fatigue, reduced speed and energy, headaches, inappropriate emotions, irritability, loss of consciousness, loss of orientation, memory deficits, nausea, nervousness, personality changes, poor balance or coordination, poor concentration, tinnitus, sadness, scomatoma, photosensitivity, phonosensitivity, sleep disturbance, vacant stare, vomiting, intracranial bleeding or edema, and death. According to the Centers for Disease Control and Prevention (CDC), more than 51,000 deaths secondary to MTBI occur each year. Neurologists are currently the only specialists trained and certified in the subtle abnormalities of the neurological exam; neuropsychologists are trained in the subtleties of cognitive dysfunction. Given the seriousness of the symptoms associated with MTBI, we must ensure that athletes are asymptomatic—with a return to baseline of cognitive function and a completely normal neurologic exam—before returning them to play.

What is second impact syndrome?

Second impact syndrome occurs when a player receives a second concussion before the first concussion has resolved. This second impact could lead to cerebral edema and herniation. This can progress to collapse and death.[2] Therefore, it is critical that we ensure that all MTBI symptoms have resolved before the athlete returns to play.

Who is currently clearing athletes to return to play?

The return-to-play decision is currently being made by many different providers. The decision on who makes the call is primarily based on the level of the athlete (professional, high school, etc.) and the professional resources available. The decision-maker could be a coach, athletic trainer, pediatrician, Ph.D. at a concussion treatment facility, team physician, or neurologist. There are several outdated concussion grading systems that people may be using that can prematurely return the athlete to play before it is safe. With the serious outcomes that can occur from repeated concussions, a physician who is trained in brain injury should be making the final decisions.

My team has computerized neurocognitive testing, so why does a neurologist or a physician who is trained in concussions need to clear the athlete?

There are a number of computerized neurocognitive testing tools on the market. They measure multiple aspects of cognitive functioning in athletes, including attention span, working memory, sustained and selective attention time, response variability, non-verbal problem solving, and reaction time. Although these computerized assessments cover some of the cognitive functions that may affect a concussed person, they are far from all-inclusive. They cannot perform a detailed neurological exam looking for minute abnormalities of the nervous system. They also do not take into account the entire clinical picture—for example, factors such as the number of concussions an athlete has had. Although a computerized test may show that an athlete is back to baseline cognitively, he still may exhibit persistent abnormalities on his neurological exam. Also, cognitive assessments can be significantly altered by treatable clinical conditions that will go unrecognized and lead to unnecessary pain and suffering if the only evaluations that an athlete receives are repeated, computerized cognitive testing. Therefore, it is necessary to consult someone who understands and can treat both transient and long-term behavioral, sensory-motor, cognitive, and underlying neural mechanisms that are affected by MTBI.

I have been following the published guidelines on concussions for the past 10 years. Why would I need to use a neurologist now?

There are many return-to-play published guidelines that are of limited value to us today. The majority of these guidelines presume that loss of conciseness is associated with severity of injury.[3] but pay little or no attention to other neighboring factors. One study has shown that loss of consciousness does not correlate with the severity of injury in patients who presented to the emergency department;[4] retrograde and post-traumatic amnesia, as well as the duration of mental status changes, have been reported to be more sensitive indicators of injury severity.[5] Currently, the universally accepted guidelines to follow are from the Zurich 3rd International Conference on Concussion in Sport.

When can an athlete return to play?

Returning an athlete to play after a concussion is a complex decision that requires taking into consideration many factors. A concussed athlete should not return to participation until it is reasonably certain that the physiologic effects of the concussion have abated.[6] This is done by making sure that the athlete is symptom-free. If the patient had pre-injury neurocognitive testing, you can repeat and compare to baseline. A full neurologic exam should be done to verify that there are no residual effects from the concussion. Once these criteria are met, the patient is able to return to play in a gradual fashion—starting from light activity and moving through sport-specific exercise, non-contact drills, full contact practice, and finally return to play, as long as the patient is asymptomatic at each step of the way.

Can you return an athlete to play the same day?

The general recommendation from the guidelines is no, with one exception: the patient must be an adult athlete being treated by a team physician experienced in concussion management with accessible sufficient resources (e.g., neuropsychologists, consultants, neuro-imaging). Having access to immediate (i.e., sideline) neurocognitive assessment management may result in a more rapid return-to-play timeline.

The problem with this decision is that changes in neurocognitive testing can have a delay in presentation and may not show up on the sideline exam.[7]

What is the greatest number of concussions you can have before there is permanent damage?

There is limited data on repeated MTBI and the data are not well understood or documented. Most of these data come from cognitive testing of boxers and football players who have suffered multiple MTBIs. Numerous studies have shown that repeated MTBI can lead to chronic encephalopathy.[2] One study shows a threefold increase in depression in football players who have endured three concussions or more. There is currently no absolute number of concussions that one can have before being unable to return to play.[6] Decision makers must take into consideration the surrounding factors with each concussion. Was there loss of consciousness and, if so, for how long? Was there amnesia? Is academic performance or performance on the job suffering? Are there personality differences that are noted by family or friends? Was the concussion associated with intracranial pathology (hemorrhage or fracture)? These are all reasons to recommend not returning to play for a longer period of time or to recommend avoiding the risk factor that caused the concussions. Because of complex social factors that may affect the return-to-play decision—such as the athlete's desire to play for scholarships or contracts—physicians can only do their best to inform the athlete of the acute and chronic risks associated with that decision. The decision to quit the activity must ultimately be made by the athlete and his or her family. Concussions are common and an unavoidable effect of some sports. They can lead to major neurologic damage to the athlete that can be life-long or even result in death. Because there is much that we do not understand about MTBI, we must take a conservative stance on who is evaluating and clearing these patients. Until there are laws protecting all athletes at each level, it is paramount that the most up-to-date information on the disorder is disseminated, not only to providers but to the athletes and their families as well.

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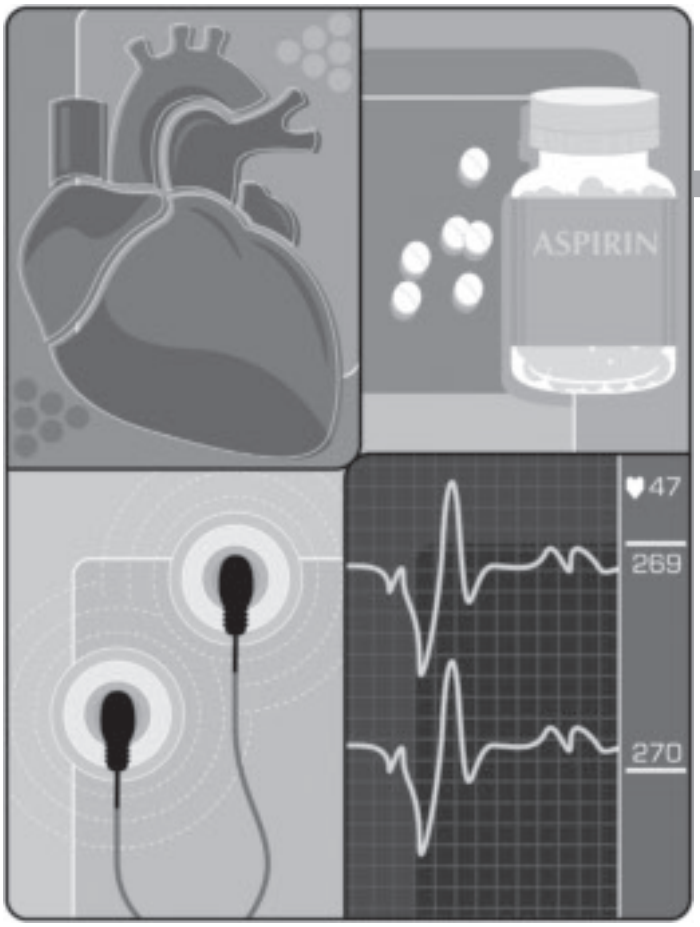

Gender Controversies in Ischemic Heart Disease

Mark G. Jameson, M.D.

In 1991, when today's women-majority freshman class of medical students were toddlers, Bernadine Healy, M.D., the first female director of the National Institutes of Health (NIH), wrote an editorial in the *New England Journal of Medicine* describing a "Yentl syndrome" of sex bias in the management of coronary artery disease. Yentl is the heroine of Nobel Prize for Literature recipient Isaac Bashevis Singer's story of a girl who had to dress and act like a boy in order to attend school and receive an education. (The story was also made into a movie directed by and starring Barbra Streisand.) Dr. Healy proclaimed that cardiac disease in women was under-diagnosed and under-treated. Of interest, one of the studies upon which Dr. Healy based her premise was conducted in Maryland.

The purpose of this article is to summarize clinically relevant gender differences in ischemic heart disease (IHD) and to highlight current controversies. The information in this article is largely adapted from a state-of-the-art article by Shaw et al.,[1] a special supplement of the *Journal of the American College of Cardiology*,[2] and an issue of *Circulation* devoted to women's health.[3]

Novel Hypothesis of Ischemic Heart Disease in Women

Among women undergoing coronary angiography, as many as 50 percent do not have significant obstructive coronary artery disease (CAD) and 10 to 25 percent will actually have "normal" angiography. Yet, more than one-half of symptomatic women **without obstructive CAD** continue to have signs and symptoms of ischemia. How can the seemingly common non-obstructive coronary artery disease in women be explained? One hypothesis is that coronary microvascular dysfunction is more prevalent in women than in men. The proposed microvascular angina is thought to be the result of vascular inflammation and remodeling, hormonal alterations and traditional risk factor clustering. It is purportedly responsible for the frequent atypical symptoms, evidence of non-obstructive ischemia and adverse outcomes in women. Currently, there are no clinical methods to document coronary micro-vascular disease. Likewise there are no ICD-9 or CPT codes for microvascular angina.

Prevalence and Mortality

In women with normally functioning ovaries, the prevalence of obstructive CAD is relatively low before menopause, presumably due to endogenous sex hormones. After menopause, comparable incidence rates for women are about 10 years older than for men. For example, CAD rates of 55-year-old men are similar to those for 65-year-old women. By the seventh decade women have as much CAD as men.

Mortality data reveal some surprises. It is well known that age adjusted death rates due to ischemic heart disease (IHD), which includes acute myocardial infarction, are lower in women than in men. According to the Centers for Disease Control and Prevention (CDC) 2007 mortality data (the most recent year for which complete data are available), the number of women in the United States dying of IHD almost equaled that of men (190,301 versus 216,050). In fact, in Maryland slightly more women than men died of IHD. When major cardiovascular diseases are grouped as a whole, both the death rates and the actual numbers of deaths are higher among women.

The increased mortality risk observed in women of low socio-economic status appears to have several etiologies.

Given the current epidemics of obesity and diabetes the mortality rates are projected to increase. According to data from the CDC a greater proportion of women die of sudden cardiac death before their arrival in the ER compared to men (52 percent versus 42 percent). Finally, while recent data show significant decreases in sudden cardiac death in men, there has been no change for women.

Traditional and Novel Risk Factors

In pre-menopausal women, disruption of ovulatory cycling, indicated by estrogen deficiency and hypothalamic dysfunction or irregular cycling is associated with an increased risk of coronary atherosclerosis and adverse coronary vascular disease events. The cardiometabolic syndrome is frequently associated with alterations in endogenous estrogens and androgens in women and is a link between obesity and cardiovascular diseases.

More than 80 percent of midlife women have one or more traditional cardiac risk factors. Clustering of risk factors is common after menopause, notably obesity, hypertension and dyslipidemia. Polycystic ovary syndrome is linked to adverse IHD post-menopausally.

Traditional risk factors may underestimate IHD risk in women. This has prompted research to investigate novel risk factors or markers that may improve the detection of IHD in women. For example, women have a greater mean C-reactive protein measure than men. This is consistent with a greater incidence of inflammatory mediated autoimmune diseases in women and supports hypotheses of an autoimmune precursor for atherosclerotic disease in women. The precise clinical role of novel risk factors such as inflammatory markers, retinal artery narrowing, and coronary calcification and others are being explored.

Symptom Assessment

Perhaps part of the gender controversy stems from the fact that IHD often has a different clinical presentation in women. There are significant differences between men and women in the type, frequency, and quality of symptoms of IHD. Prodromal symptoms in women are often unusual and may include fatigue, sleep disturbance and shortness of breath. The traditional definition of angina was derived primarily from a male population, and applying those criteria to women may significantly confound its recognition. Women present less often than men with exertional chest pain symptoms that are "typical" angina. Indeed, perhaps the singular symptom that separates women from men is the lack of an exertional component of classic angina in women.

When present, the classic symptoms of angina (chest pain or discomfort, dyspnea, diaphoresis, and arm or shoulder pain) are strongly associated with acute coronary syndromes in women. Of the classic features, chest pain and diaphoresis are closely correlated with acute coronary syndromes in women. However, it is of utmost importance for the treating physician to realize that up to one-half of women presenting with acute myocardial infarction report **no prior chest_pain** symptoms.

Evaluation of Ischemic Heart Disease in Women

The exercise electrocardiagram (EKG) is the most frequently performed diagnostic test to assess the risk of IHD. It has a lower sensitivity and specificity for detection of obstructive CAD in women compared to men. Relying on the exercise EKG alone for IHD detection may result in more misdiagnoses in women than in men.

Cardiac imaging studies are used to differentiate cardiac from non-cardiac symptoms in women. Stress-induced changes in regional myocardial perfusion or wall motion are accurate markers of IHD in women. Myocardial perfusion single-photon emission computed tomography (SPECT) is a nuclear-based technique that is commonly used for the evaluation of chest pain symptoms in women. Newer modalities include positron emission tomography (PET), cardiovascular magnetic resonance (CMR), and coronary computed tomographic angiography (CCTA). Knowledge, experience and data are evolving on the new techniques.

Evaluation of stress-induced wall motion abnormalities is assessed by stress echocardiography and although commonly used, can be suboptimal in women in the presence of obesity or lung disease.

For the practicing physician, three key points to remember are:

1. Routinely available diagnostic testing can accurately risk-stratify women;

2. Women with angina and confirmatory ischemia have an elevated IHD mortality; and

3. There is no currently readily available method to detect myocardial ischemia **in the absence** of significant obstructive CAD.

Treatment of Women with IHD

Briefly, for women with acute coronary symptoms, evidence-based guidelines support an invasive versus conservative approach based upon risk assessment. Women with a high risk assessment achieve a similar benefit from drug-eluting stents as men. Nevertheless, they have an overall greater mortality with percutaneous coronary intervention (PCI) for both segment (ST) elevation myocardial infarctions (STEMI) and non-segment elevation infarctions (NSTEMI). For women with a low risk assessment that leads to a conservative approach, one study reported that women derive an equal benefit from intensive, long-term medical therapy.

But what of women with ischemia symptoms and nonobstuctive CAD? Many anti-ischemic therapies have been evaluated. Beta-blockers improve chest pain symptoms. Statins and angiotensin converting enzyme (ACE) inhibitors improve endothelial dysfunction. However, no randomized trials comparing therapies for risk reduction and cost-effectiveness in women with angina and normal coronary arteries have been conducted. Likewise, no cardiac medication has proven to be significantly more effective in women with non-obstructive CAD versus obstructive CAD.

Perhaps the newest twist in the controversy of under-treatment among women was published recently by the *Annals of Emergency Medicine*.[4] The study enrolled men and women presenting with symptoms of potential coronary syndromes and documented that women were less likely than men to say that they would accept the physician recommendation for

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Pharmaceutical Drug Development for Women's Health Care:

Triumphs, Disappointments, and Market Needs

Sandra S. Retzky, D.O., M.B.A. &
Timothy D. Baker, M.D., M.P.H.

The modern era of drug development began after the enactment of the Food, Drug and Cosmetic Act of 1938. Since that time, a number of remarkable breakthrough medications targeting female health have been commercialized. Some of these technological achievements for women are so deeply woven into our society that it's easy to forget what life was like without them. Along the way, some big disappointments have accompanied the successes, underscoring just how hard it is to get drug development right every time.

This commentary reviews key milestone products for women's health, both successes and disappointments, and offers insights into what the market needs from the pharmaceutical industry (PhRMA) for the next generation of female patients.

Triumphs

Regardless of market category, a "triumph" is something that delights, not just satisfies, the customer. For pharmaceuticals, triumphs are game-changing therapies that go beyond what patients and doctors thought were possible. These products deliver unexpected improvements in quality of life, providing patients and physicians with options they never dreamed of. In the field of women's health care, only a handful of drugs have jumped this exceptionally high hurdle.

Oral Contraceptives

Without question, the single greatest pharmaceutical achievement for women has been oral contraceptives. The introduction of the "Pill" has improved quality of life for hundreds of millions of women since its commercialization in 1960.

The Pill's development is especially unique in that it represents many "firsts" for pharmaceutical drug development. Most notably, it was the first time consumers demanded a specific product. Typically, the market accepts whatever drug companies offer. For ordinary citizens to so strongly influence drug discovery and development was not only completely unprecedented but also quite courageous, since the Comstock Laws, which prohibited dissemination of contraceptive information and devices, were in place at the time.

The force propelling the Pill came from decades of effort by two private citizens, Margaret Sanger and Kate McCormick. Though the work of many scientists ultimately contributed to the Pill's invention, it was Sanger and McCormick who, through advocacy and personal funding, directly pushed pharmaceutical companies to develop oral contraceptives. Sanger, a nurse, was arrested for her advocacy at one point. These women envisioned a world with effective choice for family planning, allowing women to control their reproductive fate and separate sexuality from procreation. An early prophetic quote from Margaret Sanger's personal papers encapsulates this sentiment:

Science must make a woman the owner, the mistress of herself. Science, the only possible savior of mankind, must give a woman the power to decide for herself whether she will or will not become a mother. [1]

No doubt the Pill was life-changing technology for individuals and families. From a societal perspective, though, it was even more important. Post-war population growth had become a serious concern as improvements in medical care increased longevity and decreased infant mortality. As John Searle, Chairman of G.D. Searle Company, said "the Pill was a positive answer to a world threatened by overpopulation, and the resulting poor subsistence, poor shelter, and poor education that surplus peoples are forced to

Table 1: 2009 Worldwide Sales Endocrine Therapies for Breast Cancer				
Trade Name	**Generic**	**Mechanism of Action**	**Manufacturer**	**Sales (millions)**
Herceptin	trastuzumab	Mab to Her2/neu	Roche	$4,905*
Arimidex	anastrozole	Aromatase inhibitor	AstraZeneca	$4,900
Faslodex	fulvestrant	Estrogen receptor antagonist	AstraZeneca	$262
Nolvadex	tamoxifen	SERM	AstraZeneca	$88
Femara	letrozole	Aromatase inhibitor	Novartis	$650
Aromasin	exemestane	Aromatase inhibitor	Pfizer	$483
			Total sales	$10,805
			Total sales without Herceptin	$5,900

*5,300 CHF converted to 2009 USD

endure."[1] The Pill's introduction by Searle and Ortho Pharmaceuticals was a bold move in 1960. All other major pharmaceutical companies turned down the Pill's development for fear of reprisals from religious factions.

The Pill was a "first" in many other respects, too. It was the first pharmaceutical product developed to improve quality of life rather than to treat a specific illness. It was also the first time packaging was used to simplify and improve patient adherence. Many regulatory firsts that subsequently influenced future drug development also accompanied the Pill. For example, the high number of cardiovascular events experienced by women who used the Pill and smoked was the impetus for advancements in adverse event reporting systems and in the requirement for package inserts specifically for patient distribution. Also, the Pill was the first pharmaceutical product for which direct-to-consumer marketing was employed, ultimately spawning a specialized area of oversight within the Food and Drug Administration

Endocrine Management of Breast Cancer

The Pill fostered science well beyond control of human reproduction. Work directly informed by the Pill began on the hormonal control of breast cancer in the mid-1960s. Efforts to block estrogen's action on tumor cells culminated in the invention of Nolvadex (tamoxifen), a selective estrogen receptor modulator, or SERM, in the mid-1970s. Complete estrogen receptor antagonists (ERAs) and inhibitors of estrogen synthesis called aromatase inhibitors (AIs) quickly followed, though it took much longer to develop these into safe compounds.

Reading the literature on SERMs, ERAs, and AIs, one begins to appreciate how long it can take to develop compounds for new endocrine targets and, in addition, to have enough clinical experience so clinicians are comfortable routinely using them. It wasn't until the mid-1990s that profiling for the receptor triumvirate—the estrogen receptor (ER), progesterone receptor (PR), and HER2/neu[1]—was routinely done for the purposes of tailoring therapeutic interventions.

The time between discovery of novel therapies and their widespread clinical implementation can, at times, span a generation or more. When Nolvadex became standard treatment for ER-positive breast cancers in the 1990s, the patent on it had long expired—a unique marketing risk few other industries face.

The endocrine management of breast cancer is a remarkable triumph for women, and the success of Nolvadex paved the path for these therapies (Table 1).

RhoGAM (Rh immune globulin)

With the exception of anesthesia, one of the most important pharmaceutical developments for pregnancy was the introduction of RhoGAM in 1968.[2] RhoGAM contains IgG antibodies to Rh(D) antigens on red blood cells. Its use prevents isoimmunization in Rh(D) negative women exposed to fetal Rh(D) positive blood during pregnancy. Even minute amounts of maternal-fetal blood contact from a delivery, miscarriage, ectopic pregnancy, or obstetric procedure can sensitize an Rh(D) negative mother to an Rh positive fetus in a subsequent pregnancy.[2] Once commercialized, physicians began to routinely screen all pregnant women for Rh(D) status and prophylactically treat those with potential sensitization problems with RhoGAM.

Within a decade of RhoGAM's introduction, hemolytic disease of the newborn decreased from 45.1 per 10,000 live births to 14.3 per 10,000 in the United States.[2] Without RhoGAM, many Rh positive babies conceived by sensitized mothers would suffer needless morbidity, stillbirth, and neonatal death. Today, perinatal surveys report virtually no such losses.[3]

Osteoporosis Drugs

Osteoporosis is one of the most common diseases affecting women, and its incidence is rapidly rising as our population ages. "Each year, an estimated 1.5 million individuals suffer an osteoporotic related fracture."[4] The direct care expenditures for osteoporotic fractures is estimated at a staggering $12–$17 billion annually, an enormous tax on our health care system.[4]

It is not the availability of treatment options that is the biggest problem with osteoporosis. Effective pharmaceuticals have been available since the 1990s; long-term improvement in bone mineral density and substantial decreases in fracture rate characterize all of them. The earliest market entry was Evista (raloxifene), a SERM, in 1995. Bisphosphonates, such as Fosamax, soon followed. Biological therapies are also available, including recombinant parathyroid hormone, Forteo (teriparatide), and the monoclonal antibody, Prolia (denosumab). But while the pharmaceutical industry has come through with good hormonal and non-hormonal treatments with varying mechanisms, dosage forms, and regimens, allowing physicians flexibility in choice, a large gap still exists "between what has been learned and what has been applied by American consumers and health care providers."[4] As a result, osteoporosis remains the most under-diagnosed and under-treated disease in U.S. women.

1 HER2/neu is the abbreviation for human epidermal growth factor receptor 2, a transmembrane protein involved in cell growth control. HER2/neu is over-expressed in about 20–30 percent of breast cancers. Herceptin (trastuzumab) is a monoclonal antibody given to women with breast cancers that are HER2/neu positive.

2 As little as 0.2 mL of fetal blood can cause maternal sensitization.

Gardasil (HPV4)

More than 30 types of human papillomavirus virus (HPV) can infect the genital tract and cause a variety of benign and malignant proliferative diseases in both genders.[5] Women are especially vulnerable to infection with HPV. For women, while the clinical spectrum of HPV diseases includes venereal warts and/or precancerous or cancerous lesions of the cervix, vagina, vulva, and anus, by far the most important site affected is the cervix.

Cervical cancer and its precursor lesion, cervical dysplasia, are sexually transmitted diseases caused by HPV infection. More than 70 percent of these lesions are caused by HPV types 16 and 18.

In 2006, Merck introduced Gardasil, the first prophylactic vaccine for HPV. This vaccine protects women from HPV 16 and 18 and protects against more than 90 percent of the other HPV types that cause venereal warts.[3] Vaccinating young women before their sexual debut provides nearly 100 percent efficacy, with a good safety profile.

Every year, roughly 500,000 women are diagnosed and treated for cervical dysplasia, and 12,000 are diagnosed with cervical cancer. These women undergo diagnostic and therapeutic procedures that cost roughly $1 billion annually in the United States alone. Though difficult to measure in dollars, there are also social costs from anxiety, pain, absenteeism, and loss of fecundity associated with these procedures. The cost of a Gardasil regimen is $270—a bargain compared to treating HPV-related diseases.[4, 6]

Disappointments

Among the triumphs, there have been some big disappointments from PhRMA. These are more than mere marketing flops. PhRMA holds a special position in society. Supplying our medicines requires the deepest trust. When a drug disappoints, the trust is broken between industry and its customers. Unlike other industries, negative publicity from pharmaceutical product disappointment extends beyond individual manufacturers, casting a wide shadow and enduring for long periods of time.

There have been three notable pharmaceutical disappointments related to women's health care. The first was diethylstilbesterol (DES). DES, a non-steroidal estrogen, was marketed in the 1950s and 1960s as a treatment for threatened miscarriages. Unfortunately, DES was found to cause a rare form of vaginal cancer in girls and young women who had been exposed in utero. This was the first black-eye, among many to come, for hormone treatment of non-cancerous conditions in women.

The second was Norplant. First marketed in 1991, Norplant was an implantable depot contraceptive intended to be effective for five years. Compared with oral contraceptives, the key point of differentiation was ease of compliance with an implant. But by 1994, a barrage of adverse events had occurred, and device removal turned out to be difficult in some cases. Worse yet, some perceived Norplant as coercive and deemed it as "thought-free contraception" targeted at a vulnerable population of women. The heart of the Norplant debacle was not so much about product. It had much more to do with informed consent and the ease with which contraception could be terminated.

The third and biggest disappointment was hormone replacement therapies, known collectively as HRT. For decades, many women suffering post-menopausal symptoms got relief from HRT. When results from two large, prospective studies contradicted each other on cardiovascular benefit, and cancer reports started to trickle in, everything consumers and industry thought they could count on all but disappeared. Nothing was safe and secure with science. Among all pharmaceuticals, the record for the greatest number of product liability lawsuits is held by HRT products, an ignominious distinction.

On the list of basic human needs, access to safe and effective medicine is on par with a society's ability to read and write, and eclipsed only by elemental needs for food, shelter, and warmth. When so much is at stake, goodwill from consumers is priceless. Accountability and service are part of the pharmaceutical core product, no different than chemical structure.

What the Market Needs

PhRMA continues to ignore some clear areas of unmet need in women's health. Chief among these are preterm labor and pre-eclampsia. In terms of individual and societal costs, these are most burdensome. Product liability issues notwithstanding, PhRMA has made little progress in helping to improve the situation for pregnancy-associated diseases.

Endometriosis, the leading cause of infertility in this country, is another example. The last introduction of an adequate treatment for endometriosis was, in fact, the Pill. Since then, we have seen no progress for symptom relief that doesn't cause hot flashes, osteoporosis, or altered fertility status.

Several common bladder conditions have received very little interest from pharmaceutical companies. Urinary incontinence is a prime case. As a nation, we spend more than $10 billion annually on adult diapers. This is an obvious sign of a market with unmet needs. Yet, all PhRMA has offered is a handful of Ditropan knock-offs. More than $1.5 billion is spent annually on these only modestly effective medicines (Table 2). Interstitial cystitis, a condition plagued by painful urination, frequency, and nocturia, occurs in more than 500,000 reproductive age women in the United States alone. The pharmaceutical industry has completely whiffed on this indication.

The combined sales of Herceptin, ER antagonists, aromatase inhibitors, and SERMs were roughly $11 billion in 2009 (Table 1).[5] Even subtracting sales of Herceptin, a biological, the annual combined sales of small molecule therapies targeted at ER approximate $6 billion. That kind of money should point the way to development of PR antagonists for breast cancer. Several decades ago, steroidal PR antagonists such as mifepristone[6] and onapristone were tried for breast cancer with mixed results. Unfortunately, these older compounds suffered from off-target side effects and toxicities inherent in their steroidal structures.[7] It would be a reasonable goal to find non-steroidal PR antagonists or other nuclear hormone receptor modulators with good target selectivity and potency. This is exactly what has been done for therapies directed toward the ER.

Beset with patent cliffs, product warnings, recalls, and litigation, the pharmaceutical industry needs to get back to core values, focusing on new therapies for unmet needs, including those for women's health care indications.

3 Types 6 and 11 cause 90 percent of venereal warts.

4 This is the regimen cost (three doses) using prices listed for the Centers for Disease Control and Prevention's Vaccines for Children program. Administration costs are not included in this price. Drug costs may be higher in the retail sector.

5 Not inclusive of generic sales. If included, the figures in this paragraph would be even higher.

6 Mifepristone is also known as RU-486. This drug interacted with glucocorticoid receptors and, thus, women on chronic therapy became glucocorticoid deficient, an unacceptable safety profile.

7 It was also the case that trials with these compounds were done before receptor status profiling was commonplace.

We as consumers and physicians can follow the example set by Sanger and McCormick and tell PhRMA what we want. After all, the drugs are for us.

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Controversies in Concussion Management...

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Letters to the Editor...

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tion drugs with high abuse potential—and the abuse potential of marijuana is undeniable. Education is a must for prescribers of medical marijuana. We have read extensively on marijuana and have not found a single article or book chapter which comprehensively addresses all aspects a doctor needs to consider when prescribing marijuana for patients. This is different from buprenorphine, which has FDA approval and adequate labeling.

To illustrate our point, a few examples are useful: marijuana increases heart rate and blood pressure; it crosses the placenta and can be found in breast milk; exacerbation of psychotic conditions has been well documented; concomitant use with alcohol seems to potentiate the effect of both drugs; and, when smoked, marijuana exacerbates asthma and COPD.[3-6] A key issue is that much of what the authors have learned comes from specialty literature, not mainstream medical journals. Medical marijuana prescription information is not comprehensively integrated anywhere. A physician with average access to information resources and time constraints will have difficulty putting all the pieces together for a careful, comprehensive prescribing decision. We continue to believe a state medical marijuana program must have some educational mechanism in place so doctors do not have to waste time hunting for information.

Conclusion

Our culture profoundly trivializes the use of marijuana. In reality, it is a potent drug. Its use should be accompanied by great care and respect. If Maryland is to have a state medical marijuana program, we respectfully ask Maryland's legislators to consider our concerns.

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(*Dr. Retzky and Dr. Baker are the authors of "Maryland's Medical Marijuana Bills,"* Maryland Medicine*, Vol. 2. No.4; autumn 2010. For a complete list of references contact 301.921.4300 or sraskin@montgomerymedicine.org.)*

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Taking Responsibility for One's Health Helps to Run a Financially Sustainable Health Care System

In the body of their article, "Is the Sun Setting on the Private Practice of Medicine in Maryland," (*Maryland Medicine*, autumn 2010) Donald McDaniel and Dan D'Orazio made suggestions in an attempt to help physicians prepare for the future of medical practices. Among them is the notion that the global health budget is finite and cannot sustain the traditional fee-for-service model. Expanding upon this popular concept, the authors maintain that physicians will be rewarded for the improvement of a patients' health care status, rather than for the deliver of services. This notion is quickly becoming the mantra for politicians, health care policy makers, ivory tower types and others who have not had the experience of day-to-day, hands-on medical care delivery.

Before this approach becomes a fait accompli, we must step back and consider the fact that this notion puts all the burden and financial consequences on the physician and none on the patient. More specifically, the patient's health status not only involves physician input, it also requires compliance by the patient and is impacted by factors beyond the physician's control. Why should the physician be the one who is financially penalized if the patient's non-compliance, poor diet, lifestyle choices, genetic pre-dispositions, etc. result in poor health? That is patently unfair. Additionally, there is no way to boil down the differences between easily managed and difficult disease processes in order to make the financial treatment equitable between those physicians who will just "cherry pick" and those who will care for the difficult-to-manage patients. That would be an expensive bureaucratic impossibility.

A more equitable, logical, and financially sustainable way to deliver health care would be to demand that **all** patients become part of the financial equation when seeking health care. In doing so, there will be a real incentive for the patient to embrace a healthier lifestyle and be, literally, more invested in hi/her health care status/outcome. Critics of this approach will argue that many will avoid using the health care system because they can not afford to be part of the financial equation. That is nonsense.

Over-utilization is a major cause of the price of health care. Physicians themselves can be blamed for this problem. This occurs as a result of practicing "defensive medicine." It happens every day in our offices, emergency rooms, and in hospitals by over-testing, over-treating, and over-referring patients. Tort reform is the obvious remedy to this problem. But more importantly, when there is no significant financial barrier to access health care, the system becomes unsustainable. That is why almost **every** patient should be required to pay a co-payment that is **meaningful to them!** It could be a nominal ($1) or significant amount, depending on the ability of the patient to pay. It must, however, be **personally meaningful.** Surely some "think tank" could assess the proper amount of payment. There will always be a safety net needed for some patients, but most (including and especially welfare patients) can afford even a small amount of payment. It is crucial that every patient make a choice between a meaningful co-payment and something equivalent in order to access healthcare for themselves and their families. A choice must be made between buying a pack of cigarettes, getting a tattoo, having a manicure/pedicure, dining out, upgrading a cell phone, going to a movie, or making a co-payment.

Personal responsibility applies to everyone. To ignore this is to succumb to the expectation that others will always be responsible for our well-being. That is what leads to an unsustainable health care system. The cost controls resulting from a finite budget system lead to rationing when there is no meaningful patient financial component. Dependency ensues.

This latest concept of total fiscal management effectively becoming the physician's responsibility may seem like an epiphany to the public and to policy makers and advisors who are insulated from the real world of health care delivery. Our fee-for-service does work without rationing when costs are controlled by universal personal financial responsibility.

Jay Bernstein, M.D.
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Death by a Thousand Cuts. Why I Opted Out.

What a mess our medical system has morphed into. So many of us are working on a treadmill, providing more and more service for less and less compensation and respect. In order to support our office overhead and take a salary we find ourselves stressed out, putting in extra hours and contending with frustrating bureaucracies.

Threatened by congress in 2010 with a 23 percent reduction in Medicare physician fees, we are appeased by only a one percent increase. Crumbs in light of overwhelming work. We are told by Medicare that physician electronic health records (EHR) are required to avoid a future financial penalty despite the cost in dollars and a steep learning curve. This by itself will initially reduce productivity and cash flow adding to overhead costs without any guarantee of enhancing our productivity. We are told by Medicare that each physician will be reimbursed for the EHR; I wouldn't count on it. Expect other insurers to follow in Medicare's footsteps regarding EHR; all this is going forward despite conflicting data which questions enhancement in patient outcomes. With EHR, audits will be a snap and woe is the office that 'over charges' Medicare inadvertently. I envision ugly battles with government agencies with threats of civil fraud. This entire system is insulting to practicing physicians—most with over 11 years of education and training, not to mention thousands hours of experience.

All of the health insurance companies are no better with meager reimbursements, denied payments, delayed payments and a bureaucracy that rivals the Soviet Union's defunct government. Every year we're supposed to "renegotiate" with private insurers, all of them, for increased payment to cover increased office overhead. Those who miss their contract date are locked out for another year… too bad.

Like a frog in the pot of hot water we got here by jumping into cold water while the heat was gradually increased. It seems that private practice has a limited half-life. I envision that the current trend will financially force physicians to work in large clinics run by MBAs with the belief that this will reduce medical costs. Perhaps it will, but patients will have different experiences which will eliminate or reduce medical relationships and the health outcomes are unknown. Actually, this may be a life improvement working 40 hour weeks with pension, health care and vacation time, including the hope of unionizing.

I remember when it was easy to care for indigent patients pro bono because our work load and cash flow enabled us to give back to our community. No more. Now we're on the rat wheel without the time and energy to add non-paying patients to our schedule.

For me, the answer was eliminating all private insurance contracts from my practice and opting out of Medicare. Financially risky! I now ask patients to see me "out of network" and submit insurance claims on their own but the Medicare patients cannot be reimbursed due to the Federal budget reconciliation act of 1997. A shame! Eighty five percent of my Medicare patients have chosen to transfer to other physicians—something I regret after spending many years with these patients. Some are able to easily afford their visits but never the less leave the practice, while others must transfer because of their finances. I feel for them. It is better that I see fewer patients and stay alive for the others then burn out early and see no one.

For my personal life it has been the best thing I've ever done. For my financial health I'll watch the slope of the curve and eat Ramen Noodles.

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Gender Controversies in Ischemic Heart Disease...

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any intervention. Some may interpret this finding to mean that women exercise independent thinking and decision making. Surely this new report challenges physicians to better communicate with all patients.

Conclusions

The lack of access and physician bias originally described in the "Yentl syndrome" have hopefully been eliminated. The NIH is currently conducting several studies to better define some of the gender controversies. The Women's Ischemia Syndrome Evaluation (WISE) study continues to enroll patients to evaluate coronary vascular dysfunction. Other current trials include the "What is the Optimal Method for Ischmia Evaluation in Women?" (The WOMEN study) and the "Study of Women with Acute Coronary Syndromes and Nonobstructive Coronary Artery Disease" (SWAN).

Imagine, in a mere generation, a young girl named Yentl, who disguised herself as a boy to be accepted, metamorphosed into a WISE WOMAN with the regal elegance of a SWAN.

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Valuing Your Medical Practice-Part 2:

Understanding the Components Used to Determine a Fair and Marketable Price

Maureen West McCarthy, C.P.A.

Introduction

This is a follow up to our article on valuing a medical practice in the autumn 2010 issue of *Maryland Medicine*. This article will expand on the different aspects of buying or selling a medical practice. It will provide some advice on how to prepare for such a transition and how to make the most of the process. It will discuss the actual valuation components and the differences in valuation values based on who your target buyer may be.

As alluded to in the previous article, valuing a medical practice is not an exact science, so it is crucial that you hire advisors who are familiar with all aspects of medical practices, including their unique revenue stream, their third-party payor relationships, and the collectability and make-up of their accounts receivable, as well as many other aspects that make valuing a medical practice so unique when compared to other types of businesses.

My colleagues and I have reviewed many valuations prepared by accountants and financial advisors that attempt to use general valuation and business methodology without taking into account the uniqueness of a medical practice. These valuations tend to disregard important components of medical practices and have the potential to create problems in the negotiation process *because they may set unreasonable expectations of value that the seller/buyer will never be able to erase from their memory.*

Who's Buying and Why Does that Matter?

Practice selling prices are different depending on who is buying the practice. If an outside party anticipates strategic benefits to owning a specific practice, the practice may sell to the outside party at a price that is higher than if the practice was sold to an inside employed physician. Selling to a hospital creates an entirely different set of considerations in determining and documenting a sales price. Due to regulatory requirements, hospitals may be limited to paying only for fixed assets and, perhaps, medical records. Often, physicians who sell to hospitals will receive benefits in the form of enhanced compensation going forward and possibly signing/retention bonuses that can be quite substantial. These benefits will need to be substantiated as reasonable payments for physician services if the transaction is ever brought up on audit. It is important for a valuation specialist to know why the practice is being sold and who the expected buyer might be.

Due Diligence/Documentation Phase:

The first step after identifying an experienced healthcare advisor to prepare your valuation is to gather the essential documents needed for the process. They include:

- Three to five years of corporate/partnership tax returns for the practice;
- A detailed fixed asset listing, including date of purchase, description, cost, and accumulated depreciation taken to date on each asset;
- Three to five years of detailed financial statements, including the current year even if mid-year;
- Corporate documents, including articles of incorporation, operating agreements, employment contracts, office leases, as well as loan and lease documents;
- Billing statistics, including monthly charges, collections and adjustments by month for the current year and previous two years;
- Charges by payor to calculate payor mix;
- An Accounts Receivable aging report, aged based on date of service, by Payor;
- An Accounts Receivable aging report, aged based on date of service, for patient balances and;
- A credit balance report for all outstanding amounts due back to carriers/patients.

Providing these documents will assist the advisor in preparing a valuation of the practice. Although the list may seem exhaustive, all of the items are extremely important in assessing the value of the practice.

Components Examined for a Medical Practice Valuation

1. *Revenue stream over an extended period of time.* It is essential to look at the level of revenue over at least a three-year period of time to determine any variances (increases or decreases) and understand what may have caused them. For example, a decreasing revenue stream may initially cause concern, but there may be a very good reason for that to have occurred. A decrease in revenue combined with an increase in profit may indicate that the practice terminated a non-productive provider. Whatever the reason for increases or decreases, variances should be reviewed and understood, since one of the major things a prospect is buying into is the future cash flow of the practice.

2. *Physician compensation, including perks such as yellow sheet allowances and pension contributions.* The valuator will be interested to see how the current owners' earnings compare to the national and local averages within the specific specialty. A practice that is able to pay its physicians more than the average is a more valuable and marketable practice. As discussed in the earlier article, physician compensation is unique when compared to other industries because it is typically driven by the production of each physician rather than by the success of the overall business. It is important to have a healthcare advisor evaluate individual provider compensation in the practice to see if the physicians are making more in compensation and benefits than their peers. There are numerous databases and publications that can be researched to obtain normalized earnings by specialty, years of experience and unique expertise.

3. *Fixed asset value*. It can be assessed in a number of different ways:

- Net book value – This method is sometimes inaccurate and unfair to the seller because of the common use of accelerated depreciation methods, which causes the assets to be worth very little in comparison to what the real fair market value (FMV) is.

- Net book value using the straight line (S/L) depreciation method – Assets can be revalued on a S/L depreciation basis using useful lives of 3 to 20 years, depending on the type of asset (for example, software = 3 years, computers = 5 years, medical equipment = 7 years, furniture = 10 years). This, we believe, gives a much more accurate picture of an asset's FMV. In addition, we also use a 10-15 percent residual value, which means that an asset's value never goes below 10-15 percent of what the practice originally paid for it.

- Appraisal – The practice could also pay an appraiser to come in and actually value the fixed assets. This method is usually costly, and we have found that the values do not differ significantly from the S/L depreciation method described above.

4. *Medical records*. We have seen medical records valued in practice sales, especially when there are no other real assets being sold. The average value for a primary care medical chart is in the $15-$25 range for patients seen by the practice in the last 24 months, since those tend to be annuity patients. For specialty practices, depending on the particular specialty, charts will sell for $5-15. Where the charts fall in this range depends entirely on whether it is anticipated that the patient will continue to utilize the practice once the current owner is gone.

5. *Accounts receivable (A/R).* In many practice sales, the A/R is not included in the sale. The seller may retain the A/R and pay someone to collect it for the practice. They then use that to pay off outstanding debts and to cash out the owners. If the A/R is included, it must be analyzed carefully to assess the true collectible value of the accounts. This would include analyzing monies due from carriers considering filing limits, the age of all accounts, the date of last activity on each account, and historical collection percentages. The A/R is usually the largest tangible asset in a medical practice, so the valuation of this piece must be carefully evaluated by an experienced healthcare advisor.

6. *Goodwill.* Many valuation specialists believe that there is no such thing as goodwill in medical practices. We believe that the presence or absence of goodwill depends on several factors, including the type of practice, the reputation of the practice and its providers, the participation status with the carriers, and the location, as well as some other intangibles. We further believe that if a strong transition plan is put into place for the seller to transition the patients to the new owner(s) over a six to twelve month period, goodwill can be transferred to that new owner.

7. *Non-competes and non-solicitation clauses.* It will be important to the buyer that the seller agrees to sign a non-compete clause as well as a non-solicitation clause. These agreements will also add value to the practice, since they assure the buyer that the seller will not impede on the success of the practice after the sale. It will also ensure that there is no seller interference with the patient base or the practice employees after the sale.

In addition to the items mentioned above, there are other factors that can be taken into consideration when valuing a practice, including whether the practice has an electronic medical records system, the level of patient volume, and the presence of loyal, reliable staff.

Conclusion:

The expectation of many buyers is that a practice should pay for itself in approximately five years, whether that is through reduced compensation or paying off a bank loan. The time period obviously hinges on the overall total price and other factors described above. It is important to convince the buyer that it makes more sense to buy the practice than to start a new practice, and the

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Meaningful Use: The Glass Half Full

Dan Kazzaz

Automation in the Clinical Setting

Physicians are keenly aware of the antiquated billing practices prevalent in both the governmental and private sectors. In this era of applications for every purpose, the health care insurance industry lags behind, remaining stubbornly reliant on using the telephone for treatment preapprovals, mailing proofs of treatment, and asking physicians to perform a myriad of other (easily automated) manual tasks, rather than making necessary improvements to software and creating procedures for the insurance industry. Recent legislation relies on the popular misconception that the clinical community has under-invested in software and hardware. The perception is that patient care will be improved and costs lowered through an asymmetric, physician-only software upgrade. In order to truly improve care and efficiency, all clinical information about patients should be centralized. Theories about cost savings may be true at the macro-economic level, but they can only be realized if practices can leverage the current legislation to reduce overhead expenses.

Two pieces of legislation affect the clinical community. One is the Health Information Technology for Economic and Clinical Health Act (HITECH), which is part of American Recovery and Reinvestment Act of 2009 (the "Stimulus Bill"). The other is the American Affordable Health Choices Act of 2009, the "Health Care Reform Bill." HITECH contains incentives, including payments of up to $44,000 per physician, for acquiring software adhering to certain "meaningful use" requirements. That same legislation contains disincentives for failure to conform to these requirements, resulting in a reduction of Medicare and Medicaid reimbursement. Health Care Reform, on the other hand, calls for insurance companies to reimburse practices electronically, ideally with payment at the time of service. By refining the internal and external systems, taking advantage of both pieces of legislation, it may be possible to reduce expenses and improve cash flow.

State of Affairs

Since the advent of computers, and especially since the adoption of the Internet, there has been a constant push to connect physicians' offices. There have been successes, such as at Kaiser Permanente facilities, hospitals, and clinics; the Veterans Administration hospitals; and major clinics in Boston. However, even in the most advanced settings, connections outside of these groups have proven to be elusive. There is no infrastructure to enable a transfer of electronic medical records for a patient discharged from the armed forces who now subscribes to a Kaiser health insurance plan.

One of many solutions proposed is to develop large centralized web sites in which to store all patient medical information. Of course, no one web site can possibly handle all of the requirements, or the sheer volume of messages. The HITECH legislation promotes regional or statewide health information exchanges to facilitate the process. Even this is proving to be difficult. Implementing electronic medical records (EMRs) in individual practices is complicated, and the complexities of regional EMR systems are unimaginable. This is compounded by the fact that certain areas (such as Montgomery County, Maryland) border other states (in this case, Washington, D.C., and Virginia) that are not likely to be included within the same regional system. Determining which health information exchange houses each patient's data will be a challenge.

All of this was discouraging until a few months ago, when the Office of the National Coordinator (ONC) for Health Information Technology, within the Department of Health and Human Services, which is responsible for providing leadership in the development and implementation of health care standards, realized that there might be easier alternatives. ONC decided that alternatives needed to be made available—new standards that would help physicians connect directly with other physicians (and patients) through secure email. Unlike standard email (which can be easily intercepted and is therefore not HIPAA-compliant), secure email will encrypt the data, thus ensuring patient privacy. Pilot programs using these standard approaches are already underway with coordination and monitoring by the Direct Project, a workgroup under the ONC National Health Information Network (NHIN) initiative. Direct Project refers to the workgroup, the pilot implementations, and the (standard) method of confidentially exchanging information. It is the products associated with this project (Direct) that, I believe, will enable physician offices to meet many of the meaningful use requirements while also reducing office staff efforts and costs.

As part of its mission to help inform and educate its members, MedChi will be offering several health information technology conferences around the state during 2011. Check the MedChi website at www.medchi.org for more information.

> "It is the later years' requirements, Stages 2 and 3, which could prove to be beneficial to the physician. Meeting meaningful use requirements means that physicians must exchange key clinical information with one another as well as with their patients, providing an electronic copy of health records..."

Meeting the Requirements

The HITECH reimbursements are phased over four years and achieved by using software that performs certain functions. This has been termed "meaningful use requirements" of EMR software. Many of the Stage 1 meaningful use requirements, targeted for 2011, are easily accomplished in almost any electronic charting tool. These tools already store patient demographics, diagnostic codes and medication lists. Automating should be neither costly nor cumbersome. For physician offices, it will not likely provide a significant improvement over paper charts.

It is the later years' requirements, Stages 2 and 3, which could prove to be beneficial to the physician. Meeting meaningful use requirements means that physicians must exchange key clinical information with one another as well as with their patients, providing an electronic copy of health records. These connectivity requirements necessitate secure message exchange. This electronic exchange of information will save time and money currently spent on faxes, couriers, and postage.

The HITECH legislation does **not** require that practices purchase a completely integrated EMR system to comply with meaningful use. Physician compliance can be achieved through upgraded versions of existing software. It is likely that practices will need to add a module or two to take advantage of the benefits. The modules acquired must support the NHIN Direct Project standard to provide the best path forward.

How Does this Save Money?

Today's method of sending information from one physician's medical tracking system to another is accomplished by printing, mailing, and filing or re-entry. In many cases, offices are spending over $100 per day to mail information to physicians and patients. If a connection is paperless, it is only because the information is being moved from one fax server to another. Faxing works fairly well for a large percentage of the information flow; however, faxing blocks out shaded entries and the fax resolution is suboptimal for information such as highlighted abnormal labs and EKGs.

Groups requiring daily physician communication include other physicians, radiologists, laboratories, hospitals, patients, and insurance companies (payers). Using the same technology for all of these groups will significantly reduce expenses for any practice.

Meaningful use requirements only pertain to medical records and follow-up visit reminders, but there is no reason to limit secure messaging to these two actions. Further diversification of secure data transfer can alleviate staff time and expenses now expended on scheduling patients, billing patients, or conducting any other electronic communication (to any party) that contains sensitive data.

While secure electronic clinical connectivity (physician-to-physician) and physician-patient communication will reduce costs, the bulk of the savings are to be found in doctor-payer connectivity. Simple secure email can solve some problems almost immediately. For example, in order to process a claim, payers frequently request additional information from doctors. The current method using paper communications can delay payments by months. One beneficial outcome of secure electronic messaging is that it greatly increases the accountability placed on the health care insurance companies to respond and pay in a more efficient manner.

In addition to the physician-insurance financial cost savings, there can be significant savings by improving the collections from patient billings. Reducing the length of time for payer-based claim adjudication and subsequently emailing the patient bill will facilitate the patient's ability to pay faster and more accurately.

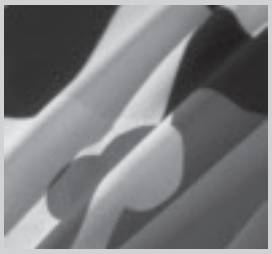
The Health Care Reform Bill contains language that can positively affect physician implementations. The specific provision in this act is "ELECTRONIC FUNDS TRANSFER: The Secretary shall promulgate a final rule to establish a standard for electronic funds transfers (as described in section 1173(a)(2)(J) of the Social Security Act, as added by subsection (b)(2)(A))." This means that in two short years, all physician reimbursements from insurers should become electronic.

The ability for insurance companies to pay electronically could be extended to include insurance companies reimbursing patients and patients paying their medical bills. Most large companies can electronically receive electronic payments originated by consumers. This capability could be provided to doctors. Although this may not increase income, it will increase cash flow and should reduce the length of time it takes for doctors to get paid.

Summary

Although there is only limited evidence that EMRs and centralized patient repositories will truly save money for the overall system, it is abundantly clear that electronic exchange of clinical and financial information will reduce doctor expenses and improve cash flow. Physicians who are interested in improving their practices' operations now have a new paradigm they can leverage to their advantage.

Dan Kazzaz is the immediate past chair of ASC X12 (The Accredited Standards Committee). He is currently a principal of Secure Exchange Solutions, a new company dedicated to helping companies leverage standard communications, semantic encoding, and encryption technology to reduce costs. He can be reached at dan.kazzaz@SecureExSolutions.com.



MEDCHI, The Maryland State Medical Society 2011 Legislative and Regulatory Agenda

Scope of Medical Practice:

MedChi will fight to assure that all patients have access to physicians and that physician extenders have appropriate training and physician oversight. The new federal health reform law will place unprecedented demands as hundreds of thousands of newly insured individuals seek doctors. It is important that these new patients find doctors and that non-doctors do not use this as an opportunity to increase scope of practice without adequate education and training.

Medical Liability Reform:

MedChi will:

1. Oppose trial lawyer attempts to increase the "cap" on damages in medical malpractice cases;
2. Support efforts to establish a pilot project for specialized health courts;
3. Study the continued efficacy of the Maryland Health Claims Arbitration system given the current fiscal environment;
4. Support efforts to limit repeated continuances in medical malpractice cases.

Public Health:

MedChi will advocate for continued improvements to Maryland's public health.

1. Work to remove criminal penalties directed at physicians who fail to comply with an order of the Governor during a public health emergency;
2. Ensure that alcohol tax increase revenues are dedicated to health care or public health programs;
3. Support legislation to mandate ignition interlocks on cars of drivers convicted of driving under the influence of alcohol;
4. Support passage of Uniform Emergency Volunteer Health Practitioners Act so as to allow out of state doctors to assist in public emergencies;
5. Work to establish annual "Check Your Medicine Cabinet" Disposal Day.

Physician Payment and Insurance Reform:

MedChi will continue its efforts to improve Maryland's reimbursement climate with several initiatives:

1. Resist the attempt of health insurers to repeal last year's passage of the Assignment of Benefits (AOB) bill which will take effect on July 1st;
2. Oppose legislation that will allow insurers to change a prescription without aphysician's approval, on the basis of the cost of the drug;
3. Persuade federal officials to approve a .1% assessment on hospital rates to support a State Loan Assistance Repayment Program for graduating medical students;
4. Seek the passage of a Joint Resolution in the Maryland General Assembly asking Congress to enact legislation to allow collective bargaining for physicians so as to counterbalance the overwhelming power of the health insurance companies;
5. Initiate appropriate legislation to provide the Maryland Insurance Administration (MIA) with full jurisdictional authority over ERISA plans and Blue Card plans operating in Maryland.
6. Work to amend Maryland's Electronic Health Records (EHR) law to direct health insurance carriers to reimburse physicians not only for the cost of implementing EHR but for maintaining such records on an ongoing basis. Continue support of privacy protection for EHR.

Medicaid and the Uninsured:

MedChi will continue to protect the integrity of the Medicaid program with respect to eligibility and benefits and to accommodate the program to the hundreds of thousands of new patients who will be enrolled as a result of the federal health reform law.

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WINTER 2010: End-of-Life, Hospice and Palliative Care in Maryland

SPRING 2010: The 2010 Maryland Legislative Session

SUMMER 2010: HIT: What You Need to Know Now!

AUTUMN 2010: Is the Sun Setting on Private Practice in Maryland?

MEDCHI NECROLOGY 2010

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ANNE ARUNDEL COUNTY
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James McMullen, M.D.

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Source: MedChi Component Societies

No cost, no obligation help navigating the incentives and penalties in the world of health information technology.

MedChi Network Services is a new offering from MedChi, The Maryland State Medical Society, to help physicians access resources and get the most out of health information technology. MedChi will provide free assistance to:

- Learn about state and federal adoption programs
- Enroll to receive applicable incentives
- Select a certified electronic health record system
- Enhance existing electronic health record systems
- Connect to the state health information exchange
- Reach meaningful use and earn up to $63,750

Fax back this form to learn about the available incentives you can receive to help transition to a paperless office.

❍ **YES,** I want MedChi to contact me about electronic health records and possible incentive programs.

PHYSICIAN NAME: PHONE NUMBER:

OFFICE CONTACT:

GET STARTED.
Fax this form to MedChi at 410-547-0915

FOR MORE INFORMATION PLEASE CONTACT RUSS KUJAN (410) 539-0872 X3322.

MedChi
The Maryland State Medical Society

Safe Disposal of Medicine Update and Prescription Drug Turn-In Program

Michele Kalish, Adriana Zarbin & Corporal Jim Holsinger

The Alliance to MedChi participated in the American Medicine Chest Challenge on November 13, 2010 at the site in Hagerstown, Maryland along with members of the Washington County Sheriff's office and the County Health Department. Our Safe Disposal of Medicine posters were displayed at the site and our materials were distributed to those bringing medicine, sharps, and aerosols for disposal. Many cars turned in huge bags of medicine. Fifty gallons of medicine were collected that day. Participating members included Gail Johnson, Lauren Kremers, Robin Thompson, and Madonna Vitarello from Frederick County, Dr. Matthew Wagner and Bernadette Wagner from Washington County, Dr. Murray Kalish and Michele Kalish from Baltimore. MedChi Executive Director Gene Ransom also participated at the Queen Anne's County site. Information was posted on MedChi's list.serv, and on the MedChi and Alliance websites.

The American Medicine Chest Challenge originated in New Jersey in November 2009 as a statewide event to collect medication and safely dispose of it. In 2010, it was expanded to a nationwide event with collection sites across the USA. Results from across the country totaled 10 tons of medicine. In Maryland, there were sites in Caroline, Harford, Kent, and Queen Anne's Counties, as well as Washington County. 1,462.9 pounds of collected medicine were reported from Maryland's collection sites. As you know, the goals of the Alliance's Safe Disposal of Medicine project are prevention of drug abuse, protection of the environment, and prevention of identity theft.

The American Medicine Chest Challenge strives to do this by encouraging everyone to:

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TURN-IN SITE CONTACT INFORMATION:

Washington County Sheriff's Patrol office:
Sheriff Mullendore
500 Western Maryland Parkway
Hagerstown, MD 21740
240.313.2103

In addition, six other Maryland Counties have programs to collect unneeded and expired household medication from residents of their counties. Most of these counties do not accept sharps or aerosols. Personal information should be removed from the containers before disposal. If the medication is not in the original container, it should be placed in a zip-loc plastic bag.

Calvert County: Sheriff Mike Evans. County residents can place unneeded and expired medication into padlocked boxes outside sheriff's office every day at 30 Church St., Prince Frederick, MD 20678, 410.535.2800.

Carroll County: Sheriff Kenneth Tregoning and Police Chief Jeffrey Spaulding. County residents can dispose of unneeded or expired medication by using drop boxes throughout the county at county police departments and one sheriff's office. For more information, contact Jolene Sullivan at the Department of Citizen Services, 410.386.3600 or jsullivan@ccg.carr.org.

Locations:
Westminster: Westminster City Police Department
36 Locust Street, Westminster, MD 21157, 410.848.4646

Taneytown: Taneytown Police Department
120 E. Baltimore Street, Taneytown, MD 21787, 410.751.1150

Sykesville: Sykesville Police Department
7547 Main Street, Sykesville, MD 21784, 410.795.0757

N.E. Greenmount:
Carroll County Sheriff North Carroll Satellite Office
2255 Hanover Pike, Greenmount, MD 21074 410.386.2464

Charles County:
Sheriff Rex W. Coffey. 3 sites, County residents can place unneeded or expired medication in boxes outside of sheriff's offices.

Locations:
District I - La Plata:
6855 Crain Highway, La Plata, MD 20646, 301.932.2222

District II - Indian Head:
4401 Indian Head Highway, Suite 2, Indian Head, MD 20640, 301.743.2222

District III and District IV - Waldorf:
3670 Leonardtown Road, Waldorf, MD 20601, 301.932.7777

Kent County: Sheriff John F. Price, IV - County residents can take expired or unneeded medicine to the sheriff's office Monday-Friday 8:30 a.m.- 4:30 p.m. 103 Vickers Drive, Unit B, Chestertown, MD 21620, 410.778.2277

Queen Anne's County: Sheriff R. Gery Hofmann III. County residents can dispose of their unneeded or expired medication at the Centreville Sheriff's Office, Monday-Friday 8:00 a.m.-4:00 p.m.
505 Railroad Avenue, Centreville, MD 21617, 410.758.0770

St. Mary's County: Sheriff Tim Cameron - County residents can leave unneeded or expired medication in a mailbox-like box labeled Prescription Drug Drop Box in the lobby every day. 9 p.m.-7 a.m., need to use a buzzer to get into the building.
23150 Leonard Hall Drive, Leonardtown, MD 20650, Phone: 301.475.4200, ext. 1900

Common Terms

WORD ROUNDS

Barton J. Gershen M.D., Editor Emeritus

Each day we use words without considering their origin. An unusual word like "misogamist" or "mountebank" might catch your attention and pique your curiosity, but so many familiar terms escape notice. For instance, when you **endorse** a check, where do you write your name? On the back of the check, from Latin *dorsum*: "back." And an **endorsement** is simply a metaphorical way of stating that a product or a candidate has a sponsor's name stamped on the back.

During the Renaissance, Florentine money lenders set up shop in the market squares of large cities. Their place of business would consist of a table or bench and one or two chairs. In Italian, a bench was called a *banca*, which evolved into the French word *banque*, from which we derive **bank**. Thus a **banker** was one who collected his usurious interest as he sat by his bench. The word *banque* is also noted in the word **banquet** – a meal served at a long table or bench. During the time of the Medici's, poisoning one's enemy was *de rigueur*, so paranoid bankers, members of the royalty, and high clergy, paid servants to taste their food and wine before they would eat it. The meal was brought in on a serving plate called a **salver** and placed on a bench known as a **credenza.** *Credenza* is an Italian word meaning "belief." (Terms such as credible, credence and credentials stem from this word.) Salver derives from Latin *salvare*, meaning "to save." (Words such as salvage and salvation also stem from this root.) The connotation implicit in these two terms was that the servant would taste the food and thus potentially save his master from death. The food and drink were thus shown to be non-toxic, and when placed upon the *credenza* – its safety was believable.

"Salver derives from Latin salvare, meaning "to save." (Words such as salvage and salvation also stem from this root.) The connotation implicit in these two terms was that the servant would taste the food and thus potentially save his master from death."

In Latin, the bud of a plant was referred to as an *oculus* because it resembled an **eye** to early horticulturists. (Today we still refer to the "eye" of a potato.) Early Roman farmers discovered that one could graft the "eye" of a young plant onto another, a process which became known as inoculation. (Latin *en*: "within" plus *oculus* – that is, to "place the eye within.") Much later it was discovered that one could "graft" infected tissue onto a healthy person and this might somehow confer immunity to the disease. Since this process closely resembled that of the horticultural one, it too was called **inoculation**.

The Old Norse word for eye was *auga*. Early log cabins were built with one or more small apertures to allow for sunlight and to offer sight holes. These openings offered an entrance for the wind as well, so they became known as *wind augas*- "wind eyes." Today, of course, we call them **windows**.

In Latin, a common, attractive flower was known as *solis oculus* – the "sun's eye." In the 14th century, Geoffrey Chaucer called it the "eye of the day," because its petals closed completely at night and reopened with sunlight. The "day's eye" soon morphed into our common term for this flower – the **Daisy**. Other flowers are named for their resemblance to familiar objects. For example, the **Aster** is a flowering plant which resembles a star – from Latin *aster*, meaning "star. The beautiful **Orchid** has a root with two bulbous protrusions. These resembled testes to botanist John Lindley, so from the Latin *orchis*: "testis," he so-named them in his 1845 publication *School Botany*. (**Orchitis** and **orchiectomy** derive from the same root.)

Another common flower, which invades our manicured lawns each spring, has numerous golden petals which resemble teeth. The similarity was so great that the flower's name in Latin was *dens leonis*, which in its French incarnation became : *dent de lion* – the "lion's teeth." As English evolved, we borrowed this term, anglified it, and now call that pesty flower the **dandelion**. The Latin *dens*, which means "tooth," is clearly present in words like dentist, denture, dentifrice, and even in the popular gum product Dentine. But it can also be found in our terms **indent** and **indentation**. A casual glance at any document that contains paragraphs (such as this column), will clearly reveal irregularities along the left edge where the new paragraphs begin. These deformities resembled teeth to some imaginative scribe, who labeled them in**dent**ations. In colonial America, it was the custom for wealthy landowners to hire laborers from Europe, by paying for their transportation, food, clothing and housing in return for 3-7 years of servitude. A contract was always drawn specifying the legal details of this transaction. The contract was then torn in two, each party receiving half of the document. At the termination of the contract, each party presented his half as proof of contract. The edges of the torn contract were irregular and appeared tooth-like, therefore the document was called an **indenture**, and the worker became known as an **indentured servant**.

In Latin *serra* meant "a saw," that is a knife with jagged or toothed edges. Our word **serrated** derives from it. Spanish altered the term slightly and it became *sierra*

– "something with jagged edges." Soon the word sierra became applied to the dentate peaks of a mountain chain. Thus we have the **Sierra Nevada** Mountains (*Nevada* is Spanish for "snowy or snow-covered"), in other words they are "snow covered jagged mountains." The **Sierra Madre** Mountains – found in California and Mexico – stem from *madre*: Spanish for "mother." Hence these mountains are the "mother mountains" or perhaps "the mother of all mountains." The West African nation of **Sierra Leone** (*leone*: Spanish for "lion") derives its name from the belief of early Portuguese explorers that roaring lions could be heard in the mountains.

In ancient Rome, two days of each month were considered to be unlucky based on astrological calculations. Those days were known in Latin as *dies mali*: "bad or evil days." As years passed and we humans became more sophisticated, we merely characterize these days as **dismal**. Roman astrologers referred to calamities as those in which the stars were in corrupt positions – Latin *dis* ("apart or away") plus *aster* ("star"). Today we call those events **disasters**, never quite recognizing that – by using the word – we have endorsed astrology.

Names of automobiles often prove interesting. The Fuji Corporation of Japan is a conglomerate of five companies, now known as Fuji Heavy Industries. One of their products is the **Subaru,** Japanese for the star cluster that we call the Pleiades, meaning the "seven sisters." Actually only five of these stars are easily seen by the naked eye. Fuji adopted them as a symbol for their five conglomerates, which explains the Subaru logo.

In 1913, two brothers – Fred and August Duesenberg – of Des Moines, Iowa, designed and built the first in a line of luxury and racing cars. They named the automobile after themselves, calling it a **Duesenberg**. For the next 25 years the Duesenberg was one of the finest and fastest automobiles in the world, until its ownership fell into bankruptcy and the factory closed. The automobile's name gave rise to a common American expression of admiration – people would say "It's a duesy" about anything they considered special. "Duesy" has morphed into **doozy**, but its origin is not often appreciated.

Karl Benz was a German engineer who is credited with having invented the first gasoline powered automobile (Gottfried Daimler also created such an engine, but Benz was first to patent the idea.) Neither man knew the other, and both went on to build and sell their automobiles. In 1902, a wealthy Austrian car dealer named Emil Jellinek, contracted with the Daimler Company for 36 new automobiles, which he would sell at his dealership. As an integral part of the negotiation, Jellinek insisted that the new automobile be named after his daughter. Shortly thereafter, the Benz Corporation merged with the Daimler Company and the rest, as they say, is history. By the way, Jellinek's daughter was named **Mercedes**.

Many cars were named for their designers: Henry **Ford** and Walter **Chrysler** obviously come to mind, as does Ransom Eli **Olds** who founded the Olds Motor Vehicle in Lansing, Michigan. The **Oldsmobile** is obviously named for him, but the **REO** automobile (created from the initials of Ransom's full name) is less well known, although by 1907 it was one of the four richest automobile companies in the United States. The **Chevrolet** is named for Louis Chevrolet, who founded that company in 1911. The **Buick** was similarly named for its developer David Buick in 1903. But Henry Leland chose to name his new car company after one of his famous ancestors, the founder of Detroit – Antoine de la Mothe **Cadillac.**

Over the past century, automobiles have been built to run on steam, electricity, propane, ethanol, hydrogen, gasoline, and diesel. The latter was developed by Rudolph **Diesel** in 1897. Unfortunately, in 1913, Mr. Diesel died mysteriously while on board a ship bound for London.

Before ending this column, if you haven't already looked them up yourself, I should describe the origins of **misogamist** and **mountebank**. The first means "one who hates marriage," from Greek *misein*: "to hate" and *gamos*: "marriage" (as in monogamy). This term is similar to **misogynist** and **misanthrope** – the first meaning "one who hates women" (Greek *gyne*: "woman" as in gynecology and gynecomastia) and the second "one who hates mankind" (Greek *anthropos*: "man or mankind" as in anthropology). **Mountebank** derives from Italian *montambanco* which is a contraction of the expression *monta in banco*: "to mount the bench," referring to charlatans and snake oil salesmen who often climb on top of a bench to promote their wares. A mountebank is, therefore, a fraud and a swindler.

In your daily reading, unusual words most often grab your attention – they virtually beg you to investigate their derivation. But don't neglect the common words – many of them have quite uncommon origins.

Barton J. Gershen, M.D., Editor Emeritus of Maryland Medicine*, retired from medical practice in December 2003. He specialized in cardiology and internal medicine in Rockville, Maryland.*

Valuing Your Medical Practice-Part 2...

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practice will need to be priced competitively based on all relevant factors. When the valuation is complete and shared with a prospective buyer, the buyer must understand the seller's vision for the practice in the future, including the transition period and any assistance with helping the buyer retain the patient base through letters and introductions to patients and referring physicians. This is true for a new associate buying in as well.

The bottom line is to remember that any business, including a medical practice, is only worth what someone is willing to pay for it. It is important to price it correctly from the start and manage expectations. It is also important to advertise the sale in medical publications, to referring physicians, and to hospital and medical society liaisons. In this economy, practices are selling more slowly (and in some cases for less) than in past years, but we are seeing that many are still selling, especially in the desirable D.C./Baltimore area.

Maureen West McCarthy, C.P.A., is the Director of the Healthcare Consulting Division of Snyder Cohn, P.C. Snyder Cohn is a C.P.A. firm located in North Bethesda, Maryland that specializes in advising healthcare organizations in the areas of tax, audit, valuations, pension administration, and a full complement of healthcare consulting services. Ms. McCarthy can be reached at mccarthym@snydercohn.com or at 240.514.5518.

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BOWIE: Practice for sale. 21 year old practice in Bowie area. Pediatrics & Adults (70%-30% mix). About 2500 active patients. Send inquiries to smkumarmd@comcast.net.

FREDERICK: (See FOR SALE OR LEASE below)

PRIMARY CARE PRACTICE: Potomac Physicians, P.A., a primary care medical practice with 7 offices in Maryland is currently looking for primary care physicians interested in moving their existing practices under our business umbrella and into our Catonsville, Annapolis, Whitemarsh and Laurel offices. If interested, please contact Carol Reynolds, M.D., Medical Director at 410.248.2651 or at carol.reynolds@potomacphysicians.com.

SILVER SPRING: Internal medicine practice for sale. Call 301.540.8146 for details.

LEASE/SUBLEASE

BETHESDA: Attractive office space for rent in physician's practice w/private office, exam rooms and shared waiting room ready for use. Walking distance to Metro, parking garage, or on street and county garage across street. Please call Avelene at 301.656.0220.

BETHESDA BORDER/NW DC: Medical office sublet available. Prime location, spacious, newly refurbished, EMR, and ready for use. Available for full-time or part-time. Convenient parking located behind building. Walking distance to Metro and Metrobus. Please call 202.237.0808 for more information.

BOWIE: New medical building, in the heart of Bowie. Conveniently located near the intersection of Rte. 450 and Rte. 193. 2,300 square feet available. Flexible terms and monthly rates. To discuss or see, call Amanda at 301.860.1200.

CHEVY CHASE: Near Friendship Heights metro, office buildings, high-rise residential and high end shopping. NIH and Suburban Hospital in MD and Sibley Hospital in D.C. Office offers 2750 sq.ft,, 6 exam rooms, kitchen, bathroom, parking,. Fully accredited outpatient surgical facility in building. Contact Elan Reisin 202.997.5007 or elanreisin@yahoo.com.

COCKEYSVILLE: Available May 2011. 2000 sq.ft., 6 exam rooms, 4 business/physician offices, one lounge, lab area, large waiting room, storage and excellent parking. Call 410.628.6100 for more information.

FALLSTON/BELAIR: Office space for lease to health professional. Approx. 1,000 sq.ft. Well maintained in a high growth area. Plenty of parking on Belair Rd. Call Dr. Scharf at 410.458.9969.

FOREST HILL: Office space available in a quiet professional building. Includes utilities, phone, copy, fax machine, receptionist area, waiting room, and parking. Two examination rooms and all other necessary accommodations for an MD (sink, closets, file areas, etc.). Part-time availability (1-3 days a week). Please contact Dr. Schmitt at 443.617.0682 or Dr. Legum at 410.852.0582.

FREDERICK: (FOR SALE OR LEASE) Available immediately fully fitted out Medical Suite in a medical condominium building. This medical suite is fitted with 5 private offices, 10 exam rooms, waiting area, lab, storage, conference room and break room. Call Jay Nathan at 240.405.1023 or 301.471.8251.

GREENBELT: Sublease available Mon.-Thurs. afternoons and all day Friday. For more information call 301.317.6800.

GREENBELT/LAUREL/BOWIE: Share spacious medical office space with GYN physician in area. Designed for two physicians, space is located in a high rise office building with more than 2,800 square feet. Space is tastefully furnished with a large waiting area, 4 exam rooms, 2 doctor's consultation offices, business office area and staff break area/kitchen. Abundant free parking, metro accessible, close to 495 and BWI parkway. Hours and usage negotiable Please contact Julie at 301.474.5400.

GREENBELT: Brand new office, 1250 sq.ft. to share, to lease or to lease with option to buy. Conveniently located 2 miles from Doctor's Community Hospital. Near intersection of Beltway (I-495) and BW Parkway (I 295), on Greenbelt Road (Rt. 193) across from NASA. Please call Paul at 301.299.9571 or email PWang@MRIS.com.

GREENBELT: Pediatric office. 1200 sq.ft next door to Safeway/CVS. Less than ½ mile from the Beltway. Call 301.318.7259.

HUNT VALLEY: 3,793 sf medical space. Formerly used by General Practitioner in Hunt Valley Professional Building. 1st floor space at $17.50 psf plus utilities and cleaning. Contact McKenzie Commercial Real Estate Services at 410.494.4868.

RIVERDALE: Office lease or sublease. 6510 Kenilworth Ave., Riverdale, MD. Close to Doctor's Comm. Hospital & P.G. Gen. Hospital. Call 301.927.6111 or 301.325.3212.

ROCKVILLE: 1,200 sq. ft. office next to Shady Grove Hospital. Available afternoons and weekends. 301.424.1904.

ROCKVILLE/BETHESDA: Ophthalmologist retiring. 1600 sq.ft. ready for occupancy. Contact Stephen Grayson, Montrose Professional Park. 301.252.7566.

SILVER SPRING/WHEATON: Lower your overhead expenses by subleasing or sharing medical office space. Luxurious penthouse suite with 3200 square feet, 7 treatment rooms, surgery center, equipment and staff available. All medical specialties welcome. Call: 301.949.3668.

SILVER SPRING, DOCTORS MEDICAL PARK: Georgia Ave. and Medical Park Drive. Close to Holy Cross Hosp., ½ mile north of #495. 3 building medical campus totaling 95,000 sq. ft. with over 100 medical practitioners and Clinical Radiology's HQ. 2 suites 1400-2750 sq.ft. avail. immediately. Call Steve Berlin at Berlin Real Estate, 301.983.2344 or steve@berlinre.com.

WHITE MARSH: Office in modern complex in White Marsh on Wednesdays. 1600 sq. feet. $700/mo. Utilities incl. Ideal for specialist. Easy access from I-695 and I-95. Call 410.812.6003 for additional information.

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SCAN/ARCHIVE RECORDS: Simple, efficient. Transition to EMR, EMR alternative, or retire with office in pocket. $1,299. Local. Go to www.PCArchiver.com or call 410.484.4297.

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FOR SALE

OB GYN EQUIPMENT: ObGyn office practice equipment. power tables, ultrasound machines, surgical instruments, colposcopes, microscopes, office furniture, etc. Ideal for starting or adding to your practice. Email storkmman@comcast.net.

ULTRASOUND MACHINE: Ultrasound machine, ATL HDI 3000 used, working condition $2,000.Used EXAM TABLE $400.00. Good condition. Call 301.927.6111 or 301.325.3212.

Safe Disposal of Medicine Update and Prescription Drug Turn-In Program...

continued from page 31

- Keep an inventory of all prescription and over-the-counter medicine;
- Keep all medicine in a secure place;
- Dispose of unneeded or expired medicine at a "take back" site or by following FDA guidelines for Safe Disposal of Medicine in the trash;
- Take all medicine exactly as prescribed. (Remember it is prescribed for an individual patient. Do not give it to anyone else to take.); and
- Talk to children about the dangers of prescription and over-the-counter drug abuse.

The Alliance article in the autumn 2010 issue of *Maryland Medicine* talked about "take back" sites at pharmacies through "Dispose My Meds" and the "Prescription Drug Repository Program." In addition, some sheriff's offices in Maryland have medicine "take back" sites available on a regular basis.

An excellent example of this is the program for Washington County residents through their County Sheriff's Office. This program is for household medication only. It does not accept medicine from physician or veterinarian offices which needs to go through the official DEA program. All types of medicine, including prescriptions, over-the-counter medications, medications for pets, as well as sharps and aerosol medications are accepted. Since February 2010, the program has gone to locations around Washington County including fire halls, churches, and community events. In addition, collection is available every day, year round at the patrol office.

Equipment cost for this program is low. Two 44 gallon Brute trash cans with four matching lids are used. Two of the lids are equipped with PVC pipe and cap assemblies that have been partially cut away, which creates a no-reach, drop-in point for drug collection. The collection container lids are secured with cable style pad locks at all times, with leg irons being used to secure the containers to a fixed object. Uniformed deputies from the community relations unit greet each citizen as they turn in their unwanted medications. This display of security has proven to boost the public's confidence and encourages more community participation. All activities are advertised in advance and the public participates with anonymity.

Sheriff Douglas Mullendore and the deputies working at the collections sites have found this program to be an extremely positive public relations tool. During the turn-in events, many citizens comment on how appreciative they are to have a secure and safe way to dispose of unwanted medications.

At the conclusion of the event the drop-in lids are removed and a solid lid is locked in place for transport. All medications are then safely destroyed in an environmentally friendly manner by a local incineration facility.

If you would like more information on this program please contact Corporal Jim Holsinger, Washington County Sheriff's Office at 240.313.2194.

For more information about the Safe Disposal of Medicine, please check the Alliance website http://www.medchialliance.org. Our brochures and flyers can be downloaded from the site.

The Alliance can be contacted by email: alliance@medchi.org or by phone: 410.539.0872 x 3350, ext.3304.

Michele Kalish and Adriana Zarbin are Co-Presidents, Alliance to MedChi. Corporal Jim Holsinger is with the Washington County Sheriff's Office.

THE LAST WORD

Preconceptions

Westby G. Fisher, M.D.

The following was originally posted as a blog by Westby G. Fisher, M.D., in December 2010. Dr Fisher is an electrophysiologist practicing at North Shore University Health System in Evanston, Illinois, and a Clinical Associate Professor of Medicine at University of Chicago's Pritzker School of Medicine.

One more to see after cases were completed. It had been a long day, and I was finding it challenging to summon the effort for one more case. I reviewed the chart. Her past medical history in the electronic medical record read much like a Rorschach blot: 91, uterine cancer, hysterectomy, colostomy, breast cancer, mastectomy, an amputated digit, hypertension, hyperlipidemia, recent stent. The medication list was complicated, but not incomprehensible — at least most of the drugs were familiar. I noticed that antiplatelet agents, but not anticoagulants, were part of the mix. "Fall risk," I thought. I braced myself for another hour's work, realizing the inevitable. What room was she in again?

The hall was bustling with activity as family members stood outside rooms discussing their loved ones, and nurses skittered from room to room, answering call lights and bed alarms. Patient-transportation personnel were lifting the last patients of the day onto neatly pressed bed linens as they promised a rapid response from the dietary staff.

Her door was closed while most others were open. Why do a procedure on someone so limited? I entered and looked for the quick-wipe alcohol foam dispenser and squirted the foam into my hand, turning to see her. Surprisingly, there was not just one person there, but around the small intervening wall, her husband could be found, too.

This was not the dismal, dreary place I had foreshadowed. Quite the contrary. I had interrupted a fiery proclamation emanating from the tiny frame lying in bed, as she challenged her husband's desire for her to stay another night. "We'll discuss this later," she said, "the doctor's here now." She turned to me, smiling, "Yes?"

I introduced myself and explained the purpose of my visit. "Yes, yes," she said, fully comprehending the circumstances, challenges, potential reasons for her six readmissions in the last three months. She was sharp, engaging, and a remarkably accurate historian — not at all what her Rorschach had predicted. She rifled through her own history, explained her symptoms concisely, and looked at me willfully: "Now, how soon can we get going?"

My Rorschach had spoken.

She was simply a delight — a firestorm of personality and drive that even the most ardent supporters of the electronic medical record could never have predicted. It was then that I realized its stony information lacked her vision, her wit, her charm. Suddenly, her procedure made sense.

And so we proceeded.

And so did she, right out the door, just as soon as her 93-year-old husband would let her.

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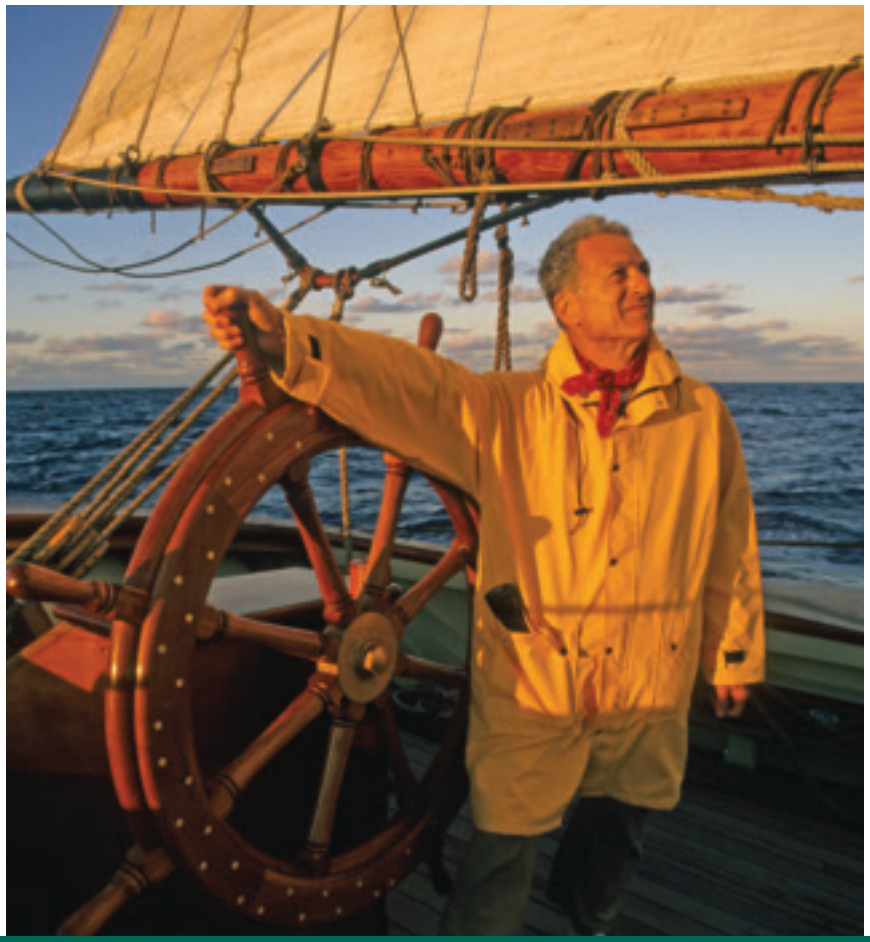

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