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—The Dalai Lama

Cover Art:
*Heading Home: Goose Patrol*
by Terence Starz, MD

Dr. Starz is a rheumatologist.
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Sorry Seems to Be the Hardest Word

TIMOTHY LESACA, MD

It’s sad, so sad
Why can’t we talk it over
It seems to me
Sorry seems to be the hardest word.
—Elton John/Bernie Taupin 1976

I have always marveled at great musicians and lyricists who are able to capture a multitude of emotions and experiences in a simple phrase. I recall the year this song was released as being a less complicated time. Common sense usually prevailed: Apologies were afforded because they were the right thing to do, and trust in others generally kept paranoia from taking over our lives.

Unfortunately, much has changed over the years, including the physician-patient relationship. No longer are treatment matters straightforward and unencumbered by outside influences. Paranoia seems to be winning the battle over common sense, and the simple act of apology is the latest victim. However, the insight of the songwriter and the lyric transcends, as sorry still seems to be the hardest word.

Some malpractice attorneys might disagree with this, but I’m certain that doctors are in fact capable of genuine emotion. Unfortunately, sooner or later, in the practice of medicine you are going to make a mistake that causes harm to your patient. In the midst of the guilt and shame associated with accidentally causing harm to someone else, it is very natural to want to apologize. In a normal world that is exactly what you would do.

In medical malpractice litigation, the world of law and the world of common sense collide in destructive fury. Technically, the legal rules of evidence allow for admission of anything that could lead to culpability; that includes any apology you might be inclined to make to a patient and/or family member. The benevolent act of an apology and the expression of remorse and regret can be entered as potentially incriminating evidence in a malpractice trial in the state of Pennsylvania.

The conventional wisdom of liability prevention teaches that apologizing to a patient and/or family member for a medical error is counterproductive and ill-advised. Doctors are usually advised by lawyers and insurers to deny and defend when an adverse situation arises. This wisdom might actually be flawed.

The American Medical Association’s Code of Ethics states that it is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients, and concern regarding legal liability that might result from truthful disclosure should not affect the physician’s honesty. Furthermore, according to the Pennsylvania Health Care Association, recent research suggests that anger, rather than greed or monetary gain, is the driving force behind most medical malpractice lawsuits.

There is a growing consensus that open communication and a genuine expression of sympathy and condolence can contribute greatly to the much needed emotional healing of the harmed patient and family. The act of apology is a time honored ritual that shows respect and empathy for the wronged individual. However, in the world of malpractice litigation, sorry seems to be the hardest word.

At this point in time, 35 states have passed apology/benevolent gestures legislation that allows physicians to speak openly with patients and families following an unforeseen medical outcome, to apologize and to offer expressions of condolence without such statements being permitted in a court of law. Many organizations, including the
Pennsylvania Medical Society, the Pennsylvania Medical Health Association, and The Hospital and Healthsystem Association of Pennsylvania, support this legislation.

Despite this broad support, Pennsylvania has not yet enacted apology/benevolent gestures legislation. On March 1, 2011, the Pennsylvania State House of Representatives did, in fact, pass House Bill 495, known as the Benevolent Gesture or Apology Bill, which would have provided that an apology or otherwise benevolent gesture—including an admission of fault—cannot be used as an admission in a medical liability action. Unfortunately, this version of the bill, along with a similar version from the state Senate (SB 565), is stuck in gridlock in the Senate Judiciary Committee.

There are subtle differences in the benevolent gesture laws passed by the 35 states. For example, Michigan allows for statements of fault to be used in court. In contrast, the Pennsylvania bills state that explanations of fault that go beyond apology would be protected speech. Senator Stewart Greenleaf, who heads the State Judiciary Committee, feels that this is going too far.

Ironically, Senator Greenleaf is known to be in support of benevolent gestures legislation. As quoted on the October 21, 2011, edition of the online e-newsletter MedCity News, the issue is, according to Senator Greenleaf, “how far the doctor or health care provider can go in describing or admitting fault and what that should be; and so far we’ve not been able to have that discussion. You can say anything you want, and it’s not admissible, that’s not a good piece of legislation.”

Senator Greenleaf prefers a more carefully worded bill that would serve as a compromise between the medical community, which supports statements of fault during the act of apology as being protected speech, and the trial lawyers, who would allow such statements to be admissible in court. Harrisburg attorney Scott Cooper, vice-president of the Legislative Policy Committee for the Pennsylvania Association for Justice (formerly known as the Pennsylvania Trial Lawyers Association), expressed his belief in the March 21, 2011, edition of the York Daily Record that the proposed legislation could interfere with the pursuit of a legitimate claim in court. The March 16, 2011, Patient Safety Blog of Washington DC-based malpractice attorneys Patrick Malone and Associates posted in regard to this legislation: “What if the doctor admits exactly what went wrong? And what if the patient has no other way to prove what happened other than what the doctor said in the apology?”

I personally doubt that a suitable compromise is possible in this situation. Any such compromise would first have to overcome the nearly insurmountable task of writing legislation that would always clearly establish the fine line between an apology and an admission of fault. The default position of a malpractice attorney has generally been that an apology from a doctor equates with an admission of responsibility and fault. If admission of fault is not protected speech as part of an apology, then every apology would have to be examined to determine if it has crossed the line.

I also see a fallacy of logic in the insistence that a doctor’s admission of fault is related to the successful litigation of a malpractice case. Neither an apology nor expression of fault by a doctor is evidence that an applicable standard of care has been breached. Plaintiffs cannot rely on a doctor’s expression of remorse or fault as evidence of negligence, as that is instead established through the medical record and expert-witness testimony.

Finally, if the comments on Attorney Malone’s blog do in fact represent legitimate concerns held by malpractice attorneys, then one must clarify under what circumstances a patient would have no other way to prove fault and negligence other than what the doctor said in an apology. I believe the most likely answer would be circumstances in which negligence was not reflected in the medical record, was being concealed by the doctor or hospital, or had not been disclosed to the patient as would be required by the Medical Care Availability and Reduction of Error Act. If such concerns are a basis for the State Judiciary Committee’s motivation to find a compromise with the trial lawyers, it should first behoove the committee to prove that such egregious acts are occurring.

But for now, doctor, I would advise that you chose your words carefully. It’s a sad, sad situation. And it’s getting more and more absurd.

Dr. Lesaca is a psychiatrist specializing in children and adolescents, and he serves as associate editor of the ACMS Bulletin. Dr. Lesaca can be reached at tlesaca@hotmail.com.
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RHEUMATOLOGY: Betsy F. Shook, M.D.
Practice administrators forum

More than 20 practice administrators attended the February 29 interactive program, Managing Your Workteam, HR Skills Made Easy, presented by Donna J. Kell, BS, MPM. Ms. Kell, who provided key information on the framework and tools required for managing a successful workteam, is CEO of the Kell Group, LLC.

Attendees were asked at the onset to provide specific challenges and issues they confront in their workday. Common issues included morale, recruitment, compensation, accountability, discipline and work ethic. An enthusiastic discussion between participants and Ms. Kell resulted in creative ideas and solutions to many of the identified challenges.

Ms. Kell outlined an important framework for successfully managing a medical workteam and identified five important tools needed to greatly enhance a practice administrator’s ability to cultivate an effective and happy workforce:

1. Create an organization chart. Who does what? Who reports to whom? The organization chart should provide details on skill sets as well as accountability.
2. Define job descriptions. Although this is a challenge, be specific in defining each job and include an outline of performance expectations.
3. Detail a compensation structure. Be prepared to constantly review the current compensation rates for each position. Keep information confidential, but share full compensation details with individuals during review period.
4. Request feedback on communication and conflict. Keep open lines of communication by providing periodic performance discussions with all employees; document employee successes and concerns. Conflict resolution can be addressed by fostering two-way and open communication; stick to the facts and develop skills through mediation training (if needed).
5. Provide an employee handbook. A detailed employee handbook given to all employees is important along with an employee acknowledgement form. Handbook material should be reviewed yearly to keep it current.

Ms. Kell noted that, for complicated human resources challenges, investing in a human resource attorney is beneficial to ensure that the practice guidelines already in place follow relevant legal parameters. She also stressed that taking time to institute a framework within the work place is key to maximizing staff productivity and providing a solid workteam environment.

The ACMS Practice Administrators Forum meets regularly throughout the year at the ACMS building. For information on how to join the forum and to receive updates on upcoming meetings, contact Nadine Popovich at npopovich@acms.org or (412) 321-5030.

continued on page 146

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Society News (from page 145)

Reminder: malpractice reporting
Under the MCare Act, physicians must report to their licensure board (either the State Board of Medicine or the State Board of Osteopathic Medicine, as appropriate to the physician) within 60 days of:
• notice of a malpractice suit;
• notice of a disciplinary action by the licensing authority of another state;
• receiving information regarding sentencing under either §15 of the Osteopathic Medical Practice Act or §41 of the Medical Practice Act (both dealing with reasons for refusal, suspension or revocation of a license); or
• being arrested for criminal homicide, aggravated assault, a sexual offense or for violation of the Controlled Substance, Drug, Device and Cosmetic Act.

For convenience, the Pennsylvania Medical Society’s website (www.pamedsoc.org) contains a self-reporting form that physicians may file with the appropriate licensure board. Failure to timely report one of the enumerated occurrences can result in a fine of up to $10,000 in addition to any other civil remedy or criminal penalty.

ACMS Alliance annual meeting
The ACMS Alliance will hold its annual meeting and luncheon on May 22 at the Pittsburgh Golf Club in Schenley Park. The business meeting will get under way at 10:30 a.m. and the social and luncheon will follow at 11. For more information, contact Patty Barnett at (412) 422-2340.

Community Notes

June 10 March for Babies
The March of Dimes will sponsor its Pittsburgh March for Babies on June 10 at PNC Park, when families and businesses throughout the area will join together to support the work of helping moms have full-term pregnancies and babies begin healthy lives. Funds raised by the event help support prenatal wellness programs, research grants, neonatal intensive care unit (NICU) family support programs and advocacy efforts. To join in, visit marchforbabies.org or call (412) 505-2200 to sign up as an individual, to start a corporate or family/friends team or to donate to the effort.

Dear Doctor

Debra T. Abell,
MD, dermatology and cosmetic skin care, contributed a Dear Doctor column about mole mapping. Mole mapping typically involves photography of the entire body. Digital photographs serve as a baseline and assist the physician during the patient’s annual skin exam to see if any skin lesions are new or have changed. This is particularly useful in monitoring people at higher risk for melanoma.

The Dear Doctor column is published regularly in the Pittsburgh Post-Gazette’s Health Section. To contribute a Dear Doctor column, call Christina Morton at (412) 916-2421 or e-mail cmorton@acms.org.

Do you suspect or know someone who is a victim of domestic violence?
Where to Turn cards give important information and phone numbers for victims of domestic violence. The cards are the size of a business card and are discreet enough to carry in a wallet or purse.

Quantities of cards are available at no cost by contacting Allegheny County Medical Society at 412-321-5030.

Help your patients talk to you about their BMI
Allegheny County Medical Society is offering free posters explaining body mass index (BMI) and showing a colorful, easy-to-read BMI chart. The posters can be used in your office to help you talk about weight loss and management with your patients.
To order a quantity of posters, call the society office at 412-321-5030.
You can view or download a smaller version at www.acms.org.

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Blair A. Jobe, MD (general and thoracic surgery), has been named director of West Penn Allegheny’s new Institute for the Treatment of Esophageal and Thoracic Disease, and he will serve as chair of the Department of Surgery at The Western Pennsylvania Hospital beginning in July. Dr. Jobe is currently the Sampson Endowed Professor of Surgery at the University of Pittsburgh School of Medicine and has served as director of esophageal research and esophageal diagnostics and therapeutic endoscopy at the UPMC Heart, Lung and Esophageal Surgery Institute since 2008.

Jonas T. Johnson, MD (otolaryngology), was recently named as recipient of the Dr. Rodman E. Sheen and Thomas G. Sheen Award. Since 1968, the award has been granted annually to a doctor(s) for the purpose of furthering the study of medicine and the science of medicine. The $25,000 award was presented by the Bank of America during the annual convention of the New Jersey Chapter of the American College of Surgeons. Dr. Johnson is professor and chair, Department of Otolaryngology, School of Medicine and UPMC.

George J. Magovern, MD (thoracic surgery and cardiovascular disease), has been appointed director of the American Board of Thoracic Surgery (ABTS). Dr. Magovern, who chairs West Penn Allegheny Health System’s Thoracic and Cardiovascular Surgery program at Allegheny General Hospital, is the only Pittsburgh area physician elected to the board and he will serve a six-year term. He will play a critical role in ensuring the quality of thoracic surgery care in the United States by helping direct the process of evaluating and certifying thoracic surgeons. He also serves as program director of the hospital’s thoracic surgery residency program and surgical director of the Gerald McGinnis Cardiovascular Institute.

Eugene N. Myers, MD, FACS, FRCS (otolaryngology), was honored by the Pancreat Association of America (PAA) for his visionary leadership and training of specialists in otolaryngology at the University of Crete Medical School. The PAA is a non-profit organization dedicated to the cultivation and preservation of the rich cultural heritage of Crete and the empowerment of its members to become effective and responsible citizens of the U.S. Dr. Myers is Distinguished Professor and Emeritus Chair, Department of Otolaryngology, UPMC School of Medicine.

Karl R. Olson, MD (ophthalmology), received the Pennsylvania Academy of Ophthalmology’s Humanitarian Service Award in March for his willingness to provide basic ophthalmologic care to the indigent people of Peru and Haiti during mission trips in the past several years. Dr. Olson, an ophthalmologist at Retina Vitreous Consultants in Pittsburgh, is a recipient of the American Academy of Ophthalmology’s Distinguished Service Award and serves on the AAO Council.

Terence W. Starz, MD (rheumatology, internal medicine), is a course director for Performing A Standardized Joint Count in Rheumatoid Arthritis, a CME program designed to provide physicians and other health care professionals with training on performing quantitative joint

## Your Photo Needed

ACMS members! Please send a recent headshot photo of yourself the medical society files, to be used with Bulletin articles and news items.

Send tiff or jpeg files via e-mail to lsmith@acms.org. Send prints to Linda Smith, ACMS, 713 Ridge Ave., Pittsburgh, PA 15212. Please indicate whether or not you would like them returned.
Christopher A. Troianos, MD (anesthesiology), was recently an invited speaker at two meetings with international audiences: the Annual Meeting of the American Society of Anesthesiologists and the Mount Sinai School of Medicine’s 30th Annual Clinical Update in Anesthesiology, Surgery, and Perioperative Medicine. He spoke on Guidelines for Performing Ultrasound Guided Vascular Cannulation: Recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists, a document that provides comprehensive practice guidelines on the use of ultrasound for vascular cannulation as an important practice to improve patient safety. Dr. Troianos, who was the document’s lead author, is professor and chair of Anesthesiology for the Western Pennsylvania and Forbes Regional Hospitals and West Penn Allegheny anesthesiology residency program director.

Send your Activities & Accolades items to Linda Smith at ACMS, 713 Ridge Ave., Pittsburgh, PA 15212 or e-mail lsmith@acms.org. We also encourage you to send a recent photograph indicating whether it needs to be returned.

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Shooting Photos for the ACMS Photo Contest

Because photos from the Bulletin’s annual photo contest are selected for use as cover’s for the magazine, care should be taken in shooting a subject from a vertical rather than horizontal perspective—that often means turning your camera on its side before snapping the photo. These examples illustrate how cropping a horizontal photo for use on a Bulletin cover can drastically alter the photo’s original intent. It’s always difficult for an editor to make these kinds of decisions, since the photos are little works of art best kept as originally shot. Details for the 2012 Photo Contest will be announced in the May Bulletin. Happy shooting!
**Continuing Education**


Free Online CME Activities. Sponsor: Pennsylvania Medical Society. All meet patient safety and risk management requirements. For information, visit www.pamedsoc.org/mainmenu/categories/cme/cme-activities.


Regional Mental Health Training Series. Sponsor: UPMC Western Psychiatric Institute and Clinic. For information, call (412) 802-6918 or visit www.wpic.pitt.edu/oerp.

This listing includes local events that are coming up soon; a more complete list is available on the medical society’s website at www.acms.org or by calling (412) 321-5030.

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April is the month for the following national awareness programs: autism, donate life, minority health, facial protection and sarcoidosis. April 21-28 is National Infant Immunization Week and April 22-28 is National Infertility Awareness Week. (Source: U.S. Dept. of Health and Human Services, www.healthfinder.gov/library/nho/)

April 24, 6-8 pm .............. ACMS Executive Committee
April 25, 5:30-8 pm ............ Pittsburgh Pathology Society
May 2, noon-5 pm............. American College of Surgeons
May 8, 10 am-12:30 pm...... ACMS Alliance
May 9, 8 am-12:15 pm...... OSHA Seminar
May 11, 8-10:30 am......... Practice Managers Forum
May 16, noon-3:30 pm..... Emergency Medical Services
May 18, 8 am-1 pm......... Three Rivers Adoption Council

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Permeability-glycoprotein (P-glycoprotein) is a molecular efflux pump that is responsible for translocating a variety of xenobiotics (foreign molecules) from an intracellular location to an extracellular location. It provides an important protective mechanism against potentially toxic foreign substances. P-glycoprotein sits in the cell membrane of the gut and searches for xenobiotics. When it locates one, it binds the molecule and then flips to a new conformation, expelling the molecule from the cell in the process. This entire process is mediated by ATP. Although P-glycoprotein is beneficial in that it helps to eliminate toxins from the body, it can have many negative implications on drug therapy. It is a very non-selective pump which ejects hundreds of structurally diverse molecules of varying sizes outside of the cell, many of which are important therapeutic drugs needed for medical treatment.1

P-glycoprotein is the product of the multidrug resistance 1 gene (MDR1 also known as ABCB1). It is a member of the ATP-binding cassette (ABC) family and was first discovered in chemotherapy resistant tumor cells that showed drug resistance due to an over expression of P-glycoprotein. This over expression was causing chemotherapeutic agents to be effluxed out of the cancer cell before they could exert their pharmacologic effects. It was later discovered that P-glycoprotein existed in a variety of normal cells involved with drug absorption and elimination such as the small intestine, liver and kidney and drug distribution such as the blood-brain barrier, blood-testis barrier and blood-placenta barrier. P-glycoprotein has three major effects on drug therapy: (1) limiting the absorption of orally administered drugs due to its expression in the luminal membrane of enterocytes; (2) increasing the elimination rate of drugs via the hepatic (bile) and renal (urine) pathways due to expression in hepatocytes and proximal tubule cells; (3) protecting various tissues (brain, testis and fetus) from toxic foreign molecules due to its expression in the respective barriers of those tissues. Although P-glycoprotein transports a variety of molecules, the majority are hydrophobic compounds and/or organic cations.2

The enteral route is the preferred method of drug administration due to a multitude of factors including convenience, cost and safety. The small intestine is the
primary site of absorption for orally administered drugs, with many factors influencing the bioavailability of these drugs including physicochemical properties and biological factors. In order for drug absorption through the small intestine to occur, the drug must diffuse or be transported across the apical (lumen) and basal membrane of enterocyte before entering the bloodstream. As drug molecules diffuse through the enterocyte, however, they are at risk for being transported out of the cell and back into the lumen of the small intestine by P-glycoprotein. This action can greatly reduce the bioavailability of drugs that act as substrates to P-glycoprotein.

P-glycoprotein is located throughout the entire intestinal tract, with expression increasing from proximal to distal regions. It acts to continually efflux the drug back into the lumen as it moves through the intestinal tract. Also, as previously mentioned, once drug molecules are absorbed into the bloodstream, P-glycoprotein increases the excretion of these substances into the bile and urine, and prevents substrates from crossing certain blood-tissue barriers. As with many other active transport processes, P-glycoprotein efflux is a saturable process that exhibits saturation/nonlinear kinetics. Based on these kinetics, when drug concentrations are at or near saturation levels, a dramatic increase in plasma drug concentration will occur. Due to these saturation kinetic principles, an increase in drug dose to the saturation point may limit the significance of P-glycoprotein on drug absorption. P-glycoprotein will, however, play a much bigger role in the bioavailability of molecules that intrinsically have poor bioavailability, making it difficult to saturate the P-glycoprotein receptor. The higher the passive transport that a molecule has across the enterocyte membrane, the less significant the P-glycoprotein mediated efflux will be. As with CYP450, there is a significant variation (10-fold) of inter-individual expression of P-glycoprotein, which can result in variable pharmacokinetic parameters between patients.

Cytochrome P450 3A, a major drug metabolizing enzyme in humans, and P-glycoprotein may act synergistically in the small intestine to further inhibit drug absorption. Along with P-glycoprotein, CYP3A is expressed in high levels in the enterocytes of the intestinal tract, although it is mistakenly thought to be only present in the liver. These two proteins share significant overlap in substrates, and substrates of both proteins have been shown to have poor bioavailability. The synergistic effect occurs as follows: A drug is absorbed by passive processes across the apical (lumen) membrane into the enterocyte. Once inside the enterocyte, the drug may be metabolized by CYP3A or effluxed back into the lumen by P-glycoprotein. This cycle of passive diffusion, followed by efflux by P-glycoprotein, allows CYP3A to have repeated access to drug molecules to metabolize them and allows the drug molecules to concentrate at less than saturating levels at CYP3A allowing more drug to be metabolized.

After outlining the mechanism of P-glycoprotein, it becomes quite apparent that it may be yet another potential source of drug interactions that should be taken into consideration when prescribing medications. Induction or inhibition of P-glycoprotein can significantly reduce or elevate drug concentrations within the body. The first drug interaction effecting absorption involving P-glycoprotein was recognized with digoxin. When digoxin was concomitantly administered with quinidine, a P-glycoprotein inhibitor, patients suffered from digoxin toxicity due to the resultant increase in
digoxin plasma concentrations. In fact, digoxin plasma concentrations are so dependent on P-glycoprotein activity that it is used to test substances to determine if they have any effect on P-glycoprotein. Studies utilizing P-glycoprotein deficient mice (mdr1 knockout mice) have implicated many other drug-interactions involving P-glycoprotein and have enhanced our knowledge on the efflux pump. Two different types of drug interactions may exist: a direct interaction with one or more of the substrate binding sites through competitive or non-competitive inhibition, or an inhibition of ATP binding, coupling or hydrolysis. P-glycoprotein appears to contain multiple drug binding sites, allowing two substrates to bind simultaneously at different sites allowing for potential allosteric interactions. P-glycoprotein induction has also been reported with several drugs. Interestingly, this induction of P-glycoprotein expression appears to be tissue-dependent with levels of induction varying depending on the tissue type. Possible P-glycoprotein inducers include dexamethasone, rifampin, clotrimazole, phenobarbital and St. John’s wort. Table 1 to the left provides a list of drugs that are known to inhibit or induce the actions of P-glycoprotein, as well as a list of P-glycoprotein substrates. It should be noted that these are not all inclusive lists. Interestingly, some drugs can be both inhibitors and inducers of P-gp. St. John’s wort initially inhibits P-gp and increases substrate concentrations, but subsequently enhances production of P-gp, thereby enhancing substrate clearance from the body.

Other clinically relevant P-glycoprotein interactions include P-glycoprotein inhibition by esomeprazole (Nexium), which was correlated to an increase in atorvastatin (Lipitor) concentration-ions. This interaction has been linked to a serious case of rhabdomyolysis. Along with clinically relevant drug interactions, it appears that some excipients (inactive ingredients) used in pharmaceutical formulations may interact with P-glycoprotein, thus impacting the pharmacokinetics of the active ingredient. Excipients that have been linked to these findings include cremophor and Tween 80. Certain foods such as grapefruit juice, black pepper and ginseng may also interact with P-glycoprotein. Another clinically relevant P-glycoprotein drug interaction that may be emerging is with dabigatran (Pradaxa), an oral direct thrombin inhibitor that was introduced to the market in 2010. Dabigatran is neither an inhibitor nor inducer of P-glycoprotein, or a substrate of the CYP isoenzyme family; however, it is a substrate for P-glycoprotein located in the intestinal tract. It shows selectivity towards P-glycoprotein located in the enterocytes because it is actually absorbed as dabigatran etexilate (a P-glycoprotein substrate) and converted to dabigatran (not a P-glycoprotein substrate) in the plasma. The P-glycoprotein inducer rifampin has been shown to reduce dabigatran plasma concentrations by 67%, whereas the P-glycoprotein inhibitors ketoconazole, verapamil, amiodarone and quinidine have been shown to increase dabigatran plasma concentra-

### Table 1. Selected Drugs That Affect P-glycoprotein

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<tr>
<th>Inhibitors</th>
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<td>Amiodarone</td>
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**Inhibitors:** Amiodarone, Clarithromycin, Colchicine, Cyclosporine, Diltiazem, Doxorubicin, Erythromycin, Esomeprazole, Felodipine, Fenofibrate, Indinavir, Itraconazole, Ketoconazole, Lansoprazole, Omeprazole, Pantoprazole, Paroxetine, Propafenone, Progerosterone, Quinidine, Ritonavir, Sertraline, Sirolimus, Tacrolimus, Verapamil, St. John’s wort

**Inducers:** Dexamethasone, Verapamil, Digoxin, Dexamethasone, Hydrocortisone, Triamcinolone, Aldosterone, Fexofenadine, Cimetidine, Cyclosporine, Tacrolimus, Omeprazole, Lansoprazole, Pantoprazole, Lovastatin, Atorvastatin, Saquinavir, Ritonavir, Nelfinavir, Indinavir, Lopinavir, Amprenavir, Etoposide

**Substrates:** Morphine, Erythromycin, Rifampin, Vinblastine, Vincristine, Paclitaxel, Docetaxel, Doxorubicin, Daunorubicin, Tamoxifen, Methotrexate, Venlafaxine, Paroxetine, Loperamide, Ondansetron, Carbamazepine, Phenobarbital, Phenytoin, Lamotrigine, Itraconazole
Ketoconazole has been shown to increase levels by 153%, quinidine by 53%, amiodarone by 53% and verapamil by a factor of 2.4. These increases in dabigatran plasma concentration may put the patient at a significantly increased risk of bleeding, especially if the patient already has poor renal function that would subsequently lead to a decrease in dabigatran excretion. Despite this evidence, Boehringer Ingelheim, the manufacturer of Pradaxa, does not require dose adjustments with these P-glycoprotein inhibitors. They do, however, warn against concomitant use with rifampin. Based on this evidence it would be theorized that other P-glycoprotein inhibitors and inducers would effect dabigatran plasma concentrations as well.

An appreciation for the effects of P-glycoprotein on drug absorption, distribution, metabolism and excretion needs to be taken into consideration when prescribing medications that are substrates, inhibitors or inducers of this efflux pump. It appears that interactions with this efflux pump may have significant clinical implications effecting the efficacy, safety and tolerability of many medications. As more is discovered about P-glycoprotein and its effect on medications, a better understanding of the necessary dosing adjustments and drug interactions involved with P-glycoprotein will be more fully understood.

**REFERENCES**


Mr. Yuhas is a PharmD Candidate at Duquesne University School of Pharmacy. Questions on this article can be directed to the Drug Information Center at Allegheny General Hospital (412) 359-3192.
Are You HIPAA Compliant?

Lee Kim, Esq

Recently, the Department of Health and Human Services (HHS) settled a case with Blue Cross Blue Shield of Tennessee (BCBST) for $1.5 million for potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. The enforcement action is the first resulting from a breach report required by the HITECH Act’s breach notification rule. This action resulted from BCBST providing to HHS a notice that unencrypted hard drives were stolen from a leased facility in Tennessee, which contained the protected health information (PHI) of more than 1 million individuals, including member names, Social Security numbers, diagnosis codes, dates of birth and health plan identification numbers. As a result of this enforcement action, BCBST has agreed to a corrective action plan to address gaps in BCBST’s HIPAA compliance program. BCBST has agreed to review, revise and maintain its HIPAA Privacy and Security Rule policies and procedures and to conduct regular and robust trainings for all BCBST employees covering employee responsibilities under HIPAA.

The HIPAA Privacy Rule establishes national standards for the protection of certain health information. The HIPAA Security Rule establishes a national set of security standards for protecting certain health information that is held or transferred in electronic form. The HIPAA Security Rule provides technical and non-technical safeguards that covered entities must put in place to secure individuals’ electronic protected health information (ePHI). A covered entity is a health plan, health care clearinghouse or health care provider who electronically transmits any health information in connection with transactions for which HHS has adopted standards. These transactions generally relate to billing and payment for services or insurance coverage. For instance, covered entities are hospitals, academic medical centers, physicians and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan. Covered entities not only include organizations and institutions, but also extend to individuals, such as physicians.

The Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, was enacted on February 17, 2009, as part of the American Recovery and Reinvestment Act of 2009. The HITECH Act requires that business associates comply with the HIPAA Privacy and Security Rules. A business associate is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A business associate may perform actuarial, accounting, consulting, data aggregation, management,
administrative, accreditation or financial services to or for a covered entity where performing those services involves disclosure of individually identifiable health information by the covered entity or another business associate of the covered entity to that person or entity.

Business associates typically enter into a business associate agreement that spells out its obligations under the HIPAA Privacy and Security Rules and the HITECH Act. Moreover, the HIPAA Privacy Rule requires that a covered entity obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information it receives or creates on behalf of the covered entity, such as in the form of a business associate agreement.

Prior to the HITECH Act, the HHS secretary could not impose a penalty of more than $100 for each violation or $25,000 for all identical violations. A covered health care provider, health plan or clearinghouse, at the time, could avoid such penalty by demonstrating that it did not know that it violated the HIPAA Rules. Now, there is no such avoidance of penalty under the HITECH Act.

The HITECH Act imposes both civil and criminal penalties. Civil penalties range from $100 to $50,000 per violation, with caps of $25,000 to $1,500,000 for all violations of a single requirement in a calendar year. The amount of the civil penalty imposed varies depending on whether: (1) the offender did not know and with the exercise of reasonable diligence would not have known of the violation; (2) the violation was due to reasonable cause and not reasonable neglect; (3) the violation was due to willful neglect but was corrected; and (4) the violation was due to willful neglect and was not corrected. Criminal penalties are up to $50,000 in fines and one year of imprisonment.

How does the federal government find out about who is violating HIPAA? (1) Anyone may file a complaint that there has been a violation of the HIPAA Privacy or Security Rule with the Office of Civil Rights (OCR), the enforcement arm of HHS. (2) The HITECH Act requires certain breach notification standards. In cases where a breach affects more than 500 individuals, health care providers and other covered entities are to promptly notify affected individuals of a breach, as well as the HHS secretary and the media. Breaches affecting fewer than 500 individuals must be reported to the HHS secretary on an annual basis.

Further, business associates of covered entities must notify the covered entity of breaches by the business associate. (3) The HITECH Act makes HIPAA audit and enforcement mandatory. The act requires HHS to provide for periodic audits to ensure that covered entities and business associates are complying with the HIPAA Privacy and Security Rules and breach notification standards. To implement the mandate, OCR is piloting a program to perform up to 150 audits of covered entities to assess privacy and security compliance.

In that vein, OCR announced a pilot program to perform audits of covered entities to assess their HIPAA Privacy and Security compliance. The covered entities to be audited include a wide variety of facilities of varying sizes, including very large health care systems and small physician practices. These entities will have an extensive review of their HIPAA Privacy and Security Rule policies and procedures, operations and documentation. OCR intends to audit health care providers, health plans,

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AUDIT RESULTS

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health care clearinghouses and business associates as part of its pilot program. Audits conducted during the pilot phase began November 2011 and are anticipated to conclude by December 2012. An initial set of 20 entities has already been audited. It is anticipated that another 130 entities will be randomly selected as part of this pilot program, including larger providers and payors with more than $1 billion in revenue and/or assets, large regional hospital systems, community hospitals, ambulatory surgery centers, regional pharmacies, community pharmacies and small health care providers.

If an entity is selected for an audit, it will first receive an audit notification letter from OCR. The letter will provide the following information: (1) basis for the audit; (2) the audit’s purpose; (3) an introduction to the audit contractor; and (4) contact information in case there are questions. (A sample audit notification letter can be found here: http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/sample-ocr_notification_ltr.pdf.) The audit contractor will then send a letter to the selected entity stating the following information: (1) an introduction to the audit team; (2) a timeline for the audit process; (3) a description of the initial document and information requests and associated deadlines for response by the selected entity; and (4) an opportunity to schedule a pre-audit conference call to discuss the on-site audit process and requirements.

Auditors will then conduct the on-site audit of the selected entity. The auditors will review the selected entity’s operations, policies and procedure and conduct interviews with personnel. The auditors will look for compliance, not only in terms of what is currently being done, but may also look at documentation of compliance dating back to the effective dates of the HIPAA Privacy and Security Rule in April 2003. After the on-site audit has been completed, the selected entity may receive additional follow-up questions from the auditors. The auditors will then compile a draft report for the selected entity to review. The entity will have the opportunity to comment on the report. In view of any comments by the selected entity, the auditor will either keep the original report or amend the report. The auditor will then forward the report and any comments from the selected entity to OCR for disposition. OCR will then decide on the outcome of the audit, which may be one of the following dispositions: (1) OCR may specify certain items that the selected entity needs to correct and may ask for voluntary remediation of these issues; (2) If significant issues are identified in the report that must be addressed, then a resolution agreement will be reached with the selected entity with agreed-upon changes in policies and procedures for HIPAA compliance; or (3) If there are serious deficiencies, then OCR may make the determination that further investigation or review is required. OCR will conduct the investigation or review (instead of the auditor); in this case, OCR may determine that the selected entity is in willful neglect of its obligations and may impose civil and criminal penalties.

The majority of HIPAA violations have been workforce violations, as opposed to external breaches, and these have been found with covered entities and business associates alike. Examples of HIPAA violations include, but are not limited to, the following: (1) No HIPAA Privacy and Security Rule policies and procedures are in place; (2) The HIPAA Privacy and Security Rule policies and procedures exist on paper, but these have not been implemented; (3) no HIPAA compliance officer; (4) inadequate or non-existent training on HIPAA compliance; (4) lack of regular security analysis and management of information systems; and (5) lack of documentation of compliance with the HIPAA Privacy and Security Rule.

Given the risk of significant fines and penalties, surprise audits and the prospects of negative publicity, it is quintessential for covered entities and business associates to review their current state of HIPAA compliance, identify any deficiencies and remedy any such deficiencies. In addition, covered entities should not only require that business associates enter into business associate agreements (or other written assurances), but should also investigate the business associates’ policies, procedures and documentation verifying such compliance. In other words, covered entities should use due diligence to ensure that the business associate will not breach its obligations under HIPAA. Otherwise, the covered entity may suffer the consequences in the event that the business associate does breach its obligations under HIPAA. For all of these reasons, HIPAA compliance by both covered entities and business associates is paramount.

Ms. Kim is an attorney with Tucker Arensberg and member of the firm’s Healthcare, Healthcare Information Technology, and Intellectual Property and Technology practice groups. She can be reached at (412) 594-3915 or at lkim@tuckerlaw.com.
Investing Like the Best: The Warren Buffett Way

GARY S. WEINSTEIN, MD, FACS

Warren Buffett, the CEO of Berkshire Hathaway, is widely considered to be the world’s greatest investor. Few duplicate his success because he purchases more than 80 percent of a company’s shares, joins corporate boards and directs the allocation of capital. He advises managers to ignore Wall Street expectations and “to think about what counts, not how it will be counted.” Although individual investors lack corporate influence, they can benefit from the advice he provides in Berkshire’s annual reports.

In 2007, he projected future stock returns of 7 percent annually (5% after inflation), consisting of dividends (2%), gross domestic product growth (3%) and inflation (2%). He cautioned investors not to expect higher returns from companies than their actual earnings (2005 report). In 1986, he observed that, “Bull markets can obscure mathematical laws, but they cannot repeal them.” Because future returns may be less than 7 percent, investors should have realistic expectations and be skeptical of financial professionals promising higher returns than mathematically possible.

Buffett avoided the 2000 high tech bubble by investing within his circle of competence. He warned that growth stock values are reduced when early cash investments exceed the discounted value of future cash inflows (2000). Investors often discount this handicap when trying to choose the next great growth stock or industry. Prudent investors follow Buffett’s advice to avoid speculating in areas outside their expertise, especially when it looks easy!

During the 2007-2008 financial crisis, Buffett warned that, because of the erosive effects of inflation, “Clinging to cash equivalents or long-term government bonds at present yields is almost certainly a terrible policy if continued for long.” In 1986 he advised, “Be fearful when others are greedy, and be greedy when others are fearful.” Investors who “stayed the course” or added equity in 2008 were rewarded with high returns. There is a high “opportunity cost” to waiting until it is “safe” to buy stocks, because most gains occur in a small number of days. Consider holding enough cash to cover possible emergencies (six months of living expenses) and major expenditures planned in the next five years. Excess cash beyond those needs should be invested according to your asset allocation plan.

Buffett observed that investors repeatedly enter the market long after an advance has been underway and exit after periods of stagnation or decline (2004). Market optimism and “cheery” consensuses are costly for rational buyers (1990) because they inflate stock prices (1997) and reduce future returns. Long-term savers should wish for lower stock prices (1997) and ignore political races, economic forecasts (1994), investment “tips” and fads (2004). These extraneous factors are always present and only serve as “distractions” for most businesses. Buffett wrote, “I never have
the faintest idea what the stock market is going to do in the next six months, or the next year or the next two.” Your best strategy is to always remain fully invested because the market’s direction is unpredictable.

Buffett believes if you are not willing to own a stock for 10 years, you should not own it for 10 minutes (1996). In 1987, he ignores the conventional Wall Street wisdom that, “You can’t go broke taking a profit,” by holding securities indefinitely if the expected return on capital, valuation and management are all satisfactory. He postulated a Fourth Law of Motion, “For investors as a whole, returns decrease as motion increases” (2005). You can minimize trading by owning broad-based index funds that only need to be sold for rebalancing or liquidation purposes.

The 2005-2006 annual reports introduced the fictional wealthy “Gotrocks” family, whose members attempted to become wealthier by trading shares of stock with each other. They hired brokers, money managers, consultants, planners, hedge funds and private equity consultants to advise them. These “helpers” consumed 20 percent of the family’s earnings and transformed the “Gotrocks” into the “Hadrocks” family. Buffett observed, “When someone with experience proposes a deal to someone with money, too often the fellow with money ends up with experience and the fellow with experience ends up with the money.” Calculate your own investment costs and work to reduce them to less than 0.2 percent annually.

Finally, Buffett emphasizes that investors need to do few things right if costly mistakes can be avoided (1992). “Know nothing” investors can actually outperform most investment professionals by periodically investing in low cost, diversified index funds (1993). In 1993 he observed, “When dumb money acknowledges its limitations, it ceases to be dumb.”

“Buff” up your portfolio and convert your savings into “smart” money by investing in diversified, low-cost index funds providing solid market returns.

Dr. Weinstein, a retired oculoplastic surgeon, teaches investing for Carnegie Mellon University’s Osher program and has co-authored a retirement planning chapter in J.K. Lasser’s Expert Financial Planning. Dr. Weinstein also serves as associate editor of the ACMS Bulletin. He can be reached at weinstein.gary@gmail.com.
Too often we hear or read of a child harmed by the mother’s paramour, who was inexperienced and poorly equipped to care for that child. While a mother may find it difficult to believe that someone she is intimately involved with could ever hurt her child, it happens; too often, a mother has placed her child in the hands of a lover, partner or boyfriend who should not be left alone with her child.

The Allegheny County Child Fatality/Near Fatality Review Team, chaired by Dr. Mary Carrasco, is mandated by State Act 33 to review all child deaths or significant injuries occurring in the county. In the three years since the act was implemented, the team has reviewed an unfortunately high number of cases resulting from this very scenario. These occurrences were the motivation for the 2011 Child Abuse Prevention Month campaign, Choose Your Partner Carefully—Your Baby is Counting on You. Now in its second year, the campaign encourages mothers to think carefully about whether their partner is responsible, mature and knowledgeable enough to care for their most precious possession(s). The campaign is a reminder that just because a woman is intimately involved with someone, it does not automatically mean that he is someone she can trust with her child(ren).

Two brochures were produced for the campaign; one is designed to guide mothers of infants and young children and the other is suitable for professionals who interact with children and families. These brochures were developed in partnership with A Child’s Place at Mercy, a part of Pittsburgh Mercy Health System sponsored by the Sisters of Mercy; Family Resources; Center for Health Equity, University of Pittsburgh Graduate School of Public Health; and The Fred Rogers Company. They were printed by the Allegheny County Department of Human Services.

As a pediatrician or health care provider who cares for infants and young children, you are among the trusted professionals a mother looks to for guidance. These brochures can be a helpful resource to assist you in reminding women that their partner choice has emotional and physical safety implications for their children.

The brochures include questions to help mothers think about one of the most important decisions she can make for her child’s safety: her choice of partners. Some of the questions are:

- How does your partner treat other women and children in his life?
- Does your partner get angry when you spend time with your child?
- Does your partner get angry or impatient when your child cries or has a tantrum?
- Does your partner call your child bad names or put him or her down?
- Does your partner think it’s funny to scare your child?

A “yes” to even one of these questions could be an indicator that the child’s welfare is at risk if left in the care of that partner.

Before a mother leaves her child(ren) in her partner’s care, she should know his experience in caring for babies and young children. She will want to make sure that:
Special Report

- her partner has the patience and maturity to care for an excited or crying baby;
- her partner understands that young children must always be watched;
- her partner will never shake, hit, yell at, make fun of or withhold food from a child as punishment;
- her partner will not abuse alcohol or drugs, carry a weapon or surround a child with others who do.

A child’s life may depend on how carefully a mother chooses her partner and answers these questions.

To order copies of the brochures for your patients, call (412) 350-3433 or e-mail christine.prendergast@alleghenycounty.us.

For more information about Child Abuse Prevention Month in Allegheny County, visit www.alleghenycounty.us/dhs/capm-overview.aspx.

Ms. Plunkett is communications specialist for the Allegheny County Department of Human Services. She can be reached at elaineplunkett@alleghenycounty.us.

Legal Summary

OIG’s First Salvo on Reassignment

On February 8, 2012, the Office of Inspector General of the U.S. Department of Health and Human Services (OIG), issued an OIG Alert advising physicians to be careful when reassigning their Medicare payments; they may be liable for civil money penalties (CMP) based on false claims submitted by the assignee.

While this is not a new theory of liability, the OIG issued the alert based on recent settlements it made with eight physicians who reassigned their Medicare payments to several physical medicine companies, allegedly in exchange for medical directorship positions. The physicians did not personally render or directly supervise any services while serving as medical directors; nevertheless, the physical medicine companies billed for services that were not performed as billed or not performed at all. Rather, the services were rendered by unqualified physical medicine “technicians” and billed as if personally performed by the physicians or by technicians directly supervised by the physicians. The OIG attributed these false billings on the physicians’ “failure...to monitor the services billed using their reassigned provider numbers.”

While the physical medicine companies and their owners were charged criminally, the OIG imposed fines under the Civil Money Penalty Law. Pursuant to the law’s implementing regulations, a person may be subject to CMPs if (1) he or she knew that a billed item or service was not medically necessary or deliberately ignored or recklessly disregarded such information, and (2) such item or service was part of a pattern.

Without the benefit of more details, it is difficult to state how this alert might be a sign of enforcement policies to come from the OIG. While the OIG’s current enforcement policy is based on the “knew or should have known” standard set forth in the CMP regulations, physicians nevertheless remain legally responsible for all services billed in their name and should take that responsibility seriously. Consequently, employed physicians should make sure that their employer has a robust compliance program that includes billing audits. Similarly, physicians who are independent contractors should not only carefully vet the entities to which they reassign their rights to payment, but also include in their contracts the requirement that the entity provide the physician with regular reports reflecting all services billed in the physician’s name. If a physician is already under contract, he or she should consider initiating periodic checks of services billed in the physician’s name. Under the reassignment rules, all physicians have the right to access data regarding claims billed under their name and NPI. If an employer or other entity to which the right to bill has been reassigned does not cooperate in providing access to claims data, the physician should contact his or her Medicare contractor (in Pennsylvania, Novitas Solutions, Inc., formerly known as Highmark Medicare Services) to obtain such data.

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Medical practices are often faced with the challenge of finding ways to increase efficiency. One of the most difficult areas that needs to be addressed is utilizing clinical staff effectively.

Medical practices utilize staff members who possess a variety of education, certification and experience. It is not uncommon to find medical assistants, licensed practical nurses and registered nurses working in medical offices along with a plethora of other types of technicians and clinicians. The first step in setting up a protocol-based system is to understand the various positions and levels of staff within your organization.

What can a registered nurse do that a medical assistant cannot? Does my practice need to employ nurses at all? Is hiring a phlebotomist necessary if other staff members can draw blood, as well as perform other services within the office? These are all questions that you need to answer. Knowing what type of staff members your office needs to employ is crucial in determining how you will provide care for patients.

The next factor to be taken into consideration is staffing levels. Keep in mind running your office “lean and mean” may not be the route you want to choose.

Some offices do extremely well using a ratio of support staff members to providers. I’ve seen offices that use a 1:1 ratio (one staff member to each provider) and I’ve seen 1:2 and 1:3 ratios as well. To determine this, you will need to look at several factors. How many patients are being seen? What services do we provide to our patients? Is the office utilizing electronic medical records? These questions along with cost factors will need to be taken into consideration.

How can a staff member’s “down time” be used to increase office productivity? Down time—what down time? You’re crazy! I have been told this before! Every medical practice has some slow periods. Physicians might be on vacation, or a provider may be ill and away from the office. Other times it could be a seasonal issue that causes a slowdown in patient volume. What can we have the support staff members do during these times? The good old standards like cleaning and organizing are always an option, but you might want to have staff work on quality initiatives or contact patients to schedule office visits for wellness programs. Of course, updating staff members on policy and procedure and holding training sessions can also be very beneficial. Once you have these issues in hand you can begin to design and implement the protocols that your office would like to have in place.

I like to use two types of protocol in our practice. The first is complaint based. This means that the staff member performs certain testing based on the patient’s reason for visiting the office on that specific day. If a patient has a sore throat, the staff member can perform a rapid strep test prior to the provider seeing the patient. If a patient exhibits symptoms that might indicate influenza as the culprit, why not perform a rapid influenza A and B test while rooming the patient? The provider can then have the results of this type of testing upon entering the exam room. You can design protocol around medical complaints such as cough, congestion, dyspnea, chest pain and any other complaint that is addressed by the providers regularly. This eliminates the need for the physician to tell the medical assistant or
nurse to perform the test and then wait for the results.

The other protocol that I utilize is problem or
history based. This is used to deal with the management
of certain disease states. For example, if a staff member is
rooming a patient who is a diabetic, the patient’s record
should be checked for certain testing that is needed to
manage diabetes. A few years ago I wrote a best practice
initiative that was geared towards increasing the fre-
quency of performing and documenting the results of
monofilament foot exams for diabetic patients. I con-
cluded that the best way to see to this was to have a
diabetic educator come into the office and educate the
clinical staff so that they could perform the foot exam
when rooming the patient instead of having the physi-
cian do this. The results are then documented utilizing a
template in the electronic medical record. This is a good
example of how a problem- or history-based protocol
works.

An added benefit of utilizing protocols is an overall
improvement in the quality of care provided by your
practice. During a time when major health insurance
providers have quality initiative and improvement
processes in place, I feel that the clinical staff can and
should be utilized in order to monitor and provide the
services outlined in these programs. This should greatly
improve the quality of care within the medical practice.

Finally, using a protocol-based system can bring the
whole team together. It allows your staff to be more
involved in the patient care process. They can now feel
like a “team player” as the outcome of their involvement
in the management of patients, and their problems can
easily be measured and shared with them. It may sound
cliché, but a good employee is a happy employee, and I
feel that happy employees are most often those whose
worth can be demonstrated and shared with them and
their “team.”

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a division of Genesis Medical Associates. He can be reached at
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As president of Gateway Medical Society (GMS), I want very much to thank the Allegheny County Medical Society for allowing this forum to discuss issues important to us. We are an organization that raises a voice for physicians of color and those physicians who care for the socio-economically challenged and underserved patients in the greater Pittsburgh community. Our central focus and mission is:

- to promote the health and general welfare of minority and socio-economically challenged populations in Southwestern Pennsylvania;
- to enhance the quality of health services by addressing racial and ethnic disparities in health care; and
- to enhance wellness by providing health education to the community.

Gateway Medical Society was formed 50 years ago by physicians Earl B. Smith, Oswald Nickens and Charles Bookert. GMS is a component society of the National Medical Association, an organization formed in 1895, a time when African-American doctors were not allowed to join the American Medical Association and were barred from most medical schools.

A part of our central focus and mission is to address racial and ethnic disparities in health care. The Centers for Disease Control produced an age-adjusted death rate per 100,000 persons by race. They looked at heart disease, prostate cancer, colorectal cancer, breast cancer, stroke, lung cancer, HIV and diabetes. African Americans have the highest death rate among all of these. If you look at breast cancer specifically, white women have the highest incidence of breast cancer; however, African-American women have the highest death rate. This is what we mean by disparities.

The American Medical Association reports 37,833 physicians are black, constituting 3.8 percent of the 985,375 physicians in the U.S. Black male doctors account for 2 percent of the overall total. To address the disproportionately low representation of African American (AA) males in health care, we first had to acknowledge the fact that, in Pennsylvania, black male high school graduation rate is approximately 58 percent as compared to white males at 84 percent, a 26 percent achievement gap as reported by the Foundation for Public Education. That report goes on to say that, besides low graduation rates, AA males are faced with demonstrably inferior education institutions, they do worse on the National Assessment of Educational Progress (NAEP), are disproportionately suspended and expelled and more frequently get assigned to special education classes.

Motivated by dire national statistics, in 2009, GMS started an enrichment academic mentorship program for AA males. Reviewing the results of existing programs, we initiated our program at the sixth grade level with 15 AA males selected from the Pittsburgh schools with parental interviews, letters from their teachers and academic evaluations. The sixth grade class, called Phase I, is a 10-month program curriculum that involves monthly scheduled lessons at the medical center’s human simulation center. These sophisticated computerized mannequins are placed in simulated emergency rooms, simulated ambulances and simulated ORs with planned lessons for the students. The students are trained...
in etiquette, to articulate, and are challenged to prepare and deliver oral presentations. During the simulation center experience they are all trained in basic CPR.

During the summer they had many field trips and a week-long science camp. At the end of the 10 months, Phase I students became Phase II, and a new Phase I class of sixth graders began.

The Phase II students continue to interact with the human simulators, but at a higher, more challenging level, and they start the Carnegie Learning pre-algebra modules. They are incentivized to perform academically by a cash reward each quarter for 4.0 grade point average. Since starting the program, the Phase II students’ average grade point has increased from a 2.9 to a 3.6, and five of the students routinely get 4.0s; all of the students are now above a 3.0. The pipeline will continue adding a new class of sixth graders every year with the older kids matriculating up to phase VI and graduating from high school. In 2012 we will start our first Phase III class, which will be ninth graders.

The Pittsburgh community has also been invested in the success of these young men. I want to take this opportunity to acknowledge the Heinz Endowments for their generous support to initiate the Journey to Medicine Youth Academic Mentorship Program of the Gateway Medical Society. Their continued support of our vision has been most appreciated. In addition to the Heinz Endowments, UPMC, the University of Pittsburgh, Highmark Blue Cross Blue Shield, the Allegheny County Medical Society, the Star Program at West Penn

Allegheny, the WISER Simulation Center of the University of Pittsburgh, The Falk Medical Library of the University of Pittsburgh, the PACE Foundation, Duquesne University’s Bayer Center for Non-Profit Management, graduate students and professors in the chemistry department at Carnegie Mellon University and countless individuals have contributed time, money and talents to the development of our students.

GMS has a robust 2012 agenda that includes:

1. A community symposium that each year addresses specific issues of disparity to fulfill our mission of providing health care education to the community. This year we are partnering with the Alpha Kappa Alpha Sorority. It is planned for Saturday, June 30th, 2012, at the Haberman Conference Center, UPMC Shadyside Hospital.

2. A provider symposium for physicians in which we address pertinent critical topics important to our practices. This year we may be partnering for the first time with the Allegheny County Medical Society to address the pros and cons of computerization of medicine. This event will take place on a Saturday in mid-September at the Haberman Conference Center, UPMC Shadyside Hospital.

3. The third year of our youth mentorship program (Journey to Medicine) has been recognized in three local articles and reprinted in papers around the country, including The Journal of Blacks in Higher Education; they also have been referenced in blogs. On January 12, 2012, the Journey to Medicine academic mentorship program received a Distinguished Achievement Award from the Pittsburgh Board of Education. GMS took in students with grade points that ranged from 4.0 to 1.5. After two years in our program, four students in that class have 4.0s and everyone else is above 3.0. One student who began with a 1.5 GPA now has a 3.4 GPA. We are presently accumulating a new sixth-grade class, and we are partnering with the University of Pittsburgh’s Department of Engineering mentorship program, Investment Now. Upon attaining the required GPA, our phase III students, soon to be ninth graders, will be eligible to apply for that program.

4. Awarding scholarships yearly to current meritorious University of Pittsburgh medical students of color.

5. Community partnership events, a fundraising gala

continued on page 171
Dr. Masucci found a better way.

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* Dr. Peter E. Masucci participates in athenahealth’s National Showcase Client Program. For more information on this program, please visit www.athenahealth.com/NSC.
and quarterly meetings that include an educational lecture and dinner to round out the year’s activities. Gateway Medical Society Inc., a 501(c)(3) organization, has just deployed a newly updated website (www.gatewaymedicalsociety.org), including a donate now feature for like-minded individuals who agree with the importance of our programs and wish to help financially. Each year our academic mentorship program grows by 15-20 students. We are approaching 60 students at present and, in three years when our pipeline has students in all six phases, we will have approximately 120 students each year. Because our students are in schools that do not have a full array of advanced placement courses, our goal for the future is to partner with CCAC to enable our students to take those courses during phases IV, V or VI. If possible, our students will not only get the necessary building blocks to be a strong candidate for colleges or graduate programs, they will graduate from high school with college credit, knowing that they already can handle the rigors of college courses.

Our critical need is for physician mentors and doctors who are willing to teach in any of our simulation sessions.

Also, as our students start phase III (ninth graders) and partner with Investment Now for math and science tutoring and PSAT and SAT prep, laptops are badly needed. I truly thank those who have donated refurbished laptops and promised to buy new ones; I encourage anyone else thinking of buying a new laptop for themselves, to donate their old ones to ACMS to be refurbished for our students. Again, we thank Allegheny County Medical Society for providing this forum for Gateway Medical Society to highlight some of the work the society does that could have broad-based appeal and far reaching effect on our community.

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In an eerie example of life imitating art, the scientific groundwork for human in vitro fertilization was being laid in the 1930s just after the literary description of the technique appeared in the novel, Brave New World, by Aldous Huxley. The fictional description of the removal of human eggs from the ovaries of “breeders” was echoed in a scientific description by Gregory Pincus in 1934. Pincus reported on the fertilization of rabbit eggs removed from the ovary. In the wake of public reaction to Brave New World, he received a great deal of negative publicity and lost his chance for a tenured position at Harvard.

One could argue that the 1930s brought the dawn of a new medical specialty: reproductive endocrinology and infertility. With each step towards actual human in vitro fertilization, public and religious criticism occurred, sometimes stalling progress and always raising important questions. Huxley’s dystopian description of a world where reproduction is separated from sex may seem to be ripped from the headlines in the 21st century. However, the once futuristic techniques of in vitro fertilization have resulted in the creation of thousands of families in the midst of childless situations, in contrast to Huxley’s world, where the family was non-existent.

In order to truly understand the remarkable events that brought forth the medical specialty that is endocrinology and infertility, one must consider the maturation of two parallel areas in human physiology: the elucidation of hormones and their actions, and the study of oocytes, sperm and the fertilization process. As of the mid-19th century, the control of reproduction was assumed to be mediated through the nervous system; the concept of blood-born factors responsible for reproductive processes was not yet validated. In a series of experiments, tissue extracts from various animals were removed and used to demonstrate in the first bioassays that specific factors exert effects in other organs. The “hormone theory” was born. Coincident to the research on mammalian fertilization and oocyte function as pioneered by Pincus and others, the 1920s and 1930s were a particularly active time in the development of endocrinology.

The isolation of steroid hormones and the many scientific endeavors that transpired to elucidate steroid hormone function in the reproductive arena continued at a steady pace during the mid-20th century. Gregory Pincus recovered from his early career setback, going on to co-develop the oral contraceptive with help from Margaret Sanger and the Planned Parenthood Federation of America. His research partners, John Rock and Celso Garcia, both obstetrician-gynecologists, oversaw the clinical trials of the first oral contraceptives in Puerto Rico, because prescribing any contraceptive was a felony in the state of Massachusetts in the 1950s. Clearly the development of the oral contraceptive gave women new control over their own reproduction—one of the seminal milestones in the advancement of women’s health.

Another major research area that would transform the understanding of the menstrual cycle and the initiation of puberty was underway here in Pittsburgh beginning in the 1960s. Ernst Knobil, who chaired the Department of Physiology at the University of Pittsburgh School of Medicine from 1961-1981, discovered the pulsatile nature of the pituitary secretion of gonadotropins in a series of elegant experiments in the rhesus...
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monkey. It is difficult to overstate the importance of these findings to contemporary medicine. From drug treatments for prostate cancer to the arrest of precocious puberty, many new developments in pharmacology were a direct result of these studies in primates, not to mention the applications within gynecology.

Meanwhile, the trial and error in human in vitro fertilization continued in the United States and in the United Kingdom, culminating in the birth of Louise Brown in 1978 in England. Many people contributed to the advances that led to the ultimate success, including John Rock, the oral contraceptive pioneer. Surgically oriented gynecologists worked to perfect methods to harvest eggs from the ovary, and biologists labored to understand the fertilization process and the growth requirements for the early embryo in a petri dish. In the end, it was the joint efforts of physiologist Robert Edwards and the clinical skills of obstetrician-gynecologist Patrick Steptoe that brought forth the first live birth, born to a couple who had struggled for nine years to conceive. This monumental achievement was recognized in 2010 when Robert Edwards was awarded the Nobel Prize in Physiology and Medicine. (Steptoe had died in 1988.)

As a result of these many historic scientific discoveries, reproductive endocrinology and infertility was recognized as a sub-specialty by the American Board of Obstetrics and Gynecology in the 1970s. The training involves a residency in obstetrics and gynecology, followed by a three-year fellowship. Patient care associated with this specialty is challenging and rewarding, since the entire female lifespan is impacted by the interplay of the hormones involved in the hypothalamic, pituitary ovarian axis. The approach to menstrual disorders, pubertal developmental disorders and management of menopausal hormonal replacement are important areas of clinical care. Surgery is also a significant component of this specialty, involving correction of acquired and congenital problems that impair fertility. Infertility presents a major life stress for women and men trying to conceive, and the ability to provide solutions requires patience, perseverance and meticulous attention to detail. In vitro fertilization is now an accepted treatment for nearly every infertility diagnosis and requires the coordination of clinical and embryology laboratory events. Research opportunities are plentiful, especially in the areas of neuro-endocrine function, embryology and implantation, and the hormonal control of pathologies such as uterine fibroids and endometriosis. New and potentially controversial frontiers include fertility preservation (egg freezing) and the use of pre-implantation genetic diagnosis. In the 21st century, reproductive endocrinologists are still at the crossroads of scientific advances and the ethical dilemmas that accompany them, challenged to uphold the best interests of women, families and society.

Dr. Albert is a medical director, Reproductive Health Specialists Inc., an independent practice specializing in reproductive endocrinology and infertility. She can be reached at jalbert@ivfpittsburgh.com.

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Who owns patient medical records?
The Pennsylvania health facility regulations specifically provide that hospital medical records are owned by the hospital. Although no Pennsylvania statute, regulation or case law directly addresses ownership of physician office records, the general consensus is that the physician office records are owned by the physician, not by the patient.

Physicians in Pennsylvania are required by state regulation to retain medical records for adult patients for seven years from the last date of service. Medical records for minor patients must be retained until he or she turns 19 (MD) or 21 (DO), a minimum of seven years. For more information on state regulations, visit www.pacode.com/secure/data/049/chapter 16/s16.95.html.

In the case of a physician who is in a group practice or employed by a hospital or other facility, who owns the medical records?
Physicians who are in a group practice or employed by a hospital or other facility should address ownership of medical records in an applicable partnership, employment, or other legal agreement.

Are patients entitled to a copy of their medical records?
Physicians are legally required under state and federal law to provide patients with access to their medical records. Patients must be permitted to review and obtain copies of their medical records. Medical ethics also require that patients be given access to their medical records.

However, in certain situations, it may be appropriate for a physician to withhold information from a patient to protect the patient or a third party from harm. These situations typically involve patients who have received mental health treatment.

Must a physician turn over the original medical record to a patient?
As noted, office medical records generally are considered to be the property of the physician or group practice. As a general rule, patients (and their designees) are only entitled to review their medical record and obtain a copy. However, when requested by patients (or their representatives) mammography facilities must provide original (not copied) mammography films.

Is a subpoena required for patients to obtain access to their medical records?
No. However, patients need to sign an authorization form and, if the patient would like someone other than himself or herself to receive a copy of the medical record, it should be noted on the authorization form.

When patients request a copy of their medical records, must the physician turn over records forwarded by other providers?
The Pennsylvania laws and regulations say: “Clinical information pertaining to the patient which has been accumulated by the physician, either by himself or through his agents, shall be incorporated in the patient’s medical record.” That includes medical records forwarded by another office. Any information in the medical record should be copied and forwarded to the patient, or the physician may face disciplinary action, not only at the state level, but the federal level under HIPAA.
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