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Opinion

Medical Editor ...................... 294
DNA Database Risks to Privacy and Safety
Deval (Reshma) Paranjpe, MD, FACS

Editorial ......................... 296
Core Values
Amelia Paré, MD, FACS

Editorial ......................... 300
Towers in Medicine
Anna Evans Phillips, MD

Perspective ..................... 302
Pharmaceutical Pricing in the United States of America: Disease or Symptom?
Bruce Wilder, MD, MPH, JD

Perspective ..................... 304
Caring for the Elderly Requires Compassion and Communication
Ed Kelly, MD

Perspective ..................... 306
In Aging Western PA... the Eyes Have It
Miguel A. Busquets, MD, FACS

Perspective ..................... 308
On Compassion
Kris Gopal, MD, FACS

Society News ...................... 320
Dr. Robert Cicco Guest Speaker at University of Pittsburgh Medical Student Luncheon

Society News ...................... 321
Medical Student Career Speed Dating Event – Monday, October 22, 2018

In Memoriam ...................... 321
James Raub, MD

Alliance News ..................... 322
Medical Marijuana Expert Jane Binakonsky Guest Speaker at Alliance Meeting September 18

Legal Report ..................... 310
Criminal Prosecutions, Insurer Actions Put Squeeze on Suboxone Prescribers
Beth Anne Jackson, Esq

Special Report ..................... 312
Stop the Bleed Campaign
Jehangir Badar, MD, FACS

Materia Medica .................... 314
Andexanet Alfa (Andexxa®), a New Factor Xa Inhibitor Reversal Agent
Kurt W. Wolfgang, PharmD, and Mark Black, PharmD Candidate

On the cover

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Kimberly A. Hennon, MD

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Dr. Cerejo earned her degree at the Seth Gordhandas Sunderdas Medical College in Mumbai, India. After completing her residency in internal medicine at Jacobi Medical Center in The Bronx, New York, she gained additional expertise during her fellowships at the Cleveland Clinic in critical care medicine and in sleep medicine.

Certified by the American Board of Internal Medicine, with specialized certification in critical care medicine and sleep medicine, she is a member of the American Academy of Sleep Medicine and the Society of Critical Care Medicine.

Dr. Cerejo sees patients at AHN Center for Sleep Medicine-West Penn Hospital in Pittsburgh.

Philip Lee, MD, PhD
Neurosurgery
Dr. Lee provides advanced and innovative care for patients with complex neurosurgical conditions. He has experience treating a wide variety of neurosurgical disorders of the brain and spine, and specializes in treating patients with epilepsy. His advanced training includes intraoperative speech and motor mapping. He also performs intracranial electroencephalography, neuromodulation, and laser thermal ablation for epilepsy.

After earning his doctoral degree in clinical psychology at George Mason University in Fairfax, Virginia, Dr. Lee completed an internship at Children’s National Medical Center and a postdoctoral fellowship in developmental cognitive neuroscience at Georgetown University in Washington, DC.

Dr. Lee attained his medical degree at the University of Pittsburgh School of Medicine and completed his neurological surgery residency, with a fellowship in epilepsy and functional neurosurgery, at the University of Pittsburgh Medical Center.

He is a member of the American Epilepsy Society, Congress of Neurological Surgeons, and American Association of Neurological Surgeons.

Dr. Lee sees patients at AHN Neurosurgery in Pittsburgh and Brackenridge.

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It was only a matter of time. The recent announcement that GlaxoSmithKline bought a $300 million dollar stake in the leading genomics company 23andMe and now has exclusive rights to 23andMe’s DNA data for drug testing research should come as no surprise to those of you who have been watching the intersection of technology companies and genomics. DNA, the ultimate identifying personal information, is now a commodity like the rest of your data. It’s official: nothing is sacred.

Over five million people have spat in a test tube, paid a fee, and sent their samples to 23andMe for analysis; about 80% have consented via an online consent form to allow their data to be used for research purposes. Now that big business has become involved, and those customers realize that the DNA that they paid out of pocket to have analyzed has been sold to and is now essentially the property of a pharmaceutical giant to be used for monetary gain, many are outraged.

I haven’t seen it mentioned yet in the press, but this brings to mind the infamous case of Henrietta Lacks, an African-American patient who did not consent to and was unaware that an immortal cell line (HeLa) had been cultured from her tumor biopsy in 1951 at Johns Hopkins (with further samples taken at her autopsy). Furthermore, this immortal cell line was used not only for research (Jonas Salk used it to develop his polio vaccine) but also for commercial purposes to generate profit. The Lacks family was never compensated. Worse still, the HeLa genome—and hence their personal genetic data—was made public without their consent. The extreme violation of privacy to which the Lacks family was subject over the decades is singular, but may be singular no more.

In an era where profit is king, what’s to stop parties from buying your actual DNA sample and replicating it—or you, one day? You can withdraw your consent to share DNA data, but it takes 30 days to take effect, and any data that’s been shared already can’t be taken back from the companies who now have it. You cannot have your data scrubbed from the books; by federal law, clinical labs are required to keep data on file for 10 years. You’re stuck. And perhaps you’re ok with this; let the pharma companies get rich, if it means that treatments for diseases comes from the research. After all, if not for the unknowing and unwilling contribution of Henrietta Lacks, polio might not have been conquered. But wait. When there is that much money at stake, how can you trust these companies to act ethically and honorably?

According to a recent Wired article, 23andMe acknowledges that a DNA database is not enough, and phenotypic data is crucially needed to correlate with the DNA information. To this end, they send customers endless questionnaires and happily capitalize on the average Joe’s
willingness to talk about himself or herself. Did I say Joe? I meant Patsy.

Once you supplement your DNA information with voluntarily donated phenotypic data about your height, weight, allergies, preferences and medical conditions, you have basically voluntarily assisted 23andMe to circumvent HIPAA with your own two hands. What’s so dangerous about this? Your previously “de-identified” data is now potentially identifiable. You can be “doxxed,” or identified as you, down to your address and social security number. How?

A recent CNBC article revealed that Facebook was recently in talks with several major hospitals and medical groups about a proposal to share data about the social networks of patients and include data about medical conditions and prescriptions. This would then presumably be cross-referenced against every profile on Facebook (are you regretting that post about your gall bladder surgery yet?) and it would be easy to identify individuals.

“The idea was to build profiles of people that included their medical conditions, information that health systems have, as well as social and economic factors gleaned from Facebook. Facebook said the project is on hiatus so it can focus on “other important work, including doing a better job of protecting people’s data.” (Christina Farr, Wired).

In other words, before it was exposed, Facebook was hoping to circumvent HIPAA and doxx you——and share the information for financial gain, presumably with anyone willing to pay for it. This could include not only pharmaceutical companies but health, life and disability insurance companies which would raise your rates or deny you coverage outright accordingly. Even more concerning—the data could be sold to clearinghouses who could in turn sell to persons with criminal intent like identity theft or worse.

Ironically, it is the government that is interested in our privacy at this point and free enterprise that builds its empire contingent on our willing surrender of that privacy. HIPAA still protects us to some degree (see my previous article on state health care data clearinghouses for an eye-opener). At this point, the government only takes DNA samples from criminals. Police departments are now solving cold-cases using data from 23andMe to identify relatives via perpetrators’ DNA samples and thus identify the perpetrators. This is wonderful, but the logical next step would be to require that everyone provide not only a fingerprint but a DNA sample for a national database when filing for a Social Security card or at the next routine blood draw in the name of preventing fraud and crime? This has not come to pass—yet—it would be hard to pass such an invasive law or enact a regulation when there is an argument to be made about unreasonable search and seizure. But perhaps we need a different kind of law.

Europeans have already seen the harm in databases which can be used or cross-referenced to identify individuals. The General Data Protection Regulation took effect on May 25, 2018 and institutes high fines for failure to ask permission from consumers to collect any sort of data, disclose promptly what data will be used for and report data breaches expediently. This applies to US companies doing business in the EU as well. The history of strict data protection regulations in Europe stems from the most horrible data abuses—those of Nazi Germany which systematically collected and used personal data (such as synagogue rosters, etc) to execute a genocide of Jews and Gypsies and the wholesale slaughter of millions of others.

A national database is inadvertently being formed by for-profit entities via data donated by trusting people who may realize too late what they are giving up in terms of privacy and safety. At this point, I can only say: beware of vampires. Vampires can only enter your home if you invite them in; they can only bite you if you allow yourself to be hypnotized and offer them your neck. And like vampires, for-profit enterprises find your blood—and your saliva—essential for their survival.

Dr. Paranjpe is an ophthalmologist and medical editor of the ACMS Bulletin. She can be reached at reshma_paranjpe@hotmail.com
The Allegheny County Medical Society is at a crossroads. The healthcare landscape may be changing but our core ideology remains the same with an envisioned future. Jeremy Bonfini began July 1 as our new CEO and Jack Krah will be available to the end of 2018. The Board convened a meeting to explore our strategic plan in July.

For any membership organization there must be 2 principles: core ideology and an envisioned future. Core values are “What are we here for?” “Why do we exist?” These are enduring characteristics of the organization. It is more important for the members of ACMS to know who ACMS is more than where we are going. Core values are not always a competitive advantage (Chick-fil-A is not open on Sunday) but, that is not the purpose of having core values. The introspection to determine core values brings members together. The ACMS tag line is Leadership and advocacy for patients and physicians. Often times, people may assume that ACMS exists simply to gain members and dues. While this is an important result of our existence, it is not the soul of ACMS. Raising membership is not the real reason for our being. With input from members and the board strategic planning, we inevitably come to the conclusion that as a group together we exist as an institution to accomplish something collectively, that we could not accomplish alone. We all hope to make a contribution to our daily lives, our current society and for generations to come. The desire to work together pushes us to determine our legacy. Purpose - this principle should last for decades and should be pursued, but may be unobtainable. This North Star principle should guide us through tough times and inspire change to meet these obligations. The fact that purpose may never be fully realized means that an organization can never stop stimulating change and progress. How do we develop and improve upon our core purpose? Some have advocated asking, “What core values do we bring to work each day?” “What core values would you tell your children about your organization?” Can you envision these values being sustainable in 100 years? What values would you hold onto despite competitive disadvantages? If you changed your industry, what core values would you bring with you regardless? What deeper sense of purpose would motivate you to continue to dedicate your energy to our collective efforts?

This deep thinking creates a distinction in our organization about what principles should remain despite changes in healthcare. I believe the organization exists to provide information to members that will allow them to be better doctors and more productive members of society. The legislative advocacy efforts benefit members and patients alike. I do believe that if you build it (the organization), they will come. When people look to our accomplishments, the accomplishments should not be reduced to numbers, but purposeful actions. Do we improve the daily lives of our members by advocating for them and their patients?

I welcome all members to join in the conversation and spend some time to share their aspirations with the Board of ACMS and be committed to our common goals. We may be contacted through the website or by calling ACMS.

Membership organizations strengthen the social fabric of our local and state communities by informing and empowering members through legislative action and social change. We are the foundation of a healthy community. Core values inspire our members. People say that people are not joining organizations. I disagree. People are more selective and have more options. People join organizations that they believe in.
The ACMS Board began exploring our core values in July to allow us to look at the horizon for our envisioned future. These objectives are what our membership wants to achieve. Maybe ACMS would become more of a philanthropic organization while the state society continues the advocacy efforts in Harrisburg. Many members have asked about volunteering efforts, for example the Mercy Free clinic. It uses the physician’s expertise for those less fortunate. These efforts do not always require money, but time and commitment. These achievements will require change. This change may require streamlining, developing new business plans and determining short term goals, while never losing site of our core values. As Peter Drucker pointed out, “The best and most dedicated people are ultimately the volunteers for they have the opportunity to do something else with their lives.” With increasing cynicism about the role between physicians and patients, we as a membership organization are confronted with a mobile, technically savvy base that demands change at a more rapid pace. What would have worked in the past will not work now. Look at Kodak. In order to maintain our organization, we must be focused on short and long term goals and communicate them effectively to our membership. Ideology cannot be faked; our members will not be fooled.

Allegheny County Medical Society’s tag line is Leadership and advocacy for patients and physicians. This core value should be attractive to all members within the organization. You cannot get people to share this core value, instead you must make our values known and attract members that share these values enough to devote time and money to the endeavor. Core values do not destroy diversity; on the contrary, people within a core ideology often come from diverse backgrounds and perspectives. The diversity is fertile ground for change that will be required to protect these values over the decades of external requirements.

Once our organization is clear about our core values, anything else may change to allow these values to survive. It is unacceptable to say, “We have always done it that way” or that it is “part of our culture, our DNA.” Change should be expected, and embraced and nurtured to adapt to the changing environment. Envisioning the future of the organization should consist of 10 to 30 year goals with vivid descriptive methods to achieve them. Ironically, an envisioned future implies concreteness, but may need to factor aspirations/dreams along an unexpected path. These goals should be clear and compelling serving as a unifying focal point of effort and serving as a catalyst for team spirit. These goals require thinking beyond the current capabilities of the organization and current environment. This is what is thought of as visionary and strategic. Often goals must be vividly descriptive to compel people to join in the enterprise. For example, a visionary goal may be to create a safe haven for new ideas that permit social justice and fight disparities in medicine. This may require partnering with like-minded organizations like the Gateway Medical Society. For ACMS, we have had a long standing relationship with Pennsylvania Medical Society. It was not that long ago that ACMS sent out separate billing and dues statements. ACMS provides grass roots advocacy and philanthropy that is unparalleled. The Pennsylvania Medical Society may help ACMS with programs, lobbying efforts in Harrisburg and information on new CME, and filing amicus briefs after Supreme Court rulings that are unfavorable. Working with like-minded organizations will promote debate about advocacy for patients and physicians; therefore, both groups benefit in the success.

ACMS may adopt a vision to democratize health care to promote the idea that all citizens making a good salary will be assured the stability and safety of fair responsible healthcare. This requires bringing stakeholders from industry and healthcare providers to broker fair rates for fair service. Harold Miller has reminded us that a healthy community is a productive one. We may not always rely on our legislature to mandate these ideas, but instead become leaders in the community to dispel disputes and manage overall social well-being. There will be winners and losers but we must persuade members that it is imperative to the well-being of our communities. It may start with a short term goal of transparency in cost and services and grow to improve effectiveness. No one would dispute that these are reasonable starting points.

Continued on page 298
Being leaders in healthcare can be lonely and is not without risk. Our state society believes that by advocating for JUA insurance through persistence and litigation that it will allow doctors to be able to use it in order to practice medicine. That legal win cost over $30,000. JUA insurance was never intended to be a tool to balance the state budget and may be challenged again. We need the house of medicine to stand up for doctors and their patients.

Some may be uncomfortable with expressing emotions about dreams for the society but often it will motivate others. Our members want to be part of a successful team that advocates and leads in healthcare in our region and works with the state society on issues that affect doctors across the state. We cannot be afraid of change but must embrace it.

Currently there are two proposals that are outlining the intersection between the state and local societies. ACMS provides a worthwhile service at the grassroots for advocacy and philanthropy. The state society is positioned to connect with Harrisburg in a more nimble manner. We must work together to avoid duplication of services and enhance our “boots on the ground”. Our success is their success and visa versa. Dues collection is an administrative task, our core mission and our envisioned future transcends these administrative tasks.

Furthermore, the HOD should be more nimble and use technology to assist our members and to be part of the Board discussions. The task force on the Virtual HOD has reviewed the Colorado model and recognizes that it allows for members to get updates on areas of interest and weigh in on issues directly with their Board member. This is available now. However, the Colorado model has created a formal website and ability to post information attached to the members name and even vote on decisions made by the Board. If the membership majority feels that the Board made a poor decision, then the topic is restudied at the next meeting and the salient points are posted again. As Board trustee you may contact me at any time amyparemd@aol.com. The Colorado tool polls members on a regular interval on topics that the members express an interest in (i.e. medical marijuana, CRNP…). This allows for diversity in ideas and accountability at the Board level. The daily Dose and EVP share and publish this information, but this Colorado virtual House model allows another way for members to be as engaged throughout the year. This will not diminish the social appeal of the physical meeting; however the meeting may be shorter and segmented to allow people to come for a portion of the meeting. The HOD costs nearly $400,000 for the state society in its current form.

The state and county societies toil to make their communities better. We must hold the torch of medicine fueled with knowledge and advocacy for our patients and physicians. Often this torch may cast a shadow that will require introspection or reflect light on areas that could be improved.

Only through constant introspection, core values and visionary goals will the society resonate in the community for decades to come.

Come join the conversation. Join the PA Med advocacy efforts through PAMPAC on preauthorization, CRNP legislation, informed consent bill, legislation on admissibility of information in informed consent, blocking JUA grab, tax on surgery centers, STATE tool kit for diabetes, opioid crisis legislation, or marijuana task force. Join ACMS in its grassroots advocacy in meeting with local insurers and employers, meeting with state legislators (i.e. Representative Turzai and Mustio), or the county health department. We look to our new CEO Mr. Jeremy Bonfini to be a steward of our members vision and propel us in to the future. Contact me with ideas.

Dr. Paré is a plastic surgeon and associate editor of the ACMS Bulletin. She also serves as district trustee for the PAMED House of Delegates. She can be reached at apare@acms.org.

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One afternoon earlier this year, the on-call pager alerted me to the admission of a 94 year-old woman who arrived at the hospital after being found unconscious by her family. Within the first 24 hours, no less than eight services were consulted: Hematology/Oncology, Nephrology, Internal Medicine, Endocrinology, General Surgery, Urology, Cardiology, and Gastroenterology. It soon emerged that she had breast cancer for over two years that never bothered her. Although her family lived nearby, she preferred to continue with her daily life, unabated by appointments, testing, and treatment. When she regained consciousness, she stated quite adamantly that she had every intention of continuing without them. No one had apparently ever bothered to ask her wishes before.

That same afternoon, a second patient – this time an 81-year-old woman - arrived at the hospital with altered mental status. Within 24 hours, eight different services (including mine) were consulted. I arrived at her bedside to find her pleasant but frightened. As we started to talk, she became overwhelmed by the information that each specialist had offered at her bedside and began to cry.

In the end, both women declined all of the specialty care, eventually choosing for themselves a route focusing on only the care that would allow them to remain comfortable for the remainder of their lives.

In our fragmented health system, we providers often approach patients from what are sometimes thought of as silos of medicine: each subspecialist focused exclusively on her specific organ system. These towers (or departments), with their distinct realms of expertise, should be linked together like a carefully constructed erector set. However, the system can be more accurately compared to a game of Jenga, full of holes and ever more top-heavy over time, eventually imbalanced enough that the whole thing comes toppling down – often on top of the patient themselves.

The situation is not for lack of interest in patients themselves. During almost every interview for a health care trainee, be it medical school, physician assistant, or nursing, I suspect that the interviewee declares “I want to help people,” at least one time. Yet in our fractured system, providers’ tasks often do not include direct help to patients: instead we are tasked to evaluate the data collected on a patient in order to diagnose a disease and prescribe an appropriate treatment. The result is patients who not only find the system inscrutable but actually often opposed to their own conception of health.

Recent criticisms of patient care have focused on the costs of overtesting and overtreatment in our health care system but these are rarely linked to the way our care system functions like independent towers of knowledge and repositories of resources, without any communication at ground level. For example, Barbara Ehrenreich, in a recent column promoting her new book, *Natural Causes*, accuses physicians of “testing us to death” in the name of preventative care. She portrays health care specialists— including primary care doctors, gynecologists, and even dentists – as a bit clownish and narrow-minded, making absurd suggestions for screening procedures and preventative measures. She not only portrays specialists as unable to defend their suggestions adequately, but also describes them as expecting patients to nonetheless “gamely submit” to the regime of testing.

How I wish I could defend us all, and claim that I had never before found myself on the doctor side of such a situation! Though she doesn’t make the connection, I suspect underlying her critique is fragmentation as much as
overtesting: at its core, her experience was of no one ultimately looking out for the patient – in this case, her.

Despite consultation of eight specialty services offering to investigate their individual organ systems, my patients that day wanted none of it. On admission, a question about the patient’s wishes and desires should be uttered in the same breath as that with which a specialty consultation or test is ordered, supplemented by a reason-able and understanding exchange with patients about their desire for addi-tional testing. Instead, we as prac-titioners seem to continuously struggle to put patients’ needs first. Subspecialists have specific ideas about what they want to do and what they want to know, but these have value only if they can be brought together to facilitate a patient’s health. Though our testing may generate more information, it may result in less understanding. Thinking of specialists and tests not as crutches to be deployed but as integrated components of patient care is increasingly important: our patients’ health will most likely benefit, and the collegiality and strength of collaboration between providers will likely deepen.

Dr. Phillips is associate editor of the ACMS Bulletin and a gastroenterology fellow at UPMC; her research is focused on pancreatitis and genetic cancer syndromes. She can be reached at bulletin@acms.org.

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The opinion expressed in this column is that of the writer and does not necessarily reflect the opinion of the Editorial Board, the Bulletin, or the Allegheny County Medical Society.
Pharmaceutical Pricing in the United States of America: Disease or Symptom?

BRUCE WILDER, MD, MPH, JD

It is no secret that the prices of many prescription drugs in the United States are exorbitant, as has been documented in the media so well and so often that it hardly needs specifics in the short space of this article (for some specifics, see Note 8 below).

Standard justifications for such outrageous prices include the idea that drug companies need to spend lots of money to develop and bring a drug to market, and that they couldn't possibly do it without the prices they ask. This is at times ironic, in that much of drug development is being done in universities with public funding. Another standard argument is that drug safety cannot be assured if drugs are imported from other countries where the price for an identical drug is significantly lower.

While these arguments may have merit in some instances, by and large they are smokescreens for the perpetuation of an unconscionable ripoff of patients. The idea that competition and price transparency will have any significant effect may apply to non-essential consumer products is simply not apposite to today's pharmaceutical market. For the most part, people with serious illnesses do not have the luxury of shopping among competitors for the lowest price, or simply deciding not to buy, if the price is beyond their budget. Moreover, we should be asking ourselves why people with illnesses they did not choose to have be the ones to fund drug research and marketing (especially if they have no control over how that funding is used). A price tag in the hundreds of thousands of dollars that must be borne by an individual patient, of a drug that could cure a potentially fatal disease seems a lot like ransom.

Some health insurers use their clout to negotiate prices, but also have varying degrees of restrictions on coverage. Individuals without insurance, or with health savings accounts, have virtually no negotiating power at all.

A major source of the problem is our system of intellectual property law relating to drug patents, in large part influenced by the powerful pharmaceutical industry lobby. A number of legal maneuvers to protect and extend intellectual property rights, doubtless due to the efforts of the pharmaceutical lobby, include the development of so-called “me too” drugs (sight modification of a drug to in effect extend the patent), and “pay for delay,” or “reverse-payment” settlements (paying generic manufacturers to settle lawsuits challenging the validity of patents). More recently, the sovereign immunity status of Native American nations has been exploited by transferring a patent and paying a few million dollars for an exclusive license (under the doctrine of sovereign immunity, a nation cannot be sued without its consent). On the flip side, compulsory licensing (akin to the concept of eminent domain in real property law), a legal means for government to license patented drugs to generic manufacturers to lower drug price is an available but seldom used process. Its critics claim that it will threaten innovation, but it seems appropriate in a situation where the public health benefit is clear, the price is prohibitively high, and the development of the drug was largely funded by public money.

The availability of drugs to people with illnesses that they mostly have no say in acquiring ought to be treated primarily as a public good, rather than an opportunity for corporate and shareholder profits. A notable exemplar of the current business-oriented philosophy is Pfizer’s recent decision to discontinue research in Alzheimer’s and Parkinson’s. To be fair, a few token measures have been enacted over the years, but the effect has been minimal. Overall, government has had little or no power to regulate the pharmaceutical industry in a meaningful way as far as drug pricing goes (of course the FDA has considerable power – although in the view of some, not enough – as to
ensuring safety and efficacy).

Despite a campaign statement that drug companies are “getting away with murder,” Trump’s recent proposal to lower drug prices is little more than lip-service and still does not allow Medicare to negotiate drug prices. It is simply window dressing that represents a virtual capitulation to the powerful pharmaceutical lobby and will accomplish nothing.

Much can be done. If they are serious about drug pricing reform, Congress and the President should convene a Commission to study and report on the causes of high drug prices in the United States, and make recommendations for a fair and equitable framework for drug pricing. Much work along those lines has already been done. The work of the US-Canadian Pharmaceutical Policy Reform Working Group, should serve as a starting point; a governmental Commission would carry considerably more weight in effecting needed policy reform. Such a Commission should be tailored to fit our existing health care financing system, but should also be suitable for transition to a single-payer system. It should study systems in other countries, and its members should include researchers, legal experts in the field, practicing physicians, and patient advocacy entities, all of whom are vetted for the absence of significant ties to the drug industry. The voice of “stakeholders” can be heard via a formal public comment period prior to issuance of the report, as can the voice of the purchasers of drugs.

At the root of our problems with drug pricing and drug shortages lies the enormous economic clout of the drug industry, to which members of Congress are beholden for campaign contributions – something that Professor Lawrence Lessig, despite its being legal, has termed “dependence corruption.” Or, in the words of Alain Braillon, “. . . the pharmaceutical system is only one of the by-products of a bigger system. Symptomatic treatment cannot be adequate for a most serious disease such as the plague of corruption.”

Dr. Wilder practiced neurological surgery in the Pittsburgh area. He currently is of counsel in the law firm of Wilder, Mahood, McKinley and Oglesby. He can be reached at bulletin@acms.org.

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Caring for the Elderly Requires Compassion and Communication

ED KELLY, MD

Many of us have crossed the hurdle where we are now referred to as “senior.” Thus, we have lived long enough so that we are able to embark on the journey referred to as the “golden years.” That term connotes that we will enjoy a life of leisure and pleasure which we have worked long and hard for. A bit of reflection perhaps will open our minds to what lays ahead and why the future may be not quite as smooth as we had expected. We have heard that being healthy will allow us to enjoy the many activities during retirement of which we have dreamed. However, pause for a moment and ponder as to how much health care spending goes to the elderly. I could list incessantly some of the problems that we may face – prostate, gynecologic, visual, musculoskeletal, mental health, gastrointestinal, and there are many more. Perhaps we may be fortunate and not develop the myriad of conditions which may afflict many senior citizens. Allow me to spend a few moments describing how and what I learned about the seniors in my life and practice.

I am the youngest of nine children. I spent most of my early adult years in locations other than Pittsburgh pursuing my education and satisfying my military obligation. When I left home my parents were in their late fifties and fairly active. I chose to return to Western Pennsylvania because of a practice opportunity, and I recall an awareness that my Mother and Father were close to twenty years older than when I lived at home.

Although they occupied the same house, there were changes in them which I gradually became aware of. They certainly did not move as briskly. Mother was always a bit hard of hearing, but it was now more obvious. Having noted diminution in my Father’s visual acuity, he had cataract surgery which at the time was followed by glasses with thick lenses. We were fortunate that their mental status remained quite sharp, but there were lapses of memory which are not uncommon in the elderly. Having made these and many more observations, I can look back and recall how it affected my demeanor with the older population in my practice.

I am often asked about my residency training, and how surgical teaching by various mentors affected my skill set. I find myself more often speaking of the lessons which I learned by observing the interactions which my teachers had with their patients rather than what I may have learned from them in the operating room.

I look back on a morning early in my residency when I was rounding with a surgeon who seemed to spend more time talking about relating to patients than operating on patients. I specifically recall him as one who seemed to devote more time to the older patient. To this day I remember his encouraging me to sit when I would enter the room. I asked him, “Why?” He responded by telling me that it may convey that I am taking the time to listen.

I also have a vivid memory of a technically gifted surgeon who was very “type A” and always in a hurry. We had entered a room to see an elderly lady whom he had operated on. It was 6:00 A.M. and as she fumbled with her hearing aid I could see that his boiling point was rising. I am sure that her concerns were not addressed, and as we exited the room his nurse was told that her room should be avoided during future rounds. I sheepishly visited her later that day to address her concern about how she will manage living alone in her two-story home while her weight bearing status was limited. I expect that this issue would have been dealt with by nursing or social service (in hospital rehab was not available when I did my residency), but I feel certain that she would rather have had the issue addressed by her surgeon.

Unfortunately, I was occasionally told when I was seeing a post-operative patient in the office that I neglected to
adequately address few points inherent in the recovery process. I do not have to spend much time figuring out why. I was in hurry, regrettably subjecting patients to frustrations that could have been avoided. As I look back on those situations I realize that I was insensitive to the needs of the patient, treating them differently than I would have if they were my parent.

I remember having operated on an elderly but very active lady who, during the evening after her surgery needed assistance and soiled the bed when no one arrived to help her. She then related to me how her dignity was ignored when she was chastised by the nurse’s aide who apparently was insensitive to the limitations with which she dealt with on the night of her surgery for a fractured hip. Her final comment was, “Someday she will be old.” Perhaps we do not give this enough thought when dealing with the elderly.

Reflect for a moment that an elderly patient who is widowed and lives alone in a free-standing home is admitted to the hospital. Her children live in faraway states, she has a pet, and no close relatives to contact. She is overwhelmed by concerns as to how will her bills be addressed, who is going to look in on her pet, and who is going to attend to the problems that may occur in her home.

The above is, unfortunately, a relatively common occurrence. The patient feels isolated in these situations, and although we may offer the appropriate medical or surgical solution for the physical problem with which they present we must not lose sight of the social problems with which they are dealing. We become their “support system.”

Some of my fondest memories over the years are associated with how the intervention by a social worker enhanced the recovery of a patient. As I became a more senior physician I developed an awareness that the healing of a physical problem was but a small part of the recovery of a person. I became more cognizant of depressive states (patients can be overcome by the concerns mentioned above), and concomitant to that was an awareness of the many additional services that were not available when I first started practice, mental health counseling and home care, just to mention a few.

Not infrequently I am called nowadays by friends of acquaintances (most of whom are “senior”) who are seeking medical advice or an opinion about the physician whom they are seeing. I remind them that I have been retired for several years as is the case for many of the physicians with whom I worked and referred to. I find myself usually spending a few moments attempting to get a sense that the person whom they may be seeing is someone who has taken the time to answer their questions and concerns. Perhaps the most frequent negative response that I hear is that the physician spent more time focused on the electronic record than with them. I was recently told by a physician whose wife was evaluated for kidney stones that on the trip home from the hospital she confided that she was never touched by a human being. The challenge for a physician presently is to not lose sight that they are dealing with a person whose diagnostic dilemma may benefit from the technology available, but compassion and communication with the patient is still a significant factor in the practice of medicine.

Dr. Kelly is on the Advisory Committee of Catholic Charities Free Health Center. He can be reached at bulletin@acms.org.

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In Aging Western PA... the Eyes Have It

Miguel A. Busquets, MD, FACS

At the conclusion of a busy day in the retina clinic, where a large proportion of the patients suffer from legitimate visual disability, I sat down to take the VFQ-25 for myself. The VFQ, or “Visual Functioning Questionnaire”, is a tool developed by the National Eye Institute with 25 questions that help assess the visual and ocular status of a patient from a real-world, practical perspective. Although the majority of the questions address activities of daily living in the context of ocular symptoms, the last five truly illustrate what it is like to LIVE with chronic visual impairment. “I stay home most of the time because of my eyesight… I feel frustrated a lot of the time because of my eyesight… I have much less control over what I do, because of my eyesight… Because of my eyesight, I have to rely too much on what other people tell me… I need a lot of help from others because of my eyesight… I worry about doing things that will embarrass myself or others because of my eyesight.”

Frustration; loss of control; over-reliance on others; embarrassment. These are all sentiments with which we can identify as human beings. As physicians, we recognize the importance of treating medical problems for the dignity of the person, not simply to eradicate an affliction. However, as clinicians, it is easy to get caught in the trap of treating a diagnosis. We understand the impact that a chronic disease will have on someone’s way of life, but it is also possible to get lost in the rote and repetitive clinical algorithms necessary to render proper care for the condition. Both of these facts are particularly true in the realm of chronic diseases like age-related macular degeneration (AMD) and diabetic retinopathy. As with many chronic conditions, their incidence and prevalence increases with age, thus making their lifestyle impact that much more significant.

Robin Casten and Barry Rovner showed in a 2008 study published in the Journal of Visual Impairment and Blindness, that rates of depression in AMD are substantially greater than those in the general population. Similarly, Pan et al. demonstrated a bidirectional association between diabetes and depression in an Archives of Internal Medicine article published in 2010. Rovner et al. also showed in the Archives of General Psychiatry in 2007 that ‘problem-solving treatment’ (PST), a type of cognitive-behavioral therapy, was effective in preventing depressive disorders in patients with AMD. Despite the strong association between chronic ocular diseases, vision loss and depressive disorders - in addition to the fact that evidence exists to support the contention that measures can be taken to address this problem - the sad reality is that few eye care clinics provide the type of comprehensive patient assessment necessary to address this issue.

We live in a time and place where finding the proper balance between the delivery of excellent clinical care and tending to patient’s psychosocial needs is becoming increasingly important. The aging of the U.S. population alone will drive this need. Forty three million Americans over the age of 65 in 2014 will become 73 million in 2030. While the over-65 demographic stands at 14% nationwide, Allegheny County’s share exceeds this number at 17%.

Over that same timespan, 24 million Americans with visually disabling cataracts will become 37 million, two million Americans with AMD will become 4 million, and 7.7 million patients with diabetic retinopathy will become 11 million. The latter is a result of an underlying condition with an already high prevalence, that is ever-increasing. The prevalence of diabetes mellitus hovers nationally around 13%. As with the age-phenomenon, western Pennsylvania will have more than its share of diabetic patients for which to care. Neighboring counties such as...
Fayette, with a diabetic prevalence of 16%, continue to outpace the rest of the nation.

It is the unique responsibility of all clinicians in western Pennsylvania to understand and address these demographic and epidemiological trends. Primary care physicians and specialists alike have a duty to identify patients at risk for chronic ocular disease and comprehensively address their needs, as early detection and referrals can minimize visual disability. We now live in an era where microsurgical advancements and a plethora of injectable pharmacotherapy have shifted the results paradigm from one where prevention of vision loss was the best possible outcome, to one where visual improvement is actually the expectation.

Coordination of care among providers is imperative, as systemic health plays a direct role in ophthalmologic outcomes. Smoking cessation programs, management of hypertension and hyperlipidemia as well as proper anticoagulation all play a role in macular degeneration and a myriad of retinal vascular diseases. The role of the family physician, internist and endocrinologist in the management of diabetic retinopathy cannot be overemphasized. When appropriate, the proper and timely introduction of low vision aids by the ophthalmologist or optometrist can greatly reduce the frustration associated with visual disability. Finally, knowing when to involve mental health professionals to address depressive disorders associated with chronic ocular disease is the responsibility of all involved - from the retinal surgeon to the PCP. As with all medical problems, it is the team approach that serves the patient best.

Miguel A. Busquets, MD, FACS is a vitreoretinal surgeon and partner with Associates in Ophthalmology and Associates Surgery Centers, LLC in Pittsburgh, Pennsylvania, where he is Director of the Division of Research and Clinical Trials and Director of the Vitreoretinal Fellowship Program. Dr. Busquets received his undergraduate degree from Harvard University, his medical degree from Duke University School of Medicine, and completed his residency in Ophthalmology at Washington University School of Medicine, where he was also a fellow in vitreoretinal diseases and surgery at the school’s Barnes Retina Institute. He is the author of numerous publications in this field and lectures on these topics at national and international conferences.

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Compassion is a word for a very positive emotion that has to do with being thoughtful and decent. When you have compassion, you’re putting yourself in someone else’s shoes and really feeling for them. When you feel compassion for someone, you really want to help them. Giving to a charity takes compassion. Volunteering to work with sick people or animals takes compassion. Anytime a disaster like a hurricane or earthquake hits, others will feel compassion for the victims.

Compassion is one of the most important attributes for physicians practicing their profession. Physicians generally identify their central duties as the responsibility to put the patients’ interests first, including the duty not to harm, deliver proper care and maintain confidentiality. Physicians who demonstrate compassion understand the effects of sickness and suffering on human behavior. The relationship between suffering patients and their caregivers provides evidence that compassion is a social emotion, which is highly related to closeness between individuals. Compassion motivates people to go out of their way to help the physical, mental or emotional pains of another.

From time immemorial, physicians were known and respected for their compassion. But unfortunately, with the paradigm shift of physicians becoming employees rather than self-employed, we often seem to neglect this aspect of our virtue and succumb to the rules and regulations imposed by others. Physicians as employees are more likely to play to the tune of employers with their guidelines and regulations. We seem to adhere to the restrictions imposed on us without realizing the implications. Employers will more likely seek for the financial gain rather than mundane virtues.

This change in our attitude caught my attention while reading the graduation address given at Yale Medical School, New Haven, Conn., by Dr. Donald Berwick. In that talk, he emphasized how we are losing that touch of compassion. He describes the experience of an elderly woman whose husband - also a physician - died after a lengthy illness in the ICU setting. During this time, the wife was only allowed brief periods of visit to her husband. The wife insisted that she was not just a visitor but rather his life companion and from whom she was never separated. She maintained that the couple’s forced separation was very cruel, and her only request was to share his last days and moments together.

Unfortunately, they were denied the quality time together in his last days because she was told, “it is our hospital policy,” and “it is against the regulations.” What is irrational is not those phrases, but what follows those phrases, in ellipsis unsaid: “It is our policy ... you cannot hold your husband’s hand.” “It is against the rules ... to let you see this or to let you know this.” “It would be a problem ... if we treated you on your own terms not ours.”

We will come across instances such as this as part of our daily routine. During those moments, we need to recall such stories and be compassionate and empathetic to the needs of families, instead of saying, “Sorry, your 30 minutes are up.”

Physicians need to be something other than a doctor; they need to be a healer. And to become a healer, we must do something even more difficult than putting on our white coat. We must take off our white coat. When we do take off our white coat, we become a healer.

Dr. Gopal is a past president of the ACMS and can be reached at bulletin@acms.org.

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2018 ACMS Bulletin Photo Contest

Please note instructions below for participating in the 2018 ACMS Bulletin Photo Contest:

1. Email your VERTICAL jpg photos with a resolution of 300 dpi or higher to bulletin-contest@acms.org. Photos should be 8”W x 10”H.
2. You must be an ACMS member physician to submit photos.
3. Include the name of the photo (please keep file names short) as well as your name, specialty, address and phone number in the email.
4. You will receive verification that your photo has been received and is eligible to be entered in the contest.
   a) Horizontal photos will not be considered.
   b) Photos with low resolution will not be considered.
   c) Panoramic shots or photos featuring specifically identifiable individuals/relatives will not be considered.
5. The deadline for submission is Friday, October 5, 2018. After this date, a group of individuals selected by the ACMS Board of Directors and ACMS Editorial Board will vote on the top 12 photos.
6. Winners will be announced on the ACMS website, in the Bulletin and via email. The 1st-place winner’s photo will appear on the January 2019 cover; the remaining winning photos will appear on Bulletin covers throughout the year.
7. Please continue to check the ACMS website and future issues of the Bulletin for further updates and reminders.
8. If you have any questions, please call Bulletin Managing Editor Meagan Sable at (412) 321-5030, ext. 105, or email msable@acms.org.
Criminal Prosecutions, Insurer Actions Put Squeeze on Suboxone Prescribers

BETH ANNE JACKSON, ESQ

News of criminal prosecutions of unscrupulous providers of Medication Assisted Treatment (“MAT”), which uses suboxone and, when done properly, psychological and other therapies to assist those with opioid use disorders, has been abundant this year. Five independent contractor physicians and the administrator of a MAT clinic with offices in Pennsylvania and West Virginia, were indicted on charges of unlawfully dispensing and prescribing controlled substances and health care fraud. At the same time, insurers have been cracking down on non-participating clinics patronized by those with insurance by covering Suboxone or other buprenorphine formulations only when they are prescribed by in-network doctors. This is not a problem when a physician is already in-network and moonlighting as a MAT provider. Those who are not (e.g., semi-retired physicians who provide MAT services on a part-time basis) find that they cannot become credentialed to provide MAT services unless they are board-certified in addiction medicine. Accordingly, in-network opportunities for such physicians to serve patients with opioid use disorder may be diminishing while need for physician authorized to provide MAT is increasing.

Legal Summary

Criminal medicine. As Pittsburgh was deemed a “hotspot” for opiate-related overdoses and deaths, the Department of Justice formed the Western Pennsylvania Opioid Fraud and Abuse Detection Unit last year. This task force combines personnel and resources from multiple federal and state agencies to combat the growing prescription opioid epidemic. The goal is not to prey on MAT providers who might make a poor judgment call, but rather to focus on criminal activity. Prosecuted physicians are not just negligent. Rather, prosecutions here and elsewhere in the United States have been based on truly criminal behavior, including:

• Prescribing Suboxone to patients who had no medical need for it (and billing insurance for the visit);
• Providing pre-signed blank prescriptions for the administrator to complete the dosage information without the doctor being in the office;
• Doling out prescriptions to addicted persons for cash;
• Exchanging prescriptions for sex;
• Creating and submitting unlawful prescriptions for narcotics and then unlawfully dispensing those controlled substances to other persons without a legitimate medical purpose (and submitting false claims to cover the costs of the controlled substances).

Negligent medicine. While physicians who provide services through MAT programs are not automatically on the radar for criminal prosecution, they – like all physicians - remain subject to investigation by the Bureau of Professional and Occupational Affairs. Pennsylvania’s Prescription Drug Monitoring Program allows the State Board of Medicine (the “Board”) to monitor data for outliers, including those prescribing large amounts of controlled substances or prescribing Subutex rather than a form of buprenorphine with naloxone (Suboxone). (Subutex is regarded as having a higher potential for diversion and abuse.) Such investigations may result in disciplinary action by the Board, including the loss of licensure, if unethical or unprofessional behavior is discovered.

These investigations can be time-consuming, embarrassing and costly, both financially and personally. Accordingly, physicians who provide MAT services on a part-time basis should thoroughly vet their arrangements with the aid of legal counsel, especially when contracting with MAT clinics that do not accept insurance. While the seemingly easy
money with limited time commitment may be attractive, legal issues such as aiding and abetting the unauthorized practice of medicine can arise, especially if the physician allows a non-physician owned clinic to impinge on his or her professional judgment.

Other legal issues, especially for physicians with an active practice in another specialty, include breach of payor contracts: if you are a participating provider with Medical Assistance or commercial insurance companies, you cannot charge their insureds out-of-pocket for covered services. If you do and are caught, you may lose your payor contract or be required to repay the patients. Most importantly, however, physicians must take care to ensure that they are both authorized (by a DATA 2000 waiver) to provide MAT services and sufficiently trained to understand and meet the standard of care.

Import. Given the size of the opioid crisis, more physicians are – and will continue to be – needed to provide professional medical services in MAT programs. As with any crisis, when money is provided to address it, bad actors often follow.

Good judgment goes a long way, but the assistance of legal counsel can help ensure not only that your contract and arrangement do not violate applicable laws, but also that you understand your obligations under the law.

DISCLAIMER: This article is for informational purposes only and does not constitute legal advice. You should contact your attorney to obtain advice with respect to your specific issue or problem.

Beth Anne Jackson is a shareholder in the Health Care Practice Group of Brown & Fortunato, P.C., which is headquartered in Amarillo, Texas and serves health care providers nationally. She is licensed in both Pennsylvania and Texas and maintains an office in the greater Pittsburgh area. She may be reached locally at 724-413-5414 or by email at bjkackson@bf-law.com. Her firm’s website is www.bf-law.com.
The top cause of preventable death in trauma is bleeding; 20% of people who have died from traumatic injuries could have survived with quick bleeding control.

The Stop the Bleed Program was born in the aftermath of the active shooter disaster on December 14, 2012, at Sandy Hook Elementary School in Newtown, CT. In April 2013, a group known as the Joint Committee to Create a National Policy to Enhance Survivability from Active Shooter Events and Intentional Mass Casualty was convened by the American College of Surgeons (ACS) in collaboration with others in the medical community and representatives from the federal government, the National Security Council, the U.S. military, the Federal Bureau of Investigation, and governmental and nongovernmental emergency medical response organizations, among others. Together, they created a protocol for national policy to enhance survivability from active shooter and intentional mass casualty events. The committee’s recommendations are called the Hartford Consensus, and currently consist of four reports. The group was formed under the guidance and leadership of trauma surgeon Lenworth M. Jacobs, Jr., MD, MPH, FACS, who today leads the ACS Stop the Bleed Program.

Among the Hartford Consensus’ recommendations was one calling for professional first responders (law enforcement and EMS/fire/rescue) to be trained and empowered to stop life threatening external bleeding. Another of its recommendations, and one that also is embraced by the White House, went one step further and called for training immediate responders—individuals who are present at the scene who can immediately control bleeding with their hands and equipment that may be available. In October 2015, responding to the Hartford Consensus recommendation that the public be trained, the White House launched the Stop the Bleed national awareness campaign with a call to action. Stop the Bleed is intended to cultivate grassroots efforts that encourage bystanders (immediate responders) to become trained, equipped, and empowered to help in a bleeding emergency before professional help arrives.

With the continuing violence in our nation’s schools, churches, and other places where people should feel safe, the American College of Surgeon (ACS) Stop the Bleed program is intended to empower the general public to make a difference in a life-threatening emergency. The Stop the Bleed stands as a clarion example of military lessens from war being translated to the civilian community for the purpose of saving lives. The campaign has been successful to the date in its efforts to inform, educate, and empower nonprofessional community. ACS Fellows are educating medical providers and the community on bleeding control in all 50 U.S. states and almost 40 countries internationally. To date there are almost 15,332 instructors in USA and 16,160 instructors worldwide. Thousands of individuals already taught on what to do in a bleeding emergency and we will continue this mission.

The Pittsburgh area, although consistently ranked among the safer cities of its size, has not been immune to violence. Recent incidents of handgun violence and, most notoriously, the Franklin Regional mass casualty school stabbings, highlight the need not only for robust first responder capability but also widespread bleeding control education. By teaching bleeding control in an accessible manner with age-appropriate and cultural sensitivity, we are empowering our local communities. The Bleeding Control Basics course takes participants through a 60-minute training session that describes the three ways to control bleeding in an emergency. Participants learn how to identify different types of bleeding, techniques for wound-packing, and compression through hands-on skills training, and crucially the proper placement and use of a combat application tourniquet. AHN (agh and Forbes) began to participate
in this program in February 2017 with Norwin School district and has trained around 5000 individuals to date.

Spearheading this effort for the Allegheny Health Network is Trauma Prevention coordinator Sarah Zelazny, MPH. A graduate of the University of Pittsburgh’s School of Epidemiology and Public Health, Ms. Zelazny has been at the forefront of AHN’s efforts to spread Stop the Bleed throughout the South West Pennsylvania region. Recent events organized by Ms. Zelazny include the March 31st National Stop the Bleed Day training session where she and her AHN colleagues instructed over 50 members of the greater Pittsburgh community at three different sessions at Allegheny General Hospital, Western Penn Hospital, and Forbes Hospital. She has also led training sessions for local Army Reservists at the 316th Expeditionary Sustainment Command in Coraopolis, PA, reinforcing their basic lifesaving skills as part of their annual training. She hopes that all attendees will encourage friends and family members to participate in Stop the Bleed training.

“A person can die from blood loss within five minutes, and bystanders are often the first on the scene no matter how fast emergency services arrive,” she explained. “In some cases, such as in an active shooting situation, medical help might even be further delayed. That is why it is so important for the general public to know how to stop or greatly minimize blood loss under a variety of circumstances. It can save someone’s life.” The ACS Committee on Trauma’s goal is to train every American in basic bleeding control techniques and to work tirelessly toward placing bleeding control kits in every public venue, including schools, community centers, places of worship, and stadiums. With the support of Highmark Health and the Allegheny Health Network, and through the work of dedicated experts such as Sarah Zelazny, Stop the Bleed training is being realized here in Pittsburgh and in our surrounding communities.

Dr. Badar is director, Surgical/Trauma, ICU; Trauma and Acute Care surgeon and surgical intensivist; and director, Emergency Surgery at Forbes Hospital, Allegheny Health Network, Monroeville. He can be reached at bulletin@acms.org.
Since 2010, several new anticoagulant medications have been FDA approved for a variety of indications. Unlike warfarin (Coumadin®), the classic anticoagulant works by inhibiting the body’s natural production of vitamin K-dependent clotting factors, the new agents each work by inhibiting a single factor and have been largely termed Direct Oral Anticoagulants (DOACs). More recently, new anticoagulant reversal agents have been FDA approved. KCentra®, a prothrombin complex concentrate containing human clotting factors II, VI, IX, and X, Protein C, and Protein S was approved in April 2013 to reverse bleeding related to warfarin. Idarucizumab (Praxbind®) was approved in October 2015 to reverse bleeding or anticoagulation related to dabigatran. On May 7, 2018, the FDA approved andexanet alfa under the brand name Andexxa® to reverse life-threatening or uncontrolled bleeding related to either rivaroxaban (Xarelto®) or apixaban (Eliquis®). This is the first agent specifically designed to reverse anticoagulation of the factor Xa antagonists.

**Pharmacokinetics and Dosing**

Andexanet alfa acts as a decoy factor that binds directly to factor Xa inhibitors to specifically target and reduce the action and concentration of the drug. Andexanet alfa has been shown to work within 2 minutes after the end of the bolus dose, but because of its 1 hour half-life, its direct action tends to cease relatively quickly. The pharmacokinetic profile allows the drug to be managed with a high level of control, so long as adequate monitoring and care is achieved. Andexanet alfa does not act as a pro-coagulant, as the drug is modified in a way that alanine replaced the active-site serine, rendering it catalytically inactive.

Two regimens exist for dosing of andexanet alfa, a low dose and a high dose approach which are described in Table 1 on page 317. Each regimen consists of a bolus dose and infusion lasting up to two hours, the duration of which was chosen to exceed the time necessary for the body to form a hemostatic plug during a bleeding event. The proper choice of regimen is dependent on factor Xa inhibitor being used, the specific dose and timing of previous dose. Choice of dosing regimen is described in Table 2 on page 317. Andexanet alfa is only approved for IV administration via the appropriate regimens to reverse anticoagulation from apixaban and rivaroxaban. It should not be used to reverse anticoagulation from any other factor Xa inhibitor.

There are no dosage adjustments based on varying levels of renal or hepatic function. Patients with a variety of renal functions including those with a creatinine clearance of <30 mL/min were studied although no mention was made to patients dependent on renal replacement therapy. Results specific to patients with different levels of renal function have not been discussed. Andexanet alfa has not yet been shown to significantly interact with any drugs.

**Preparation, Administration, and Price**

Currently, andexanet alfa is available as a sterile powder in 100 mg vials ready to be reconstituted for administration. It has only been made available at certain sites and full manufacturing and availability is expected to be in 2019. A low-dose regimen will require nine 100 mg vials and a high-dose regimen will require eighteen 100 mg vials. Reconstitution of the sterile powder is aided by gently swirling each vial and not shaking as this can lead to foaming of the reconstituted product. All reconstituted solution is removed from the individual vials and combined in a sterile empty IV bag. The bolus dose is administered at a rate of 30 mg/minute and the continuous infusion begins 2 minutes after the bolus dose is complete. Due to the time-sensitive nature, the entire regimen should be compounded.
before administration. The potential delay while preparing the finished product should be considered although additional vial sizes may be available when the full release occurs in 2019. Either a 0.2 or 0.22 micron in-line filter is required for administering the infusion.4

A 100 mg vial of andexanet alfa currently has an Average Wholesale Price of $3,300.4 Based on this, the cost required for a low-dose regimen is $29,700 and for a high-dose regimen is $59,400.

Efficacy
The landmark study in support of andexanet alfa and largely resulting in its FDA approval was the ANNEXA-4 trial. This is an open-label, prospective trial examining the effects of andexanet alfa on patients receiving apixaban, edoxaban, enoxaparin, or rivaroxaban. Preliminary results were published in the New England Journal of Medicine by Connolly et al. in August 2016 although the study remains open and is expected to be completed in 2022.8

In ANNEXA-4, the hemostatic efficacy of andexanet alfa was monitored in addition to its effect on anti-factor Xa activity. Hemostasis was defined in different populations according to criteria defined in Table 3. All 67 patients were included in the safety population, but only 47 were included in the efficacy population because 20 patients either didn't have an adequate baseline anti-factor Xa activity or did not meet the criteria for an acute major bleed. Of the 47 patients in the efficacy population, 31 patients had excellent hemostasis and 6 patients had good hemostasis 12 hours after the andexanet alfa infusion, based on predetermined criteria. Twelve hours after the infusion, 79% of patients in the efficacy population fell into either the categories of either excellent or good hemostasis. For gastrointestinal bleeding, the hemodynamic efficacy rate in the excellent or good category was 84%. For intracranial bleeding, the hemodynamic efficacy rate in the excellent or good category was 80%. Nine of the 47 patients had poor or no hemostatic efficacy resulting from andexanet alfa. According to Siegel et al., thrombin generation was restored to at least the lower limit of normal range in 100% of apixaban patients and 96% of rivaroxaban patients within the first two to 10 minutes following the andexanet alfa bolus administration. Maximal effect of the anticoagulant reversal was seen within two to five minutes following the administration of the andexanet bolus.5

ANNEXA-4 will continue until 162 patients have been evaluated for efficacy and it is anticipated that 230 patients will be evaluated for safety.8

Safety
The greatest risk with anticoagulant reversal agents is subsequent development of thrombosis. Twelve out of 67 patients (18%) treated with andexanet alfa in the ANNEXA-4 trial experienced thrombotic events within 30 days of receiving treatment.6 This is a higher rate than seen in previous studies with other anticoagulant reversal agents. Sarode et al. described 8 out of 103 patients (7.8%) treated with 4-factor prothrombin complex concentrate (manufactured in the United States as KCentra®) having experienced thrombotic events within 45 days of receiving treatment for vitamin K antagonist reversal.10 Pollack et al. described 24 out of 503 patients (4.8%) treated with idarucizumab (manufactured as Praxbind®) having experienced thrombotic events within 30 days of receiving treatment for dabigatran reversal.11 It is unclear what caused the large variation in thrombotic events in these landmark trials, but it’s important to recognize that the ANNEXA-4 results at this point are based on the small number of patients published in the interim report and this may change as the study continues. Comparing studies in this manner should always be done cautiously as these all feature unique methods and analyses, sometimes different endpoint definitions, and are not controlled against each other. Of significance, only one patient who suffered thrombosis in ANNEXA-4 received a full therapeutic anticoagulation dose within 30 days following the administration of andexanet alfa, suggesting the increased prevalence of thrombosis was due to a lack of anticoagulation. All patients enrolled in the trial had a history of thrombotic events and cardiovascular disease.8

Impact on prescribing
The direct oral anticoagulants can improve patient outcomes for certain indications and have fewer drug and food interactions and easier dosing compared to vitamin K antagonists.12, 13 Despite these benefits and the advantage of not having frequent INR lab testing with associated dose adjustments, some prescribers may be reluctant to utilize direct oral anticoagulants for certain patient populations. Apixaban, dabigatran, and rivaroxaban all have detailed dosage adjustment for patients with renal

Continued on page 316
impairment depending on the indication.\textsuperscript{14, 15, 16} Although these adjustments are helpful in ensuring accurate dosing, the possibility for inter- and intra-patient variability exists as renal function can unpredictably change and can be difficult to estimate. Unlike warfarin, the DOACs do not have a common way to monitor anticoagulant activity which could lead to hesitation to prescribe particularly to patients at risk of over- or under-dosing due to their pharmacokinetic variances.

When the DOACs were initially FDA-approved, no specific reversal agents existed and instead, recommendations to emergently reverse centered on fresh frozen plasma and combinations of factor VIIa with various prothrombin complex concentrates.\textsuperscript{17, 18} These options were not heavily supported with strong literature. Although idarucizumab was approved in 2015 to reverse dabigatran, the factor Xa inhibitors still had no specific reversal agent. It is possible that with the introduction of andexanet alfa, prescribers may feel more comfortable utilizing factor Xa inhibitor anticoagulants.\textsuperscript{19} This will also depend on the availability of andexanet alfa at hospitals and further results of the ANNEXA-4 trial and other published data as it becomes available.

**Conclusion**

Andexanet alfa is the first available factor Xa inhibitor reversal agent and it is currently approved for reversal of apixaban and rivaroxaban. Data from ANNEXA-4 trial supports its place as a safe and effective option to reverse factor Xa inhibitors although the study is ongoing and full results will not be published for years. Prescribers should be aware of the limited availability until the full product launch and hospital pharmacy departments should take note of the time required to prepare doses for administration, although this may change as larger vial sizes become available. It remains to be seen if the development of thrombosis will be similar to other anticoagulant reversal agents and full results of ANNEXA-4 may clarify this question as well as provide data on andexanet alfa’s ability to reverse other factor Xa inhibitor agents, namely edoxaban. Despite the questions practitioners may have at this time, andexanet alfa is a novel agent with the demonstrated ability to reverse the often-used factor Xa inhibitor agents to treat major bleeding complications.\textsuperscript{8}

Dr. Wolfgang is an assistant professor of pharmacy practice at Duquesne University School of Pharmacy. He also practices as a clinical pharmacy specialist in critical care at University of Pittsburgh Medical Center Shadyside Hospital. He can be reached at wolgank@duq.edu or (412) 396-2370. Mr. Black is a doctor of pharmacy candidate at Duquesne University School of Pharmacy.

(See page 318 for references)
### Table 1. Andexanet alfa dosing regimens

<table>
<thead>
<tr>
<th>Low dose regimen</th>
<th>Infused dose, 2 minutes after bolus</th>
<th>Total dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg IV</td>
<td>4 mg/minute for up to 120 minutes, 480 mg</td>
<td>880 mg</td>
</tr>
<tr>
<td>800 mg IV</td>
<td>8 mg/minute for up to 120 minutes, 960 mg</td>
<td>1760 mg</td>
</tr>
</tbody>
</table>

### Table 2. Choice of andexanet alfa dosing regimen

<table>
<thead>
<tr>
<th>Factor Xa inhibitor</th>
<th>Factor Xa inhibitor last dose</th>
<th>Timing of factor Xa inhibitor last dose before initiation of andexanet alfa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rivaroxaban</td>
<td>≤ 10 mg</td>
<td>≥ 8 hours or unknown</td>
</tr>
<tr>
<td></td>
<td>&gt; 10 mg / unknown</td>
<td>Low dose</td>
</tr>
<tr>
<td>Apixaban</td>
<td>≤ 5 mg</td>
<td>≤ 8 hours or unknown</td>
</tr>
<tr>
<td></td>
<td>&gt; 5 mg / unknown</td>
<td>Low dose</td>
</tr>
</tbody>
</table>

### Table 3. Definitions of hemostatic efficacy in ANNEXA-4

<table>
<thead>
<tr>
<th>Hemostatic efficacy</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intracranial hemorrhage</td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>Increase in hemorrhage volume 20% or less from baseline to 1 and 12 hours after andexanet infusion</td>
</tr>
<tr>
<td>Good</td>
<td>Increase in hemorrhage volume 35% or less from baseline to 1 and 12 hours after andexanet infusion</td>
</tr>
<tr>
<td>Subarachnoid and subdural bleeding</td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>Increase in maximal hematoma thickness 20% or less from baseline to 1 and 12 hours after andexanet infusion</td>
</tr>
<tr>
<td>Good</td>
<td>Increase in maximal hematoma thickness 35% or less from baseline to 1 and 12 hours after andexanet infusion</td>
</tr>
<tr>
<td>Nonvisible bleeding (Including all gastrointestinal bleeding)</td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>Decrease in hemoglobin and hematocrit of less than 10%</td>
</tr>
<tr>
<td>Good</td>
<td>Decrease in hemoglobin and hematocrit of 20% or less and use of no more than 2 units of coagulation intervention (e.g., plasma or prothrombin complex concentrate)</td>
</tr>
<tr>
<td>Visible bleeding</td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>Cessation within 1 hour of andexanet infusion</td>
</tr>
<tr>
<td>Good</td>
<td>Cessation within 4 hours of andexanet infusion and no additional intervention required</td>
</tr>
<tr>
<td>Musculoskeletal bleeding</td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>Pain relief, unequivocal improvement in objective signs of bleeding, and no increase in swelling within 1 hour of andexanet infusion</td>
</tr>
<tr>
<td>Good</td>
<td>Pain relief, unequivocal improvement in objective signs of bleeding, and no increase in swelling within 4 hours of Andexanet infusion</td>
</tr>
</tbody>
</table>
REFERENCES


3. PRAXBIND (idarucizumab) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; revised April 2018.


13. PRADAXA (dabigatran etexilate mesylate) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; revised March 2018.


Please share with a colleague!

APPLICATION FOR MEMBERSHIP

ALLEGENY COUNTY MEDICAL SOCIETY
75 Ridge Avenue • Pittsburgh, PA 15210
p: 412-321-5030 • f: 412-321-5353

Full Name (please print):

Office: ____________________________

Home: ____________________________

E-Mail: ____________________________

Sex: ____________________________ Date of Birth: ____________________________

Primary Specialty: ____________________________ Secondary Specialty: ____________________________

License: ____________________________ Date Issued: ____________________________

Preferred Method of Contact:
Mail: ________ (Office or Home)
E-mail: ________
Fax: ________

Present Type of Practice:
☐ Employed by Hospital/Health System
☐ Employed by Physician(s)
☐ Employed by Industry or Government
☐ Owner of Physician Practice
☐ Independent Contractor
☐ Other (Specify) ____________________________

Employment Status:
☐ Practicing full-time
☐ Practicing part-time
☐ Retired from practice
☐ Currently not in practice
☐ Other (Specify) ____________________________

Present Hospital Appointments:

Within the last 5 years, have you been convicted of a felony crime? ☐ Yes ☐ No. If yes, please provide full information.

Within the last 5 years, has your license to practice medicine in any jurisdiction been limited, suspended or revoked? ☐ Yes ☐ No. If yes, please provide full information.

Within the last 5 years, have you been the subject of any disciplinary action by any medical organization or hospital staff? ☐ Yes ☐ No. If yes, please provide full information.

If elected to membership, I agree to conduct myself professionally and personally according to the principles of medical ethics and to be governed by the Constitution and Bylaws of the Allegheny County Medical Society and the Pennsylvania Medical Society.

I hereby release, and hold harmless from any liability or loss, the Allegheny County Medical Society, the Pennsylvania Medical Society, their officers, agents, employees, and members, for acts performed in good faith and without malice in connection with evaluating my application and my credentials and qualifications and hereby release from any liability any and all individuals and organizations, who, in good faith and without malice, provide information to the above named organizations, or to their authorized representatives, concerning my professional competence, ethical conduct, character and other qualifications for membership.

I also authorize the above named organizations, in the consideration of my application, to make inquiry of any of my references and institutions by which I have been employed or extended privileges, as to my qualifications. I further authorize any of the above persons or institutions to forward any and all information their records may contain and agree to hold them harmless for any actions by me for their acts.

Date: ____________________________ Signature: ____________________________
Dr. Robert Cicco Guest Speaker at University of Pittsburgh Medical Student Luncheon

Robert Cicco, MD, was the invited guest speaker at the University of Pittsburgh Medical Student Luncheon held August 14th. He presented an overview of ACMS, including the importance, impact and avenues for physicians to advocate for patients and the profession of medicine to over 160 incoming medical students attending the event.

Robert Cicco, MD, and second year medical students attending the University Pittsburgh who organized the medical student luncheon include (l to r): Nicole Paul, Julia Pantalone, Patricia Campos, and Alexandria Harris.
Medical Student Career Speed Dating Event –
Monday, October 22, 2018

Mark Your Calendar! The University of Pittsburgh’s medical student AMA chapter is hosting a Medical Student Career Speed Dating event on Monday, October 22 at the Herberman Conference Center (5230 Centre Avenue, Pittsburgh, PA 15232). Registration begins at 6:00 pm; dinner and rotations at 6:30; and conclusion at 8:30 pm.

Co-Chaired by Ms. Patricia Campos and Mr. Emade Jaman, both M.D. candidates, Class of 2021, University of Pittsburgh School of Medicine, this informal program serves as a ‘career exploration’ for medical students by providing an opportunity to speak with physicians to learn about a variety of specialties.

In question and answer roundtable-by-specialty sessions, physicians will have the opportunity to provide insight into their respective specialty and address questions such as: what it’s like to practice on a day-to-day basis, why they chose a specific specialty; what attributes are important to medical students considering a specialty and how to balance career and personal life. No formal preparations are needed, just the willingness to share your experience with the students.

In collaboration with this program, we are asking practicing physicians to mentor students by allowing the students to ‘shadow’ them for a day at a later time. If you agree to be contacted for arranging a shadowing opportunity, ACMS will pass your name along to the respective interest groups to add to their shadowing database for follow-up.

A formal request to participate and/or offer a shadowing experience will be emailed in September. Interested participants can also send an e-mail to specialtynight@acms.org to receive updates.

In Memoriam

James Raub, MD

Dr James Raub retired from Sewickley Valley Hospital as an OB/GYN and as Speaker of the House for the Pennsylvania Medical Society. He dedicated over 25 years on various committees and boards throughout those years. He passed away July 7, 2018 at home with his wife Janie of 40 years. After his retirement, he moved to Dana Point, CA. He leaves behind two daughters and four grandchildren. His private memorial service will be in September.
Members and friends of the ACMS Alliance, the new Alliance year has begun. At this point, you should have received your dues notice. If you are a physician’s wife, mother, daughter or son, 21 years of age or older, you are invited to join the Alliance. If you have any questions, please contact Dorothy Hostovich at (412) 321-5030.

The first major Alliance meeting will be held at 11 a.m. Sept. 18 at South Hills Country Club. We are indeed fortunate to have medical marijuana expert Jane Binakonsky as our guest speaker. The title of her presentation is: “The Risks and Benefits of Medical Marijuana.”

Ms. Binakonsky is a graduate of the University of Pittsburgh School of Law. She is the first juris doctor to be awarded the National Institute on Drug Abuse’s postdoctoral training program fellowship in drug dependence epidemiology. She completed this program at Johns Hopkins Bloomberg School of Public Health in Departments of Mental Health and Health, Behavior and Society. In addition to attending meetings across the world on the issue of alcohol and drugs including at the World Health Organization, she has trained lawyers across the country and worked on legislation in the area of alcohol and drug dependence. She also holds a BA in International Economic Policy and a BS in Political Science from American University.

Ms. Binakonsky is co-authoring a book on drug dependence and is affiliated with Carnegie Mellon University’s BrainHub. She is involved in programming and activities related to neuroscience, government and addiction treatment in the western Pennsylvania community. From mountain expeditions in Poland to herbal research in rainforests of Malaysia, her determination to cure addiction combined with her curiosity leads her across multiple continents to research evolving approaches to health and wellness.

A luncheon will follow the business meeting and speaker presentation. Reservations are necessary. Invitations will be sent out by the meeting committee to our members. Additional invitations can be requested by contacting Patty Barnett at (724) 934-1952.

**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 online at www.acms.org.

**CONTENT AND TEXT BY CO-CHAIRS PATTY BARNETT AND BARBARA WIBLE**
Save the Date
Pennsylvania Geriatrics Society – Western Division
Presents the

Fall Program
Living a Good Life - Not Just a Long One

Guest Speaker
Karen Wolk Feinstein, PhD
President and Chief Executive Officer of the Jewish Healthcare Foundation (JHF) and its three operating arms, the Pittsburgh Regional Health Initiative (PRHI), Health Careers Futures (HCF), and the Women’s Health Activist Movement Global (WHAMglobal)

Synopsis: As we age, we’re challenged to find new meaning and purpose in life. The roles that defined our adult years—doting parent, accomplished professional, weekend warrior athlete—start to fade. In a society that glamorizes youth and novelty over experience and wisdom, older adults can feel marginalized. A growing body of research suggests that finding renewed purpose later in life can, quite literally, be a life-saver. Seniors who have a clear sense of purpose in their lives tend to have better physical, mental, and even spiritual health compared to those who don’t. Thankfully, a life without purpose is a preventable, and modifiable, condition. All of us—from health providers and policy-makers to next-door neighbors—have a role to play in ensuring that older adults remain active, engaged community members who derive meaning from their Golden Years.

Thursday
NOVEMBER

1
6:00 pm
Registration, Networking and Visit with Exhibitors
7:00 pm - 8:00 pm
Program

The University Club
123 University Place Pittsburgh PA 15260

Complimentary Registration for Members Guests welcome (nominal fee)

ON-LINE REGISTRATION begins September 27th
Visit www.pagswd.org periodically for program updates

or contact Nadine Popovich, Administrator for details: npopovich@acms.org
August is National Breastfeeding Month, with August 1st-7th being World Breastfeeding Week.

Open doors to connections.

Allegheny County has free home visiting programs that provide ongoing support and resources to your patients, starting from pregnancy through school age.

Have your patient call Allegheny LINK to learn more, 866-730-2368.