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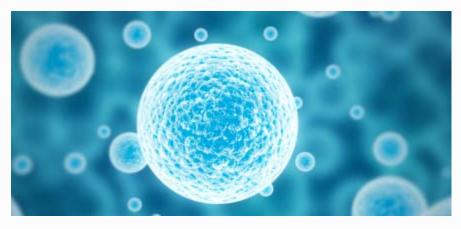
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Better Healthcare Newsletter from Patrick Malone

Deflating the hype and exposing the risks of stem-cell treatments



Dear Jessica,

Stem cells and regenerative medicine—a promising and complex field that has been a preoccupation of no less than popes, presidents, and top health policy makers—have become medicine's new "Wild, Wild West."

Companies have thrown up hundreds of web sites, advertising unproven and largely unregulated stem cell treatments. Providers, some operating out of strip malls, have taken to the airwaves to tout stem cell products and services with full-blown commercial broadcasts, while others have advertised heavily in print and wrapped some of the nation's major newspapers with multi-page promotions.

Without rigorous evidence, claims are circulating freely that patients can benefit from "regenerative" therapies for a staggering array of conditions, including autism, aging, macular degeneration, Lou Gehrig's disease, Parkinson's, multiple sclerosis, lupus, and erectile dysfunction.

IN THIS ISSUE

Big bills and big harms in therapeutic 'Wild, Wild West'

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Why skepticism is smart

A caution on the placebo effect

Stop following celebrity trends

BY THE NUMBERS

570+

Number of 'clinics' uncovered in a nationwide online 2016 study and purporting to provide stem cell treatments for array of conditions Patients are flocking to "clinics," paying from \$5,000 to as much as \$50,000 a pop, to have fat, blood, and other tissues extracted from their bodies, processed and preserved in ways they likely don't fully grasp, then re-introduced (injected) into areas of their bodies that give them pain or other problems.

Scott Gottlieb, the head of the federal Food and Drug Administration, has just promised anew in a major policy statement that Uncle Sam will step in more aggressively to protect Americans by stemming a rising tide of stem cell fraud while allowing important and beneficial research to advance.

So what do you need to know to avoid getting suckered by one of the nation's fastest growing and popular health scams?

Big bills and big harms in therapeutic 'Wild, Wild West'



Nightmare cases about patients undergoing unapproved stem cellrelated and regenerative medical treatments have become public in recent months:

- Federal marshals raided a Southern California facility and seized five 100-dose vials of a smallpox vaccine, which officials said had been mixed with fat-derived stem cells and injected into seriously ill patients as a purported cancer therapy.
- Three women with age-related macular degeneration were blinded after receiving injections in their eyes at a South Florida clinic.
- A onetime corporate lawyer, debilitated by a stroke, was found

\$5,000-\$50,000

Patients' out-of-pocket costs, not covered by insurance, for various types of stem cell treatments

\$67.5 billion

Estimated 2020 global market for regenerative medicine and its various treatments and therapies

QUICK LINKS

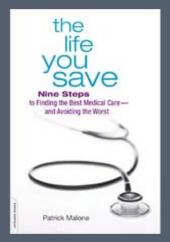
Our firm's website

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Nine Steps

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to have a huge mass of primitive abnormal cells growing, tumor-like, at the base of his spine after he received multiple treatments at clinics in Mexico and Kazakhstan.

- A baby was twice hospitalized in intensive care for a persistent strep infection that clinicians eventually traced to his mother's consumption of her placenta as an improperly commercially prepared post-pregnancy health nostrum.
- A Southern California senior had bone and bone-like growths surgically excised from her eyelids and her eye area after she underwent a cosmetic procedure and apparently had the wrong kinds of cells implanted there.

What's going on here? Consumer advocates and health journalists have been sounding alarms for years now: Americans slowly have succumbed to the hype surrounding stem cells and their regenerative capacities, which many in medical science have regarded as one of world's major advances in our knowledge of how the human body operates.

As jurors of the 2012 Nobel Prize in Medicine proclaimed, British biologist John B. Gurdon and Japanese physician Shinya Yamanaka "discovered that mature, specialized cells can be reprogrammed to become immature cells capable of developing into all tissues of the body. Their findings have revolutionized our understanding of how cells and organisms develop."

The prize citation went on to note that the scientists' "groundbreaking discoveries have completely changed our view of the development and cellular specialization. We now understand that the mature cell does not have to be confined forever to its specialized state. Textbooks have been rewritten and new research fields have been established. By reprogramming human cells, scientists have created new opportunities to study diseases and develop methods for diagnosis and therapy."

Gurdon and Yamanaka offered medical science a path around one of its giant obstacles in stem cell and regenerative medicine research: Since 1981, thanks to British scientist Martin Evans (who shared in a 2007 Nobel Prize), researchers had known of the formidable powers and promise of stem cells, notably those found in humans' earliest stages of development, the so-called embryonic stem cells. But those cells in people, which took some time to isolate, required human embryos to be destroyed to be cultivated. This caused major political and religious issues, with popes and presidents weighing in and acting on the related scientific controversies.



Read our Patient Safety Blog, which has news and practical advice from the frontlines of medicine for how to become a smarter, healthier patient.



PAST ISSUES

Medicine's dirty secret: Tens of thousands die of preventable error Read this before you get a metal joint put in your body

Medical testing can be harmful to your health Spring clean your meds to save costs and health Our vehicles are killing us - and we can do a lot to stop it

More...

Over time, researchers have advanced, simplified, and spread the alternative use of "induced pluripotent stem cells," allowing for serious study of conditions that might be treated with materials (such as stem cells) from patients' own bodies and further advancing regenerative medicine. It's a field that some trace to ancient Greeks' observations that the body can repair itself and regrow key components as some lizards do with missing limbs and tails.

But the rigorous study that was supposed to occur in major, careful institutions didn't always occur exactly that way. Stem cells and regenerative medicine are important, promising areas for medical advancement (see below). They also quickly became areas for exploitation, first overseas, then on American shores.

Before authorities could blink, "stem cell clinics" had popped up and begun to flourish in China, Thailand, Russia, and other former Soviet states. Patients, many desperate and in dire shape, flocked from the United States, Canada, Britain, Ireland, and Spain to undergo dubious treatments in sketchy facilities—paying sizable sums and with undocumented and unproven outcomes. Stem cell tourism became sufficiently common, and outrageous, as to be the topic of a 2013 Harvard health panel.

But if doctors in the Western developed world had umbrage for unproven stem cell treatments in the East, that fast fell with the rapid spread of such practices into places where regulation and oversight supposedly was tougher.

Basketball superstar Kobe Bryant stunned the sports world when it became public that he had traveled to Germany to receive plateletrich plasma (PRP) therapy. It's a treatment in which patients' blood is extracted, and then spun down so it is concentrated with purportedly healing platelets and stem cells. This viscous material is injected into joints, supposedly helping them repair themselves and reducing the wear and tear of rheumatoid arthritis, age, and professional play. Bryant recommended PRP to baseball star Alex Rodriguez, who was outspoken about how he said it helped him with his bad knee.

Although football Hall of Famer Peyton Manning hasn't publicly acknowledged it, news organizations widely reported that he traveled to Europe in 2011 for stem cell treatments for his surgically repaired neck. The NFL has become rife with players receiving regenerative therapies, though there is a dearth of scientific evidence as to their effectiveness. With golf legend Tiger Woods publicly discussing how his knee rehab included stem cell treatments , was it any wonder that this treatment, with or without regard to the scientific evidence for it, took off in the United States, including in the Washington, D.C., area.

By 2016, Leigh Taylor of the University of Minnesota and Paul Knoepfler of the University of California at Irvine published a medical journal study, finding that "351 U.S. businesses engaged in direct-toconsumer marketing of stem cell interventions offered at 570 clinics." Their research was conducted largely online. They did not visit facilities nor delve deeply into their practices. But they documented from provider websites that facilities promoted how, chiefly, they extracted patients' blood and fat cells for use in unproven stem cell treatments. Some facilities, without explaining the sourcing, promised "amniotic" stem cells, and one said it used "bovine" (cow) cells.

Further, they wrote: "U.S. businesses promoting stem cell interventions claim to treat a wide range of diseases and injuries, as well as advertising stem cells for cosmetic applications, 'anti-aging,' and other [niche] purposes ... such procedures as 'stem cell facelifts' and 'stem cell breast augmentation,' as well as sexual enhancement procedures. Orthopedic and sports medicine clinics often promote stem cell interventions for joints and soft-tissue injuries. Other clinics ... list stem cell interventions for 30 or more diseases and injuries [including] neurological disorders and other degenerative conditions, spinal cord injuries, immunological conditions, cardiac diseases, pulmonary disorders, ophthalmological diseases and injuries, and urological diseases, as well as cosmetic indications."

The scientific duo said the proliferating practices raised troubling medical, ethical, and regulatory issues, not only because they offered little or no evidence for their use or outcomes but also because the targets for the medical services included parents or their underage kids with health conditions or diseases, including autism, cerebral palsy, and muscular dystrophy.

Taylor, Knoepfler, and Healthnewsreview.org, a health information watchdog site, deserve credit for chronicling the growing woes with unregulated stem cell ventures—and the lax oversight and questioning they get from government regulators and news organizations, the later apparently eager to accept their increasing advertising.

As consumers suffer harms, are subjected to risks, and fork over big money for "regenerative" care, the FDA has, on occasion, taken action and warned about unapproved stem cell therapies. The agency earlier this year tried to rattle and thunder about regulatory action. But there were real, solid, and tough questions even about the FDA's latest moves, including the federal raid on a facility mixing smallpox vaccine with stem cells as part of a cancer treatment and a detailed statement from agency chief Gottlieb.

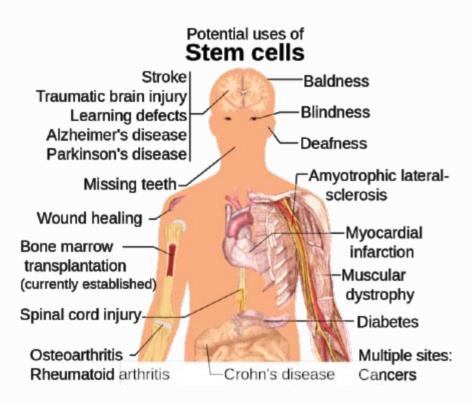
That's because those hustling commercial stem cell care, sometimes in vanilla office buildings or store fronts and outside of well-known academic medical centers and top-line hospitals, have managed to tap dance on a fine legal line about stem cell and regenerative treatments.

The FDA, as Gottlieb notes, sees a gray area when providers take blood, fat, or other cells from patients and do little to the materials before reintroducing them into their bodies. The more that they process, add, or otherwise alter the cells, the higher their regulatory exposure. But as Gottlieb has written, when materials are "taken from and given back to the same individual or when the cells or tissues do not undergo significant manufacturing, are intended to perform the same basic functions, and are not combined with another drug or device, among other factors; their benefits and risks are well understood."

He says the FDA will provide further guidance to ensure that regenerative medicine, a field with a 2013 estimated annual market of \$51 billion and a projected 2020 growth to \$67.5 billion, develops properly and delivers on its real promise and is not undercut by harmful hype.

The field changes rapidly, however, as do the promises and downright scams.

Regenerative medicine holds great promise still. But not for patients right now.



It would be great if medical science made progress easily and quickly. It just doesn't happen that way. Experts estimate it typically can take almost two decades for clinicians to fully and safely adopt a medical advance.

Stem cells and the research field they are part and parcel of, regenerative medicine, have been in the public eye and consciousness for decades now. Major medical research facilities and support for both are embedded at places like the National Institutes of Health, Johns Hopkins, Georgetown University Medical Center, the University of Virginia School of Medicine, and various Veterans Affairs facilities around the nation's capital.

In California, 59 percent of voters in 2004 approved a ballot initiative, Proposition 71, establishing the right to conduct stem cell research, authorizing \$3 billion in state funding for it, and creating a publicprivate institute to speed it in ways that the federal government had been reluctant to do.

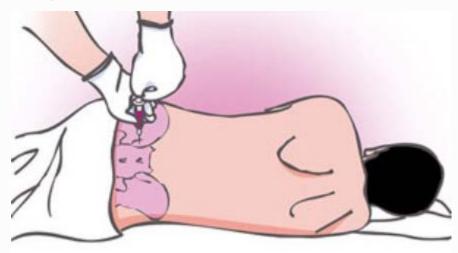
Still, for all the attention devoted to stem cells and regenerative medicine, careful and precise medical scientists talk mostly about the numerous investigations under way, and how indications are still solid that various lines of research will prove beneficial. They do not boast about "cures" or "breakthroughs" or mostly proffer purely anecdotal support for their research outcomes.

The International Society for Stem Cell Research (ISSCR) is a respected organization with a membership of more than 4,000 esteemed and elite investigators in more than 60 countries. It lists on its website four key areas where scientists are making headway in understanding stem cells, what they do, and whether they can help patients with damaged tissues and functions due to: macular degeneration, multiple sclerosis, heart disease, and diabetes.

The society insists that safe and effective stem cell and regenerative treatments can best be advanced through stringent science, including rigorous clinical trials that can take years to conduct correctly. Such medical research may seem pokey and cumbersome to non-scientists. But its emphases on transparency and results that are fully documented (with hard data and scientific evidence) and can be repeated are invaluable. So, too, are the many safeguards built into these time-tested processes. This includes researcher oversight, by Institutional Review Boards and external regulators, and robust, careful communication about human experimentation: Clinical trial participants must know fully what will and may happen to them when they are subjected to tests or procedures. This informed consent is a critical, fundamental part of safe, ethical studies involving human subjects.

It's troubling to note that the NIH is under some fire now for failing to closely monitor its vital, central database on clinical trials, with some direct-to-consumer purveyors of purported stem cell treatments getting onto this list (www.clinicaltrials.gov) in what one researcher has termed "pay to participate" ploys. As a result of his publication criticizing non-FDA approved testing getting on the clinical trials list, bioethicist LeighTurner has received legal threats. So now there may be dual, unacceptable challenges to stringent medical science from those claiming to offer stem cell care: Will they undercut the deep, hard-earned respect that careful clinical trials have won, and will they stifle appropriate, scientific publications questioning how the (in this case, tax-supported) medical establishment operates?

Why skepticism is smart



Caveat emptor applies to faddish stem cell and regenerative therapies.

Before you decide to undergo any treatment, take time to research it carefully. The FDA has resources available, and the ISSCR offers excellent resources online, including their pieces on "9 things you need to know about stem cell treatments," and their "Patient Handbook." Talk to friends and wise colleagues. Consult with your doctor. Or maybe even talk to several different medical specialists.

In my practice, I see the significant harms that patients suffer while seeking medical services, and I can't see any good reasons for most Americans to even consider stem cell or "regenerative" treatments, especially as long as they're not FDA-approved and offered by folks who can't or won't provide detailed data as to their outcomes and benefit. The FDA, doctors, licensing authorities and others must do more to crack down on providers promising, without scientific evidence, stem cell or regenerative treatments for myriad diseases and conditions.

Anecdotes aren't evidence. Patient stories can be powerful, but they shouldn't be decisive for your health choices. Doctors can give some patients sugar pills and saline (sterilized salt water) injections, and they will report improvements in their condition. That's because of the placebo effect, which is well documented and can play a role in patients' sense of a treatment's effectiveness (see below). But even where they may be evidence-based regenerative and stem cell treatments, such as cord blood banking, public health officials must ensure claims for them don't get exaggerated and their use out of hand.

There are, however, less parlous ways than "regenerative" treatments to feel better. Let's be clear: Every medical service carries a risk. Providers may insist that jabbing you, repeatedly, in the arm for blood or the hip for fat or marrow causes little discomfort, particularly because they'll give local anesthesia. But how certain will you be about your safety from infection, including for hepatitis or even HIV-AIDs? Or that the extraction needle will go exactly where it is supposed to without other harm? When your blood or fat or marrow has been harvested, how can you be sure it will be handled in sterile, appropriate ways? Or will you get back, as one mother did, a supposedly regenerative product—in this case, her processed placenta from her recent delivery— tainted with strep?

While you're serving as a human guinea pig for unproven stem cell approaches, are you harming yourself by delaying more appropriate care? Growing research, for example, suggests that patients and orthopedists may be taking a less than optimal path with minor joint procedures like "scoping" of knees, hips, and shoulders, or injecting them with steroids or natural body lubricants. They may benefit patients more, instead, by determining their joints are sufficiently damaged, unlikely to function better, and to replace them. By the way, when you're researching purported regenerative joint care, don't ask only your orthopedist but maybe also consult your family doctor, internist, or a rheumatologist. Orthopedists are, by practice, actionoriented specialists, and, as mentioned, research shows their inclination to injections (of steroids or lubricating substances) isn't always the prime course.

It isn't easy to think ahead about seemingly morbid topics. But it's always worth having some frank, thoughtful, early discussions with your friends, loved ones, caregivers-and, yes, your lawyers, accountants, and insurance agents-about your key wishes and desires if you become gravely ill and reach the end stages of your life. Advance health directives and the crucial conversations that go into them are invaluable and worth getting done. It looks likely that some portion of the patients seeking largely unregulated stem cell or regenerative treatments do so because they think they may have exhausted their options in existing medicine. They may have the means to travel far in hopes of "miracle" treatment-for late-stage cancer, advanced heart or lung conditions, or the unchecked debilitation of diseases like Lou Gehrig's (amyotrophic lateral sclerosis). It's tragic to see providers exploit patients in this fashion, providing them meager and false hope while adding to what research already says is the significant financial drain of medical services in the final months of life. As a matter of public policy, it also doesn't make sense for states like Texas to wink and give tacit approval to untested stem cell and other treatments for its citizens, offering them hope for medical services without scientific evidence in the name of free choice, aka the "right to try."

But my hope, always, is that you stay so healthy that you can steer clear of any need for medical services, most especially those that are dubious and potentially harmful!

Stop following celebrity trends

A caution about the placebo effect



It's not just the big-time jocks who are popularizing stem cell and regenerative treatments. The therapies also have become the darlings of Hollywood and its celebrity crowd.

Take, for example, the press play given to *Stem Cells: The Next Frontier,* a new "documentary," shown at the Cannes international film festival. The film, favorable to stem cell tourism, spotlights an orthopedist who operates "clinics" in China and Slovakia, attracting patients whose American physicians may be disinclined to provide stem cell injections as he does.

Though *Vanity Fair* tries to present some balance and notes in its coverage the absence of scientific support or FDA approval for stem cell therapies, the magazine also offers this flat statement that the film "offers a persuasive side of the story, with rapturous testimonials from patients, some of whom who have regained the ability to walk after their stem cell vacations. Added bonus: They come home with better skin, bigger sex drive, and (in the case of at least one balding patient) more hair."

Gwyenth Paltrow, the actress and controversial health and beauty mogul, has made clear that her own cosmetics and other lines she has talked about using employ "plant stem cells." It isn't clear exactly how the "Yummy Mummy" benefits, but fawning TV reports say she endorses beauty care involving "stem cells extracted from a rare variety of Swiss apple."

Got that? Maybe it makes more sense when a Kardashian is involved—in this case Kim, who, news reports said, paid \$500 for a "stem cell facial" before marrying Kanye West. The cells, again, reportedly were from a "marine plant." And a prominent Los Angeles plastic surgeon and dermatologist said such care might have its benefits.

Stem cells have become a trendy beauty and cosmetic treatment, though the procedures,



The mind can exercise great sway over the body, and patients often report reactions—positive and negative— to medical treatments based not on measurable evidence but on hope and belief.

This is the well-known and increasingly studied placebo effect, dubbed by a noted magazine as "the power of nothing."

Doctors long have known that some patients respond simply to the attention they get, not necessarily to a given medical service. They have found they can get good results just by taking the time to chat with patients and then by giving some—not just hypochondriacs or those too tightly wired—a sugar pill or a shot of saline.

To be sure, the placebo effect isn't typically credited with reversing a disease or condition. It's unlikely to move the metrics for fever, blood cell counts, or other body markers. But it can buoy patients' spirits, reduce their perception of problems like pain, and make them feel better.

Placebo effects can pose big woes for serious medical science, which tries to sort out biological from psychological effects by conducting "doubleblind" studies. That means that neither clinicians nor participants in a study on a given medication will know who got an experimental drug or service and who got the sugar pill.

Because providers of untested stem cell and regenerative treatments haven't subjected their approaches to rigorous scientific studies, it's unknown whether patients feel better after getting them because they work or due to the placebo effect. Researchers speculate that the latter may be truer.

When patients make major financial and emotional investments in a medical service, it also can amp up the placebo effect. It makes sense that patients who are paying as much as \$50,000 for a regimen of stem cell treatments really want including "stem cell face lifts" in fashionconscious spots like Beverly Hills, cost more (thousands of dollars), are more extensive—and they are more risky, too.

Why should we care? As the California agency charged with boosting stem cells and regenerative medicine in rigorous and beneficial fashion has observed: "The bulk of the danger with [celebrity] stories like these is not that the individuals involved are likely to be harmed (though they may be) but that the attention their famous names draw to stem cell therapies could lead others to copy their example, and undergo procedures for which there is no evidence to show they are safe and effective."

Fans clearly follow not only the entertainments offered by stars but also their serious and wellfounded or spurious and imprecise views on important health and medical issues, as Paltow, Angela Jolie, and Ben Stiller, have shown. Prominent personalities' growing sway over ordinary patients' medical decision-making has been the topic already of some serious research, and more is on its way.

This is a good thing, because celebrities' power to do good—by raising health awareness or public or financial support—must be balanced by their possible harms, including popularizing risky therapies. Skepticism and moderation matter where our health is concerned.

Recent Health Care Blog Posts

Here are some recent posts on our patient safety blog that might interest you:

Although Grandma and Grandpa didn't live as long nor as well as many of us do, they still can provide valuable insights into how modern Americans can avoid painful debilitation that now leads to some of the most commonly performed surgeries on seniors. Want to avoid an inconvenient, costly knee or hip replacement? Keep your weight down and keep moving—two steps that researchers say may have helped reduce the prevalence of the joint rheumatoid arthritis (RA) that pushes tens of thousands of baby boomers each year to seek medical treatment, up to and including knee and hip procedures that cost taxpayers billions of dollars through the Medicare and Medicaid health programs.Sure, the boomers have been one of the largest demographic groups in U.S. history (until millennials

to believe they work. Careful scientific research takes this into account, and typically it is considered unacceptable and even unethical for bona fide studies to include "pay to participate" patients. recently surpassed them) but researchers launched their study, published in Proceedings of the National Academy of Sciences, when they began to ask why RA seemed to have burgeoned among this aging group in recent decades. Though arthritis has afflicted humans for eons, its diagnosed prevalence has doubled just since the middle of the 20th century, the researchers found, based on, among other things, a scrutiny of more than 2,500 skeletons.

- It's more than happy hour chardonnays with office mates or malt liquors at a summer barbecue. Public health experts are warning that alcohol drinking is rising sharply, and in especially worrisome fashion for women, seniors, African Americans, Latinos, and Americans of Asian descent. As the nation struggles with addiction crises—especially a plague of opioid drug abuse—booze woes may be getting less than their deserved attention. Our heavy and increasing alcohol consumption, as captured in a sizable and regular survey of Americans' tippling habits, should be of big concern. That's because experts note that it can "portend increases in many chronic co-morbidities in which alcohol use has a substantial role."
- The quest for beauty—whether skin deep or in the eye of the beholder—not only carries high costs. It also can be health risky. Jane Brody reminds us in the New York Times that due "to a lack of federal regulations, the watchword for consumers of cosmetics and personal care products should be caveat emptor: Let the buyer beware." Citing a recent editorial in the Internal Medicine publication of the Journal of the American Medical Association, Brody reports that, despite a \$26.3 million lawsuit settlement involving 200 women, a hair care maker continues to tout the benefits and safety of its products, about which federal regulators have received more than 20,000 complaints of hair loss or scalp damage. She says the incidents involving the WEN product line show the flaws of relying on makers to voluntarily report "adverse" results with "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance."
- Although patients can protect their own health by getting copies of their medical records, few consumers get them, and fewer still take advantage of the federal government's push to make records easily available electronically, one of Uncle Sam's big public protection agencies reports. The U.S. Government Accountability Office also warns that tumult in the nation's health care system, notably in Congress' roller-coaster deliberations to repeal and replace the Affordable Care Act, aka Obamacare, may disrupt patients' relationships with caregivers. That makes it even more vital for consumers to have their health records. The Association of Health Care Journalists deserves a tip of the cap for pointing to the GAO

blog, where experts note that the ACA had supported a national push to get doctors and hospitals to adopt electronic health records with the aim of providing patients and caregivers more access and transparency about these crucial materials. Now, through various provider sites online, 90 percent of Americans can get some part of their records, though only 33 percent of them do so, the GAO says. The watchdog agency says it has recommended to the Health and Human Services department that it develop regulations and enforcement to make it more convenient for patients to access and download information about themselves and their care. Patients have expressed frustration that the materials now are split up across too many different portals, each with their own architecture, passwords, and other demands.

 Football players and fans, if they had doubts before, have taken yet another hit to their favorite sport, with a retrospective study of hundreds of pro players' brains finding a damaging disorder in a startling percentage of the donated organs. Experts reported in the Journal of the American Medical Association that 110 of 111 brains of onetime players in the National Football League, examined by neuropathologists and other experts, showed evidence of chronic traumatic encephalopathy, or CTE. It's a degenerative disease that experts think is caused by repeated head blows. It has been linked with multiple symptoms, including memory loss, confusion, depression and dementia. The problems can crop up long after the head trauma stops. Caution needs to be exercised with this research because the athlete-brain donors and their families were extremely self-selecting. They participated in the post-mortem study, some with guarantees of confidentiality about identities, because they had experienced or started to show likely CTE-related debilitation before their deaths. Still, the NFL athletes made up only half the study group, and other onetime football players—those who had played in college, semi-pro or other pro leagues -also showed unusually high evidence of CTE, especially when compared with individuals who did not experience the sport's routine head blows.

HERE'S TO A HEALTHY 2017!

Sincerely,

Trick Molone

Patrick Malone



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