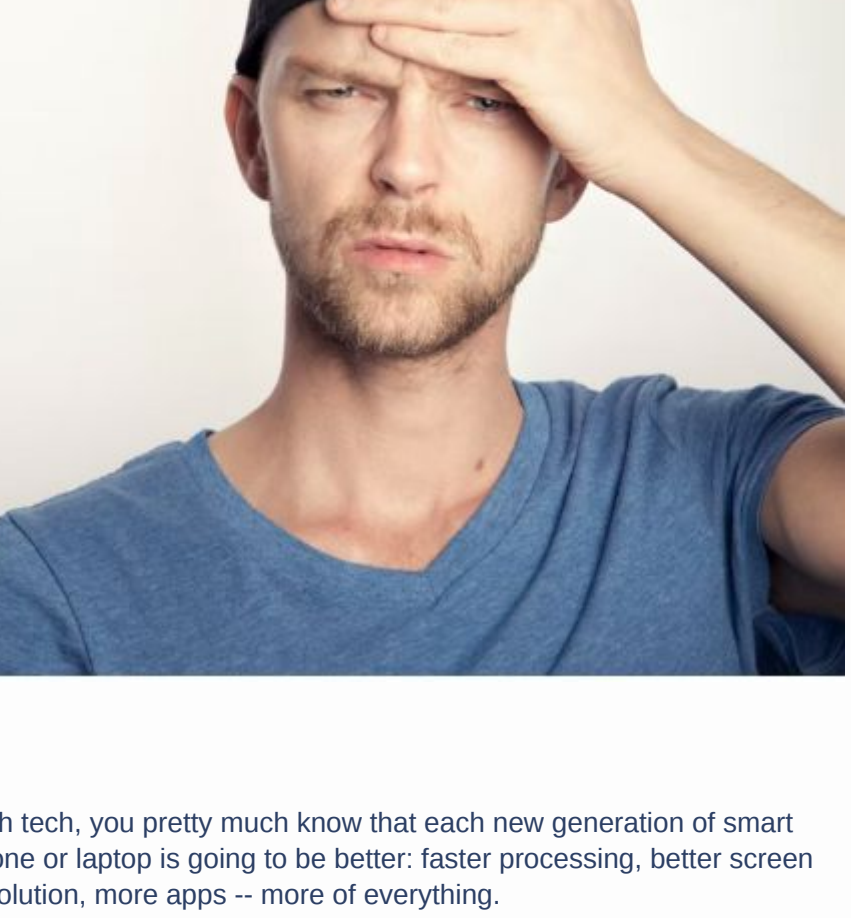
PATRICK MALONE & ASSOCIATES

Better Healthcare Newsletter from Patrick Malone



With tech, you pretty much know that each new generation of smart phone or laptop is going to be better: faster processing, better screen resolution, more apps -- more of everything.

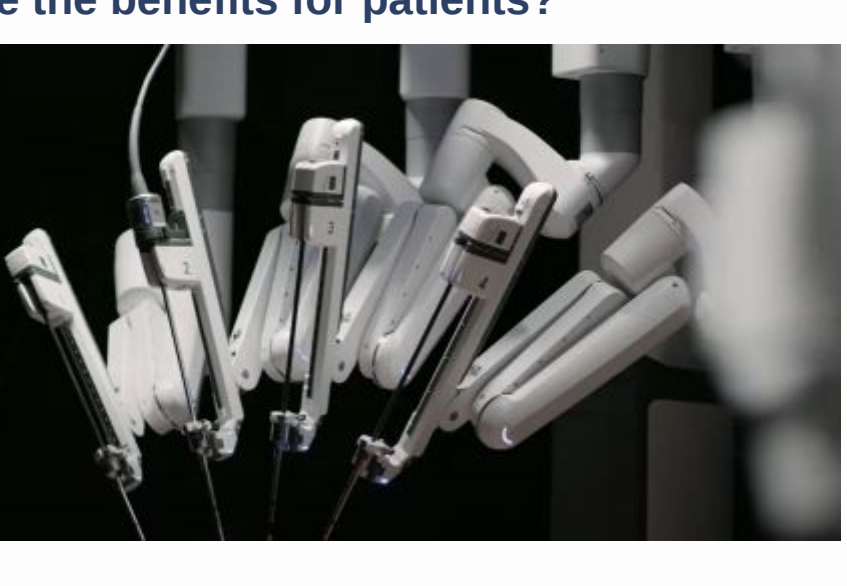
Medical care doesn't work that way.

Not that you would ever know that from the steady drumbeat of breathless "breakthrough!" publicity from medical institutions. They want patients to think that the latest innovation really is the greatest. Often, it's not. Time and again, new treatments and tests offer no proven benefit to patients. They just cost a lot more.

Yes, there are genuine medical advances that help patients heal better and live longer. Many selfless researchers are focused 24/7/365 on making things better. The problem is, patients get hurt when they're lulled into new stuff that's really no better than the old ways. So we need to sort the genuine from the inflated.

This month, we focus on five examples of overhyped medical treatments and testing. Readers may see some common themes that will help make for clear-eyed focus next time you're presented with the chance to jump on board with a new innovation for your own care.

1. Robotic surgery costs a ton, but where are the benefits for patients?

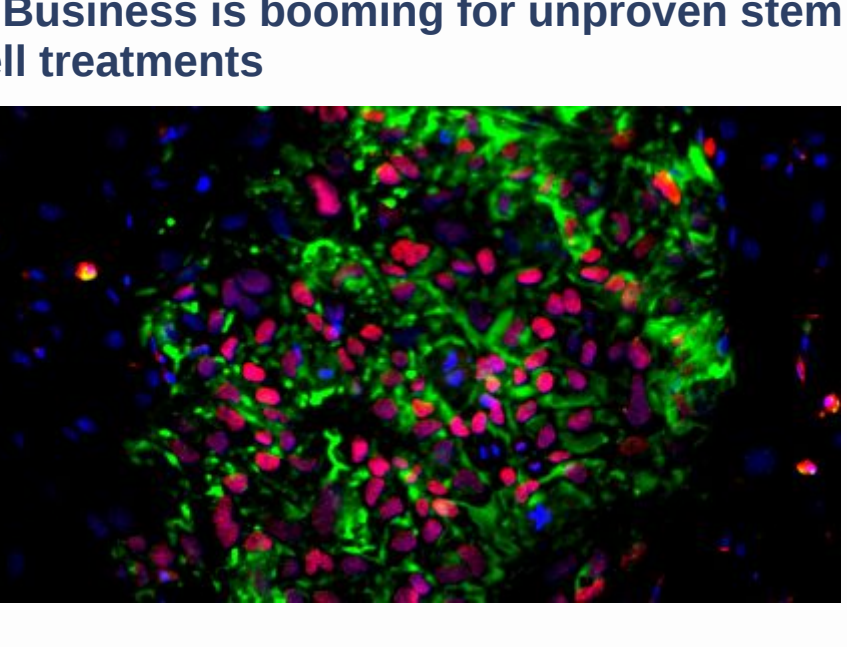


It's an infomercial pitch still common on local TV stations in hours far from prime time. A wide-eyed broadcaster turns to a scrubs-wearing surgeon who extols the virtues of robot-assisted procedures. The hype for the machines, which cost hospitals millions of dollars or more annually, asserts that they do wonders — in surgeries for the knee, abdomen, pelvis, and more.

But after years of rigorous, independent research, the devices that doctors and hospitals push so hard have not shown better results for patients. Surgeons say robots make it more comfortable for them to work in keyhole or laparoscopic procedures. But robotic procedures often last longer, cost more, and do not produce measurably better results. In August 2021, researchers conducted a meta-analysis, digging into 50 published studies on robotic surgery. Dr. Naila H. Dhanani, a lead author of that work, told the New York Times that for a patient, there is no reason to choose robotic surgery over other approaches: "Just because something's new and fancy doesn't mean it's the better technique. Yes, robotic is safe, we've proven that. But we haven't proven it's better." Dr. James A. Eastham, chief of urology at Memorial Sloan Kettering Cancer Center, who was not involved in the study, told the newspaper: "It is far more important to select an experienced surgeon with specialization in a particular field rather than picking a technique."

Critics also have drawn a starker picture of the risks posed by surgical robots, arguing that they harm patients, particularly because doctors can jump on them and begin operating on people with thin training. The federal Food and Drug Administration has warned surgeons anew that robots should not be used — including in clinical trials — in mastectomies and other breast cancer procedures.

2. Business is booming for unproven stem cell treatments



For decades, medical researchers have reveled in the possibility that life-changing treatments would flow from scientists' remarkable discovery that they could reproduce a seemingly magical building block of human life: stem cells. Enthusiasm for research on these transforming cells — and the hope that they might play a major role in battling cancer, diabetes, and other disorders, while also rejuvenating or replacing organs — led California voters to commit $8 billion for study in this field.

While stem cell research has dominated headlines and become an obsession of elite medical centers, the federal Food and Drug Administration as of March had approved only a handful of stem cell therapies.

That has not halted a costly, dangerous stampede of purveyors claiming to use stem cells in unapproved treatments for arthritis, Alzheimer's, disease, Covid-19. and many other conditions. This is how the Verge news site described the risks of this trend, which the FDA was supposed to crack down on but has not: "[T]he products have a dubious safety record. People have gone blind after receiving unregulated stem cell treatments. Non-FDA-approved treatments have also been linked to kidney failure and bacterial infections. Unproven and potentially dangerous therapies have become so prevalent that in 2019, Google announced it would ban ads for them."

The FDA in 2017 gave stem cell proponents three years to prove specific, alleged treatments would work and not harm patients. But the agency has dithered while the business has exploded. As the Verge reported, based on the published work of Leigh Turner, a University of California, Irvine, professor: "As Turner sees it, with nearly 1,500 businesses operating 2,754 stem cell treatment clinics in the U.S. in March 2021, whatever warnings regulators have issued to try and rein in the industry aren't working." Instead, the business is morphing, with providers now claiming to extract patients' own tissues — including fat from their posteriors — and supposedly *processing, manipulating*, or *repurposing* it for dubious use in patients.

By the way, big, fancy hospitals also have jumped into the stem-cell clamor, pressing what critics have assailed as the evidence-light and highly lucrative area of "regenerative medicine."

3. Prenatal genetic tests sound too many false alarms

Critics have watched with dismay as Silicon Valley entrepreneurs have shoved their way into U.S. health care, including with the rapid expansion of prenatal testing. The firms found initial success with blood screens to detect Down syndrome. These tests —intended to detect minute deletions in fetal chromosomes (microdeletions) — were cheaper than conventional testing of the mother's amniotic fluid, and the hard-charging marketing whizzes saw opportunities to persuade expectant parents to rely on them.

They then advertised that the screenings, administered early in pregnancy and requiring just a few vials of blood, could detect rarer and rarer developmental disorders in the unborn. Without disclosing supporting data, the companies boasted about the tests' accuracy.

The New York Times dug into why so many couples spend thousands of dollars on screens and what they purport to tell potential parents.

Major problems surfaced fast in what experts say soon may be a billion-dollar-a-year business, the newspaper found: "The grave predictions made by those newer tests are usually wrong …To evaluate [them], The Times interviewed researchers and then combined data from multiple studies to produce the best estimates available of how well the five most common microdeletion tests perform. The analysis showed that positive results on those tests are incorrect about 85% of the time."

Further, the companies, at best, glossed over warnings to patients that the tests both can produce false positives and require follow-up. They are screenings, not diagnostic tools, meaning their alerts must be confirmed with further exams that can be costly and invasive. While patients often receive extensive counseling about genetic tests and their results, this has not occurred with the speedy blood tests. Sadly, the newspaper learned about couples who terminated pregnancies based on alarming blood screens alone.

Federal officials say they typically neither regulate nor approve the "laboratory developed" screenings. Still, the FDA has publicly cautioned consumers, with the New York Times reporting: "The agency warned doctors not to diagnose genetic disorders based on these results alone and stressed the need to follow positive screenings with more reliable 'diagnostic' testing. It said it was 'aware of reports' that some women 'have ended pregnancies based only on the results' of these genetic screening tests. 'While genetic noninvasive prenatal screening tests are widely used today, these tests have not been reviewed by the FDA and may be making claims about their performance and use that are not based on sound science,' " the agency's top testing official said.

4. Excess imaging hikes costs and risks

Walmart has said it is so. So has the insurer Anthem. Ditto medical experts publishing in the Journal of the American Medical Association. They all have criticized doctors' and hospitals' excessive use of medical imaging — not mammograms or routine X-rays, say, of broken bones. No, for years critics have targeted the excessive use of CT, PET and MRI scans.

As a study in JAMA found in 2018 (as reported by the trade publication *Health Imaging*): "The U.S. performed the second highest number of imaging exams … and had the second highest MRI and CT technology utilization rate, following Japan … The average cost of a CT exam in the U.S. was $896 per scan as compared to $97 in Canada, $279 in the Netherlands, and $500 in Australia …. The U.S. [after Japan] had the second highest number of MRI units [per million patients] … and the third highest number of CT scanners ..." This country could save billions of dollars if it reduced the number and cost of imaging, wrote Dr. Ezekiel Emanuel, of the University of Pennsylvania's medical school, in an accompanying [JAMA] editorial. He noted that evidence showed that "up to a third" of the procedures "may be deemed unnecessary and carry radiation risks …"

Walmart and Anthem both have cracked down on CT and MRI scans they will pay for, telling patients over whom they have a say to use imaging providers they recommend. That's because they have found not only over-use of imaging but also issues with its cost and challenges with the accuracy or interpretation of results. As the Kaiser Health News service reported: "Studies show a 3% to 5% error rate each work day in a typical radiology practice, but some academic research has found mistakes on advanced images such as CT scans and MRIs can reach up to 30% of diagnoses. Although not every mistake affects patient care, with millions of CT scans and MRIs done each year in the United States, such mistakes can have a significant impact."

Patients with concerns— and who don't want to get caught up in big hospitals nearby competing with each other by buying and promoting the fanciest, most expensive, and latest imaging devices and services — can study guidelines provided by reputable experts. They can consider the American College of Radiology recommendations for the Choosing Wisely program on imaging options that patients should question when doctors order them. Or they can consult advisories on imaging procedures like lung cancer scans or mammograms as issued by the U.S. Preventive Services Task Force, a top federal panel that provides independent, influential guidance on medical tests and screenings.

5. More cancer drugs ≠ better, longer lives

Big Pharma, with its mastery of public messaging, would love for Americans to think that this is a Golden Age for cancer care. After all, federal regulators are approving more cancer drugs than ever, many of them at an accelerated pace. For patients, this must mean that doctors have more and better options to battle one of the nation's leading killers, right?

Well, not exactly. Cancer treatment has improved, and increasing numbers of people who have survived bouts of various types of the disease attest to this. Still, a rising chorus of critics argue, as one recent study explained: "Although several oncology and malignant hematology drugs receive FDA approval each month, it is unclear how many of these cancer drugs transform the treatment landscape significantly … It remains unclear how many of these newly approved cancer drugs displace the existing standard-of-care therapies … compared with providing simply an alternative treatment option."

The researchers, in their scrutiny, determined that "14% of new drug approvals displaced existing standards of care, and an additional 15% provided market competition. At the same time, 29% were add-on or maintenance drugs that can only increase the cost of care. Forty-two percent were drugs approved for patients who had exhausted other treatment options." Another critic summarized his stark reality check about many "wonder drugs" thusly: "For the most part, cancer drugs cost too much and deliver too little. Because of this, their value is poor."

Cancer specialists, at last, have recognized the tough challenges patients confront with the bankrupting cost of prescription medications and other treatments that create the disease's "financial toxicity." A big reason for the nightmares: Big Pharma has gotten the FDA to approve drugs that cost tens or hundreds of thousands of dollars, not because they improve or extend patients' lives. Instead, the agency bases its decisions on "surrogate endpoints," measures such as whether a medication shrinks a tumor for a given period. This means that patients — if their finances or insurance allows it — can be forced into impossible choices: Is a 2.5-month increase in survival (the median for a typical cancer drug) worth going broke over or seeing that happen to their loved ones? And how many times should a late-stage patient try different, expensive cancer drugs in hopes of finding a helpful treatment?

IN THIS ISSUE

BY THE NUMBERS

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Estimated number of years it takes published research on innovative therapies to become part of doctors' regular practice. Critics say this is too slow, while other experts say that medicine should be conservative in its practices to protect patients.

$3 billion

Estimated sum hospitals paid for robotic surgical devics in 2017 alone. Researchers also estimated that patients' paid $1,866 on average just for providers' proprietary instruments and accessories used in robotic procedures.

1 in 20,000

Number of births in which a child will have Prader-Willi and Angelman syndromes. These can cause seizures and an inability to control food consumption. Despite the conditions' rarity, many couples still pay thousands of dollars for genetic blood tests. The New York Times found they are 93% wrong in detecting these diseases.

$93 million

Estimated sum patients paid in 2015 alone for a 'regenerative' treatment for knee arthritis. While clinicians say patients clamor for experimental platelet injections, the American College of Rheumatology and the Arthritis Foundation strongly recommend against it for knee and hip care.

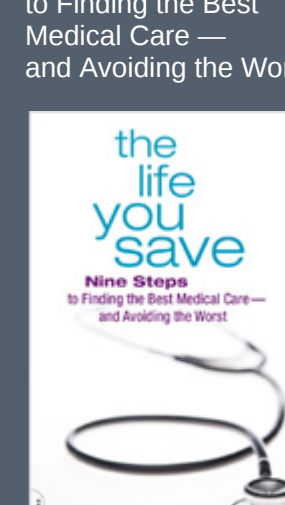
QUICK LINKS

Our firm's website

Read an excerpt from Patrick Malone's book:

The life you save

Nine Steps to Finding the Best Medical Care — and Avoiding the Worst



LEARN MORE

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

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PAST ISSUES

It's easy to bedazzle even best and brightest with medical hokum

Two former U.S. Secretaries of State, and two others who served as Secretary of Defense. A onetime Secretary of Education. Two U.S. senators. A titan of civil litigation. A Silicon Valley legend. A global media mogul. The former CEO of a leading U.S. bank.

What do all these folks have in common? They are proof that excess exuberance can be too hard to see through — even for those with great sophistication —when it comes to a supposed breakthrough in medical technology.

These prominent figures — including Henry Kissinger, George Shultz, William Perry, James Mattis, Betsy DeVos, Bill Frist, Sam Nunn, David Boies, Larry Ellison, Rupert Murdoch, and Richard Kovacevich — all were ensnared in the fraudulent Theranos blood-testing enterprise.

Elizabeth Holmes, (shown above) notorious for wearing black turtlenecks and talking in an unusually low voice, was convicted earlier this year on four fraud-related charges in Theranos' collapse. Her gulling some of the nation's leading lights — and costing them hundreds of millions of dollars in losses — have captured attention in:

§ *Bad Blood: Secrets and Lies in a Silicon Valley Startup*, a book by investigative journalist John Carreyrou, who broke the Theranos story in *The Wall Street Journal*. The book is set to be made into a feature film.

§ The HBO documentary *The Inventor: Out for Blood in Silicon Valley*, directed by Academy Award-winner Alex Gibney

§ And in *The Dropout*, Hulu's acclaimed miniseries starring Amanda Seyfried.

These works, along with a barrage of news reports, have reminded big audiences that Holmes sold heaps of hokum for more than a dozen years before Carreyrou, in particular, asked tough questions that burst the fantasy bubble its CEO-founder created around Theranos.

Holmes, a chemical engineering student, dropped out of Stanford University to found Theranos and to pursue a vision of a compact, portable device that could quickly analyze just a few drops of blood and provide complex, extensive medical results for far less cost than commercial labs. She exploited her own story and connections, demonstrating a jaw-dropping knack for persuading older men, mostly, of her business and scientific acumen based on little or no evidence. She got rich, prominent, and powerful.

A key cause for her downfall came due to her contacts, notably with the important whistleblower in the Theranos case — Shultz's grandson, a 22-year-old biology major. Tyler Shultz met Holmes through his grandfather and got a job at Theranos.

In his eight months there, he fast figured out that more was wrong than right. He contacted Carreyrou and federal regulators. He confronted his beloved grandfather and had a brutal family falling out that wasn't fully repaired before Shultz's death. Tyler and his family were saddled with onerous debt due to lawsuits filed against him by the company. Tyler, who is working on a biotech startup of his own, told NPR that he celebrated Holmes's conviction with a champagne toast. Talk about bittersweet.

Photo / image credits: National Cancer Institute, HBO, California Institute for Regenerative Medicine, National Human Genome Research Institute, Intuitive Corp., Unsplash.

What about waste and fraud? Big problems in health care

It's a national embarrassment. Americans spend more on health care than any other nation, yet we get some of the poorest outcomes among advanced economies. Critics long have pointed out that too many of the trillions of dollars expended in the U.S. goes not for direct health care but to pay for wasteful procedures, burdensome administrative costs, and sky-high prices on prescription drugs.

CBS News reported in 2019 on a study in the Journal of the American Medical Association that: "Activities such as medical coding and billing, record keeping and other clerical activities result in roughly $266 billion in excess spending annually, according to the study … But the overall amount of money that goes down the drain is even greater. Factoring in other inefficiencies, such as a lack of price controls for health services, poor coordination of care, and fraud and abuse, the total tab that is wasted every year runs between $760 billion and $935 billion, according to the researchers. That's fully a quarter of all annual health care spending in the U.S., not to mention greater than the entire 2019 defense budget."

In a 2018 JAMA editorial, Dr. Ezekiel J. Emanuel, chair of the department of Medical Ethics and Health Policy at the University of Pennsylvania medical school, criticized big differences in America's huge health spending versus what Europeans pay [as reported by his institution]:

"Emanuel highlighted several key drivers of this huge spending difference. One consists of high-price, high-volume surgical procedures such as caesareans, knee and hip replacements, coronary artery bypasses, and angioplasties. Americans per-capita spend 2 to 6 times more on these procedures than their peer country counterparts ... Administrative bloat in the U.S. is a second major spending driver, with per-capita costs that are three to five times higher than costs in peer countries. Medical imaging procedures, meaning mostly CT scans and MRIs, are a third major driver of spending differences, and also involve both high prices and high volumes …

"The fourth major driver, pharmaceuticals spending, is the only one where high prices are the dominant factor. Americans spend $1,443 per capita on pharmaceuticals, versus $566 for Swedes, for example, yet this huge excess is almost entirely due to higher U.S. prices, not higher volume."

Law enforcement and other authorities, by the way, say this country takes a huge hit from crooks and fraudsters ripping off money in the health care sector. The National Health Care Anti-Fraud Association estimates that "the financial losses due to health care fraud are in the tens of billions of dollars each year. A conservative estimate is 3% of total health care expenditures, while some government and law enforcement agencies place the loss as high as 10% of our annual health outlay, which could mean more than $300 billion."

Federal prosecutors are going after health care criminals with increasing force, the Justice Department has reported, noting of its strike forces working since 2007:

"Since its inception, Strike Force prosecutors filed more than 2,100 cases charging more than 4,600 defendants who collectively billed federal health care programs and private insurers approximately $23 billion; more than 3,000 defendants pleaded guilty and over 390 others were convicted in jury trials; and more than 2,800 defendants were sentenced to imprisonment for an average term of approximately 50 months. Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts."

Recent Health Care Blog Posts

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

- The opioid abuse and drug overdose crisis has veered into a frightening new phase in which the rise of the easy-to-make, exceedingly powerful synthetic painkiller fentanyl is causing multiple, interconnected deaths at one time. The nation's capital already has experienced this grim situation, which only shows signs of worsening, the Washington Post reported.
- Its official title is the federal *Food* and Drug Administration. But taxpayers are ill-served by the $1 billion they fork over to this behemoth agency to safeguard the foods all of us must consume and to provide sound nutritional guidance in especially confusing times. That's a significant takeaway for readers of a new, magazine-length takedown of the FDA's food programs by the news site Politico. It has joined ProPublica, the Pulitzer Prize-winning investigative site, in hammering the federal government — which divides food regulation also with the U.S. Department of Agriculture — over its sluggish and poor protection of the public.
- A glaring gap in the U.S. health care system — the giving of care at home — is growing into a costly chasm. Pretty much everybody involved needs to pay close attention and finally act to deal with the nation's failure to support home caregiving for the sick, injured, debilitated, and aged. The consequences of inaction already are becoming clear, as the dearth of home care is smacking the recovering economy, "contributing to labor shortages around the country and playing a role in overall inflation," the Washington Post reported
- The nation's nursing homes and other long-term care facilities are in dire need of drastic overhaul to dramatically improve the quality and safety of their treatment of the aged, sick, and disabled. They too often now get what one expert has described as "ineffective, inefficient, inequitable, fragmented, and unsustainable" care. To repair the glaring, longstanding wrongs in these facilities — problems that critics say contributed to 150,000 resident deaths during the coronavirus pandemic — requires sweeping practical, regulatory, and financial changes in an industry focused on profits and resistant to change, according to newly published expert research report by the National Academies of Sciences, Engineering, and Medicine.
- While regular folks howl about the need to slash skyrocketing prescription drug costs, Big Pharma is showering lawmakers on Capitol Hill with campaign contributions and favoring Republicans in the House and Senate who show political promise — and an aversion to efforts to ensure the affordability of medications for the sick.The crushing costs of drugs has returned to the policy-making spotlight as Democrats in the House, with a few defecting Republicans, have approved a bill to limit the soaring price of insulin to $35 a month for most Americans who have insurance and whose health and lives depend on the increasingly unaffordable medication.
- Alcohol abuse blew up from a rising concern to a significant killer during the coronavirus pandemic, with 100,000 Americans losing their lives to booze-related causes, a 25% increase year-over-year in the first 12 months of the global infection's outbreak. The figures from research newly published in the Journal of the American Medical Association shows the lethal damage caused by the pandemic, not only directly by the 1 million-plus deaths blamed on the virus but also in its closely linked menaces

HERE'S TO A HEALTHY 2022!

Sincerely,

Patrick Malone
Patrick Malone & Associates