



Message from Alliance for Retired Americans Leaders

Alliance Marks Older Americans Month



Robert Roach, Jr.
 President, ARA

Wednesday, May 1 was the first day of Older Americans Month and Alliance members across the country are celebrating seniors'

positive impact on their communities. This year's Older Americans Month theme, Powered by Connection, **recognizes** the power in building meaningful relationships and social connections that promote health and well-being.

President Biden issued an Older Americans Month **proclamation** that recognizes seniors' contributions to the nation but also acknowledges how the government can ensure that seniors retire with financial security.

The proclamation underscores the success of Social Security and Medicare in reducing the number of older Americans living in poverty and also highlights the Biden Administration's new budget, which would strengthen Social Security by asking the highest-income Americans to pay their fair share into the program. The budget would also extend Medicare's Hospital Insurance Trust Fund indefinitely.

The proclamation noted that the Biden administration passed a

law to require Medicare to negotiate lower drug prices, as the Department of Veterans Affairs has done for years. It also caps insulin prices at \$35 a month and out-of-pocket annual drug costs at about \$3,200 this year for Medicare beneficiaries. In 2025 the cap will be lowered to \$2,000.

"President Biden's accomplishments have given seniors breathing room when it comes to health costs and retirement savings," said **Robert Roach, Jr., President of the Alliance**. "As he said in his proclamation, going forward we need Congress to pass his budget, which protects seniors from cuts to our hard earned Social Security and Medicare benefits." **Another Federal Judge Rejects Drug Corporations' Challenge to Medicare Drug Price Negotiations**

On Monday, a federal judge in New Jersey **rejected** a challenge to Medicare drug price negotiations from large drug corporations Johnson & Johnson and Bristol Myers Squibb. The case was another in a slew of drug company lawsuits seeking to dispute drug price negotiations as unconstitutional.

Drug companies are seeking so-called **split decisions** in federal courts, a strategy that aims to escalate the case to the Supreme Court. However, Monday's

decision is another win for the Biden administration, and consistent losses for the drug industry have significantly reduced the likelihood of that outcome. The judge's 26-page opinion rules that, contrary to drug companies' claims that drug price negotiations violate free speech, participation in the price talks are voluntary.

The judge said that just because selling to Medicare means lower profits does not make participation in the program is any less voluntary.

The first round of price negotiations are already underway, and if court rejections of drug companies' cases continue, seniors will see reduced prices for the first 10 drugs in 2026. "The decision is a win for the Biden Administration and for seniors," said **Richard Fiesta, Executive Director of the Alliance**.

"This latest courtroom victory brings Medicare beneficiaries one step closer to seeing more affordable drug prices, something the Alliance has been working to achieve for 23 years.

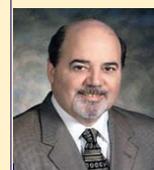
This Year's May Day: A Time to Celebrate UAW Victories
 Wednesday, May 1 was May Day, International Workers' Day



Rich Fiesta,
 Executive Director, ARA



and the labor movement. It is also a day of remembrance, since it honors the workers who died during the Haymarket affair bombing in 1886 in Chicago while protesting for an eight-hour workday. "This year's May Day is a special opportunity to celebrate the **Volkswagen workers in Tennessee** who recently voted to join the UAW, as well as the **UAW deal last Friday** with Daimler Truck in North Carolina that gave workers 25 percent raises over the next four years,"



Joseph Peters, Jr.
 Secretary
 Treasurer ARA

said **Joseph Peters, Jr., Secretary-Treasurer of the Alliance**. "These breakthroughs mark the first successful unionizations of foreign-owned automakers in the South and are likely an indicator of future victories to come in the region, victories that will benefit retirees as well as active workers."



Happy Mother's Day



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Survey: 80% of Women Say the United States Faces a Retirement Crisis

According to new research from the National Institute on Retirement Security (NIRS), 80% of working age American women believe the country faces a retirement crisis, and 78% say the typical worker just can't save enough on their own to guarantee a secure retirement.

Most American women (82 percent) also say all workers should have a pension so they can be independent and self-reliant in retirement. The report found nearly all U.S. women (86 percent) agree Congress should

act now to shore up funding for Social Security rather than waiting ten years to enact a solution.

The findings, a supplement to a national survey of working age Americans conducted by Greenwald Research, are detailed in the report, **"What Do Women Think About Retirement."** The research also found:

◆ Eighty-one percent of women



say employers should contribute more money to workers' retirement plans. More than three-fourths (76 percent) say retirement is only getting harder, due to inflation, rising health care costs, debt, and fewer pensions.

◆ Eighty-one percent of women are worried about the costs of long-term care, and only 38 percent feel confident they will be able to pay for any needed long-term care costs. Most

women (86 percent) agree that the government should do more to help Americans get access to quality long-term care when the need arises.

"The wage gap remains persistent for women and they typically live longer than men, affecting their finances in retirement. They also have more caregiving demands, which hurts their earning potential," said **President Roach**. "Women clearly see increasing pension coverage as a major piece of the solution to their concerns."

Millions of Americans May Get Their Medicare Advantage Benefits Cut

Millions of Americans on Humana's **Medicare Advantage plans** could see their **health care benefits** cut after the company makes major profit-boosting adjustments to its plans.

Humana said it would be ending some plans and cutting benefits for patients in 2025 as it hopes to boost its financial performance. Altogether, 6 million Americans are insured through Humana's Medicare Advantage.

"The insurer recently warned that rising health care costs are squeezing their business model, forcing them to slash benefits and potentially exit some markets altogether in 2025," Michael Ryan, a finance expert and the founder of michaelryanmoney.com, told *Newsweek*. "And with over 6 million enrollees, Humana's moves will ripple across the entire Medicare Advantage



market."

A few weeks ago, Humana warned that its 2025 profit targets were down due to the upcoming payments by the federal government to Medicare Advantage plans.

Humana joins several other insurers who have said Medicare Advantage payments likely won't keep up with the surging costs the plans take on as more seniors use their insurance for hospital and

outpatient treatment.

"We acknowledge that the industry is experiencing a dynamic and challenging time that we must navigate," CEO Bruce Broussard told investment analysts during a quarterly call Wednesday.

Humana is feeling the hits from the federal government's low reimbursement rates because of how many people are insured through its Medicare Advantage programs. ... **Read More**

Social Security's 2025 COLA: Here's What We Know So Far

At this point, many consumers are beyond frustrated with what economists are calling sticky inflation. Workers and retirees alike have been grappling with higher living costs since 2021. And while we're not seeing the same runaway inflation now as we did in 2022, many people are still feeling the strain at the supermarket, drugstore, and pump.

In 2023, seniors on Social Security got a massive **8.7% cost-of-living adjustment**, or COLA, following a period of truly rampant inflation. At the start of 2024, however, benefits only **rose 3.2%** -- a generous COLA in the context of the past 20 years, but nowhere close to 8.7%.

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context of the past 20 years, but nowhere close to 8.7%.

Next year's Social Security COLA, meanwhile, is shaping up to be even smaller than 2024's. And while that's bad news for seniors in one regard, there's a big silver lining.

Smaller COLAs mean cooling inflation

Social Security COLAs are pegged to inflation -- specifically, data from the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W). The nonpartisan Senior Citizens League recently put out an estimate stating that the group expects a 2.6% Social Security COLA for 2025 based on recent inflation data. For context, in March, the CPI-W was up 3.5% annually.

Given that many seniors were disappointed in their 2024 COLA, a 2.6% COLA in 2025 is unlikely to sit well. But it's important to recognize that a smaller COLA is an indication of



easing inflation. And that could have a truly positive impact on seniors.

A 2.6% COLA applied to a \$2,000 monthly Social Security benefit results in an additional \$52 a month, assuming part of that sum isn't eaten up by **Medicare** Part B premium hikes. But cooling inflation could lead to \$52 in monthly savings on things like groceries, gas, utilities, and other common expenses. So all told, seniors might fare reasonably well financially with a raise at that level.

It's too soon to know for sure Social Security COLAs are calculated based on third quarter data from the CPI-W and are announced in October each year. As such, the above 2.6% projection is really just that -- an estimate.

It's too soon to know what next year's COLA will look like. And while there's a chance it'll come in at less than 2.6%, it could also end up being similar to this year's

COLA if inflation continues to creep upward.

Either way, it's a good idea for seniors to try to avoid being COLA-dependent. To that end, those with the ability to do so should consider trying to boost their income by joining the gig economy. There are numerous flexible job opportunities out there, and the extra money could buy a lot of people more financial wiggle room.

Of course, for those who aren't yet retired, boosting savings is a great way to end up in a situation where Social Security COLAs don't matter quite so much. It may be too late for current beneficiaries to boost their nest eggs, but those who are still collecting a paycheck can pad their savings to become less reliant on **Social Security** in retirement on a whole. Given the potential for **benefit cuts** down the line, that's a prudent thing to do regardless of how COLAs shake out in the coming years.

Millions of American Seniors Face Annual Losses of Over \$3,000 Due to Social Security Tax

As millions of American seniors rely on Social Security for their golden years, a growing issue looms that threatens their financial stability. Changes made to Social Security taxation in the 1980s and 1990s are causing a significant impact, with half of the recipients now facing losses averaging over \$3,000 annually. This predicament underscores a systemic flaw that has gone unaddressed for decades, forcing many to reconsider their retirement strategies.

A Troubling Legacy of Tax Reforms

Originally, Social Security benefits were designed to be a tax-free sanctuary for retirees, ensuring they received full financial support in their post-work years. However, this changed dramatically with legislative amendments in 1983 and again in 1993. Initially, these changes were intended to help preserve the financial health of the Social Security system. In 1983, up to 50% of benefits became taxable if a retiree's

provisional income exceeded certain thresholds. By 1993, this taxable portion could go up to 85% for some retirees.

The problem, however, lies in the static nature of the income thresholds set during these reforms. In 1983, a single filer would need to earn more than \$25,000, or \$32,000 for joint filers, for their benefits to be taxed. Fast forward to today, and these figures remain unchanged—not adjusted for inflation—despite the fact that the dollar's buying power has sharply declined since then. The Current Impact on Retirees

This oversight has profound consequences. What was once a tax aimed at wealthier retirees now indiscriminately affects nearly half of all Social Security recipients. According to The Senior Citizens League, a senior advocacy group, this figure is expected to rise, with more than 56% of retirees likely to owe taxes on their Social Security benefits in the near future.



The average tax paid by those affected in 2020 was \$3,211—a substantial amount considering that many depend on these benefits as their primary source of income. **As inflation continues to push** the cost of living higher, the real value of Social Security diminishes, compounded further by these significant tax obligations.

Looking Ahead: Strategies for Future Retirees

For future retirees, proactive financial planning is more crucial than ever. Investing in a Roth IRA could be a savvy move, as distributions from these accounts do not count towards the provisional income threshold for taxing Social Security benefits. For current and soon-to-be retirees, understanding these tax implications is vital for managing their finances, especially as the likelihood of legislative relief remains slim.

Additionally, **seniors might explore opportunities** to generate risk-free passive income.

With interest rates at their highest in decades, some top-rated savings accounts offer returns significantly above the national average, coupled with FDIC insurance to safeguard their investments. For a limited time, new account holders can also benefit from a \$200 bonus, **providing a small but meaningful** boost to their retirement savings.

Securing Retirement Amid Outdated Social Security Policies

The taxation of **Social Security** benefits reflects a broader issue of outdated policies that fail to keep pace with economic realities. As seniors navigate these financial hurdles, awareness and preparation will be key to securing a more stable and prosperous retirement. While the battle to adjust these outdated thresholds continues, the resilience and strategic planning of America's retirees will play a pivotal role in safeguarding their financial futures.

Beware of These 5 Medicare Scams

Medicare is a big deal. Offering health insurance for those 65 and older, as well as younger folks with certain disabilities or End-Stage Renal Disease, it serves more than 65 million people. It's valued highly by enrollees and is eyed greedily by scam artists as well.

1. May I help you?

Many seniors have gotten scammed by responding to people who knock on their door saying they're from Medicare and can help, perhaps offering tempting "free" services or just asking to verify information. Others are approached similarly but via email, phone, or even texts. Medicare does not cold-call people in person or otherwise. If they're truly calling you, it's because you called them first, perhaps with a question.

Note, too, that scammers these days have gotten very good at being convincing. They may have some of your information, such as your address or your Social Security number due to a data breach somewhere, and they can get you to trust them by sharing

that. Stay skeptical! Even if the email or ID card *looks* legit, doubt it -- and verify, or better yet, just say no.

2. Your Medicare plan has been canceled!

Another scam is contacting a senior and frightening them by announcing that their Medicare plan has been canceled -- or may be canceled soon -- and they'll be in deep trouble if they don't go along with whatever the scammer is asking of them.

Know that Medicare plans generally don't just get canceled, leaving enrollees in the lurch. They may get canceled if you fail to pay your premiums, though. One way to avoid that occurrence is to have your premiums taken out of your Social Security benefits directly.

3. Want some free products or medical services?

Read up on your Medicare plan to see just what it offers you. For example, **"original" Medicare covers** things such as inpatient hospital care, annual wellness visits with your doctor, some in-



home health services, some mental health treatments, preventive screenings, wheelchairs, oxygen equipment, and much more. It does not cover dental, hearing, or vision services -- though many **Medicare Advantage** plans do cover those -- along with everything covered by original Medicare.

If someone is approaching you offering additional services or products for free or at a big discount, don't believe them. You can always call Medicare, too, to see whether a certain product or service is covered by your plan.

4. You need a new Medicare card

A few years ago, Medicare enrollees did receive replacement Medicare cards featuring a randomized ID number instead of the Social Security numbers previously used. That event inspired some scammers to start targeting seniors, telling them they need a replacement card (perhaps one with a chip -- though Medicare cards do not use

chips) or that they need to activate their current card by telling the scammer their new number. Don't fall for it if someone is asking you to reveal or confirm your Medicare number. Enrollees should have their new cards by now and shouldn't need to replace them again (unless they lose them).

5. Here's a better -- or cheaper -- plan for you!

One more scam is when someone is trying to get you to sign up for a special, better Medicare plan -- perhaps telling you you've been pre-approved for it. This scam is most prevalent in autumn during the **annual Medicare open enrollment period** when enrollees can switch between plans.

Resist this scam, too. It *is* good to comparison-shop and weigh your options each year during the enrollment period, but do your own homework on plans available to you. You can get a lot of research done right at Medicare.gov's website.

This Group Is Less Satisfied With Medicare Than Other Enrollees

By and large, Americans love Medicare. But one group of enrollees is a little less thrilled with the program.

The vast majority of people with Medicare for their health care coverage are 65 or older. But there is another, smaller group of Americans who enroll in the program before that age.

As we reported in **“3 Groups Who Can Get Medicare Before Age 65,”** these are younger folks who qualify for Medicare due to having a long-term disability, end-stage renal disease (ESRD) or amyotrophic lateral sclerosis (ALS).

In 2022, 7.7 million people under the age of 65 — or 12% of all Medicare recipients — fell into this category of coverage.

These are the people who are **less happy with their Medicare coverage,** according

to responses from 3,600 adults in the latest annual KFF Survey of Consumer Experiences with Health Insurance.

While 92% of those over the age of 65 give positive marks to their Medicare coverage, that number dips to 79% for those under the age of 65 with disabilities.

KFF reports that people under the age of 65 who are on Medicare are more likely to report:

- Worse access to care
- More cost concerns

Lower satisfaction with care

Among beneficiaries under age 65 who have disabilities, 70% said they experienced some type of issue with their health insurance over the prior 12 months. Meanwhile, just 49% of those 65 and older report such



problems.

According to a summary of the KFF findings:

“At least one in five

Medicare beneficiaries

under age 65 with disabilities who reported problems say they were unable to receive recommended treatment (24%) or experienced significant delays in receiving medical care or treatment (21%), compared to very small shares of those 65 or older who said the same (6% for both).”

Although Medicare offers the same benefits to everyone who is enrolled — regardless of age — KFF speculates that because Medicare was designed for older adults, it might not work as well for their younger counterparts.

Other factors also could be at play. For example, KFF notes that among people with Medicare

under age 65 who have disabilities, about half said their physical health is “fair” or “poor.” Just 19% of those 65 and older said the same.

In addition, 3 in 10 people with Medicare under age 65 who have disabilities report “fair” or “poor” mental health status. Just 1 in 10 people age 65 and older say the same.

As KFF states in a summary of its findings:

“The higher rate of poorer self-reported health among beneficiaries under age 65 could contribute to a higher rate of health insurance problems.”

Regardless of what age you enroll in Medicare, it is important to understand the program’s limitations. For more, check out **“Medicare Will Not Cover These 10 Medical Costs.”**

Dave Ramsey's Risky Plan For Social Security Is Unrealistic for Most Retirees. Here's Why



You get to choose when to claim your Social Security benefits, but the consensus among most financial professionals is that delaying your claim for as long as possible is the best move. Although you can start getting benefits at 62, the amount you get goes up every month you delay until 70. For most people, waiting gives you the best chance at maximizing the lifetime income these benefits offer.

There's one financial guru who has some different advice, though. Dave Ramsey has suggested that taking Social Security at 62 (the earliest age available) is actually a good move in some situations. The problem is, most people can't really follow Ramsey's advice -- and those who can perhaps shouldn't, as it could put them at unnecessary risk of financial loss.

Here's when Ramsey said you can claim Social Security at 62. Ramsey commented on the issue of when to claim **Social Security** in response to a question he received on a podcast in 2019. The question

focused on whether to start retirement benefits at 62 or wait until **full retirement age.**

In response, Ramsey said that “it usually makes sense to take it early if you're going to ... invest every bit of it.”

Specifically, he advised claiming your benefits and then putting all of the money into a good mutual fund. He said doing so will more than make up for the extra money that would have been included in your Social Security checks if you'd waited longer to claim them.

Here are the big problems with Ramsey's advice

While Ramsey's advice, in theory, might seem smart, there are a few *really* big problems with it.

For one thing, most people who are considering taking Social Security at 62 are doing so because they need the money to cover the bills if they want to retire. They can't just make their early claim and invest the funds.

The other, bigger issue, though, is that an increase in your Social Security benefits due to delay is a sure thing. If you claim at 67 or 70 instead of 62, it is guaranteed that your monthly checks will be larger than if you



filed earlier. In fact, you will definitely get more money in each check if you delay claiming even a month beyond the time you become eligible for

Social Security.

So, if it turns out you need to start your payments at 64 or 65 or 66 instead of waiting as long as you'd hoped, you'd still have a higher benefit as a result of having waited. And any future Social Security raises will be based on the higher benefit you earned due to delay, so your choice will continue to pay off over time.

Making money by investing your Social Security, on the other hand, is not a 100% sure thing. In fact, a lot could go wrong. You may not actually follow through with investing every dollar, even if you have good intentions. Even if you do invest it all, returns from the stock market might not be as high as they've been in the past.

As a general rule, you shouldn't really be investing money you're going to need to live off within the next couple of years in the stock market. There's too great a chance you could buy into the market when stock prices are up, then find yourself facing a prolonged downturn that

leaves you forced to choose between locking in losses or holding off on withdrawing funds until a market recovery that could take years to happen.

If you take Social Security at 62 with the goal of investing and you end up *needing* more money at 64 because of a health issue or other pressing financial needs, you'll have permanently shrunk your Social Security benefit. And, if the market was at its peak when you started investing your Social Security benefits and it's since tanked and not recovered, you could have *lost* money on your investments. Those losses would become permanent if you had to sell your stocks to help cover living expenses.

The bottom line is, Social Security is a guaranteed lifetime benefit. And retirees can't afford to take unnecessary risks with retirement money they're going to need in a few years' time. So, rather than gambling on claiming Social Security, investing, and hoping everything goes right, it makes a whole lot more sense for most people to get the guaranteed income boost that comes with a later Social Security claim.

Choosing when to apply for Social Security is one of the most influential retirement decisions you'll make. There's not a wrong call per se, but there are definitely some claiming ages that could net you a better quality of life than others.

Understanding how the government calculates your checks is crucial for maximizing your benefits, but that's where a lot of people get tripped up. For example, some believe they'll get a benefit boost at 65, maybe enough to offset the early claiming penalty for signing up at 62. But the truth is more complicated.

What happens to your Social Security benefit at 65?

There's actually nothing special about age 65 when it comes to Social Security, at least not anymore. The three big claiming ages are:

◆ **62:** This is when you become eligible for Social Security benefits. About 23% of Americans claim within a year of becoming eligible.

◆ **Full retirement age (FRA):** This is when you become eligible for the full Social Security benefit you've earned based on your work history, also known as your primary insurance amount (PIA). It used to be 65, but now it's

between 66 and 67, depending on your birth year. Fifteen percent of workers claim then.

◆ **70:** This is when you become eligible for your largest Social Security checks. Less than 9% of workers manage to claim these.

You can claim Social Security at other ages as well. How much you'll get depends on where you're at relative to your FRA. Claiming under your FRA, including at 65, reduces your benefit. You lose 5/9 of 1% per month for up to 36 months of early claiming. That amounts to a 6.67% to 13.33% reduction for 65-year-old applicants. It would knock about \$128 to \$255 off the \$1,931 average Social Security benefit as of March 2024.

But that's a small reduction compared to those who **apply immediately at 62**. They'll face a 20% penalty for claiming three years early, plus an additional penalty of 5/12 of 1% per month for an extra one to two years. This brings the total benefit reduction to 25% for those with an FRA of 66 or 30% for those with an FRA of 67.

Looking at things from this angle, you could say that claiming at 65 increases your Social Security checks compared to starting right at 62. But this only counts for those who haven't



signed up yet. Once you apply for Social Security, your checks are usually locked in for the rest of your life. However, there are a few exceptions to this rule.

How to boost your Social Security checks if you applied early

There are three ways you can boost your future Social Security checks if you claimed early and regret penalizing yourself: Withdraw your Social Security application

This is only an option for those who applied for Social Security less than a year ago. You must **contact the Social Security Administration** and notify it of your wishes. Then, you have to pay back all the money you and any family members claiming on your record have received from the program to date.

If you manage that, the government will treat you as if you've never claimed before. When you apply again later, you'll get larger checks. But this is a one-time option.

Earnings test
The Social Security Administration automatically withholds some benefits from workers who claim under their FRA if they earn too much from a job. This is known as the **earnings test**. You'll lose:

- ◆ \$1 for every \$2 you earn above \$22,320 if you're under your FRA all year, or
- ◆ \$1 for every \$3 you earn above \$59,520 if you'll reach your FRA in 2024 and exceed this amount before you reach your FRA

This will shrink your checks in the short term, but the money comes back to you when you reach your FRA. The Social Security Administration recalculates your benefit then and increases it to make up for what it withheld previously.

Suspend your benefits at your FRA

You can also voluntarily suspend your benefits when you reach your FRA. If you do this, the government won't send you any more checks until you request that they start again or reach 70. Your benefit will grow by 2/3 of 1% per month, or 8% per year, during the time it's suspended.

You don't have to take any of the above steps if you don't want to. If you're happy with your decision to claim at 65 or earlier or you cannot afford to give up your checks, that's OK. Everyone's situation is unique and even if you claim early, you could still wind up with hundreds of thousands of dollars in benefits over your lifetime.

Data Shows That Americans May Retire an Average of 7 Years Sooner Than Planned. Here's Why That Could Be a Problem.

At some point during your career, you may start to think seriously about retirement. And you might actually land on what you think is an optimal retirement age. But what if your estimate ends up being way off? A recent **Nationwide survey** of older Americans found that, on average, current workers wish to retire at age 67. That's **full retirement age (FRA)** for Social Security purposes for anyone born in 1960 or later.

However, when Nationwide asked current retirees when they left the workforce, they said age 60, on average, which was an earlier age than most had planned for. This means that current workers may be at risk of retiring seven years sooner than expected. And that's something

it's really important to gear up for, just in case. **The problem with retiring sooner than planned**

There are plenty of reasons you may end up in a situation where you're kicking off retirement sooner than expected. For one thing, although it's illegal to force older workers out of a job, some companies manage to get away with it, leaving senior members of the labor force in a tough spot.

Also, you might have to wrap up your career early due to health issues. And those issues don't even have to be your own. You may have to stop working to care for an aging parent or a partner whose health seriously declines.

The problem there, though, is that if you're forced to retire



early, you might miss out on several crucial savings years. Remember, older workers get to make catch-up contributions in **IRAs and 401(k) plans** that can greatly boost savings. If you retire earlier than planned, it limits the number of years in which you can make those catch-up contributions.

Along these lines, let's say your original plan is to end your career at age 67, only you wind up retiring at 60, instead. At that point, not only might you have less money in savings, but your savings will then need to cover your expenses for an additional seven years.

Furthermore, you may not be entitled to your complete monthly **Social Security** benefit,

based on your personal wage history, until age 67. If you're forced to retire early, you might have to claim Social Security early. And while the earliest age to do so is 62, for each month you sign up for benefits ahead of FRA, you'll receive a reduced benefit on a permanent basis.

Save extra, just in case

Since early retirement can be a tricky thing to predict and manage, you may want to assume you may end up leaving the workforce at a younger age than you're planning for. From there, you can make an effort to ramp up your savings while your career is still going strong to make up for potentially losing out on some savings years later... **Read More**

HHS Strengthens Protections Against Discrimination in Health Care

On Friday, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) **issued a final rule** under **Section 1557** of the Affordable Care Act (ACA), also known as the Health Care Rights Law. The Medicare Rights Center welcomes these new and **restored anti-discrimination protections**. Key provisions:

◆ **Prohibit discrimination among Medicare providers.** For the first time, HHS will consider Medicare Part B payments a form of Federal financial assistance for purposes of triggering civil rights laws, ensuring that all health care providers and suppliers receiving Part B funds are prohibited from discriminating on the basis of race, color, national origin,

age, sex, and disability.

◆ **Protect LGBTQI+ patients from discrimination and clarifies Section 1557's prohibition on sex discrimination.** Consistent with the U.S. Supreme Court's holding in **Bostock v. Clayton County**, the final rule affirms that protections against sex discrimination include protections against discrimination on the basis of sexual orientation and gender identity. The final rule also clarifies that sex discrimination includes discrimination on the basis of sex stereotypes, sex characteristics, including intersex traits, and pregnancy or related conditions.



◆ **Require those covered by the rule, including providers, insurance issuers, and HHS-administered programs, to let people know that language assistance and services are available.** The notices must be provided in English and in at least the 15 most common languages spoken by people with limited English proficiency (LEP) in the state (s) served, placed in prominent locations both physically and on their websites, and made available upon request.

◆ **Clarify that nondiscrimination requirements apply to health programs and activities provided through**

telehealth services. The final rule specifically notes that covered entities must not discriminate in their delivery of health programs and activities provided through telehealth services. This means ensuring that such services are accessible to individuals with disabilities and providing meaningful program access to people with LEP.

The Medicare Rights Center strongly supports these critical updates, many of which were reflected in our **policy recommendations, collaborative comments** on the proposed rule, and our responses to **previous rulemaking**. We are continuing to review the final rule and look forward to working with policymakers and stakeholders to build upon its successes.

Does Medicare Cover Ozempic?

Many people have questions about whether GLP-1 receptor agonists can help them and **Medicare coverage, Original Medicare**, which consists of Parts A (hospital costs) and Part B (medical expenses), does not provide coverage of prescription drugs. That's why most seniors enroll in Medicare Part D or **Medicare Part C (Medicare Advantage)** to obtain health insurance that covers the costs of prescription medication

Medicare Part D and some Medicare Advantage plans cover Ozempic to treat Type 2 diabetes and cut cardiovascular risk in those with Type 2 diabetes and known cardiovascular disease, if deemed medically necessary by a doctor.

To determine if Ozempic is covered by your specific Medicare Part D or Medicare Advantage plan and what your costs will be, you should:



◆ **Check your plan's drug formulary.** Each plan has a list of covered medications, called a formulary. You can review the formulary to see if Ozempic is included. Ozempic is usually considered a tier three drug, which means it is a brand-name medication with no generic versions available and it typically has a higher copayment.

◆ **Contact your plan.** You can call your Medicare Part D or

Medicare Advantage plan directly to inquire about coverage for Ozempic. The plan's customer service representatives can provide information on coverage, cost-sharing and any restrictions.

◆ **Consult your health care provider.** Your health care provider may also be able to help by providing information to support a coverage request if needed.

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CVS profits from manufacturing its own generic drugs

CVS has become the sixth largest corporation in America, owning not only a chain of pharmacies, but health insurance company Aetna, and Pharmacy Benefit Manager (PBM), Caremark, among other big businesses. To maximize profits, CVS offers many private label products. To increase those profits further, CVS has begun to sell its own prescription drugs, reports David Wainer for the **Wall Street Journal**.

Bottom line, CVS believes that selling its own biosimilar prescription drugs will generate handsome profits. CVS can steer its customers to these drugs through its Pharmacy Benefit Manager or PBM, which

determines the drugs on many insurance companies' formularies, including Aetna's. In the process, CVS can put competitor manufacturers with lower-cost biosimilars out of business.

The Cordavis unit of CVS Health – lord knows how CVS came up with the name—works with drug manufacturers to create the biosimilar drugs CVS sells. Biosimilars are the generic version of biologicals, prescription drugs made from living cells. The biosimilar market is booming as more blockbuster biologicals, such as Humira, lose their patents.

Beginning shortly, Humira will



no longer be available on CVS formularies. CVS will offer its biosimilar. Similarly, Cigna, which has its own PBM, Express Scripts, will take Humira off its formulary and instead offer its private label biosimilar. For now, the cost will be low for patients, 85 percent lower than Humira's list price, with no out-of-pocket costs to patients.

CVS projects that the biosimilar market will grow exponentially in the next five years to \$100 million. It was not even \$10 million just two years ago. CVS will steer its customers away from brand-name biologicals to its biosimilars and profit big time in the process.

Over time, will patients save money and how much? That's largely up to CVS, an untenable truth.

The bigger question is how will patients fare as biologicals are replaced by biosimilars? It's not at all clear, as at least for now it is out of government hands. PBMs, such as CVS Caremark, can and will use their power to determine which drugs people use and at what cost in order to maximize their profits. Before long, some say it's likely that there will be no prescription drug price competition, only strategies among the PBMs and insurers to maximize profits.



Johnson & Johnson Will Pay \$6.5 Billion to Settle Talc Ovarian Cancer Lawsuits

Johnson & Johnson announced Wednesday that it would pay out more than \$6.5 billion over the next 25 years to settle existing lawsuits claiming that its talc-containing products caused ovarian cancer.

The settlement still awaits approval from claimants.

Claims from consumers that baby powders and other J & J talc-based products cause ovarian cancer have dogged the company for years, leading J & J to discontinue sales of these products.

According to *NBC News*, J & J

attempted to resolve the lawsuits through the bankruptcy of a subsidiary, LTL Management, but courts twice blocked that effort.

LTL Management was created to absorb the company's talc liabilities, and this is the third time bankruptcy has been filed in an effort to resolve the lawsuits.

However, in the prior bankruptcy proceedings, claimants did not have an opportunity to vote. This time, J & J is initiating a three-month voting period for claimants. If



75% of voters approve, it would signal a bankruptcy settlement that would end the litigation entirely and prevent future lawsuits,

J&J executives said on a call with investors on Wednesday.

"We firmly believe this plan is in the best interest of claimants and should receive a favorable and immediate confirmation from the bankruptcy court," said Erik Haas, J&J's worldwide vice president of litigation, *NBC News* reported.

A few cases involve claimants

who contend that long-term use of talc products caused a form of lung cancer called mesothelioma; those cases are being resolved outside the new settlement plan. According to *NBC News*, J & J said it has already resolved 95% of the mesothelioma claims.

J & J also announced that it has reached "final and comprehensive" settlements that should end a probe launched by 40 states investigating whether the company misled patients about the safety of its talc baby powder and other talc-based products, *NBC News* reported.

AI Won't Replace ER Doctors Anytime Soon: Study

Artificial intelligence might be able to help doctors by filling out rote paperwork, but it's not going to be useful in the ER anytime soon, a new study shows.

OpenAI's ChatGPT program provided inconsistent conclusions when presented with simulated cases of patients with chest pain, researchers report.

The AI returned different heart risk assessment levels for the exact same patient data -- not something doctors want to see when responding to a medical emergency.

"ChatGPT was not acting in a consistent manner," said lead

researcher Dr. Thomas Heston, an associate professor with Washington State University's Elson S. Floyd College of Medicine.

"Given the exact same data, ChatGPT would give a score of low risk, then next time an intermediate risk, and occasionally, it would go as far as giving a high risk," Heston said in a university news release. The AI also failed to perform as well as traditional methods doctors use to just a patient's heart risk, according to the findings published recently in the



journal *PLOS One*.

For the study, researchers fed ChatGPT thousands of simulated cases of patients with heart pain. Earlier research showed the AI program can pass medical exams, so the hope was it would be of use when responding to medical emergencies.

Chest pains are a common complaint in the ER, and doctors must rapidly assess the urgency of a patient's condition. Very serious cases can be easy to identify from symptoms, but lower-risk cases can be trickier, Heston said. It can be tough to

decide whether a person should be kept in the hospital for observation or sent home. Doctors today often use two measures to assess heart risk, called TIMI and HEART, Heston explained. These checklists serve as calculators that use symptoms, health history and age to determine the sickness of a heart patient.

By contrast, an AI like ChatGPT can evaluate billions of variables quickly, ostensibly meaning it might be able to analyze a complex medical situation faster and more thoroughly....Read More

MRNA Vaccine Fights Deadly Brain Tumor in Small Trial

An experimental cancer vaccine can quickly reprogram a person's immune system to attack glioblastoma, the most aggressive and lethal form of brain cancer, a small, preliminary study has found.

The cancer vaccine is based on mRNA technology similar to that used in COVID vaccines, but in this case a patient's own tumor cells are used to create a personalized vaccine, researchers said.

The vaccine teaches the immune system to see tumor cells as a dangerous virus, prompting a vigorous immune response against the cancer, researchers said.

One of the most impressive

results was how quickly the injectable vaccine turns the immune system against a brain tumor, said

senior researcher Dr. Elias Saylor, a pediatric oncologist with University of Florida Health who pioneered the new vaccine.

In a first-ever human clinical trial with four adult patients, the vaccine prompted a quick and apparently effective immune attack on cancer.

"In less than 48 hours, we could see these tumors shifting from what we refer to as 'cold' -- immune cold, very few immune cells, very silenced immune response -- to 'hot,' very active immune response," Saylor said



in a university news release.

"That was very surprising given how quick this happened,

and what that told us is we were able to activate the early part of the immune system very rapidly against these cancers, and that's critical to unlock the later effects of the immune response," Saylor added.

The results mirror those seen in 10 pet dogs with brain tumors who served as early test subjects, as well as lab mice. Dogs offer a natural opportunity to test brain cancer therapies because they're the only other species that regularly develops brain tumors, the researchers explained.

The vaccine now will be tested in a phase 1 pediatric clinical trial for brain cancer, researchers said.

The trial will include up to 24 adult and child patients to validate the findings of this early study.

Glioblastoma is a very deadly cancer, with an average survival of around 15 months. Currently, doctors use surgery, radiation and chemotherapy to fight the tumor.

The four patients either lived disease-free longer than expected or survived longer than expected, although it's too early to draw firm conclusions about the vaccine's effectiveness, researchers said....Read More

Spinal Cord Injury Damages Metabolism, and Scientists Now Know Why

Patients with a spinal cord injury frequently develop **diabetes** and heart health problems, and researchers now think they know why.

It appears that neuron activity following the injury causes belly fat to break down into compounds that leak and pool in the liver and other organs, a new animal study has discovered.

"These are quite rapid changes. As soon as we disrupt sensory processing as a result of spinal cord injury, we see changes in the fat," said senior study author **Andrea Tedeschi**, an assistant professor of neuroscience in Ohio State University's College of Medicine.

This causes a "chain of reactions -- triglycerides start breaking down into glycerol and free fatty acids that are released in circulation and taken up by the liver, the heart, the muscles, and accumulating, setting up conditions for insulin resistance," Tedeschi added in a university news release.

The team also has identified a potential treatment to ward off illnesses caused by this phenomenon: The seizure medication **gabapentin** prevented these damaging metabolic effects from spinal cord injuries in lab mice.

Gabapentin inhibits a



neurotransmitter that becomes overactive and causes communication problems within the body following damage to the nervous system, researchers explained.

"Through administration of gabapentin, we were able to normalize metabolic function," Tedeschi said.

Heart disease and type 2 diabetes are among the leading causes of death in people with a spinal cord injury, researchers explained in background notes.

Researchers suspected these disorders might be related to dysfunction in the regulation of belly fat, which has a complex

metabolic role.

Such fat -- also called adipose tissue -- stores energy and releases fatty acids as needed for fuel, helping keep blood sugar levels on an even keel, researchers said.

Sensory nerves regularly send messages to fat tissue under healthy conditions, so researchers suspected they might play a role in these health problems.

Lab mice were given a spinal cord injury that affected only the sensory nerves but did not interrupt the sympathetic "fight-or-flight" nervous system....[Read More](#)

Fewer Americans Are Suffering Most Dangerous Form of Heart Attack

Many fewer Americans are falling prey to the most dangerous form of **heart attack**, a new study says.

STEMI (ST-segment-elevation myocardial infarction) heart attacks have declined by nearly 50% during the past 15 years in the United States, researchers found.

STEMI heart attacks are caused by a near-total blockage of a coronary artery, researchers said in background notes.

This blockage can cause severe damage to the muscle of the heart's lower pumping chambers,

the ventricles. Too much damage and the heart loses its ability to pump a sufficient amount of blood, resulting in death.

"Seeing a decline in STEMI overall was surprising," lead researcher **Dr. Fares Ghanem**, a cardiovascular disease physician at Southern Illinois University, said in a news release.

For the study, his team analyzed nationwide hospital data from 2004 to 2020 involving more than 3.4 million heart attack patients.

The overall incidence of



STEMI heart attacks decreased to 49 per 100,000 hospitalizations in 2020 from nearly 99 per 100,000 in 2004, results

show.

Death rates fell from 25% to 22% in people older than 85 and from 13% to 10.5% in people 65 to 84, results show. Deaths increased slightly for people between 45 and 65 years of age, from 4% to 5.5%.

However, the study did reveal disparities based on how much money people make.

Higher-income people suffer

STEMI heart attacks about 20% less often than low-income folks, results show, in a trend that's remained consistent for the past 15 years.

The high-income STEMI rate was 42 per 100,000 in 2020, compared to the low-income rate of 54 per 100,000.

Low-income patients are also about 12% more likely to die from a STEMI heart attack, researchers said....[Read More](#)

Blood Test Might Predict Knee Osteoarthritis Years Early

A blood test could help doctors spot the signs of knee osteoarthritis at least eight years before it shows up on X-rays, a new study claims.

After analyzing the blood of 200 white British women, half diagnosed with knee osteoarthritis and half without, researchers discovered a small number of biomarkers distinguished the women with osteoarthritis from those without it.

"We found we were able to identify people who are at risk for knee osteoarthritis, but what was exciting was that we were able to identify it eight years before they had any X-ray changes," said senior study author **Dr. Virginia Byers Kraus**, a professor in the departments of Medicine, Pathology and Orthopedic Surgery at Duke University School of Medicine, in Durham,

N.C.

The study, published April 26 in the journal *Science Advances*, builds on previous research where the blood test demonstrated 74% accuracy in predicting knee arthritis progression and 85% accuracy in diagnosing knee arthritis.

Knee arthritis strikes approximately 35 million adults in the United States. While there are no cures, the success of new therapies could hinge on identifying the disease early and slowing its progression.

The researchers emphasized that just like heart disease, osteoporosis or Alzheimer's disease, knee osteoarthritis is a chronic disorder that is typically diagnosed late in the game. By identifying it earlier, doctors could potentially stop the disease



before it becomes debilitating, the researchers said.

"The reason that this is really important is that until now, we have been thinking about osteoarthritis as a disease with X-ray changes. But it turns out that, in fact, there are a lot of things going on prior to that and by actually identifying it much earlier, we can prevent disability, pain and the deterioration of quality of life that people who develop the X-ray changes usually get," Kraus said.

According to Kraus, if patients discover through a blood test that they are at a high risk for knee osteoarthritis, they could make **lifestyle changes** that include weight loss, exercise, eating healthy or even getting steroid injections.

Researchers also emphasized

that knee osteoarthritis is more than just painful for patients: It also leads to the majority of all joint replacements, creating a massive economic burden.

These concerns were echoed by **Stephen Messier**, a professor of health and exercise science at Wake Forest University and an Arthritis Foundation-funded investigator.

"The burden of osteoarthritis [OA] continues to rise, driving higher healthcare costs and poorer patient outcomes," Messier said. "Early detection of knee OA could help clinicians intervene sooner and reduce the pain and loss of function of patients before joint replacement surgery is necessitated."...[Read More](#)

When in Life Are Folks Most Lonely?

At what age does loneliness strike adults the hardest?

A new review maps it out, finding that people are more lonely as young adults, grow less lonely as they approach middle age, and then fall back into loneliness in old age, researchers reported April 30 in the journal *Psychological Science*.

“What was striking was how consistent the uptick in loneliness is in older adulthood,” said researcher **Eileen Graham**, an associate professor of medical social sciences at Northwestern University Feinberg School of Medicine in Chicago.

“There’s a wealth of evidence that loneliness is related to poorer health, so we wanted to better understand who is lonely and why people are becoming lonelier as they age out of midlife, so we can hopefully start finding ways to mitigate it,” Graham said.

Social isolation can increase the risk of premature death to levels comparable to daily smoking, according to the U.S. Surgeon General.

For the review, researchers evaluated data from nine long-term studies conducted around the world.

All of the studies showed a U-shaped **loneliness** curve, even though they tested different groups of people from the United States, the U.K., Germany, Sweden, the Netherlands, Australia and Israel, researchers said.

“Our study is unique because it harnessed the power of all these datasets to answer the same question -- ‘How does loneliness change across the lifespan, and what factors contribute to becoming more or less lonely over time?’” Graham said.



All of the studies were conducted prior to the pandemic, which has made loneliness even more pronounced, researchers said.

Graham said the dip in loneliness during middle-age might be because people that age have many demands that require more social interaction -- like being married, having kids and going to work.

However, social interaction on its own isn’t a marker for less loneliness, Graham noted.

“You can have a lot of social interaction and still be lonely or, alternatively, be relatively isolated and not feel lonely,” Graham said in a Northwestern news release.

The studies’ data start right at the end of adolescence, when young adults are navigating a number of important life

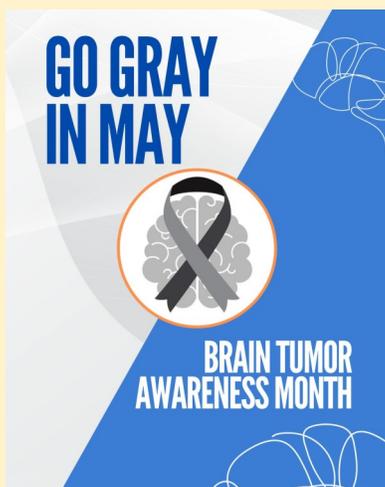
transitions, said researcher **Tomiko Yoneda**, an assistant professor of psychology at University of California, Davis.

These include finishing their education, embarking upon their careers and ever-evolving changes to their relationships with family, friends and romantic partners.

“As people age and develop through young adulthood into midlife, they start to set down roots and become established, solidifying adult friend groups, social networks and life partners,” Yoneda said. “We do have evidence that married people tend to be less lonely, so for older adults who are not married, finding ongoing points of meaningful social contact will likely help mitigate the risk of persistent loneliness.”

National Brain Tumor Society

#GrayMay is a time to come together with more than 1 million people living with **#braintumors** and their loved ones to spread awareness about this deadly disease. **Brain Tumor Awareness Month**



More than **one million** Americans are estimated to be living with a brain tumor.

#GrayMay



Approximately **72%** of all brain tumors are benign and approximately **28%** are malignant.

#GrayMay



An estimated **25,400** new primary malignant brain tumors (brain cancer) will be diagnosed in 2024.

#GrayMay



Approximately **94,390** people received a primary brain tumor diagnosis in 2023.

#GrayMay



The five-year relative survival rate for all malignant brain tumor patients is only **35.7%**.

#GrayMay



An estimated **18,870** people will die from a malignant brain tumor in 2024.

#GrayMay



Gas Stoves Could Leave Your Lungs Vulnerable to Nitrogen Dioxide

People in homes with gas or propane stoves regularly breathe in unhealthy levels of nitrogen dioxide, a new study says.

Typical use of these stoves increases exposure to nitrogen dioxide (NO₂) by an estimated 4 parts per billion, averaged over a year, researchers report.

That’s three-quarters of the way to the NO₂ exposure level deemed unsafe in outdoor air by the World Health Organization, researchers noted.

“That’s excluding all outdoor sources combined, so it makes it much more likely you’re going to

exceed the limit,” lead researcher **Yannai Kashtan**, a doctoral student in Earth system science at Stanford University, said in a news release.

Breathing high levels of NO₂ over time can intensify asthma attacks, and has been linked to decreased lung development in children, researchers noted.

The mix of pollutants coming from gas and propane stoves could be responsible for as many as 200,000 current cases of



childhood asthma, with one-quarter attributed to nitrogen dioxide alone, researchers estimated.

Long-term exposure to NO₂ from gas stoves also is high enough to cause as many as 19,000 deaths each year, researchers added.

For the study, researchers used sensors to measure concentrations of NO₂ throughout more than 100 homes of various sizes, layouts and ventilation methods.

“I didn’t expect to see pollutant concentrations breach health

benchmarks in bedrooms within an hour of gas stove use, and stay there for hours after the stove is turned off,” senior researcher Rob Jackson said in a news release. He’s a professor with the Stanford University Doerr School of Sustainability.

People who live in homes smaller than 800 square feet — roughly the size of a small two-bedroom apartment — are exposed to twice as much NO₂ over the course of a year compared to the national average, researchers found....**[Read More](#)**

Living Healthy Counters Effects of 'Life-Shortening' Genes

Doctors argue that genetics aren't destiny when it comes to a person's health, and a study appears to support that notion.

A healthy lifestyle can offset the effects of life-shortening genes by more than 60%, researchers found.

People at high genetic risk of a curtailed lifespan could extend their life expectancy by nearly 5.5 years if they've adopted a healthy lifestyle by age 40, results show.

On the other hand, an unhealthy lifestyle is associated with a 78% increased risk of an early death, regardless of a person's genetic predisposition.

The study highlights "the pivotal role of a healthy lifestyle in mitigating the impact of genetic

factors on lifespan reduction," concluded the research team led by **Dr. Xue Li** with the Center of Clinical Big Data and Analytics of The Second Affiliated Hospital at Zhejiang University School of Medicine in Hangzhou, China.

"Public health policies for improving healthy lifestyles would serve as potent complements to conventional healthcare and mitigate the influence of genetic factors on human lifespan," the researchers said.

For the study, researchers analyzed data drawn from nearly 354,000 people participating in the UK Biobank genetics and health study. More than 24,000



died over an average follow-up of nearly 13 years.

Each person was scored based on their genetic health risks, and they also received a score regarding the healthiness of their lifestyle.

A healthy lifestyle included no **smoking**, moderate drinking, regular physical activity, a healthy body shape, adequate sleep and a healthy diet, researchers said.

About 23% had a completely healthy lifestyle based on those measures, 56% had a moderately healthy lifestyle, while 22% had an unhealthy lifestyle.

Those genetically predisposed to a short lifespan were 21% more likely than those genetically

predisposed to a long life, regardless of lifestyle.

But those with an unhealthy lifestyle were 78% more likely to die early than those with a healthy lifestyle, regardless of their genetics.

Overall, those who combined bad genetics and an unhealthy lifestyle were twice as likely to die as those with good genes who were living healthy, results show.

Four factors in particular contributed to healthy living that made a difference in longevity, researchers said -- not smoking, regular exercise, good sleep and a healthy diet.

The new study was published April 29 in the journal ***BMJ Evidence Based Medicine***.

Combo Therapy May Be Advance Against Liver Cancer

A new combination therapy appears to boost the response rate for liver cancer patients receiving **immunotherapy**, according to results from a phase 2 clinical trial.

The combo therapy involves bavituximab, a drug that neutralizes a fatty substance called phosphatidylserine that cancer cells use to avoid detection and attack by immune cells, researchers said.

Bavituximab essentially doubled the response of liver tumors to **pembrolizumab** (Keytruda), an immunotherapy drug approved in 2016 to treat various cancers.

About 32% of liver cancer patients responded to the bavituximab/pembrolizumab combination, compared with

about 16% response in previous studies for pembrolizumab alone, researchers said.

Pembrolizumab also works by blocking a means that cancer cells use to avoid attack from immune cells, but it blocks a different process than that targeted by bavituximab, researchers noted.

"This study shows the promise of improving the success of cancer immunotherapies by targeting other immunomodulating proteins simultaneously," lead researcher **Dr. David Hsieh**, an assistant professor of internal medicine with the UT Southwestern Simmons Comprehensive Cancer Center in Dallas said in a news release.



The combo treatment targets hepatocellular carcinoma (HCC), the most common form of liver cancer.

For many years, the only treatment for HCC tumors that couldn't be surgically removed was a drug called **sorafenib**. Sorafenib slows the growth of tumor-feeding blood vessels, but extends survival by only a few months.

More recently, immunotherapies have emerged as effective treatments for HCC. Unfortunately, only a fraction of patients respond to these drugs when they're delivered alone, and combining multiple immunotherapies increased the risk of serious and sometimes deadly side effects.

For the new clinical trial, researchers recruited 28 patients with HCC to receive the combo bavituximab/pembrolizumab therapy and followed their progress for an average of nearly 29 months.

Two patients had a complete response, with no evidence of liver cancer on imaging scans taken at the end of the trial.

The combined therapy also halted progression in another 32% of patients, results show.

For those who responded to the combo therapy, it continued to shrink their tumors for an average 13 months, researchers said. Four patients were still responding to the combo therapy when the study ended... **Read More**

More Medical Lab Tests Will Soon Face Federal Scrutiny, FDA Says

Laboratory tests used by millions of Americans are soon to be classified as medical devices, and as such be regulated by the U.S. Food and Drug Administration, the agency announced Monday.

The new rule does not apply to tests and kits made by big medical device manufacturers -- those already face FDA review.

Instead, the agency is widening its oversight to include thousands of tests made by labs, large hospitals and universities, so-called "laboratory developed tests" (LTDs) or in vitro diagnostic products (IVDs).

"The FDA announced a final rule today amending the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug and Cosmetic Act," the agency said in a **statement**.

FDA Commissioner **Dr. Robert Califf** said the change, phased in over the next four years, is necessary to protect Americans from inflated claims about the accuracy of LDT results or inaccurate tests.

"LDTs are being used more widely than ever before -- for use in newborn screening, to help predict a person's risk of cancer,



or aid in diagnosing heart disease and Alzheimer's. The agency cannot stand by while Americans

continue to rely on results of these tests without assurance that they work," Califf said in an agency news release. "The final rule announced today aims to provide crucial oversight of these tests to help ensure that important health care decisions are made based on test results that patients and health care providers can trust."

The FDA said that LTDs have had lax oversight because in decades past many were "lower

risk, small volume and used for specialized needs."

That's changed in recent years.

"Now, many LDTs are used more widely, for a larger and more diverse population, with large laboratories accepting specimens from across the country," the agency said. "LDTs also increasingly rely on high-tech instrumentation and software, are performed in large volumes, and are used more frequently to help guide critical health care decisions."... **Read More**