7 Prescription-Drug Price Hikes Cost U.S. Nearly $1.7 Billion in 2020

Higher prices come despite no increased benefits from those medicines, new report finds

Prescription-drug price increases among seven of 10 top-selling medications cost the U.S. health care system almost $1.7 billion in 2020, according to a recent report from the Institute for Clinical and Economic Review.

The institute looked at 10 of the top 250 best-selling prescription drugs last year and found that seven of the 10 price hikes did not come because the effectiveness of these medications increased. The report called these price increases "unsupported."

One drug — Humira, used for severe Crohn's disease — alone accounted for $1.4 billion of the $1.67 billion increase in U.S. drug spending.

While many brand-name drugs continue to hit the market with very high prices, the yearly price increases have moderated, the institute found. "However, there remain many high-cost brand drugs that continue to experience annual price hikes," David Rind, the institute's chief medical officer said in a statement. "The most extreme of these is Humira, with an ever-escalating U.S. price that contrasts starkly to its falling price in every country where Humira faces biosimilar competition." Biosimilars are generic alternatives to biologic medications.

Here's a look at the seven medications the institute analyzed. The costs to the U.S. health care system were calculated after accounting for pharmaceutical company rebates and other discounts.

- The price of Humira, which treats severe Crohn’s disease, increased by 9.6 percent. Cost to U.S.: $1.4 billion.
- The price of Promacta, which treats a blood disorder called chronic immune thrombocytopenic purpura (ITP), increased by 14.1 percent. Cost to U.S.: $100 million.
- The price of Tysabri, a monoclonal antibody used to treat multiple sclerosis, increased by 4.2 percent. Cost to U.S.: $44 million.
- The price of Xifaxan, used to treat irritable bowel syndrome, increased by 3 percent. Cost to U.S.: $44 million.
- The price of Trokendi, used to prevent migraine headaches, increased by 12.4 percent. Cost to U.S.: $36 million.
- The price of Lupron Depot, used to treat endometriosis in women and prostate cancer in men, increased by 5.9 percent. Cost to U.S.: $30 million.
- The price of Krystexxa, used to treat chronic gout, increased by 5.2 percent. Cost to U.S.: $19 million.

The report's findings are consistent with AARP Price Watch reports that show brand-name drug price increases continue to outpace inflation. The latest AARP report found that in 2020, prices for 260 commonly used medications whose prices AARP has been tracking since 2006 increased 2.9 percent while the general rate of inflation was 1.3 percent.

AARP's Fair Rx Prices Now campaign has been focused on convincing federal and state lawmakers to take action to lower the prices of prescription drugs.

On Nov. 19, the U.S. House of Representatives passed legislation that would provide some financial relief to patients. Under the Build Back Better Act, supported by AARP, Medicare would be able for the first time to negotiate the price of some drugs, the cost of some insulin would be capped at $35 a month, drugmakers would face tax penalties if they raise prices more than inflation, and out-of-pocket costs for Part D prescription drugs would be capped at $2,000 a year. The bill now moves to the U.S. Senate.

Sen. Sanders Asks President to Reduce Medicare Premium Hike

According to Bloomberg News, “Sen. Bernie Sanders is asking the White House to cut back on a big Medicare premium hike set to take effect in weeks and tied to a pricey Alzheimer’s drug whose benefits have been widely questioned."

We reported previously that about half of the large increase in the Medicare Part B premium is because Medicare wants to have the extra money on hand if it decides to cover the cost of the new Alzheimer’s drug Aduhelm. The maker of Aduhelm, Biogen, has listed the cost of the drug as $56,000 per year. The Bloomberg report added, “If Biden agreed and found a way to do it, a planned January increase of $21.60 a month to Medicare’s ‘Part B’ premium for outpatient care would be slashed closer to $10. The monthly premium for 2022 would drop from $170.10 to about $159."

“The jump of $21.60 a month is the biggest increase ever for Medicare premiums in dollar terms, although not percentage wise. As recently as August, the Medicare Trustees’ report had projected a smaller increase of $10 from the current $148.50. Medicare said it had to boost the rate higher to set aside a contingency fund in case the program formally approves coverage for Aduhelm.”

Aduhelm is the first Alzheimer’s medication in nearly 20 years, although it does not cure the disease. The Food and Drug Administration approved the drug this year, but its decision was very controversial because it overrode its own outside advisers. Many experts say Aduhelm’s benefit has not been clearly demonstrated. The Department of Veterans Affairs declined to list the medicine on its roster of approved drugs.

Medicare has begun a formal assessment to determine whether it should cover the drug, and a final decision is not likely until at least the spring.

TSCL has sent a letter to Sen. Sanders letting him know we support his effort on this issue.
In 2022, retirees will receive more money in each Social Security check. Social Security beneficiaries are getting a 5.9% cost-of-living adjustment (COLA), which is the biggest benefits increase in decades. While this may seem like a generous income bump, there's one number older Americans need to know that shows why this raise really isn't good news at all -- and is actually likely to leave them falling further behind financially.

This key number is bad news for retirees:

For retirees who are excited about their Social Security raises, the latest data from the Bureau of Labor Statistics (BLS) shows why this COLA is actually _not_ very generous at all. According to the BLS, the Consumer Price Index for All Urban Consumers (CPI-U) in October of 2021 showed there was a 6.2% increase in prices, compared with the year prior. The CPI-U tracks the price of a wide range of products and services, including rent, gas, groceries, and medical care.

If seniors are getting a 5.9% raise, and current data shows that inflation at 6.2%, it doesn't take a lot of math knowledge to see that retirees will end up losing ground. And this is a huge problem since the COLA is supposed to help ensure benefits don't lose buying power.

Unfortunately, Social Security's COLAs are calculated based on the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W). And the government specifically looks at CPI-W data for the months of July, August, and September in order to determine the next year's raise. If inflation is running rampant and prices increase substantially after these months, then the annual raise seniors receive will end up being too small.

Making matters worse, COLAs _often_ end up being insufficient, even if a huge increase in prices doesn't occur after the key months. That's because the CPI-W price index doesn't perfectly mirror the spending habits of seniors. Benefits have ended up losing around 30% _of their buying power_ since 2000 because the CPI-W underestimates the percentage of income seniors tend to spend on things like medical care and housing -- both of which have seen huge price increases that have outpaced inflation over time.

Since seniors have already fallen behind and the raise they're getting this year is too low compared to inflation, retirees will find their checks can't buy nearly as much as they did in the past -- despite the fact that each monthly payment they get is larger.

President Joe Biden and several Democratic lawmakers have proposed a bump up in Social Security benefits for at least some retirees. However, it's not clear if any legislation providing more benefits will be able to pass in Congress.

That leaves seniors stuck trying to adjust their budgets to deal with the fact their checks won't go as far. Retirees need to carefully watch their spending and look for options to trim their costs if they were counting on Social Security's large annual raise to help them maintain their quality of living, despite rising prices.

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### This one drug threatens to tank Medicare's entire prescription drug model

When Biogen's new Alzheimer's drug, Aduhelm, was officially approved for use by the Food and Drug Administration (FDA) back in June, it was a decision that flouted _overwhelming pushback_ from doctors in the field, dozens of whom argued that Biogen had failed to demonstrate whether the drug had any clinical value. Since then, only about a _hundred_ Americans have been prescribed the medication -- a vanishingly small amount for a disease that afflicts 5.8 million. But even as the scope of Aduhelm's use remains limited, critics are now warning that its fiscal implications could spell disaster for American healthcare as we know it.

Aduhelm alone, priced at a whopping $56,000 a year, has already contributed to an approximate $10 spike in monthly Medicare Part B premiums, according to a recent _CNN_ report. Comprising about half of this year's price increase, Aduhelm will bring the monthly cost of Medicare up from $148.50 to $170.10 -- the biggest jump in dollar terms throughout the program's entire history, according to _NBC15_. It should be noted that the $10 upcharge applies to all Medicare enrollees -- that is, over _62 million Americans_ -- most of whom will never directly benefit from Aduhelm. And for the drug's actual recipients, the $10 add-on is just the tip of the iceberg.

First, there are co-payments. Because Medicare recipients are typically required to cover 20% of Part B treatments as part of the program's co-insurance policy, Aduhelm patients have to cough up an extra $11,600 out of pocket annually. An $11,600 copayment is already cost-prohibitive for the vast majority of Americans. But when it comes to Medicare enrollees -- whose median income is _roughly_ $30,000 a year -- it's easy to see how just a year's worth of treatment is completely out of the question. Then there's the cost of routine screening. In order to monitor the risk of brain bleeding and swelling -- side-effects which occurred in about _41% of clinical patients_ from 2019 and may have led to the _recent death_ of a 75-year-old woman -- Aduhelm patients will also have to cover 20% of the cost of PET or MRI scans. To put this into context, the average national price range for _brain MRI scans_ is $1,600 to $8,400. _PET scans_ can be as pricey as $10,700. And Medicare does not guarantee coverage for either, at times leaving patients to pay for them in full.

Unsurprisingly, Aduhelm is expected to be a massive burden on the American healthcare system.

According to a _conservative estimate_ by the Kaiser Family Foundation, if Medicare covered the drug for 1 million Americans, spending on Aduhelm would exceed $57 billion in a single year -- $20 billion more than was spent on all Part B drugs in 2019 combined.

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Judging by the numbers alone, the U.S. healthcare system cannot afford to absorb Aduhelm, David Mitchell, founder of Patients For Affordable Drugs, told Salon. "It's a back-breaking drug for Medicare and for Medicare beneficiaries," Mitchell explained in an interview. "We're going to have to confront the fact that we can't keep paying whatever [Big Pharma] demands, because it'll just break the bank."...

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Social Security benefits can be a substantial source of income in retirement, and if you're married or divorced, you could be entitled to more than you might think.

Before you retire or start claiming benefits, it’s wise to consider how your marital status could affect your strategy. If you’re married or divorced, there are a few moves to make now to maximize your monthly payments.

1. **See if you’re entitled to spousal or divorce benefits**

If you're currently married or divorced from someone who is entitled to Social Security benefits, you could qualify for spousal or divorce benefits based on his or her work record. To receive spousal benefits, you must be married to someone who will receive Social Security. For divorce benefits, your marriage must have lasted for at least 10 years, and you cannot currently be married.

For both types of benefits, the maximum you can receive is 50% of the amount your spouse or ex-spouse is entitled to at his or her full retirement age (FRA). If you're entitled to benefits based on your own work record, you'll only receive the higher of the two amounts.

So, for instance, say you're entitled to $600 per month based on your own work record, and your spouse will receive $2,000 per month at his or her FRA. In this case, you’d be entitled to $1,000 per month in spousal benefits, so you’ll collect $1,000 per month -- not $1,600 per month.

2. **Determine a claiming strategy**

The age you begin claiming can have a significant impact on the amount you receive each month, and if you're married or divorced, it pays to come up with a strategy to maximize your retirement income.

- **The earliest you can begin claiming is age 62**, but if you delay benefits past that age (up to age 70), you'll receive higher monthly payments. If you're married and both you and your spouse are entitled to benefits, consider whether you both want to claim at the same time or at different ages.

3. **Consider how your life expectancies might affect your strategy**

Although it’s not the most pleasant topic to think about, your lifespan can affect your Social Security strategy — particularly if you're married.

When one spouse passes away, the other is generally eligible to collect the deceased spouse's entire benefit amount in survivors benefits. If you expect your spouse to outlive you, it may be smart for you to delay benefits so that your spouse will receive a higher benefit amount later in life if you pass away first.

While survivors benefits are generally reserved for widows and widowers, other family members -- including ex-spouses -- are sometimes eligible as well. Although you may not be able to influence your ex-spouse's claiming strategy, it can be helpful to be aware of the types of benefits you may be entitled to if you're divorced.

Social Security benefits can go a long way in retirement, so it's wise to make sure you're collecting as much as possible. By double-checking all the types of benefits you're entitled to and heading into retirement with a strategy, you can maximize your income and enjoy your senior years more comfortably.

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**Senator Manchin must support lower drug prices in Build Back Better Act**

On November 19th, the House passed the **Build Back Better Act**. Among the bill’s most popular provisions are several steps towards lowering prescription drug prices. Now, the bill goes to the Senate. It is a moral and political necessity for Senate Democrats to pass Build Back Better into law swiftly and without weakening any of the drug pricing provisions.

Not surprisingly, the PhRMA lobby hates the drug pricing reforms in Build Back Better. Currently, pharmaceutical corporations can charge as much as they’d like for prescription drugs, and they are desperate to keep it that way. Any delay in passing Build Back Better into law gives PhRMA lobbyists more time to weaken it.

That’s why Senator Joe Manchin’s threats to delay a Build Back Better vote until 2022 are so dangerous. Manchin has already undermined Build Back Better by demanding the removal of one of the bill’s most popular policies — expanding Medicare coverage dental and vision coverage. However, Manchin claims to support drug pricing reform. If he means it, he must support holding a vote on Build Back Better as quickly as possible.

It’s not just Democratic voters who support Build Back Better’s drug pricing reforms. They are **extremely popular** among Republican and Independent voters as well. Not only is lowering drug prices a moral imperative, it’s also a political necessity.

Build Back Better would give Medicare the power to negotiate lower prices on 30 of the most expensive prescription drugs. This is an important step towards giving Medicare the power to negotiate lower prices on all drugs. Ninety-three percent of Democratic voters support this policy — as do 81 percent of Independents and 78 percent of Republicans.

In the last decade, drug prices rose three times faster than the rate of inflation. Build Back Better would effectively prevent this from happening in the future by requiring drug companies to pay a fine when they raise prices faster than inflation. This means that regardless of if you are on Medicare or private insurance or uninsured, no drug price will go up faster than the rate of inflation. This provision is supported by 92 percent of Democrats, 83 percent of Independents, and 78 percent of Republicans.

Additionally, Build Back Better would add a $2,000/year cap on out-of-pocket prescription drug spending for Medicare beneficiaries. This would transform the lives of seniors across the country, who are currently forced to choose between filling their prescriptions and paying their rent. Eighty-four percent of Democrats support this cap. So do 77 percent of Independents and 74 percent of Republicans.

No prescription drug shows the depths of Big Pharma’s greed better than insulin. Pharmaceutical corporations are colluding to raise the price of insulin, which has tripled in the last decade. Build Back Better would save and improve the lives of Americans with diabetes by adding a $35/month cap on insulin co-pays, as well as giving the government the power to negotiate a lower price. Ninety-four percent of Democrats support this plan, along with 84 percent of Independents and 82 percent of Republicans. Read More
Dear Marci:

Will Medicare cover my durable medical equipment?

Dear Patricia,

Durable medical equipment (DME) is equipment that helps you complete your daily activities. It includes a variety of items, such as walkers, wheelchairs, and oxygen tanks. Medicare usually covers DME if the equipment:

- Is durable, meaning it is able to withstand repeated use
- Serves a medical purpose
- Is appropriate for use in the home, although you can also use it outside the home

And, is likely to last for three years or more

To be covered by Part B, DME must be prescribed by your primary care provider (PCP). If you are a skilled nursing facility (SNF) or hospital inpatient, DME is covered by Part A.

Whether you have Original Medicare or a Medicare Advantage Plan, the types of Medicare-covered equipment are the same. Examples of DME include:

- Wheelchairs
- Walkers
- Hospital beds
- Power scooters
- Portable oxygen equipment

Under the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) category, Medicare Part B also covers:

- Prosthetic devices that replace all or part of an internal bodily organ
- Prosthetics, like artificial legs, arms, and eyes
- Orthotics, like rigid or semirigid leg, arm, back, and neck braces
- Certain medical supplies

Medicare Part B also covers certain prescription medications and supplies that you use with your DME, even if they are disposable or can only be used once. For example, Medicare Part B covers medications used with nebulizers. Medicare also covers lancets and test strips used with diabetes self-testing equipment.

Note that there are also certain kinds of equipment and supplies that Medicare does not cover, such as equipment for use mainly outside the home, and most equipment that is thrown out after one use or not used with equipment.

To find out if Medicare covers the equipment or supplies you need, or to find a DME supplier in your area, call 1-800-MEDICARE or visit www.medicare.gov. You can also learn about Medicare coverage of DME by contacting your State Health Insurance Assistance Program (SHIP).

-Marci

Chain pharmacies found responsible for opioid crisis

After a six-week trial and five days of deliberation, a federal jury in Ohio recently found that three very large chain pharmacies were responsible in a significant way for the opioid crisis in two Ohio counties. Jan Hoffman reports for The New York Times that CVS Health, Walmart and Walgreens were found accountable for opioid overdoses and deaths. The insurers covering the opioids that were dispensed should also be found accountable.

Germany never had an opioid crisis. The federal government there controls the drugs insurers cover and restricted coverage of opioids by health insurers. It’s unacceptable that corporate health insurers in the US, allegedly in business to manage people’s care, approved coverage of opioids in millions of cases where alternative non-addictive pain relievers were available.

Thousands of lawsuits have been filed across the United States against pharmaceutical companies for fueling the opioid public health crisis and creating a “public nuisance.” California and Oklahoma judges have not bought the argument, saying that the opioid manufacturers were not directly linked to the overdoses and deaths.

Unfortunately, most of these lawsuits are still working their way through the system. And, opioid overdoses and deaths are on the rise. Many of those overdoses were of illegal opioids such as heroin and fentanyl bought on the street. But, those purchases are a by-product of people becoming addicted to opioids that were legally prescribed.

Over the summer, Nassau and Suffolk counties in New York State settled an opioid case with Walgreens, Rite Aid, CVS and Walmart for $26 million.

In the Ohio case, the chain pharmacies claim that they will appeal. As far as they are concerned, they were just doing what they are supposed to do, fill legal prescriptions. In the process, of course, but left unsaid, they were profiting wildly.

Of note, the lawyers defending the pharmacies in the Ohio lawsuit laid blame with manufacturers and doctors but did not mention the health insurers approving coverage of the opioids. CVS Health, Walmart and Walgreens are also insurers or linked to them.

The Senior Citizens League

Congress Punts Once Again

Late last week Congress dealt with funding the federal government for fiscal year 2022, which began last October 1, in the way we have been predicting: they punted.

They managed to agree on a bill to keep funding the government but only until February 18 of next year. By that time, they will be into the fifth month of the fiscal year. But at least for now, there will be no government shutdown.

* * * *

Lowering Drug Prices Still Waits for Action in Senate

Now that the government will be open for a while, the Senate still has major issues to deal with and very little time to do it. However, Senate Majority Leader Chuck Schumer (D-N.Y.) has said in a letter to other Senators that the Senate still plans to vote on President Biden’s economic agenda, which includes the provision to lower drug prices, as well as legislation to address voting rights, the debt limit, and an annual defense authorization bill by Christmas.

We wish the Majority Leader well but to say he is being optimistic is an understatement. Congress must address the debt ceiling or the U.S. government will default on paying its bills, which could result in serious economic consequences.

In addition, the debt ceiling is the one issue that really does have a deadline, even if the exact date on which the government would default is not known. While far from desirable, the other issues could go into next year for action.

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A new survey finds that health care costs are driving retirees with Medicare back to work. Yes, Medicare may offer some of the best health care coverage in the US, but it still leaves enrollees with high out-of-pocket costs. One in seven older adults have gone back to work in order to pay their health care bills. Medical costs can be substantial, even with Medicare. Medicare typically only covers about half of a person’s health care costs. It has deductibles, coinsurance and does not cover dental, vision, hearing or long-term care services. Many older adults rely on Social Security as their sole or principal source of income. They can no longer depend on defined benefit plans are pensions. Consequently, some older adults have taken part-time jobs and others full-time jobs. Motley Fool advises that, to protect yourself, you should set aside funds to cover your healthcare costs in retirement before you retire. Understandably, given the high cost of living and typically low salaries, it is hard to make ends meet as a working person, let alone save. But, if you can put some money aside for retirement, you should consider an IRA or 401(k) plan. Money you put into an IRA or 401(k) plan is tax-free at the time you save it, as is money you put in a health savings account. And, if you’re lucky, the money will grow tax-free. You could easily need it in retirement. The latest Fidelity projection is that a 65-year-old newly retired couple will need $300,000 to cover their health care costs this year. One way to maximize your savings is to delay taking Social Security benefits. You receive larger Social Security benefits if you do not enroll in Social Security until after your full retirement age. Click here for more information.

Prior authorization: How dangerous is it?

Health insurers argue that requiring you to get prior authorization before you receive certain services allows them to better manage your care. In fact, prior authorization requirements often lead health insurers to delay your receipt of care and can jeopardize your health. Traditional Medicare does not require prior authorization for medical services, but Medicare Advantage plans do, as do all commercial health insurers. What are the dangers of prior authorization? Prior authorization requirements give health insurers the ability to come between you and your treating physician to decide whether the care your doctor recommends is medically reasonable and necessary. Too often, health insurers take their pretty time in deciding whether it will cover the care your treating physician recommends. And, if it’s a specialty procedure, the person deciding often has no specialty expertise. That health insurer employee might even have a financial incentive to delay or deny your care. Lola Butcher reports for Medscape on one oncologist who believes prior authorization requirements resulted in the death of his patient. In that case, the health insurer refused to approve a PET scan when the oncologist initially sought authorization for it. The insurer came between this physician and his patient, delaying the patient’s care and allowing more time for the patient’s cancer to spread. The oncologist fought the health insurer’s denial of the PET scan, insisting that it was standard care for a patient in his condition. During the more than three weeks it took the doctor to get the insurer to approve the procedure, the patient was hospitalized because his symptoms grew worse. Unfortunately, inappropriate denials resulting from prior authorization are not uncommon. Inappropriate delays of three to four weeks or more while physicians argue with the health insurer, are also not uncommon. And, physicians say that insurers are using prior authorization requirements for medical procedures and prescription drugs more often. No question that there are two sides to the story. Prior authorization could keep doctors who are not following standard protocols from providing improper treatments. But, do they do more harm than good?...Read More

President Biden on Monday touted the Build Back Better Act's provisions to lower prescription drug prices in his latest call on the Senate to act on the House-passed legislation.

Biden called prescription drugs "outrageously expensive in this country," saying, "It doesn't need to be that way."

"To really solve this problem, we need the Senate to follow the House of Representatives' lead and pass my Build Back Better bill," he said.

Lowering drug prices is one of the most popular parts of Biden's sweeping climate and social spending measure, and Democrats are looking to tout the changes and hammer Republicans for opposing them. A Kaiser Family Foundation poll found that 83 percent of the public supports allowing the government to lower drug prices.

Biden met on Monday with patients with diabetes who had to ration their insulin because they could not afford it and noted that his legislation would impose a $35 per month cap on what patients have to pay for insulin, one of its most concrete changes.

The measure would also cap what seniors on Medicare pay out of pocket for drugs at $2,000 per year and limit price increases to the rate of inflation. Medicare would be able to negotiate lower prices on some drugs for the first time, though that provision was scaled back significantly to win over moderate Democrats including, Sen. Kyrsten Sinema (Ariz.) and Rep. Scott Peters (Calif.), who expressed worries about harming innovation from drug companies.

That negotiation provision will now apply only to older drugs that have been on the market for either nine or 13 years, depending on their type. Senate Majority Leader Charles Schumer (D-N.Y.) is aiming to pass the overall package through the Senate by Christmas, but negotiations with centrist, particularly Sen. Joe Manchin (D-W.Va.), have put that timeline in danger.

Biden did acknowledge the innovation coming out of drug companies, particularly the development of COVID-19 vaccines, but said there is a distinction between that genuine breakthrough and "jacking up prices" on older medications.

"We acknowledge the groundbreaking, lifesaving work that many pharmaceutical companies are doing," he said.

The Pharmaceutical Research and Manufacturers of America, which strongly opposes the provisions, hit back on Monday, saying that Build Back Better fails to address the role of "middlemen" known as pharmacy benefit managers, saying the package should do more to ensure that savings actually make their way to patients at the pharmacy counter. Progressives are still pushing to make the legislation stronger, including by extending the $35 cap on insulin costs to people who are uninsured.
President Joe Biden on Thursday announced a new round of measures to protect Americans against the spread of coronavirus variants.

The strategy will include making rapid at-home COVID-19 tests free for more people, extending rules on mask wearing on planes and other modes of transport, launching public awareness campaigns on vaccinations and booster shots, starting family mobile vaccination clinics, and implementing tougher testing requirements for travelers arriving in the country.

"Free and highly available rapid tests would be a game-changer," Charity Dean, a former California health official and CEO of the Public Health Company, told the Washington Post. "If we had rapid tests at every door for every school, every movie theater, anyone can go and get them — just like they can in many other countries — it would enable people to have personal responsibility and know when they’re infectious."

Under Biden’s new plan, Americans covered by private health insurance would be reimbursed for buying rapid, at-home coronavirus test kits. "We now have at least eight at-home testing options and prices for those tests are coming down, but it still isn’t good enough in my view," Biden said during a speech announcing the new strategy. "That’s why I’m announcing that health insurers must cover the cost of at-home testing, so that if you’re one of the 150 million Americans with private health insurance, next month your plan will cover at-home tests."

"The bottom line, this winter you will be able to test for free in the comfort of your home and have some peace of mind," Biden added.

As part of the overall strategy, it's also expected that a rule requiring travelers to wear masks on airplanes, trains and buses and at airports and transit stations that was set to expire on Jan. 18 will be extended until mid-March, a person familiar with the decision told The New York Times. The measures will enable businesses and schools to remain open while keeping people safe, according to the White House. "We are pulling out all the stops to get people the maximum amount of protection as we head into winter months," a senior administration official said during a conference call with reporters on Wednesday night, the Post reported.

New measures to combat the coronavirus are long overdue, according to some public health experts.

They say vaccine hesitancy makes the nation vulnerable to a potential winter surge of infections, the Post reported. As of Dec. 1, only 59.4% of Americans were considered fully vaccinated against the virus, the Post reported.

"We’re going the wrong way" on vaccination status, said Eric Topol, director of the Scripps Research Translational Institute, adding that the United States should aim to immunize at least 80 percent of its population. But "we’re at 59 percent and fading," Topol told the Post, and many vaccinated Americans’ protection has likely waned because they have yet to get booster shots.

The nation’s testing capability also remains inadequate, with many Americans unable to obtain rapid tests they could take before going to work or family gatherings, especially during regional outbreaks, Topol and other experts noted.

“So much of the next phase of COVID depends on easy, rapid access to testing, whether it’s Omicron or quick access to oral treatments” or compliance with employer vaccine mandates, said Nirav Shah, president of the Association of State and Territorial Health Officials and director of Maine’s Center for Disease Control and Prevention.

“About the only thing I am sure of in this is that I would rather confront Omicron vaccinated and boosted,” William Hanage, an epidemiologist at the Harvard T.H. Chan School of Public Health, told the Post. “So boosters should be a major deal.”

As more indoor venues require proof of vaccination for entrance and with winter — as well as omicron, a new covid variant — looming, scientists and public health officials are debating when it will be time to change the definition of “fully vaccinated” to include a booster shot.

It’s been more than six months since many Americans finished their vaccination course against covid; statistically, their immunity is waning.

At the same time, cases of infections with the omicron variant have been reported in at least five states, as of Friday. Omicron is distinguished by at least 50 mutations, some of which appear to be associated with increased transmissibility. The World Health Organization dubbed it a variant of concern on Nov. 26.

The Centers for Disease Control and Prevention has recommended that everyone 18 and older get a covid booster shot, revising its narrower guidance that only people 50 and up “should” get a shot while younger adults could choose whether or not to do so. Scientists assume the additional shots will offer significant protection from the new variant, though they do not know for certain how much.

Dr. Anthony Fauci, chief medical adviser to President Joe Biden, during a White House press briefing Wednesday was unequivocal in advising the public. “Get boosted now,” Fauci said, adding urgency to the current federal guidance. About a quarter of U.S. adults have received additional vaccine doses.

“The definition of ‘fully vaccinated’ has not changed. That’s, you know, after your second dose of a Pfizer or Moderna vaccine, after your single dose of a Johnson & Johnson vaccine,” said the CDC’s director, Dr. Rochelle Walensky, during Tuesday’s White House briefing on covid. “We are absolutely encouraging those who are eligible for a boost six months after those mRNA doses to get your boost. But we are not changing the definition of ‘fully vaccinated’ right now.” A booster is recommended two months after receiving the J&J shot.

But that, she noted, could change: “As that science evolves, we will look at whether we need to update our definition of ‘fully vaccinated.’”

Still, the Democratic governors of Connecticut and New Mexico are sending a different signal in their states, as are some countries — such as Israel, which arguably has been the most aggressive nation in its approach. Some scientists point out that many vaccines involve three doses over six months for robust long-term protection, such as the shot against hepatitis. So “fully vaccinated” may need to include shot No. 3 to be considered a full course.

“In my view, if you were vaccinated more than six months ago, you’re not fully vaccinated,” Connecticut Gov. Ned Lamont said Nov. 18 during a press briefing. He was encouraging everyone to get boosted at that time, even before the federal government authorized extra shots for everyone. … Read More
Andrea Barrio. She is an... Swelling in the arms and legs. Treatment that can lead to side effect of breast cancer confirmed as Omicron cases or... They found a jump in repeat infections with the new Omicron variant that didn't occur when two previous variants -- including Delta -- swept through the country, the Associated Press reported. The study didn't say what portion of the reinfections were confirmed as Omicron cases or whether they caused serious illness. Experts have been surprised by the sheer number of mutations in the Omicron variant, and there's been concern that such changes might render it less vulnerable to antibodies generated by prior infection or vaccination. The South African findings were posted online Thursday. They are considered preliminary and have not yet undergone scientific review, the AP reported.

"Previous infection used to protect against Delta and now with Omicron it doesn’t seem to be the case,” said von Gottberg at the WHO briefing.

While the researchers didn't examine how effective vaccines might be against Omicron, von Gottberg said they "believe that vaccines will still, however, protect against severe disease.” The study suggests that "Omicron will be able to overcome natural and probably vaccine-induced immunity to a significant degree,” Paul Hunter, a professor of medicine from the University of East Anglia in England, said in a written response to the findings, the AP reported.

"But just how much ‘is still unclear though it is doubtful that this will represent complete escape,” Hunter added.

In the United States, the nation's top expert on infectious disease, Dr. Anthony Fauci, also believes that vaccines plus booster shots should offer protection.

"Although partial immune escape may occur, vaccines, and particularly boosters, give a level of antibody that even with variants like Delta give you a degree of cross-protection, particularly against severe disease,” Fauci said on Tuesday. So far a total of nine cases of coronavirus infection tied to the Omicron variant have been detected in the United States, with cases occurring in California, Colorado, Hawaii, Minnesota and New York, according to CBS News.

In the meantime, President Joe Biden on Thursday announced a new round of measures to protect Americans against the spread of coronavirus variants such as Omicron as winter approaches.

The strategy will include making rapid at-home COVID-19 tests free for more people, extending rules on mask wearing on planes and other modes of transport, launching public awareness campaigns on vaccinations and booster shots, starting family mobile vaccination clinics, and implementing tougher testing requirements for travelers arriving in the country.

Black Women Have Triple the Odds for Lymphedema After Breast Cancer Surgery

A condition called lymphedema is a well-known side effect of breast cancer treatment that can lead to swelling in the arms and legs.

New research suggests that Black women experience at more than three times the risk of this painful issue compared to white women.

"Lymphedema worsens quality of life for breast cancer patients,” said the study’s lead author, Dr. Andrea Barrio. She is an associate attending physician in the breast service department at Memorial Sloan Kettering Cancer Center in New York City.

Understanding the links between race, cancer treatment and the effects of treatment could ultimately help improve quality of life for breast cancer patients and survivors, Barrio said in a news release from the San Antonio Breast Cancer Symposium.

Lymphedema has been somewhat overlooked in the research arena, said Dr. Stephanie Bernik, an associate professor of breast surgery at Icahn School of Medicine at Mount Sinai in New York City. She was not involved in the study.

"This study hints at some of the possible reasons for racial disparity, as women with lymphedema were more likely to undergo radiation therapy and chemotherapy before surgery,” Bernik said.

"Black women with lymphedema were also more likely to have a higher BMI [body mass index], a known risk factor for developing lymphedema. There very well may also be a genetic component..."

Still, the findings should not send anyone running to the doctor for a Viagra prescription, the researchers cautioned. But they do argue for clinical trials to test the drug against Alzheimer's, said senior researcher Feixiong Cheng, of Cleveland Clinic's Genomic Medicine Institute.

Viagra, a drug long used to treat erectile dysfunction, may double as a potential weapon against Alzheimer's disease, a new study suggests.

Looking at data on more than 7 million Americans, researchers found that those taking the drug were 69% less likely to develop Alzheimer's, when compared to non-users.

Then, in lab experiments, the investigators showed that the medication seemed to target part of the underlying disease process in Alzheimer's.

Could Viagra Help Prevent Alzheimer's?

Viagra, sold generically as sildenafil, was approved over 20 years ago for treating erectile dysfunction. Sildenafil was later approved under a different brand name (Revatio) for pulmonary hypertension, a form of high blood pressure affecting the lungs.

The drug works by inhibiting a protein called phosphodiesterase-5, which in turn allows blood vessels to relax and widen, improving blood flow. But phosphodiesterases also exist in the brain, Cheng said.

And recent lab research has suggested sildenafil may inhibit the abnormal protein buildup that is a hallmark of Alzheimer's disease. In lab mice engineered to have an Alzheimer's-like condition, sildenafil has shown action against those proteins, and boosted memory and brain-cell formation.

The new findings, published online Dec. 6 in the journal Nature Aging, bolster the case for studying the drug as an Alzheimer's treatment, Cheng said. read more
A diagnosis of mild cognitive impairment (MCI) might worry an older adult, who could see it as a stepping stone to dementia. But a new study suggests one does not necessarily lead to the other.

In fact, nearly half of seniors tracked in the study -- all of who had been diagnosed with issues in memory and thinking and received an MCI diagnosis -- no longer had the condition a few years later.

The study was conducted to help better understand what factors might be important to a person's risk for dementia.

"We wanted to gain more knowledge about the earliest stages of dementia, as a potential time window for dementia prevention or intervention strategies," said study lead author Jennifer Manly, a professor of neuropsychology at Columbia University in New York City.

During the research period, 752 participants were diagnosed with MCI. Those diagnoses happened when the participants reported problems with memory or thinking and a test showed cognitive impairment. They were still able to maintain daily activities and had problems with fewer than three activities, such as shopping or handling medications, according to the study.

Of those with MCI, 480 did follow-up assessments. Two years later, 13% of those with MCI had dementia. Another 30% still had MCI but had not developed dementia. About 10% had declines in mental functioning, but still did not meet the criteria for MCI or dementia.

But nearly half — 48% — of those who had previously been diagnosed with MCI were "cognitively normal" on a follow-up visit an average of 2.4 years later. They may have met one or two of the three criteria for MCI initially.

Among the modifiable risks that predicted a lower risk of developing MCI, researchers found that having more years of education and taking part in more leisure activities like reading, visiting a friend or going for a walk could make a difference. So, too, could a higher income.

Specifically, those who had more education or participated in more leisure activities were 5% less likely to develop MCI.

Predictors that increased the risk of someone with MCI developing dementia included the use of antidepressants, having symptoms of depression, having the particular gene that increases Alzheimer's risk and having MCI that affects several aspects of thinking skills, including memory, language and spatial skills. Read More

Clearing Out Clutter Might Not Help People With Dementia

You might think de-cluttering would make it easier for people with dementia to do daily tasks. Not so, says a new study from the United Kingdom.

"It is generally assumed that a person with dementia will be better able to carry out daily tasks when their home space is tidy and clutter-free," said Eneida Mioshi, a professor in the School of Health Sciences at University of East Anglia (UEA).

"However, there has been very little research to really test this hypothesis," Mioshi added in a university news release.

The study included 65 people with either mild, moderate or severe dementia. They were asked to carry out daily tasks such as making a cup of tea or a simple meal.

Their ability to do these tasks was assessed in two locations: their own homes and in a fully furnished research facility meant to replicate a home setting. The research facility was free of clutter while the participants' homes were left as they were and had varying amounts of clutter.

Occupational therapist Julieta Camino said, "We thought that the complete absence of clutter in our research bungalow would play a beneficial role in helping people with dementia with daily living activities. But we were wrong." Camino is a PhD student in the UEA School of Health Sciences.

"We were surprised to find that, overall, people with moderate dementia, in particular, performed daily tasks better at home — even though their homes were significantly more cluttered than our research bungalow," she said.

"And it didn’t seem to make any difference how cluttered the participant's home was," Camino added. "The only factor that contributed to how well they could carry out tasks at home was their level of cognition — with those with severe dementia encountering the same difficulties to perform the tasks at home and in the research bungalow."

The study was published recently in the journal Alzheimer Disease and Associated Disorders.

Mioshi noted that the "majority of people with dementia live in their own home and usually want to remain living at home for as long as possible."

That makes it important to know how people with dementia can be best supported at home, she added. "One possible route would be by adapting the physical environment to best suit their needs," Mioshi said. More information The U.S. National Institute on Aging has more about dementia.

Health Tip

As the weather gets colder, it is important to keep yourself safe and healthy. If your body temperature drops too low, you are at a risk for hypothermia, which can cause health problems including heart attack, kidney problems, and liver damage. The National Institute for Aging recommends some of the following tips to keep yourself warm this winter:

• Set the heat to at least 68-70°F. You can save money on heating bills by closing off rooms that you are not using, placing a rolled towel in front of doors to prevent drafts, and keeping your blinds and curtains closed to avoid losing heat through your windows.

• Even indoors, make sure you dress warmly. Wear socks and slippers in your home and keep blankets available to place over your legs. At night, use extra covers and wear a cap or hat.

• Ask a friend or family member to check in on you when the weather is cold. If a power outage leaves you without heat, try to stay with a relative or friend.

• Try to stay inside on cold, windy days. If you need to go outside, wear warm, waterproof clothes in loose layers to keep your body warm.

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New Hormonal Pill May Boost Outcomes for Older Breast Cancer Patients

An experimental hormone therapy pill can effectively stall the progression of breast cancer, even in older patients whose tumors have mutated to make such therapy less effective, new trial results show.

The drug elacestrant reduced the risk of breast cancer progression and death by 30% in postmenopausal patients whose cancers were fueled by the female hormone estrogen, compared to people receiving new rounds of other hormone therapies, according to results to be presented Tuesday at the San Antonio Breast Cancer Symposium.

Elacestrant was even more effective in people with cancers that had mutated to make them less vulnerable to hormone therapy, causing a 45% reduction in risk of progression or death compared to standard hormone therapy, the researchers added.

"Clinically, elacestrant has the potential to become the new standard of care in the studied population," said lead researcher Dr. Aditya Bardia, director of the breast cancer research program at Massachusetts General Hospital in Boston.

Elacestrant is the second selective estrogen receptor degrader (SERD) to be developed for use in treating breast cancer. It works by latching onto the estrogen receptors of breast cancer cells and preventing them from working, eventually causing them to break down.

The first such drug, fulvestrant, is widely used but literally a "pain in the butt" because it's administered by two injections monthly, said Dr. Charles Shapiro, a professor of medicine, hematology and medical oncology with the Icahn School of Medicine at Mount Sinai in New York City.

People with breast cancers fed by estrogen — called estrogen receptor (ER)-positive — are typically treated with hormone therapy designed to deny tumors the fuel they need to grow. However, resistance to these treatments usually develops, sometimes because the receptor genes mutate.

Bardia and his colleagues tested elacestrant's potential as a new hormone therapy in a phase 3 trial involving 477 postmenopausal patients with advanced ER-positive breast cancers who'd received one or two prior rounds of hormone therapy.

Half of the patients were randomly chosen to be treated with elacestrant, while the other half were given another round of hormone therapy picked by their doctor.

Elacestrant blocked progression of breast cancer for 12 months in about 22% of patients given the drug, while other hormone therapies did the same in about 9% of patients.

The new drug particularly helped people with cancers that had mutated. Nearly 27% of elacestrant patients with these mutations had the progression of their cancer stall for 12 months, compared with about 8% of those on standard hormone therapies.

"The results clearly suggest that this new SERD may become a treatment option for patients with breast cancer, not only as a single therapy but also in combination with other targeted therapies," said Dr. Carlos Arteaga, director of the Simmons Comprehensive Cancer Center at UT Southwestern Medical Center in Dallas.

Elacestrant's most common side effect was nausea, affecting 25% of patients. However, Bardia said that no one became so nauseated that they had to withdraw from the clinical trial.

The clinical trial results mean that "elacestrant is off to a great start in the race to replace fulvestrant with oral SERDs," Shapiro said.

However, Shapiro believes this clinical trial was flawed because the control group remained on hormone therapy alone even if they'd developed a resistant mutation, without any accompanying chemotherapy.

That's why progression-free survival was 8% to 9% in the control group, Shapiro argued, noting that in clinical practice women who've developed resistance to hormone therapy are treated chiefly with chemotherapy.

Bardia disagreed, saying that treatment guidelines for ER-positive breast cancers call for doctors to "simply use endocrine therapies until all the endocrine therapy options have been exhausted before moving to chemotherapy. The reason for that is that chemotherapy is more toxic and often less effective than standard endocrine therapy."...

With Holidays Ahead, COVID Boosters a Must for People With Weak Immune Systems

(HealthDay News) -- If you're a patient with a weakened immune system, roll up your sleeves to stay safe over the holidays and winter months.

"Immunocompromised patients absolutely should get a flu shot as well as an additional COVID-19 vaccine dose," said Dr. Marwa Kaisey, a neuroimmunologist and assistant professor of neurology at Cedars-Sinai in Los Angeles.

"Otherwise, they are more likely to have worse outcomes if they get COVID-19 because they may not have built the same level of immunity from two doses of vaccine as those with healthy immune systems," she said in a hospital news release.

The U.S. Centers for Disease Control and Prevention estimates that about 3% of U.S. adults (7 million) have moderately to severely compromised immune systems.

That makes them especially vulnerable to COVID and flu because they're less able to mount an effective immune response to infections.

Immune systems can be weakened due to cancer, organ or bone marrow transplants, chronic diseases or medications for these conditions.

The CDC says immunocompromised people should get a third dose of Pfizer or Moderna vaccine at least one month after their second dose, and it's fine to mix or match vaccines.

While many consider the terms "additional dose" and "booster shot" interchangeable, they're actually different, Kaisey noted.

An additional shot is meant to give immunocompromised patients a level of protection similar to that of fully vaccinated people with healthy immune systems.

In contrast, a booster shot is given to fully vaccinated people whose protection against the virus is naturally wearing off over time, Kaisey explained.

When immunocompromised people should get an additional shot depends on their specific conditions.

"Timing decisions should be based on when patients take their immune-suppressing medications," Kaisey said.

"They should consult with their doctor to determine that." Dr. Stanley Jordan, director of Cedars-Sinai's Nephrology and Transplant Immunology programs, said an additional dose is "very, very important for transplant patients." That's because they take medications that suppress their immune system in order to prevent organ rejection.

"After two vaccinations, only about 20%-30% of our transplant patients are positive for COVID-19 antibodies," Jordan said, adding that this has caused great concern among transplant patients.

"A couple of excellent studies have found that patients got about a 60% immune response to the additional dose," he said in the release. "We recommend that all of our patients get it."
## Black Americans Less Likely to Lose Hearing as They Age

Older Black Americans are much more likely to have good hearing than white Americans, and the difference is especially notable among men, a new study shows.

“We found that among males, non-Hispanic Black Americans have a prevalence of hearing loss that is similar to non-Hispanic white Americans who are 10 years younger,” co-author ZhiDi Deng, a pharmacy student at the University of Toronto, said in a school news release.

Learning more about racial/ethnic differences in hearing loss may help improve prevention efforts, according to the authors. They found that Black Americans 65 and older were nearly half as likely to report serious hearing loss in 2016 and 2017 (about 9%) as white Americans in that age group (about 15%).

After accounting for sex, income and education levels, the researchers concluded that older Black Americans were 91% less likely to have hearing loss than white people in the same age group, according to the study.

The results were recently published in the *Journal of Speech, Language, and Hearing Research*.

“The racial/ethnic difference in hearing problems is intriguing,” said study co-author Esme Fuller-Thomson, director of University of Toronto’s Institute of Life Course and Aging.

“Hearing loss is one of the most common chronic problems affecting older adults,” she said in the release. "Those with hearing loss tend to have lower quality of life and a higher prevalence of depression and hospitalization. Understanding the causes and drivers behind the racial/ethnic differences in hearing loss can help us design better preventative strategies as the Baby Boom cohort ages.”

Relevant factors may include racial/ethnic differences in diet, smoking, noise exposure and bone density, the researchers suggested.

“More research is needed to understand the extraordinary differences in hearing,” Fuller-Thomson said.

## New California Law Eases Aid-in-Dying Process

During her three-year battle with breast cancer, my wife, Leslie, graciously endured multiple rounds of horrifically toxic treatment to eke out more time with our two young children.

But after 18 cancer-free months, the disease returned with a vengeance in June 2003. It fractured her bones and invaded her spinal canal, bathing her brain in malignancy.

During the final six months, as she lay on her home hospice bed in constant pain, attached to a morphine drip around-the-clock while losing her eyesight and withering to a skeleton, the idea of ending her suffering by ending her life didn’t even enter into our conversations. I’ve been thinking a lot about those bleak days while looking into California’s *End of Life Option Act*, which allows terminally ill patients with a life expectancy of less than six months to end their lives by taking medications prescribed by a physician. In October, Gov. Gavin Newsom signed a revised version of the law, extending it to January 2031 and loosening some restrictions in the 2015 version that proponents say have become barriers to dying people who wish to avoid themselves of the law.

The original law, which remains in effect until Jan. 1, contains numerous safeguards meant to ensure that patients are not being coerced by family members who view them as a burden or a potential financial bonanza.

Some patients were so sick they died during the 15 days they were required to wait between their first and second requests for the medications. Others were too weak or disoriented to sign the final attestation.

The revised law reduces the 15-day waiting period to just two days and eliminates the final attestation.

It also requires health care facilities to post their aid-in-dying policies online. Doctors who decline to prescribe the drugs ― whether on principle or because they don’t feel qualified ― are obliged to document the patient’s request and transfer the record to any other doctor the patient designates... Read More

## Keep Your Holidays Allergy-Free This Year

(HealthDay News) -- Planning ahead will reduce the risk of allergies and asthma interfering with your holiday plans, an expert says.

"In addition to concerns about COVID-19, those with allergies and asthma sometimes have an added layer of anxiety because they need to always be thinking about allergy and asthma triggers that can cause serious symptoms," said Dr. Mark Corbett, president of the American College of Allergy, Asthma and Immunology (ACAAI).

"With a bit of preparation ahead of your events, you can make sure everyone is safe from allergy and asthma flares, in addition to possible COVID-19 exposure," he said in an ACAAI news release.

The medical association offered a number of tips:

- In addition to a COVID vaccine or booster, consider a flu shot this year. The flu can make asthma symptoms more severe, so it's recommended that anyone with asthma get a flu vaccine.
- Think twice about using candles or lighting the fireplace. Smoke of any kind can be a problem for people with asthma. And while products such as air fresheners, artificial snow, potpourri and other scents are not technically allergic triggers, they can irritate already inflamed airways.
- Food is an essential part of holiday celebrations, but it can be risky for those with food allergies. If you or a family member have a food allergy and you're going to a gathering, you should alert the host about potential problem foods, bring a safe dish or two to share, and be sure you have your epinephrine auto injectors with you.
- Some people are allergic to the terpene in the sap of trees or bothered by mold found in trees and wreaths. Artificial trees don't pose those problems, but can trigger dust allergies if they're not cleaned off. The same is true of other holiday decorations.
- Take prescribed medications before you leave the house, and work with your allergist if your allergies or asthma symptoms seem particularly bad.