PRI CENTER FOR MEDICAL ECONOMICS AND INNOVATION

ISSUE BRIEF

Drug Pricing Proposals Threaten America's Most Vulnerable Patients

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Introduction

Lawmakers in both chambers of Congress are considering legislation that would artificially cap the price of prescription drugs purchased through Medicare Part B and Part D. The House proposal would set the price of certain brand-name drugs based on the prices paid in six reference countries.[1] An alternative proposal in the Senate would peg Medicare's drug reimbursements to those paid by the Department of Veterans Affairs (VA).[2] Some version of either of these approaches could find its way into the forthcoming multi-trillion-dollar budget reconciliation bill.

Proponents often say these policies would empower the government to "negotiate" drug prices with pharmaceutical firms. They also often assert that such price negotiation enjoys broad support among voters from across the political spectrum. Both claims are deeply misleading.

The reforms in question wouldn't lead to "negotiations" between drug firms and the government. Rather, they would impose a top-down system of price controls that is certain to reduce access to the latest medicines for millions of Americans.

In particular, the reforms could usher in a form of controversial cost-benefit analysis that has been used to deny life-saving treatments to patients in countries around the world. Those analyses are based around a metric known as a quality-adjusted life year (QALY). If it becomes a standard here in the United States, the result will be systemic discrimination against America's most vulnerable seniors, forcing them to do without the latest treatments.

Despite false claims to the contrary from supporters, the goal of these proposals isn't to save patients money. Rather, it's to cut costs for the federal government. It would likely do so by limiting access to new medications through QALY-style analysis. Most Americans are unaware of this aspect of the proposed reform. They have been kept in the dark—because when provided with detailed information, as findings from recent polls and focus groups demonstrate, a strong majority of Americans oppose these reforms.

Overview of the House's Drug Pricing Proposal

The House is currently weighing several reforms first introduced in 2019 as part of the Elijah E. Cummings Lower Drug Costs Now Act, also known as H.R. 3. The bill's ostensible aim is to allow the Secretary of Health and Human Services to negotiate drug prices with pharmaceutical firms. But this framing is misleading on the actual substance of the bill.

Under H.R.3, drug companies would be required to set their prices no higher than 120 percent of the average volume-weighted prices paid in Australia, Canada, France, Germany, Japan, and the United Kingdom.[3] Any company that doesn't comply with the government's demands would be subject to an excise tax as high as 95 percent of gross sales for a given drug.[4]

In other words, the government would take nearly every penny a drug earned, leaving pharmaceutical firms unable to recoup their upfront costs on a medicine, much less turn a profit.

To call this arrangement a "negotiation" is plainly inaccurate. It's a "take it or leave it" proposition.

When it passed the House in 2019, the bill received universal support from Democrats and garnered two Republican votes as well.[5] That vote was largely symbolic, however, as the policy had no real chance of passage in a Senate then led by Republicans.

In recent months, however, House Speaker Nancy Pelosi has expressed her intention to include these reforms in the reconciliation bill, which could be passed on a purely party-line vote, since it isn't subject to a Republican filibuster in the Senate. And now that Democrats control both chambers of Congress as well as the White House, the chances that something like H.R.3 could become law are far greater.

Overview of the Senate's Drug Pricing Proposal

In recent weeks, the Senate Finance Committee has been weighing an alternative to H.R. 3 that would base Medicare drug prices on the prices paid by the VA—which are lower than Medicare's current reimbursements, but higher than payment rates in other countries. Like the House's proposal, this policy aims to reduce how much Medicare spends on drugs by placing a strict limit on how much pharmaceutical firms can charge for their products, thereby creating a system of price controls. And by one estimate, it is projected to save the federal government $350 billion over the next decade.[6]

That the federal government could save money on drugs by emulating the VA should surprise no one—because the drug coverage provided for American veterans through the VA system is notoriously inadequate, especially compared to what Medicare offers. The agency simply doesn't cover many available medications. If a treatment doesn't make its "master list" for all beneficiaries, they generally cannot obtain it through their VA coverage, regardless of their unique medical needs.[7] This is vastly different from Medicare Part D, which enables patients to choose from a diverse array of privately-administered drug plans.

Making matters worse, the one-size-fits-all VA formulary often fails to include the latest medicines, forcing patients to settle for older and, in many cases less-effective, alternatives. Of the top 200 brand-name drugs paid for through the Medicare Part D drug benefit, barely half are covered by the VA. And whereas Part D covers 62% of a list of 25 first-in-class brand-name medicines, the VA covers a meager 40%.[8]

These numbers mirror what one would see when comparing the availability of branded drugs in the United States versus H.R. 3's reference countries.

In fact, the VA's drug formulary is so inadequate that over 80% of veterans rely on supplemental health coverage, including Medicare Part D or Medicare Advantage (which generally includes Part D benefits). Over half of VA enrollees fill at least some of their prescriptions outside of the VA—and nearly 35% obtain *none* of their medicines through the VA.[9]

In other words, Medicare effectively backstops the VA. Millions of veterans currently get the medicines they need through Part D when those prescriptions aren't available through the VA.

But if Congress upends Part D, and makes it more like the VA's skimpier coverage, tens of millions of seniors—veterans and lifelong civilians alike—will no longer have access to certain lifesaving medications.

The Tragedy of the QALYs

The paltry level of drug coverage offered by the VA is partly attributable to the price controls the program imposes. The same is true for the reduced availability of medications in foreign healthcare systems with price controls—including the reference countries that would be used in setting U.S. prices under the House plan.

To help determine the prices they are willing to pay, and the medications they will include and exclude from coverage, both foreign governments and the VA rely on QALY-style analysis to determine a medication's value.

In its simplest form, a QALY-style analysis aims to quantify the effectiveness of various medications at extending and improving patients' lives, so that regulators can make apples-to-apples comparisons between different treatments. A therapy that extends patients' lives by an additional year, on average, with no symptoms, side effects, or other limitations would be said to deliver one "quality-adjusted life year."

This seemingly neutral approach supposedly enables insurers to select the most cost-effective treatments. Consider two hypothetical cancer treatments, both of which extend patients' lives by 12 months, on average. So both deliver one QALY. But if one drug costs $50,000 annually, and the other costs $100,000, insurers would deem the former a better value. They might steer patients towards the cheaper, equally effective drug by placing it on a "preferred" formulary tier, by making doctors jump through regulatory hoops to prescribe the more expensive treatment, or by refusing to cover the latter medication at all.

In theory, QALY-based assessments are supposed to be just one tool in regulators or insurers' arsenal, helping inform their coverage decisions and grounding them in supposedly objective realities.

In practice, however, QALY-based assessments are used to justify rationing access to lifesaving treatments. Especially in countries with government-run health systems, regulators assign an arbitrary value to what an additional year of human life is worth—perhaps $50,000 or $100,000.[10]

If a drug costs less than that arbitrary threshold per QALY delivered, regulators cover it. If it costs more, they don't. In other words, patients who could potentially survive years, even decades, longer, are left to die because their lives aren't deemed valuable enough to save.

QALY analyses are also inherently discriminatory. That's because they value the lives of healthy, able-bodied patients over those of chronically ill or disabled patients. Consider that, if a treatment will cause a person to live one more year at full health, the treatment would have a QALY value of 1. But if it extends the life of a patient with a degenerative illness or disability—someone who will never attain "full health"—that treatment may carry a QALY value of just 0.5.

As my Pacific Research Institute colleague Wayne Winegarden has noted in his extensive research, QALY analyses also undervalue medicines that improve—but don't necessarily extend—the lives of patients suffering from serious but not *fatal* illnesses.

"How does one quantify the discomfort of poorly tolerated treatments for psoriasis or the pain and daily inconveniences of rheumatoid arthritis?" he asked in a report published earlier this year. "How does one quantify the benefits from more days without the crippling pain from a migraine? Treatments for some disease states simply do not lend themselves to economic number crunching."[11]

The very logic of QALY analyses, in other words, dictates that the lives of sick or disabled patients are less valuable than those of healthier patients.

Under the House proposal, the United States would be importing the inhumane QALY-based analyses that underlie drug prices reference countries pay. Similarly, the Senate's proposal would base Medicare's drug prices on the prices set through the VA, which relies on QALY-based analyses in determining which medicines to cover.

If QALY-style analysis comes to Medicare, medicines aimed specifically at treating less healthy and disabled patients are unlikely to win coverage, even if they would dramatically improve the lives of patients.

The Rehabilitation Act of 1973 bans programs administered by the Department of Health and Human Services from discriminating against individuals on the basis of disabilities.[12] Cost-benefit analyses that employ QALYs have this form of discrimination built into them.

If either the House or Senate proposal becomes law, American seniors, especially sick and disabled patients, will see their access to the latest medicines diminish. That's what the proposals are designed to do.

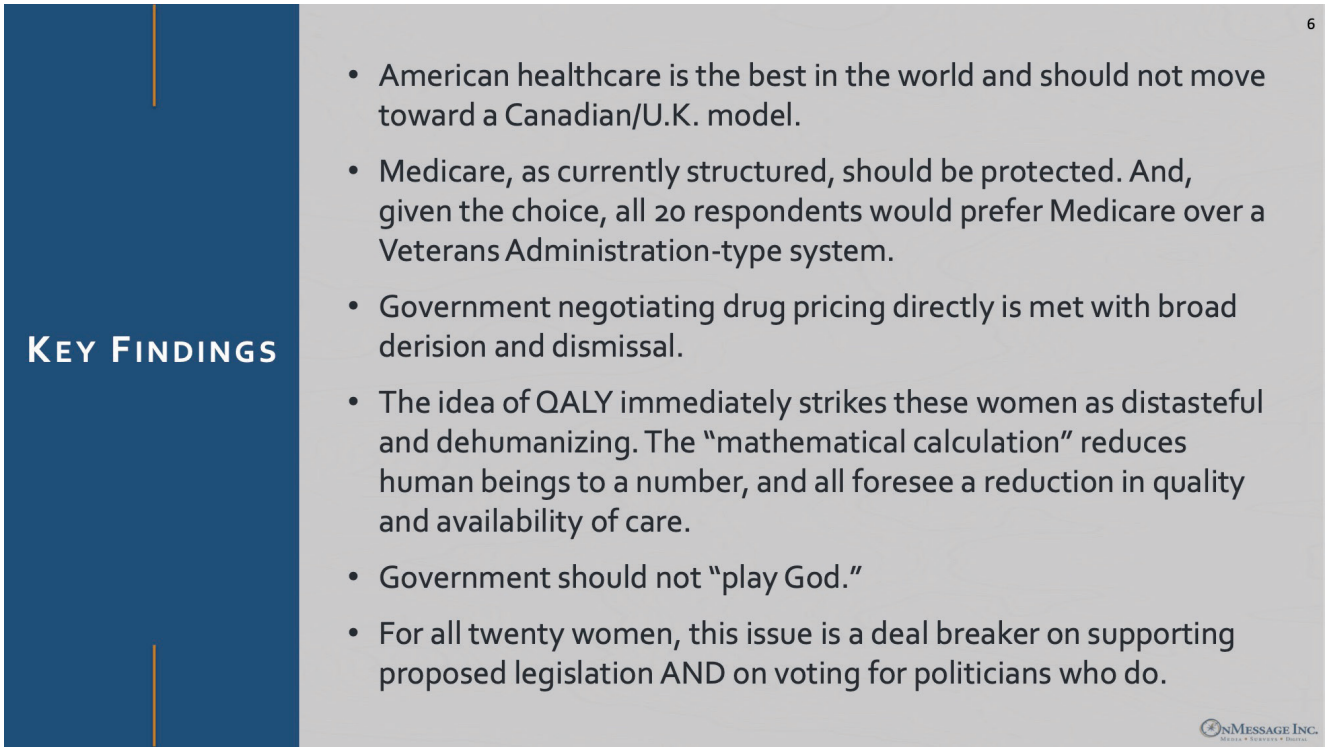
Indeed, whereas almost 90% of the new medicines released between 2011 and 2018 were available here in the United States, according to a 2019 report from the Galen Institute, fewer than half are available in Canada, and just 60% are on offer to patients in the United Kingdom.[13] These disparities in access are the direct result of the QALY-based price-control policies employed in these countries.

Unsurprisingly, proponents of these proposals often leave out such facts. That's because when people learn what these reforms actually entail, support for them plummets.

The More People Know, the Less They Like

By significant margins, Americans have little interest in having Medicare adopt the ruthless cost-benefit analyses used in other countries and at the VA. In a recent survey of likely voters commissioned by the Pacific Research Institute, nearly 78% opposed the use of QALYs to set prices under programs like Medicare.[14]

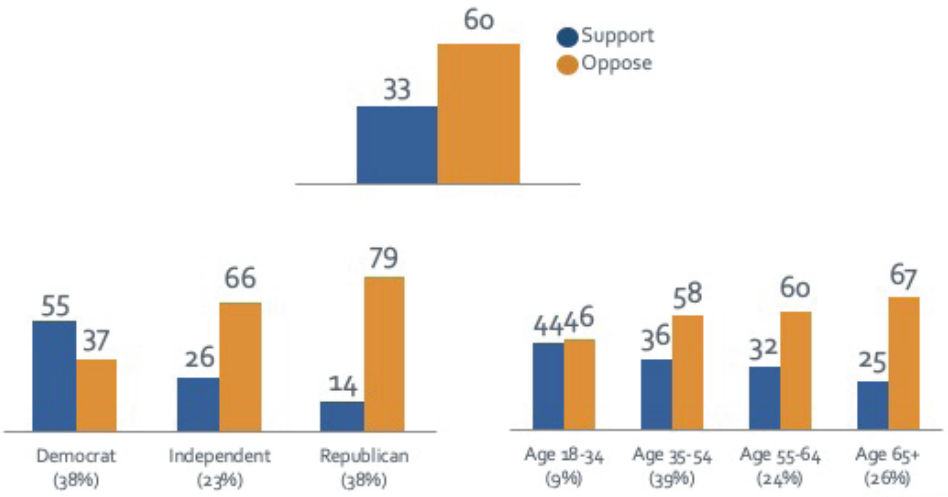
When asked whether Medicare should base its drug prices on decisions made by government officials in Canada and Europe, nearly 60% opposed the idea.[15]



Source: The following focus group data was collected by OnMessage from a group of 20 female suburban swing voters on September 13, 2021, in Pittsburgh, PA. The following survey was conducted of 800 likely general election voters across the nation. Telephone interviews were conducted September 28–30, 2021.

DRUG PRICING

One proposal in Congress is to base our drug pricing on systems used in Canada and European countries where government officials, not doctors, decide which drugs the government will pay for and which patients will qualify for them. Do you support or oppose changing programs like Medicare to be more like health care systems in Canada and Europe?



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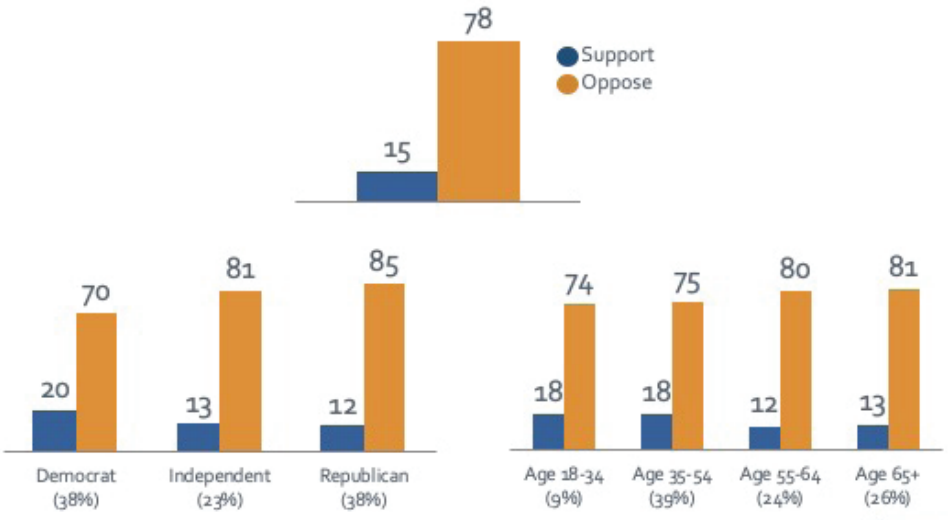
Source: The following survey was conducted of 800 likely general election voters across the nation. Telephone interviews were conducted September 28-30, 2021.

DRUG PRICING

Another proposal in Congress would have the U.S. government set prices for prescription drugs based on a mathematical calculation of the value of a patient's life. This mechanism is known as a QALY. Do you support or oppose using the mathematical value of a person's life to determine what drug and treatment options the patient qualifies to receive?



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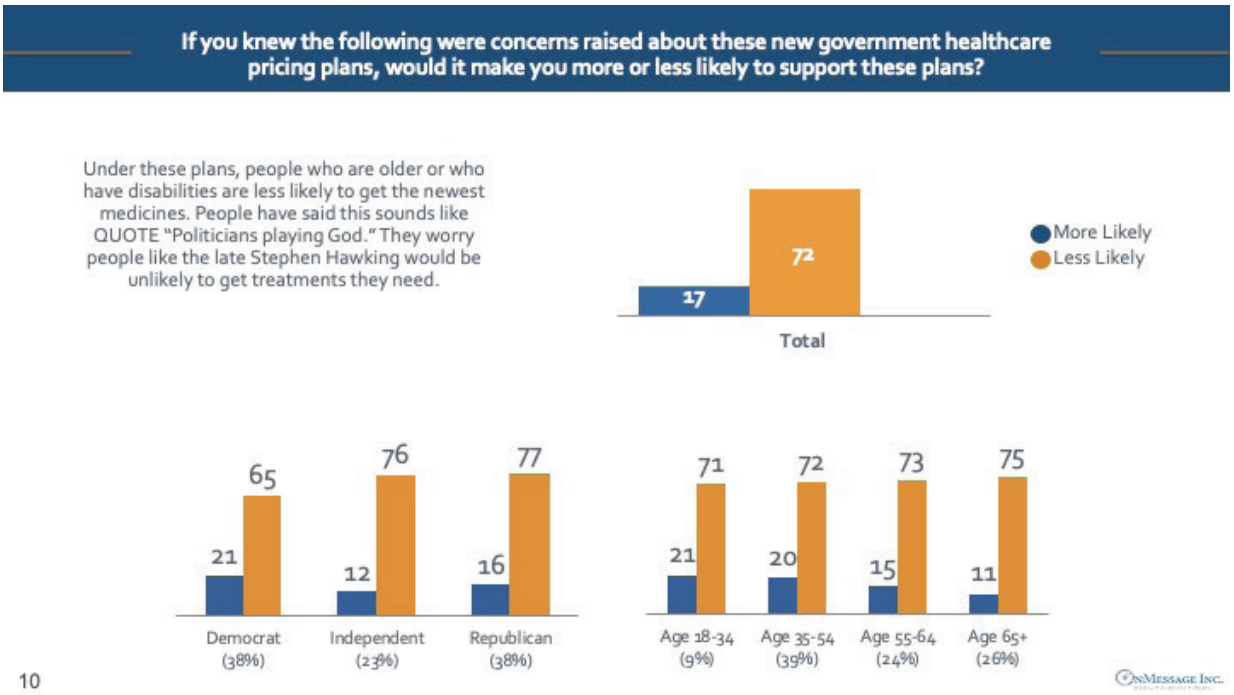
Source: The following survey was conducted of 800 likely general election voters across the nation. Telephone interviews were conducted September 28-30, 2021.

When informed that under such plans as the House and Senate are considering, "people who are older or who have disabilities are less likely to get the newest medicines," 72% of voters said they were less likely to support the reform.[16]

And when further informed that these proposals "take away power from doctors to prescribe the medicines that best meet the needs of their patients" and that they empower the government to make "those decisions based on a calculation of the value of a patient's life," more than 75% said they were less likely to support the reforms.[17]



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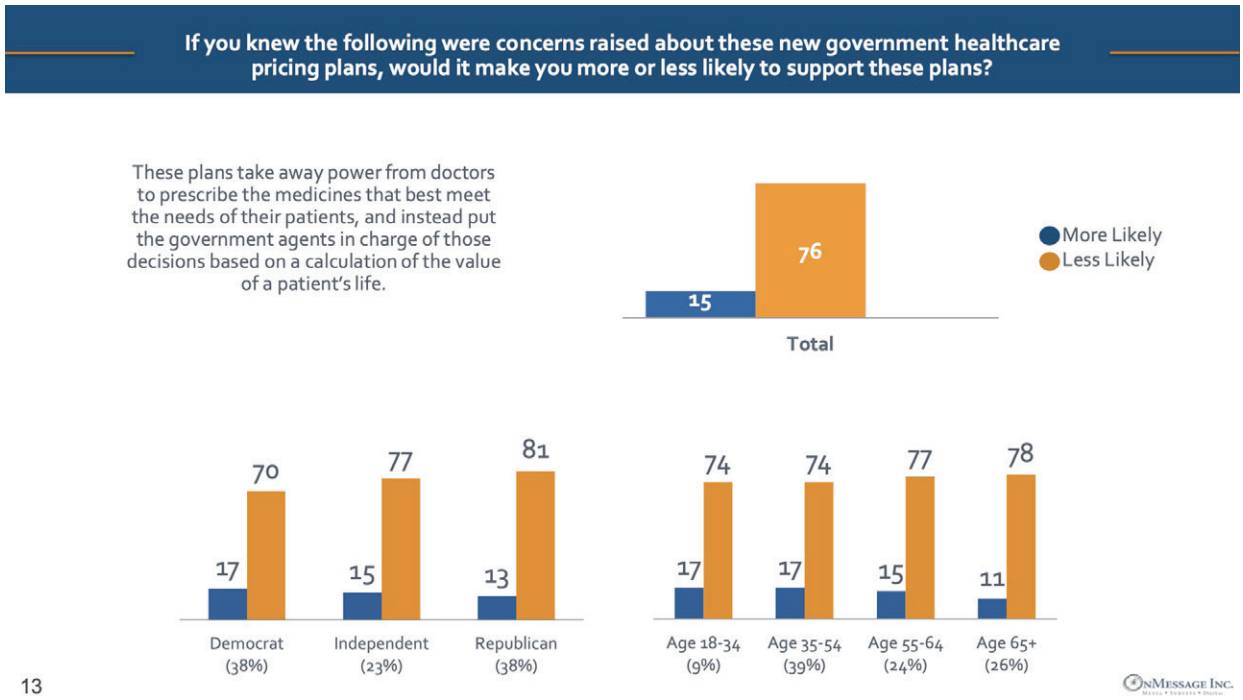
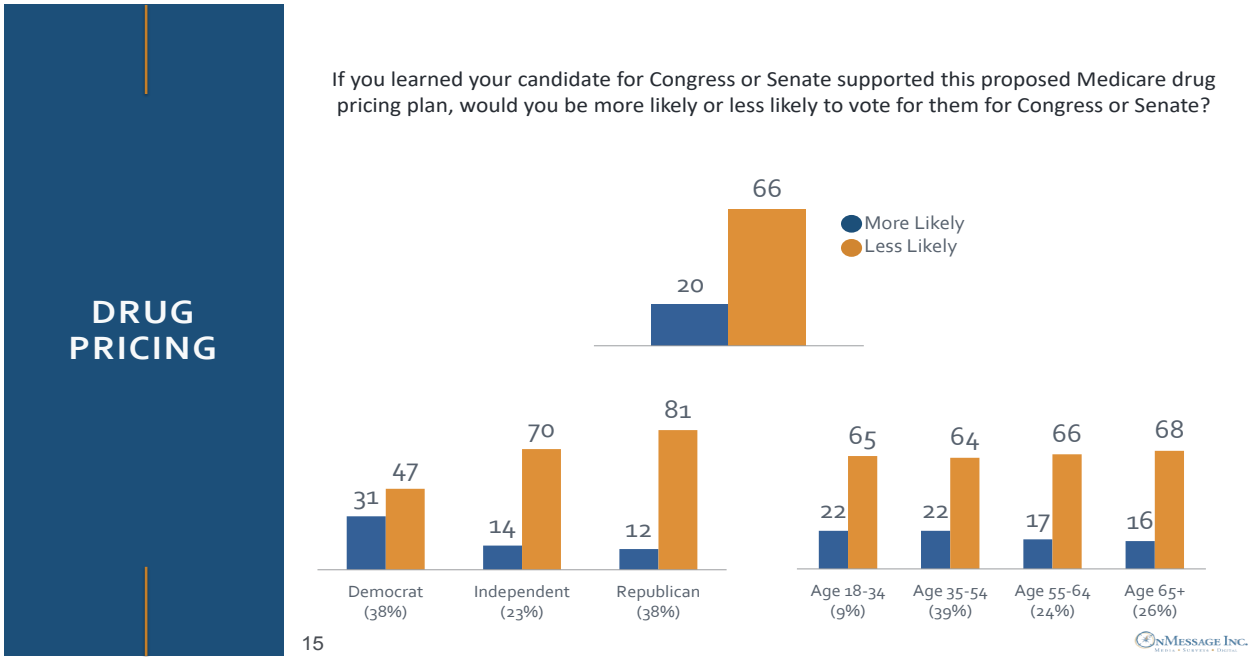


Source: The following survey was conducted of 800 likely general election voters across the nation. Telephone interviews were conducted September 28-30, 2021.

When asked if they would be more or less likely to support candidates for Congress who voted in favor of one of these drug pricing reforms, nearly 66% said "less likely," with over half saying "much less likely."[18]



Source: The following survey was conducted of 800 likely general election voters across the nation. Telephone interviews were conducted September 28-30, 2021.

In fact, when the moderators of a focus group commissioned by the Pacific Research Institute accurately described the concept of a QALY to participants, their reactions were often extremely negative, sometimes to the point of disbelief. One described policies that rely on QALY as "Government playing God."

Another pointed out that "They would [have] probably euthanized Stephen Hawking. And he was brilliant."

As another respondent put it, "it's an unnecessary evil, having anyone make those decisions outside of the doctor."

The Power over Life & Death

- "It's just treating humans like a business. Y'know, we have to cut costs, we're gonna cut numbers and the only way to cut numbers is (gestures in exasperation)." -Kathy K, College Grad, Somewhat Conservative, Registered Republican Trump Voter
- "Government playing G-d. If you don't believe in G-d, government believes." -Joanne S, Some College, Somewhat Conservative, Registered Independent, Trump Voter
- "My father is 89, he was just taken to Presby three nights ago. And if this were in effect there would be no need to treat him. He has congestive heart failure, he's 89, he has the beginning of dementia, he's delirious right now, you might as well just throw the towel in." -Kathy H, High School Grad, Moderate, Registered Republican, Biden Voter
- "They want to play Dr. Kevorkian. When they say it's illegal but they want to do it. That's exactly what I think they're doing. If we have no right to end our life then they shouldn't be allowed either." -Nadene L, High School Grad, Moderate, Registered Democrat, Biden Voter
- Moderator: This proposal requires using a mathematical calculation of the value of the patient's life to decide if they qualify for medical treatments. Have you heard of this?
  Senior Group All: (silence, head shaking)
- "The Charlton Heston movie where they were eating the people. That was your value, you were the food. Soylent Green. Exactly. That's what popped into my mind" -Nadene L, High School Grad, Moderate, Registered Democrat, Biden Voter
- "They woulda probably euthanized Stephen Hawking. And he was brilliant" -Sue K, Post-Grad Degree, Somewhat Conservative, Registered Republican, Trump Voter

OnMessage Inc.

Source: The following focus group data was collected by OnMessage from a group of 20 female suburban swing voters on September 13, 2021, in Pittsburgh, PA.

QALY Introduction and Reactions

- Moderator: Quality Adjusted Life Year, or "Qaly" for short so that's what I'm going to refer to it as.
  Joan H: Seems terrible!
- Moderator: So what's your reaction?
  Kathy K: Shocking.
- "I don't know who gives people the right to determine that." -Barb N, Some College, Somewhat Conservative, Registered Republican, Trump Voter
- "I would be like 10,000% against it. Because my son takes a drug that's $24,000 a month, a month. He's perfectly healthy, like on paper he's not healthy, but to look at him no one would ever know there was anything wrong with him. Yet, because he has this diagnosis, there gonna put him like, they're gonna say 'well, he's, y'know what, he's y'know' … (gesturing stop/hesitation)." -Maura G, College Grad, Somewhat Conservative, Registered Republican, Trump Voter
- "I'm just saying because, if I think YOU can give a qualification of the value of my life? I'm saying no freakin' way." -Constance S, College Grad, Somewhat Conservative, Registered Republican, Trump Voter (Note: "Usually Vote Dem")
- "Hard enough when a loved one has to make a decision, but there's emotion involved. There's no emotion involved in someone looking at a paper and you're a number, saying no you're done, you're a drain on the system." -Joanne S, Some College, Somewhat Conservative, Registered Independent, Trump Voter
- Moderator: This idea, if you have to compromise, is this [QALY proposal] a hard no?
  Near-Senior Group All: (nodding agreement)
- "What it's doing, it's just looking at people not as humans, it's looking at people as a liability." -Joanne S, Some College, Somewhat Conservative, Registered Independent, Trump Voter
- "It's an unnecessary, it's an unnecessary evil, having anyone make those decisions outside of the doctor." -Constance S, College Grad, Somewhat Conservative, Registered Republican, Trump Voter (Note: "Usually Vote Dem")
- "So now we just don't value people if they have a disability? If they have a physical or a mental ore emotional … suddenly their life isn't worth as much? I don't think that's true." -Constance S, College Grad, Somewhat Conservative, Registered Republican, Trump Voter (Note: "Usually Vote Dem")
- "I think year's ago, it seemed, probably before us, men where more valuable than women and all the medical research was on men and like they had better results if they had a heart attack and everything. And, it was just lately within our lives women have kind of caught up like we're valuable too. So now this is like a step back." -Joyce B, Post-Grad Degree, Somewhat Conservative, Registered Democrat, Trump Voter

OnMessage Inc.

Source: The following focus group data was collected by OnMessage from a group of 20 female suburban swing voters on September 13, 2021, in Pittsburgh, PA.

Conclusion

Lawmakers have insisted for years that American voters favor drug-price negotiations in Medicare. But much of the apparent public support is premised on basic misunderstandings about the nature of the proposals and their consequences for patients.

These policies aren't designed to save patients money at the pharmacy. They are designed to reduce how much the government pays for drugs. They achieve that goal through a cost-benefit analysis system designed to deprive Americans access to new medications.

When the truth becomes clear, Americans overwhelmingly reject such policies. They also say they are far less likely to support candidates who push price-control plans. Leaders who insist on pursuing such misguided reforms will be putting the lives of seniors, as well as their own electoral prospects, in jeopardy.

For a full summary of the poll's results, click here. For a full summary of the focus group findings, click here. To view a summary of the poll and the focus group's findings, click here.

Endnotes

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About the Author

Sally C. Pipes is President, CEO, and Thomas W. Smith Fellow in Health Care Policy at the Pacific Research Institute, a San Francisco-based think tank founded in 1979. Prior to becoming president of PRI in 1991, she was assistant director of the Fraser Institute, based in Vancouver, Canada.

A celebrated speaker, Ms. Pipes regularly addresses national and international audiences on health care. A prolific writer, Ms. Pipes is a weekly columnist for *Newsmax.com*, a bi-weekly columnist for *Forbes.com*, a contributor to the *Washington Examiner's* Beltway Confidential blog, and former weekly columnist for *FoxNews.com*. Her commentary has appeared in the *Wall Street Journal, New York Times, Washington Post, USA Today, Financial Times, Los Angeles Times,* and elsewhere.

In January 2020, Encounter Books published her book *False Premise, False Promise: The Disastrous Reality of Medicare for All,* with a foreword by former Senator Tom Coburn, MD. Previously, she published three other books with Encounter, and two with Regnery. She published her first book, *Miracle Cure: How to Solve America's Health Care Crisis and Why Canada Isn't the Answer,* with a foreword by Milton Friedman in September, 2004.

In 2008, she founded the Benjamin Rush Institute, a nonprofit that unites medical students, faculty, doctors, healthcare professionals and others who believe that free enterprise and a direct patient-doctor relationship are the best means of ensuring optimal patient outcomes at affordable prices. She now serves as Board Chairman.

In addition, Pipes serves on the national advisory board of Capital Research Center, the advisory boards of the Council for Affordable Health Coverage, the California Association of Scholars, Docs4PatientCare, and the Heartland Institute. She also serves on the president's advisory council for the State Policy Network and has served as a trustee of St. Luke's Hospital Foundation in San Francisco, a board member of the Independent Women's Forum, and as a governor of the Donner Canadian Foundation.

In April 2018, she received an honorary Ph.D. from Pepperdine University's School of Public Policy for her work on health care reform.

A former Canadian, she became an American citizen in 2006. She is married to Charles R. Kesler, a professor at Claremont McKenna College and editor of the *Claremont Review of Books*.

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