# PUTTING PATIENTS FIRST:

## INNOVATIVE SOLUTIONS FOR PRESCRIPTION DRUGS & OLDER AMERICANS

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# EXECUTIVE SUMMARY

**"God uses a lot of different things to get you where you need to be," said James Deer, a lawn care businessman from Ulmer, South Carolina, who, at the age of 59, faced a rare bone marrow cancer diagnosis.[1] As he quickly discovered, treatments are scarce. Now 62, Mr. Deer is doing better after participating in a trial to treat his cancer with medication called AG-120. It produced a complete response.**

**For Mr. Deer and countless others, particularly older Americans, access to treatments and the innovation that drives them makes all the difference, often, between life and death. Today's biomedical innovations bring about modern miracles that have extended lifespans by millions of years over the last four decades, which is cause for celebration, particularly for the United States Senate Special Committee on Aging.[2] These advances ought to inspire wonder, appreciation, relief, and hope. They also deserve policymakers' support.**

**As part of their $3.5 trillion tax and spending plan, the Biden Administration and Congressional Democrats are including H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. This proposal reflects the very best of intentions—a commitment to care for each other, to support the most vulnerable, to better the lives of the suffering and the forgotten—by helping patients afford lifesaving medicine. The problem is that the Democrats' plan endeavors to remedy the current situation through price controls. In other words, Democrats propose the federal government should be in charge of deciding the price of treatments, instead of a competitive free marketplace sustained by companies driving innovation.**

**This report serves to inform policymaking debate by exploring the consequences of H.R. 3 and price controls, which include long-term drug shortages (an almost 50 percent decline in access to medicines);[3] shattered innovation (a 50-90 percent decline in new medicines);[4] and bankrupt businesses (an economic loss in the trillions of dollars).[5] Further, this report outlines policy options that will lower drug prices and expand access to treatment by way of four key mechanisms:**

1. **Allowing seniors to have lower out-of-pocket costs for Medicare drugs;**
2. **Expanding choices for older Americans through Medicare Part D;**
3. **Supporting fair insulin prices in Medicare; and,**
4. **Increasing individualized care like value-based arrangements.**

**These policies will help older Americans find affordable treatments that meet their needs while maintaining the market dynamism that makes new medicine available in the first place. For Mr. Deer and those like him, innovation is hope.**

# INTRODUCTION

Research shows that since 1982, new drugs provided an extra 150 million years of life—and that the United States led the way with 719 new drugs.[6] This is nothing short of miraculous. For seniors, and for all Americans, it is impossible to put a price on living longer and living better. Sadly, that is exactly what H.R. 3 would do, to tragic effect.

Consider James Deer of South Carolina, whose life has been improved by innovative cancer medicine: gains from cancer treatments make up 73 percent of the advances in surviving over the past three decades, and 1.3 million people have survived cancer since 2000 because of new drugs.[7,8] The first section of this report explains how H.R. 3 would place decades of medical advances at risk; the second section posits how Congress can affordably preserve and advance our nation's tremendous rhythm of developing breakthrough, lifesaving medical achievements.

## H.R. 3, pricing out innovation

By institutionalizing Democrats' driving mechanism for lowering drug costs—federal regulation of drug price caps—H.R. 3 is a compassionate idea that would lead to a disastrous outcome. Sadly, this proposal is a core component of their $3.5 trillion tax and spending plan to remake the economy. Here is how it would work: the federal government would tell manufacturers how much they can charge for medicine. The price could not exceed 1.2 times the average price in the United Kingdom, Canada, France, Germany, Australia, and Japan. Price controls would also be enforced.

## Enforcing price controls

The federal government would set prices below this limit for some number of drugs in a given year. Manufacturers would pay a tax—as high as 95 percent—if they did not comply. If the federal government decided that manufacturers had asked for too high a price for a treatment in the past, they would be forced to pay even more. The six countries on which the plan bases its regulations and taxes strictly control drug prices to lower them. The hope is that the same would happen in the U.S. Historically, there is good reason to believe this hope is misplaced.

## The problem with price controls

Patients and families need lower prices and more options. Controls produce the opposite effect. Price controls limit consumer choice by forcing industry to cut investment in critical business aspects such as research and development, innovation compliance costs, and ultimately manufacturing and production. This has happened repeatedly throughout history. When the U.S. put price controls on oil and gas in the 1970s, production fell, and working people spent hours (and their paychecks) in long lines waiting to fill their tanks.[9] The controls failed to lower prices, but prices did fall when President Reagan repealed the regulations. For economists, this is common sense.

### Lessons learned: good intentions, bad policy

Today, economists consider the United States' experiment with price controls on gas a canonical example of well-intentioned but counterproductive regulation.[10] In extreme cases, like Venezuela or the Soviet Union, price controls can ruin the economy.[11] While H.R. 3 alone is not an extreme case, it is a step in the wrong direction that could lead to extreme and harmful effects for seniors in need. Policymakers should remember history's lessons—price controls limit the availability of goods and services, and would restrict access to prescription drugs.

### The same shortage story for prescription drugs

In 21 countries using price controls, according to one review, access to treatments is limited.[12] Cancer drugs are limited in Canada.[13] Cardiology drugs are denied to patients in France, and multiple sclerosis treatments to patients in the United Kingdom.[14] In Australia, patients are left with outdated drugs.[15] Over 400 new medicines were available to almost 90 percent of Americans in the last decade, compared to only 52 percent of the H.R. 3 countries.[16] U.S. patients have access to 95 percent or more medicines for rare diseases, cancer, vision, mental illness, HIV, Parkinson's, Epilepsy, Cystic Fibrosis, and Multiple Sclerosis. Patients in the H.R. 3 countries can access 70 percent or less of these medicines.[17] These shortages point to significant declines in future innovation.

## SHORTING THE FUTURE: INNOVATION, MEDICINE, AND THE INVISIBLE PATIENT

In public policy, the future lives affected by medicine innovation should not be invisible.[18] Hundreds of thousands more may have died during the pandemic without the innovation of American vaccines. Dorothy Nielsen, 88, from Mt. Pleasant, South Carolina writes, "[t]he biopharmaceutical industry has really done amazing work creating not just one, but multiple vaccines. The research and development these amazing scientists have created should make all of us proud."[19] She adds, "[i]t is important that these companies continue to strive for innovation on other diseases that will remain once COVID-19 has been tamed." The Congressional Budget Office (CBO) says that H.R. 3 would prevent a substantial amount of new drugs from coming to market.[20] Price controls could cost businesses almost $2 trillion, a death sentence—unless they severely slash investment in new treatments.[21] As a result, consumers would lose access to more medications than the CBO predicts.[22] Lost access would have dire consequences for seniors.

## The tragedy of lost innovation

Price controls led to 25 percent fewer new drugs, and two years of lost life expectancy, according to one study.[23] New drugs also reduce disability by up to 30 percent, according to another.[24] Research discovered that in 30 countries, drug innovation made up three-fourths of a 1.74-year increase in life expectancy.[25] For older Americans in particular, these are not dry academic numbers on a spreadsheet; they are marked improvements in the quality of daily life. Innovative drug breakthroughs represent precious time on our livelihood and mortality clocks, the sacrifice of which would be an immeasurable tragedy.

## Pricing economic growth out of the market

Research suggests that if cancer mortality fell by 10 percent, Americans would gain $5 trillion—and maybe more if new drugs drove the decline.[26] Yet H.R. 3 would curtail that innovation, forfeiting trillions. It would hurt small businesses that make new medicines the most. The investments on which they rely would dry up as regulations reduced their income by almost 60 percent.[27] Price controls would eliminate 4 percent of pharmaceutical jobs.[28] On top of overall economic decline, new drugs from small businesses would fall by 90 percent, which means 16 fewer medications for ovarian cancer, prostate cancer, leukemia, and breast cancer; 10 fewer for hypertension, pulmonary fibrosis, and brain cancer; and two fewer for diabetes and COPD.[29] On the ground, the magnitude of this impact becomes even clearer.

### H.R. 3 on the ground: South Carolina

The biopharmaceutical sector contributes almost $7 billion to South Carolina's economy every year, and nearly 25,000 jobs.[30] The state has 28 cutting-edge plants involved in creating new medicines.[31] H.R. 3 would put them in jeopardy. It would do the same to over 18,000 South Carolinians who participated in clinical trials in 2017, and to the $290 million in yearly tax revenue generated by industry.[32] For South Carolina seniors, price controls would even impact retirement—three-quarters of company shares are held by mutual funds, endowments, and pension funds. Policymakers should also keep in mind that the lives of everyday Americans are the driving concern behind these figures.

### A name behind the numbers

> William Donevant, 71, of Georgetown, South Carolina said, "[w]e haven't gone fishing in a while."[33] Three years into retirement, he was diagnosed with a rare cancer. As is too often the situation, his case was hard to treat. He is in remission thanks to CAR-T-cell therapy, which changes genetics in the immune system. He now finds happiness in resuming his life, and in time spent with his granddaughter. "Without chemotherapy, it will set me free."

Policy should not curb the innovation that gets Mr. Donevant his life back. It should help him resume activities he loves, like fishing.

Fortunately, there are common-sense, achievable paths forward.

# POLICY SOLUTIONS

**Americans are blessed with the best medicine in the world. What older Americans need and deserve is more of it, at lower prices and a quicker pace. Instead of pursuing a rigid pricing dictate, Congress and the Administration should adopt practical, achievable strategies for promoting innovation and lower consumer costs, including:**

- **An out-of-pocket cap for Part D;**
- **Allowing plan sponsors to offer more plan options;**
- **Codifying the insulin demonstration program to lower insulin prices introduced under President Trump's Administration; and,**
- **Modernizing value-based arrangements.**

## Medicare Part D: the value of choice

**Created in 2006, Medicare Part D provides seniors access to private, stand-alone prescription drug plans or Medicare Advantage prescription drug plans that cover a wide range of medication. Part D is a bipartisan success story, keeping costs low by empowering patients through choice and a market-oriented structure, not heavy-handed bureaucracy. In fact, research finds that Part D's market mechanisms are responsible for its low costs.[34] This is exactly the kind of initiative to which policymakers should look when considering the affordability of medicines for older Americans. Some practical steps to modernize Part D would lead to significant gains for patients.**

## Out-of-pocket cap for Part D

**Part D beneficiaries pay a monthly premium, an annual deductible, and co-payments or coinsurance. Their relative share of overall costs is low. The lack of an annual cap on out-of-pocket spending, however, can expose them to dramatic costs, according to a new analysis. In 2019, nearly 1.5 million beneficiaries paid above the catastrophic threshold. Over 3.6 million older Americans faced that hardship in the last decade.[35] For seniors, the majority of whom live on fixed incomes, establishing a reasonable, annual cap on out-of-pocket costs would help better support their finances and deliver more peace of mind. Enhancing seniors' access to Part D plans would similarly contribute to lower overall costs.**

## Increase plan choice for Part D beneficiaries

**Part D works best for seniors because of time-tested principles like choice, flexibility, and a fair role for the market. Unfortunately, Obamacare shrunk the number of available Part D plans offered, thereby curtailing choice by limiting older Americans to only one basic plan benefit and two enhanced plans per service area. Because of this arbitrary cap, seniors now lack access to innovative, flexible plans. Repealing this intrusive regulation would give them more options—plans that best fit their needs, not the interests of distant bureaucrats, improving access to medicines. Supporting patients' unique health needs was also the inspiration for President Trump's cost-cutting insulin initiative.**

## Codify the Trump Administration insulin demonstration program

As seniors throughout the country know all too well, diabetes is becoming an increasingly pressing health challenge. It is affecting more Americans in recent years. In 2018, 34 million adults (13 percent) had diabetes—including 27 percent of those aged 65 years and older.[36] This impacts costs for many vulnerable seniors. A recent study found that Part D beneficiaries' spending on insulin products quadrupled between 2007 and 2017, rising from $236 million to $934 million. While coverage of insulin products varies across Part D plans, the problem is generally in the coverage gap, which has a coinsurance rate of 25 percent. This coverage gap pushes out-of-pocket costs for older Americans as high as $100 per insulin prescription.[37]

Responding to this price spike, President Trump created a voluntary Part D benefit allowing seniors to access insulin for $35 or less a month.[38] Absent this flexibility, they would have to pay much more. According to the Kaiser Family Foundation, President Trump's program cut older Americans' insulin costs by almost 30 percent.[39] This is a remarkable gain for seniors' mental, physical, and financial wellbeing, and policymakers should make it permanent to address their health needs in a flexible manner. They should also endorse broader measures to expand flexibility in Medicare, such as value-based arrangements (VBAs).

## Modernize value-based arrangements

Traditionally Medicare pays "fee-for-service." It reimburses for each item or service provided. By incentivizing hospitals, physicians, and other providers to focus on service quantity over quality, the fee-for-service model better serves limited healthcare access than it does older Americans. VBAs help address this problem.

VBAs reward providers who focus on quality over quantity. They prioritize individual care and patient outcomes. They also reduce costs for taxpayers, no longer on the hook for perverse incentives. By expanding and modernizing the number of Medicare VBAs, policymakers can help ensure that seniors are receiving the very best care, at affordable cost, tailored to their needs.

## Reform for the future

"I do hope that when the pandemic is over," economist Alex Tabarrok, a George Mason University health expert, said, "we don't forget that for patients with life-threatening diseases, it's always been an emergency."[40]

Mr. Tabarrok echoes South Carolina's Dorothy Nielsen in this sentiment, which is worth emphasizing: the Food and Drug Administration's (FDA) imposition of overbearing standards interferes with access to vastly more treatments than COVID vaccines. Innovation saves lives, now and in the future.

Streamlining the FDA's review process, boosting patient voice in its decisions, and allowing innovative trial designs will encourage the growth of lifesaving treatments. It is imperative for Congress and the Administration to constantly search for effective measures that achieve this kind of regulatory fairness and flexibility—one of the best possible ways to put patients first.

# CONCLUSION

**For James Deer, Dorothy Nielsen, and William Donevant, and for so many older Americans across the country, metrics indicating a higher quality of life or better life expectancy are not just statistics. They represent the most valuable resource we have: time—more time to share with a grandchild, laugh with a spouse, or just go fishing.**

**Putting patients first by expanding access to quality treatments is and should be an urgent goal for policymakers. Sharing the medical innovation miracle's bounty is a moral priority. There are strategies and paths available to achieve this goal—to help seniors and all Americans live well, and with dignity—that avoid the pricing pitfalls of H.R. 3. Quality, affordable treatments can be available for patients without sharp shortages, diminished innovation, and economic losses. Policy today can and should effectively support patients, taxpayers, and the competitive marketplace that has extended and improved so many lives in the United States. Let us work to diligently legislate precious time back to ourselves and our loved ones for the chance to enjoy more tomorrows together.**

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