BREAKING DOWN BARRIERS TO OPPORTUNITY #3

# Empowering Entrepreneurs to Address America's Healthcare Challenges

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# Executive Summary

In response to the coronavirus pandemic, the federal government relaxed many healthcare regulations making it easier for patients to access beneficial healthcare innovations such as tele-medicine. The result has been a surge in healthcare entrepreneurship to the benefit of millions of patients. But, these gains are merely scratching the surface.

A healthcare system driven by entrepreneurial innovations can solve many of the problems plaguing the U.S. healthcare system including the issues of affordability, access, and stagnant productivity. In contrast to empowering entrepreneurs, many politicians advocate for an expansion of the government's control over healthcare by implementing a single payer system or a public option that is available to all citizens. Expanding government control will fail to resolve many of the healthcare system's current problems. Worse, the government already pays for 41-cents of every dollar spent on healthcare, and government regulations and tax subsidies fundamentally influence the remainder. Since government spending and government policies drive the current system, it is reasonable to conclude that government failures are driving the current problems that plague healthcare.

> "Unfortunately, the overly restrictive regulatory environment and an ineffective payment system are discouraging entrepreneurial innovations.

Consider that on a per enrollee basis, Medicare's administrative costs are consistently higher than the costs for private insurers.[1] Medicare and Medicaid also reimburse providers at unsustainably low rates, an indication that implementing either a single-payer system or a public option would impose tremendous financial stress on many providers and healthcare facilities. The government has also shown itself unable to efficiently adopt cutting-edge technologies that hold the promise of revolutionizing healthcare. When combined with the record of single-payer systems in other countries that includes lengthy waiting lists, access issues, and doctor shortages, the argument that the system's current problems can be fixed by expanding the government's control over healthcare falls short.

Unlike the results from expanding government, there is evidence that greater entrepreneurial innovations are already helping patients, despite the large disincentives that currently impede such efforts. Beyond the benefits patients have received from the expanded use of tele-medicine during the pandemic, healthcare entrepreneurs have developed new technologies and new delivery models that, if widely implemented, could substantially improve the quality of healthcare in the U.S. while simultaneously reducing its cost.

Unfortunately, the overly restrictive regulatory environment and an ineffective payment system are discouraging entrepreneurial innovations. Starting with the current third-party payment system, the incentives of those paying the bill vary from the incentives of many patients because payers set coverage policies based on group averages, but effective patient health is individualized. The more dispersed an individual's needs are around the averages, the higher the number of patients who will be receiving care that is not reflective of their preferences and requirements. Even if entrepreneurial healthcare providers could somehow discover patients' preferences and needs, they will still find it difficult to serve them because the blessing of the payers are also required.

Ultimately, payers (as distinct from the patient) are driving the demand-side of the market. Consequently, healthcare providers, as the supply-side of the market, are responsive to the needs and preferences of payers rather than patients. This structure precludes vibrant entrepreneurial experimentation that could address the high-cost/low-productivity problems that plague the healthcare system. Fixing this problem is politically complex, but economically straightforward—reforms are needed that prioritize the preferences of patients over payers.

Patient preferences can only be prioritized if they control more of the spending, which is why expanding the scope and reach of Health Savings Accounts (HSAs) are an essential part of the solution. HSAs should be open to all individuals. Employers, employees, and the self-employed should be able to contribute to the account. The owner of the HSA should have wide latitude to use the funds to pay for healthcare costs including daily expenses, health insurance premiums, and co-insurance costs. Account holders should be able to save any money that is not used during the year it was contributed for use in future years or (if never used) as part of their retirement income.

> "Overly burdensome federal and state regulations prevent the adoption of cutting-edge technologies or prevent innovative healthcare providers from providing services in new and more effective ways.

Beyond the benefits from enabling consumers to seek more affordable healthcare services and avoid unnecessary care, HSAs empower patients to financially reward those providers who find new or innovative ways to deliver healthcare that reflect their values and needs. This ability to reward entrepreneurs who provide healthcare services that meet patient preferences incentivizes entrepreneurs to better serve patient needs and efficiently adopt innovative new technologies and healthcare delivery models.

Changes to the delivery model also hold great potential for improving the quality of healthcare. Instead of the typical fee for service model where payers reimburse physicians and healthcare providers based on the quantity of services provided, entrepreneurial ventures are introducing value-based payment models, such as capitation and pay for performance models that connect payments to meeting specific care benchmarks. There are important advantages to these alternative payment models because they sever the link between payment and the quantity of care. Instead, the focus is on improving the quality of care.

Flexible HSAs also empower patients to separate out their purchases of routine healthcare services from the need to purchase insurance to protect against the financial consequences of specific healthcare risks. Separating out these functions helps insurers focus on mitigating the actual financial risks patients currently face and addressing emerging issues such as payment innovations to enable the wide adoption of cutting-edge healthcare innovations.

Creating a vibrant entrepreneurial healthcare system also requires reforms to the supply-side. Overly burdensome federal and state regulations prevent the adoption of cutting-edge technologies or prevent innovative healthcare providers from providing services in new and more effective ways. There are many examples of these burdens. The need for physicians to obtain licenses in every state is one such regulation, as are overly stringent scope of practice laws that prevent many healthcare professionals from practicing medicine to the full extent that their training enables. Other regulations, known as Certificate of Need

(CON) laws, which are effective in 35 states and the District of Columbia, require healthcare providers to obtain government permission to expand their capacity or purchase capital equipment.

Regulations like these have erected barriers that make it more difficult for potential entrepreneurs to implement cost-saving/quality-enhancing innovations or delivery models that would better serve patients. The surge in the use of telemedicine during the coronavirus pandemic once the regulatory burdens were lifted exemplify the potential entrepreneurial innovations that could follow if permanent and widespread regulatory relief was instituted.

Implementing innovative new healthcare delivery models and applying innovative new technologies to better serve patients is the key to addressing the problems of cost, accessibility, and lack of productivity growth. Unlike the government-centric solutions that dominate the headlines, an entrepreneurially focused healthcare system is well positioned to achieve these goals. Instead of assuming that a few people sitting in D.C. offices have all of the answers, an entrepreneurial-incented healthcare system empowers millions of healthcare professionals to devise the innovations that could improve our health outcomes.

The entrepreneurial efforts that continue to occur despite the myriad obstacles standing in their way demonstrate that these entrepreneurs already exist. All that is required to reap the benefits of their efforts is to remove the systemic barriers standing in their way.

# Introduction

Despite numerous attempts to "bend the cost curve", the problem of unaffordable healthcare persists. The failure to control costs harms patients by imposing financially ruinous debt on too many families and reducing some patients' ability to seek treatment. Worsening the outcomes for patients, excessive waste in the U.S. healthcare sector is expanding while productivity growth is stagnating.

In response to these problems, more and more policymakers are turning toward plans that would expand Medicare or create a public health insurance option. Further socializing the U.S. healthcare system is not the answer.

Of all the problems that ail the healthcare sector, too little government control is not one of them. As of 2018, Medicare, Medicaid, and other federal insurance programs accounted for 41 percent of total national health expenditures.[2] The government's influence is arguably even greater than this expenditure share indicates. According to a 2016 study in the *American Journal of Public Health,* the government's estimated share of overall health spending including the value of the tax subsidies for private health insurance "was 64.3 percent of national health expenditures in 2013 and will rise to 67.1 percent in 2024."[3] Any organization that funds (either directly or indirectly) a majority of the total healthcare expenditures already has, undoubtedly, an outsized influence on the system.

> "If empowered in the healthcare sector, entrepreneurs have the proven ability to effectively solve the problems plaguing the U.S. healthcare system by applying the technology and Big Data revolutions that have transformed most other parts of the economy.

This oversized role of the federal and state governments has led to structural rigidities and empowered bureaucrats at the expense of entrepreneurs. Instead of expanding the bureaucracy, examples from the broader U.S. economy, as well as the healthcare innovations that are still emerging despite the entrepreneurially-stifling environment, demonstrate that empowering entrepreneurs is a more effective means for addressing the problems that plague the healthcare system. In fact, the increased use of telemedicine (e.g. the use of technology to deliver healthcare services remotely) during the coronavirus pandemic exemplify this potential.

If empowered, entrepreneurs have the proven ability to effectively solve the problems plaguing the U.S. healthcare system by applying the technology and Big Data revolutions that have transformed most other parts of the economy. The result will be increased healthcare affordability, constantly improving quality, and expanding access.

Fully empowering entrepreneurship requires reforms to the demand-side and supply-side of the healthcare industry that, if comprehensively implemented, would make the system responsive to the needs of patients rather than the demands of government programs and large payers. While implementing comprehensive reforms would be ideal, partial progress in any of these areas will still create positive incentives to expand entrepreneurship in healthcare and improve quality and cost effectiveness.

The purpose of the demand-side reforms is to strengthen the connection between patients (the ultimate consumers of healthcare services) and healthcare providers. Current payment models create multiple layers of purchasers with oft-conflicting incentives. The conflicting incentives distort the information entrepreneurs rely upon to innovate, restricting their ability to discover more effective ways to deliver healthcare services.

Creating a more competitive payment landscape aligns incentives and encourages entrepreneurial healthcare providers to find more efficient ways to deliver higher quality healthcare at lower costs. These reforms need to be applied to both the private insurance markets and government-financed healthcare programs (e.g. Medicare and Medicaid).

On the supply-side, the federal and state governments impose excessive regulations that restrict competition, discourage innovation, and artificially raise costs. These restrictions, such as overly stringent scope of practice laws, hinder entrepreneurs. Not only do they harm current entrepreneurs, these burdens are also prohibitive for prospective entrepreneurs and are important reasons why entrepreneurship is lacking in healthcare. Eliminating or lessening these restrictions will reduce these costs and incentivize greater entrepreneurship.

Taken together, these reforms eliminate the disincentives thwarting large potential efficiency gains that could be created by an entrepreneurial healthcare system. The result will be expanded access, increased quality, and decreased costs.

## The Benefits of an Entrepreneurially Focused Healthcare System

Before documenting the inefficiencies of the current system, it is useful to precisely define healthcare entrepreneurship and the potential benefits these entrepreneurs can create. Broadly speaking, entrepreneurs and entrepreneurial firms play a wide variety of beneficial roles.

Some entrepreneurial firms turn waste and inefficiencies—two problems that plague the U.S. healthcare sector—into large profit opportunities. Take Amazon as an example. Before the innovations introduced by Amazon, retail supply chains were unnecessarily inefficient. These inefficiencies led to billions of dollars in waste that increased costs and decreased quality for customers.[4] Recognizing that customers can be better served, Jeff Bezos applied data management tools, eliminated these inefficiencies, and vastly improved the ability of the retail industry to serve customers. The billions of dollars in waste incentivized Jeff Bezos to develop a new business model that provided customers with higher quality services at lower overall costs.

Other entrepreneurial firms create new products and services that vastly improve consumer lives. Take Apple as an example. Steve Jobs, seeing the state of mobile technologies, realized he could create a better technology. He created new mobile devices with capabilities and ease of use that vastly exceeded its competitors and revolutionized the industry. His vision of what the technology could be drove Apple to provide consumers with a product they did not know they could not live without.

Often, entrepreneurial innovations tear down the old way of doing things while charting the future. Joseph Schumpeter called this process "creative destruction" back in 1942,[5] and it is a necessary part of the process

to reap the net benefits entrepreneurs create. After all, Google's phenomenal rise came at the expense of Yahoo!, the rise of Netflix drove Blockbuster video out of business, and the iPhone revolution hastened the obsolescence of the previous cutting-edge technology underlying the Blackberry. Google, Netflix, and Apple exemplify why entrepreneurship is essential. Without the disruption caused by these entrepreneurial firms, innovation stagnates. Stagnating innovation in the face of new challenges is a recipe for decline.

Applying these concepts to healthcare, entrepreneurs should be re-imagining how healthcare is delivered, how technology can improve the quality and price of healthcare, and how healthcare providers can more efficiently serve the evolving needs of patients. And, it is a testament to the entrepreneurial spirit of many healthcare professionals that, despite the many obstacles, some entrepreneurial progress is occurring.

> "Arguably, the continual improvements in medical discoveries exemplify where the entrepreneurial spirit is the healthiest.

Arguably, the continual improvements in medical discoveries exemplify where the entrepreneurial spirit is the healthiest. Entrepreneurs continue to drive the science behind medicine forward whether it is the development of wireless brain sensors, the creation of new medicines, the creation of artificial organs, or the development of cutting-edge gene therapies.[6]

Using gene therapies as the example, these treatments exemplify how technological entrepreneurship can improve the quality of our healthcare system. Gene therapies modify a patient's DNA in order to address the genetic causes of diseases. As such, they are transformative treatments that fundamentally differ from traditional medical and pharmaceutical options. They are akin to the technology revolutions in other sectors of the economy and have the potential to dramatically improve the lives of millions of Americans living with life-threatening or life-altering diseases. Since gene therapies directly address the genetic causes of diseases, doctors and scientists anticipate that these therapies will be cures. If successful, the goal will no longer be treating these devastating diseases—but curing them. These innovative technologies are already available for several diseases and offer the hope for a cure for millions of people living with Alzheimer's Disease, Cystic Fibrosis, Hemophilia, HIV, Cancer, Muscular Dystrophy, Parkinson's Disease, and Sickle Cell Disease.

Gene therapies also offer patients living with these devastating diseases a future with a dramatically improved quality of life, and these benefits cannot be overstated. The focus on curing diseases, rather than treating them, is also expected to create widespread long-term health care cost savings that will offset the direct costs of the treatments. Since these new therapies offer the hope of cures, patients who were formerly living with these diseases would need fewer hospital admissions, significantly reducing future hospital expenditures. Patients will also require fewer medicines and fewer visits to their physicians over their lifetimes, particularly fewer visits to expensive specialists. Consequently, lower future expenditures on medicines and doctor visits would translate into more future systemic savings.

The application of telemedicine during the coronavirus pandemic is another example of how entrepreneurs empowered to apply technological innovations can improve the quality of care for patients today, while also reducing costs and improving convenience. As discussed in more detail below, restrictions created by government regulations and the current payment model have prevented wider use of telemedicine despite its demonstrated value to patients.

In the case of the coronavirus crisis, telemedicine has become an invaluable tool for resolving the conflict between the rising demand for medical services during the pandemic and the clinical recommendations for people to socially distance from one another that requires fewer patients to physically visit an office. As documented by Kaiser Health News,[7] the combination of these concerns convinced Medicare and private insurers to significantly relax the restrictions on patients regarding telemedicine visits, enabling patients to express their desire for these medical services. Furthering the benefit, the federal government is temporarily allowing doctors, through telemedicine technology, to treat patients across state lines even if they are not licensed in the patient's state. The result has been a surge in telemedicine visits. For instance,

> The Cleveland Clinic is on track to log more than 60,000 telemedicine visits in March, according to officials there. Before March, that health system, which has hospitals in Ohio and Florida—averaged about 3,400 virtual visits a month.
>
> Its Express Care Online system serves patients across the country 24 hours a day. About 75 percent of the calls now come from people worried they have COVID-19, said Dr. Matthew Faiman, medical director of the service. Like many other health systems, Cleveland Clinic's virtual urgent care is waiving patient copays during the pandemic.
>
> "We are seeing a significant upsurge in demand from patients seeking care—both the worried well and patients who are sick and wanting to know how to manage their symptoms," Faiman said. The clinic has pulled more doctors into the telehealth work since elective surgeries were canceled and fewer patients are making in-person visits.
>
> He applauded the Medicare changes and predicted such changes will likely stay after the national emergency ends.[8]

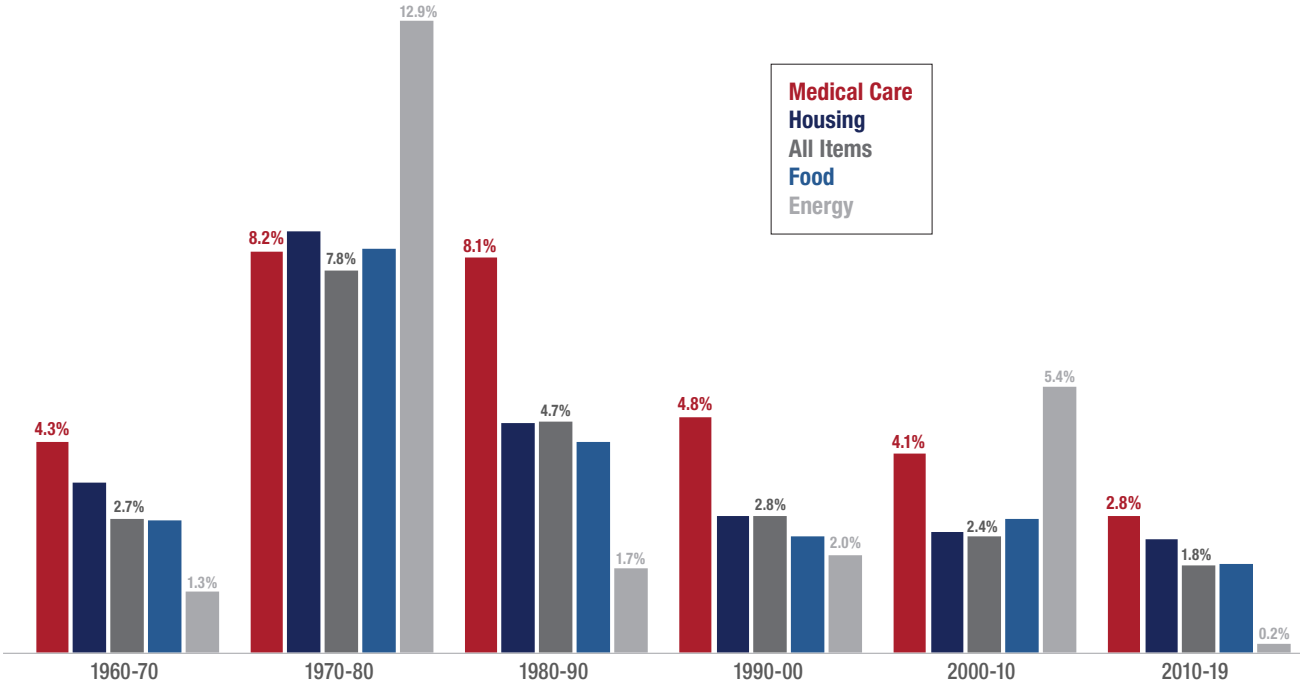
As detailed below, these examples are only scratching the surface. However, as Part 1 of the *Breaking Down Barriers to Entrepreneurship* series noted, "the wrong policy environment disincentivizes entrepreneurs from serving consumers' interests and, thus, reduces the social benefits created by entrepreneurial efforts."[9] The healthcare system exemplifies the consequences that result when the wrong policies disincent entrepreneurial efforts—the drive to continuously improve how healthcare services are delivered is dampened.

In the healthcare sector today, entrepreneurs neither have the incentive nor the ability to develop alternative practices or delivery models to increase overall efficiency and eliminate waste at the scale needed. The result is a massive and unnecessary amount of waste in the healthcare system. The same is true with the adoption of cutting-edge technologies. As the above efforts testify, cutting-edge information and data technologies are being applied to the healthcare sector. But, often these technologies do not enhance healthcare productivity as expected, nor to the same extent they have enhanced productivity in other industries. The healthcare system contains a prolific amount of waste and too-often ineffectively adopts cutting-edge technologies because bureaucratic fiat drives outcomes. The result are the rising costs and declining productivity that plagues the healthcare system. These issues are explored in more detail in the next section.

# The Healthcare System Is Plagued by Rising Costs and Declining Productivity

The cost of health care continually grows faster than the rest of the economy. Figure 1 demonstrates this problem by comparing the average annual growth in the medical care component of the consumer price index (CPI) measure of inflation to the average annual growth in overall CPI inflation (e.g. all items) and to the average annual growth in inflation for other core necessities of food, housing, and energy.

**FIGURE 1**
AVERAGE ANNUAL GROWTH RATE IN CONSUMER PRICE INFLATION BY DECADE
ALL ITEMS, HOUSING, FOOD, ENERGY, AND MEDICAL CARE
1980 - 2019




*Source: Bureau of Labor Statistics*

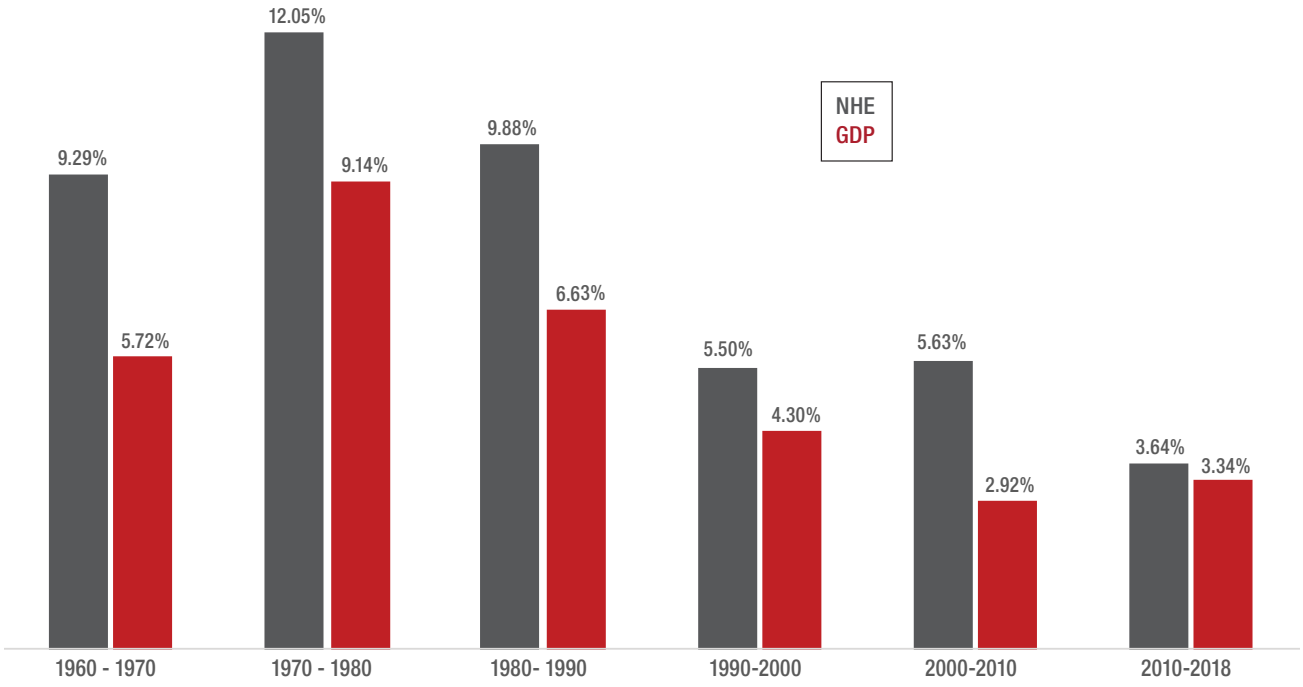
Over the past 10 years (between 2010 and 2019), medical care prices increased 2.8 percent annually, which was 1 percentage point faster than the overall rate of consumer inflation. Historically, the excessive growth in health care was even worse. The average annual growth in medical care inflation outpaced the average annual growth in overall consumer inflation during the entire period between 1960 and 2010, often by wide margins, even during the high-inflation 1970s, which was plagued with crippling oil crises.

All other necessities excluding energy have risen in line with overall inflation. Further, unlike healthcare, inflation in energy prices has balanced out over time—following the large spike in energy inflation during the 1970s, energy inflation grew below average during the 1980s and 1990s. A similar pattern occurred following the 2000 and 2009 spike that was followed by a significant slowdown during the 2010s. The tendency for the energy inflationary spikes to be counterbalanced by relatively slower price increases emphasizes that the healthcare industry faces a unique cost problem.

The unique cost problems are further demonstrated by the healthcare expenditure data. After adjusting both health expenditures and total economic activity for population, national health expenditures have consistently outpaced the growth in the broader economy (e.g. GDP per capita). Using the same pattern of average annual growth rates by decade between 1960 and 2018 (the latest health expenditure data available), Figure 2 demonstrates that the amount of income we devote toward healthcare expenditures continues to grow relative to the size of the U.S. economy—often by wide margins. It is also noteworthy that the excessive average narrowed to its smallest premium for the 2000 through 2018 period.

**FIGURE 2**

AVERAGE ANNUAL PERCENT CHANGE IN NATIONAL HEALTH EXPENDITURES PER CAPITA COMPARED TO AVERAGE ANNUAL PERCENT CHANGE IN GROSS DOMESTIC PRODUCT PER CAPITA - BY DECADE
1960 - 2018




*Source: Bureau of Economic Analysis and Centers for Medicare & Medicaid Services*

One theory to explain these cost and price trends is the Baumol effect.[10] Named for the late economist William Baumol,[11] the Baumol effect argues that

> while rising wages are typically attributed in part to rising labor productivity, there can be upward salary pressure at jobs that haven't experienced productivity gains.
>
> The example Baumol and the late William G. Bowen made famous is that of the string quartet. The number of musicians and the amount of time needed to play a Beethoven string quartet for a live audience hasn't changed in centuries, yet today's musicians make more than Beethoven-era wages. They argued that because the quartet needs its four musicians as much as a semiconductor company needs assembly workers, the group must raise wages to keep talent—to keep its cellist from chucking a career in music and going into a better-paying job instead.

Applied to healthcare, the Baumol effect argues that because productivity growth in services like healthcare will lag the productivity growth in other economic sectors like manufacturing, the costs of healthcare services will grow faster than the costs of manufactured goods. And, the growth trends in the prices of services and goods are consistent with this theory—while the prices of goods (e.g. computers) have been declining, the prices of services (e.g. healthcare and education) have been rising.

Several healthcare trends, which are actually positive from a patient welfare perspective, reinforce the argument that the rising prices and expenditures are not unexpected. Lifespans, for instance, have been generally rising, which increases total expenditures on healthcare. As discussed in the previous section, and inter-related to the increase in lifespans, numerous medical advancements have occurred over the past several decades despite the anti-entrepreneurial environment. These innovations improve the quality of care and health outcomes for many Americans, but are also expensive.

Finally, overall income growth has been increasing in the U.S., and countries with higher incomes per capita tend to spend more on healthcare per capita. These explanations attempt to justify that the higher than average growth in prices and expenditures are not a sign of inefficiency. If true, they would portend vastly different implications for reforms. However, these arguments are inconsistent with important realities.

## Healthcare Innovations Are Not A Cost-Driver

While innovations such as new medicines and gene therapies are often expensive, the improvements in health outcomes they enable create other systemic savings, such as eliminating the need for hospital stays and surgeries. The reduced need for these other more expensive healthcare interventions will offset the costs of these innovations. Often these cost savings are more than sufficient to fully cover the costs of the innovation, meaning that healthcare innovations are actually causing healthcare expenditures to decline on net. Since many innovations will save money on net, it is unlikely that medical innovations are the driving force behind the persistent healthcare inflation problem.

Many empirical analyses have illustrated that technological advancement is not a driving force behind the healthcare inflation problem, particularly the advancements in pharmaceutical and gene therapy treatments. Lichtenberg (2013) updated his previous work and estimated that the cost savings enabled by greater use of newer drugs, which included lower hospital and physician expenditures, exceeded the increased drug cost.[12] Citing the results from the study,

> a reduction in the age of drugs utilized reduces non-drug expenditure 7.2 times as much as it increases drug expenditure. For example, reducing the mean age of drugs used to treat a condition from 15 years to 5.5 years is estimated to increase prescription drug spending by $18 but reduce other medical spending by $129, yielding a $111 net reduction in total health spending. Most of the savings are due to reductions in hospital expenditure ($80) and in physician office-visit expenditures ($24).[13]

An analysis by Civan and Koksal (2009) confirm these results finding

> that newer drugs increase the spending on prescription drugs since they are usually more expensive than their predecessors. However, they lower the demand for other types of medical services, which causes the total spending to decline. We estimate that a 1-year

> decrease in the average age of prescribed drugs causes per capita health expenditures to decrease by $45.43. The biggest decline occurs in spending on hospital care due to newer drugs.[14]

Supporting these findings with respect to the impact for a specific disease, Philipson and Jena (2005) evaluated the benefits to consumers (measured as consumer surplus) and producers (measured as producer surplus) from the development of the new drugs to treat HIV/AIDS.[15] In this case the authors found that

> innovators captured only 5 percent of the social surplus arising from these new technologies. More precisely, consumer and producer surplus from these drugs amounted to roughly $1.33 trillion and $63 billion, respectively. We argue that if the new HIV/AIDS therapies are representative of other technologies, the lack of appropriation of social surplus by innovators has strong policy implications for how to adopt and evaluate new health care technologies. Despite the high prices of many therapies such as the new HIV drugs, patients and health plans are getting too good a deal in the short run which, of course, hurts them in the long run by insufficient R&D.[16]

In a review of the literature with respect to the Medicare population, the Congressional Budget Office (CBO) concluded that "a 1 percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of 1 percent."[17] Putting the CBO's estimate in perspective, Pope (2019) estimated "this means that, on average, an extra $100 in prescription drug utilization (including products still covered by patents) by Medicare beneficiaries can be expected to reduce the program's spending on other medical services by $95 while delivering better outcomes."[18] While not a complete offset, these cost trends essentially cancel out one another—keeping overall healthcare expenditures flat while improving overall health outcomes.

> "Since many innovations will save money on net, it is unlikely that medical innovations are the driving force behind the persistent healthcare inflation problem.

Based on the findings of these studies, it is unrealistic to link the healthcare system's cost problems to the high cost of drugs or other innovations. More realistically, improved innovations are helping to control systemic expenditures. Policies that attempt to artificially control costs using various price control measures are destined to fail because this approach does not address the root cause of the problem.

In contrast to this innovation-driving-cost theory, the findings from these studies exemplify the beneficial outcomes that result when healthcare entrepreneurship is promoted. In the case of the innovative drugs evaluated, the entrepreneurial firms that invested in developing the new treatments improved the quality of healthcare and, by enabling offsetting systemic savings, helped control total costs. Entrepreneurial innovations in the broader healthcare industry, particularly with respect to the delivery of care, are not encouraged. There are reasons to be optimistic that promoting entrepreneurship can extend these cost-saving/quality-enhancing benefits to the entire healthcare sector.

## The Healthcare System Is Rife with Wasteful Spending

There is strong evidence that part of the cost problem in the healthcare sector arises from the excessive, and growing, amount of waste. Inter-related with the rising waste problem is the problem of inefficiently low productivity growth.

The existence of an excessive amount of waste is well documented. Healthcare waste is typically defined as spending that does not create value, improve health outcomes, and in some cases could even cause harm. Bentley et. al. (2008) classified waste in the U.S. healthcare system into three categories: administrative, operational, and clinical. "Both administrative and operational waste are components of inefficient production, and clinical waste is a form of allocative waste. Administrative waste is the excess administrative overhead that stem primarily from the complexity of the U.S. insurance and provider payment systems, and operational waste refers to other aspects of inefficient production processes. Clinical waste is waste created by the production of low-value outputs."[19] In total, these sources of waste comprise an excessive amount of total healthcare spending in the U.S.

Evans (2013), citing a report from the Institute of Medicine of the National Academy of Sciences, noted that total waste in the healthcare system in 2009 was $765 billion, or about 30 percent of total healthcare expenditures.[20]

**TABLE 1**
WASTE IN THE U.S. HEALTHCARE SYSTEM - 2009[21]

| | |
|---|---|
| Unnecessary services | $210 billion |
| Inefficiently delivered care | $130 billion |
| Excess administrative costs | $190 billion |
| Excessively high prices | $105 billion |
| Missed prevention opportunities | $55 billion |
| Fraud | $75 billion |
| TOTAL | $765 billion |

*Source: Evans (2013)*

O'Neill and Scheinker (2018), citing research by Berwich and Hackbarth, note that the estimated amount of waste in the healthcare system grew between 2009 and 2011, with the "midpoint of reasonable waste estimates even higher, at 34 percent. A crude extrapolation of these figures, given the steady rise in overall health expenditures, implies that wasted spending now comfortably exceeds $1 trillion annually, a sum that could fund the entire Medicaid program twice over."[22]

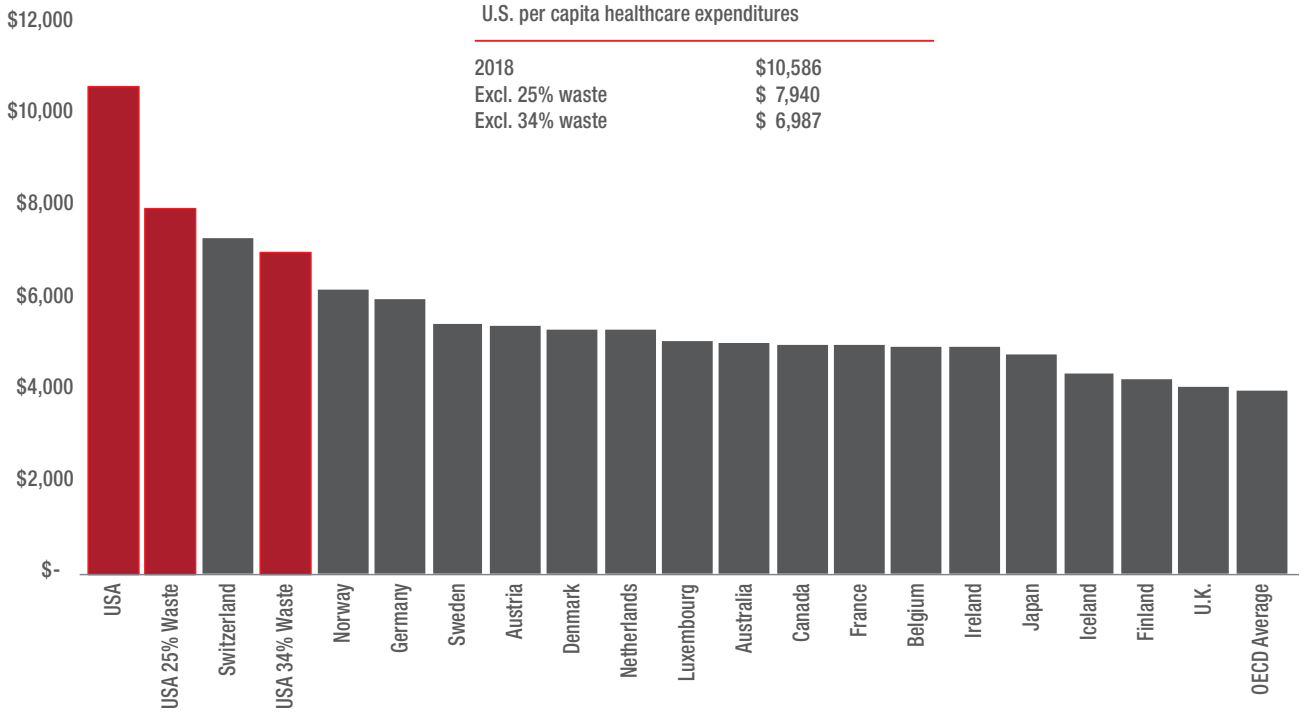
In a 2019 study published in *JAMA*, (the *Journal of the American Medical Association*) Shrank et. al. found that "the estimated cost of waste in the U.S. health care system ranged from $760 billion to $935 billion, accounting for approximately 25 percent of total health care spending, and the projected potential savings from interventions that reduce waste, excluding savings from administrative complexity, ranged from $191 billion to $282 billion, representing a potential 25 percent reduction in the total cost of waste. Implementation of effective measures to eliminate waste represents an opportunity to reduce the continued increases in U.S. health care expenditures."[23]

There are several important implications from the excessive amount of healthcare waste. With respect to the Baumol effect, the pervasive amount of waste raises questions regarding its applicability to the healthcare sector. If the Baumol effect helped explain why the cost of healthcare is growing faster than costs in other sectors of the economy, then it must be the case that the potential growth in healthcare productivity is constrained. The excessive amount of waste raises doubts regarding the limits to productivity growth in the healthcare sector, because there is no reason why the excessive waste in the U.S. healthcare system cannot be reduced by effectively applying modern information technologies and new delivery models. Such innovations can help healthcare providers deliver the same amount of healthcare services for less money and with higher quality. Delivering better quality goods and services with fewer resources is the textbook definition of productivity growth. Therefore, since the existence of waste represents untapped productivity enhancements, there are sound reasons to be skeptical that the Baumol effect dooms the healthcare sector toward ever-rising prices and expenditures.

“There is no reason why the excessive waste in the U.S. healthcare system cannot be reduced by effectively applying modern information technologies and new delivery models.

Beyond the Baumol effect considerations, the excessive amount of waste that pervades the U.S. healthcare system is often cited as a driving factor behind the healthcare cost problem. To get a sense of how large a problem the identified waste is, consider that the 25 percent to 34 percent waste estimates means that, in theory, the healthcare costs in 2018 could have been reduced between $912 billion and $1.2 trillion while still providing the exact same amount of healthcare services to patients.[24] Eliminating this waste would also align the U.S. per capita healthcare expenditures closer to the average of other industrialized countries. Figure 3 presents the per capita healthcare expenditures of the U.S. as well as other, wealthy, industrialized countries who are members of the Organization for Economic Cooperation and Development (OECD).[25] As of 2018, the per capita healthcare expenditures in the U.S. ($10,586) was about double the per capita expenditures in these major industrialized economies ($5,189). Eliminating the estimated waste in the U.S. healthcare system (between 25 percent and 34 percent of expenditures) would lower the per capita health expenditures in the U.S. to between $6,987 and $7,940—significantly closer to the per capita expenditures in these comparison countries.

**FIGURE 3**
NATIONAL HEALTH EXPENDITURES PER CAPITA
U.S. CURRENT, U.S. EXCLUDING ESTIMATED WASTE, AND SELECTED OECD COUNTRIES
2018




*Source: Author calculations based on OECD data*

Consistent with this excessive amount of waste, and reflective of the current anti-entrepreneurial environment, healthcare productivity has lagged the productivity growth experienced in the broader economy. From an economy-wide perspective, growth in productivity is essential for improving our living standards. For the healthcare sector, growing productivity would mean that healthcare professionals could provide patients with higher quality healthcare services for less (or the same) money. This is the exact opposite of what has been occurring. For instance, a McKinsey study that examined the productivity growth trends for the healthcare sector noted that "between 2001 and 2016, healthcare delivery contributed 9 percent of the $8.1 trillion ($4.2 trillion in real terms) growth in the U.S. economy—but 29 percent of the 14.4 million net new jobs."[26] Kocher (2019) examined these trends in more detail finding that

> more than three-quarters of new jobs from 2001 to 2016 have been support roles, both clinical (half of new jobs) and nonclinical (one-quarter of new jobs). The ratio of support staff to clinicians is actually getting worse. It is now 3.6 for each clinician—exactly the opposite of what one would expect since health care providers typically have low margins, which should create disincentives to add administrative overhead. Other service industries in the U.S. have lower ratios of support staff to value-creating people (for example, lawyers and judges in legal services). Outside of health care, the U.S. economy is great at eliminating non-value-added jobs, so good that policy makers are debating ideas such as "universal basic income" to mitigate a future where robots and software replace many more humans.

> It would be easier to defend the rising premiums driven by health care job growth if the added jobs were patient-facing clinical roles, such as mental health clinicians, primary care physicians, clinicians of all types in rural communities, and clinicians serving Medicaid patients. But shortages in all of these categories persist.[27]

Several studies that empirically measured the growth in productivity have concluded that productivity growth in the healthcare sector is stagnant or even declining. Triplett and Bosworth (2004), for example, found that productivity declined 1.5 percent annually between 1987 and 1995, and 0.4 percent annually between 1995 and 2001.[28] Harper, Khandrika, Kinoshita, and Rosenthal (2010) examined a longer period between 1987 and 2006, finding that the productivity growth in hospitals and nursing homes fell 0.9 percent annually.[29]

# Expand Government or Empower Entrepreneurs?

There is widespread agreement that policy reforms are imperative in order to eliminate this large amount of waste and raise the woefully slow growth in productivity. Proponents of nationalized healthcare claim that further increasing the government's control over the healthcare system is the best way to capture these savings—particularly the administrative savings. In addition, advocates claim that universal coverage is best achieved through a complete government takeover of the healthcare system. As a result, the calls to increase the government's role in the healthcare sector are growing louder.

For example, the Urban Institute claims that the pros of a single payer system include universal coverage, greater equity, increased access, and various methods for reducing administrative costs.[30] Physicians for a National Health Program similarly claim:

> A national health insurance program could save approximately $150 billion on paperwork alone. Because of the administrative complexities in our current system, over 25 percent of every health care dollar goes to marketing, billing, utilization review, and other forms of waste. A single-payer system could reduce administrative costs greatly.[31]

As a final example of these arguments, Christopher (2016) argues in the Harvard Health blog that

> overall expenses and wasteful spending could be better controlled through cost control and lower administrative costs, as evidenced in other countries. Furthermore, a single payer system has more incentive to direct healthcare spending toward public health measures. For example, targeting funding towards childhood obesity prevention programs in elementary schools and daycares reduces the rates and complications of obesity more effectively and at lower costs than paying for doctor visits to recommend healthier diets and increased physical activity.[32]

Part of this faith is predicated on the belief that a government-run healthcare system can reap the benefits from adopting productivity-enhancing technologies. The government's record does not warrant this faith. For instance, the American Recovery and Reinvestment Act (ARRA), required public and private healthcare providers to adopt and use electronic health records (EHR). EHR's were supposed to apply cutting-edge data management technologies that the private sector has used in other industries to increase productivity and lower costs. However, as documented by a *Kaiser Health News* investigation

> 10 years after President Barack Obama signed a law to accelerate the digitization of medical records — with the federal government, so far, sinking $36 billion into the effort — America has little to show for its investment. KHN and *Fortune* spoke with more than 100 physicians, patients, IT experts and administrators, health policy leaders, attorneys, top government officials and representatives at more than a half-dozen EHR vendors, including the CEOs of two of the companies. The interviews reveal a tragic missed opportunity: Rather than an electronic ecosystem of information, the nation's thousands of EHRs largely remain a sprawling, disconnected patchwork. Moreover, the effort has handcuffed health providers to technology they mostly can't stand and has enriched and empowered the $13-billion-a-year industry that sells it.[33]

Not only is the federal government's proficiency at effectively implementing cutting-edge technology questionable, the widely quoted administrative savings are illusory too. Typically, advocates for a single payer system, or public option plan, claim that administrative savings will occur. This assertion is based on the statistic, which is arithmetically correct, that Medicare's administrative costs as a share of expenditures is lower than private insurance plan administrative costs as a share of expenditures. It allegedly follows from this statistic that a single payer system or a public option will reduce the excessive amount of administrative waste documented above.

The problem with this statistic is that it does not measure what its proponents claim. As Robert Book illustrated in testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions:

> … most reports give administrative costs as a percentage of total spending, including spending on direct patient care. So, for example, someone might claim that Medicare's administrative costs are 2 percent or 5 percent, but private insurance has administrative costs of 10 percent or 20 percent. It sounds much higher. But the difference is, Medicare has patients who are aged 65 or older, or disabled, or who have end-stage renal disease. Private insurance mostly covers patients who are under age 65 and not disabled, and on the whole require lower levels of health care services. The result is that Medicare spends a lot more per patient on direct health care, which means administrative costs as [a] percent of health care costs is almost guaranteed to be lower.
>
> Using percentages might make sense if administrative costs scaled with the level of direct care spending, but it doesn't.[34]

The apples-to-apples comparison evaluates administrative expenses on a per-person basis, not as a share of total expenses. Book (2009) makes this comparison finding that

> when administrative costs are compared on a per-person basis, the picture changes. In 2005, Medicare's administrative costs were $509 per primary beneficiary, compared to private-sector administrative costs of $453. In the years from 2000 to 2005, Medicare's administrative costs per beneficiary were consistently higher than that for private insurance, ranging from 5 to 48 percent higher, depending on the year. This is despite the fact that private-sector "administrative" costs include state health insurance premium taxes of up to 4 percent (averaging around 2 percent, depending on the state)—an expense from which Medicare is exempt—as well as the cost of non-claim health care expenses, such as disease management and on-call nurse consultation services.[35]

The claim that the single payer healthcare saves money also fails to acknowledge that government reimbursement rates are too low to cover the actual cost of care. In order to remain viable, healthcare providers shift these costs to the private plans, driving up private sector costs while artificially lowering the government's costs. For example, "more than two-thirds (67 percent) of medical practices report that 2019 Medicare payments will not cover the cost of delivering care to beneficiaries according to a new MGMA Stat poll. Practices often rely on commercial contracts covering non-Medicare patients to offset the shortfall."[36]

While unable to address the problem of waste, where implemented, single-payer programs have significantly worsened the quality of healthcare.[37] Pipes (2020) documents that due to its single payer system, Canadians must wait 20 weeks (or around 5 months) before receiving treatment from a specialist following a referral by a general practitioner.[38] Confirming these results, the Fraser Institute found that despite being a top spender, Canada's health system has one of "the longest waiting lists, low levels of medical technologies and perhaps the problem that hits closest to home, a short supply of doctors."[39]

> "Due to its dampening impact on entrepreneurship, the growing role of the federal government as a direct payer of healthcare services has become part of the problem.

The same problems plague the National Health Service (NHS) in the U.K. According to the Royal College of Surgeons of England, as of January 2019, NHS hospitals have over 220,000 patients on waiting lists for more than six months, and over 36,000 patients waiting more than nine months for treatment—up 30.7 percent and 38.7 percent respectively on the same period last year.[40] Similarly, the Foundation for Economic Education (FEE) described the U.K.'s healthcare sector as being "in a state of perpetual crisis characterized by doctor shortages, long wait times, and rationing. The U.K. lost 441 general practitioners last year and had 11,576 unfilled vacancies for doctors as of last June."[41]

Another justification for implementing government-run single payer, or public options, is the desire to ensure universal healthcare access—often under the slogan that "healthcare is a right". However, universal access is not enabled by the mandates of the Affordable Care Act, the creation of a public option, or the complete government takeover of the health insurance market (e.g. Medicare for All schemes). As Ohanian (2019) argued,

> Ironically, one of the main sales pitches for single-payer healthcare—"You can't be denied"—is false. Current and future procedures that are deemed by those running the state's health board to be "too expensive" will indeed be denied or severely rationed. And you may need to wait in line a long time before receiving healthcare. The healthcare market does not magically avoid the economic realities of all other markets. If society provides a good at zero cost to the consumer, then the good will be allocated by rationing rather than price. No ifs, ands, or buts.[42]

Increasing access to healthcare is an issue of resources. Due to its dampening impact on entrepreneurship, the growing role of the federal government as a direct payer of healthcare services has become part of the problem. Reforms that reduce waste, improve productivity, and encourage new models for delivering healthcare services will improve the quality of healthcare while lowering its costs. The result will be a significant reduction in the amount of resources required, substantially increasing access to healthcare.

As the above examples illustrated, neither single-payer healthcare nor government options reduce waste or increase productivity. Therefore, these programs will not improve patient access, increase the quality of care, or decrease costs.

# An Entrepreneurial Approach to Healthcare

In contrast to programs that expand government's role, reforms that encourage greater healthcare entrepreneurship can be expected to meaningfully reduce costs, increase access, and improve the quality of care. These benefits will arise because the same dynamics that enable entrepreneurs to raise our living standards in the broader economy also exist in the healthcare sector. The previous sections have documented several entrepreneurial innovations—from the development of new technologies to the implementation of telehealth services in the midst of the coronavirus pandemic—that demonstrate the potential systemic benefits entrepreneurial efforts offer.

However, as Baumol (1993) argues with respect to entrepreneurship

> the nature and intensity of the productive activities of entrepreneurs are determined by current economic circumstances and, *in particular, by the relative size of the rewards offered to different allocations of entrepreneurial activity.*[43] (emphasis added)

Put differently, the entrepreneurial spirit responds to incentives. Applying Baumol's theory of entrepreneurship, there are many innovative healthcare delivery models that are emerging. But, the incentives of the current system do not support the *creative destruction* that is a necessary part of this process. But, if the incentives supported these new ways of delivering healthcare, then current and prospective entrepreneurs would be incented to implement the good ideas that already exist and even propose new ones that we don't realize we can't live without. The same process holds for new delivery models that could eliminate the wasteful expenditures in the healthcare system.

Unfortunately, the current healthcare system dis-incents healthcare entrepreneurs from implementing the innovations and new delivery methods that would address the system's problems. For ease of exposition, it is useful to categorize these obstacles by their primary impact—either the demand-side of healthcare or the supply-side of healthcare.

## Demand-Side Obstacles—It's the Payment System

Healthcare reforms are typically couched in terms of reforms to the current payment system. And, such reforms are necessary because they are a prerequisite for improving the incentives of the demand-side of the healthcare system. There are two anti-entrepreneurial incentives that arise from the current payment model that connect with the two types of entrepreneurship discussed earlier in the section *The Benefits of an Entrepreneurially Focused Healthcare System*. First, the current payment model separates the patient (the customer) from the healthcare provider (the seller), which prevents entrepreneurial providers from finding new and better ways to help patients (the Amazon-type innovations). Second, the current payment model is biased against revolutionary healthcare changes, which, unless fixed, will discourage transformational entrepreneurial changes in healthcare (the Apple-type innovations).

Starting with the first problem, Cutler (2010) describes the inefficiencies by comparing the problem of aligning incentives in healthcare to how efficiently incentives align in most other parts of the economy, using Wal-Mart as the example.[44] Specifically, Cutler states,

> if Wal-Mart finds a way to save money, it can pass that along to consumers directly. In health care, in contrast, the situation is more complex, because patients do not pay much of the bill out of pocket. Rather, costs are passed from providers to insurers to employers (generally) and on to workers as a whole. If this process is efficient, the system will act as if the individual is the real customer, because that person is ultimately paying the bill. It may be, however, that the incentives get lost in the process, and efforts to innovate are not sufficiently rewarded.[45]

In practice, providers will always respond to the needs and desires of the person or organization that is paying the bill. The incentives of those paying the bill vary from the incentives of many patients, however, because payers set coverage policies based on group averages, but effective patient health is individualized. The wider the distribution of individual preferences around the averages, the higher the number of patients who are receiving care that is not reflective of their preferences and needs. But, it is exceedingly difficult for entrepreneurs to serve these patients because the patients cannot directly express their preferences and needs to the healthcare provider. Patients must work through their payer, who must manage services based on the needs of the large group. Therefore, entrepreneurial healthcare providers do not have the information necessary to better serve these patients, and even if they could somehow discover these preferences and needs, they will still find it difficult to serve these patients because the blessing of the payers are also required.

Ultimately, because the payers (as distinct from the patient) are driving the demand-side of the market, healthcare providers, as the supply-side of the market, are responsive to their needs and preferences. This structure precludes the type of vibrant entrepreneurial experimentation that could address the problems outlined above. Fixing this problem, while politically complex, is economically straightforward. Since the current healthcare system discourages entrepreneurship by prioritizing the preferences of payers over patients, removing these disincentives requires reforms that prioritize the preferences of patients over payers.

In order to prioritize patient preferences and encourage entrepreneurial innovations to address the problems plaguing the healthcare system, reforms have to empower patients. As with any transaction, patients are empowered only when they are the ones directing how the healthcare expenditures are spent. While we typically discuss healthcare as if it is one service—it is, in fact, many distinct services. The market dynamics for routine preventive services, such as screenings, checkups, counseling, and vaccinations differ from the dynamics when patients seek treatments for sicknesses such as the seasonal flu or bacterial infections. And, the dynamics for treating common sicknesses are distinct from managing more devastating diseases such as cancer, Alzheimer's, or heart disease. And, these services are different from the patient's needs for emergency services such as broken bones or heart attacks.

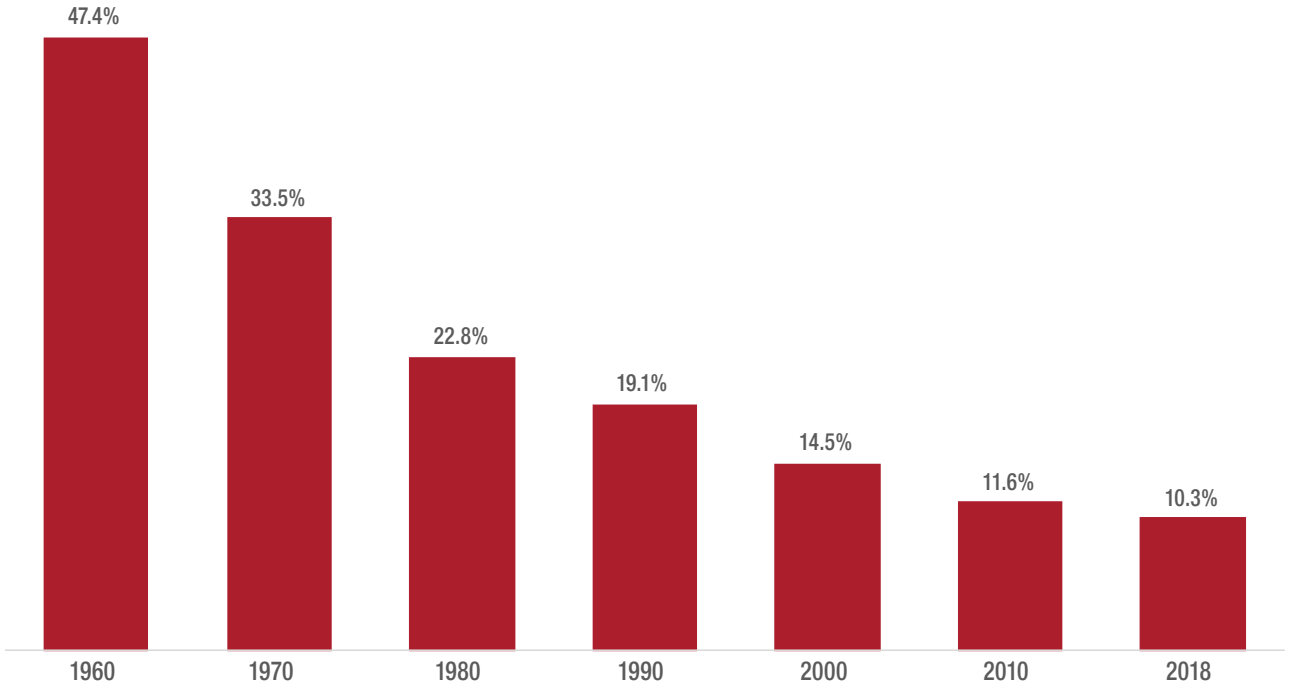
Health insurance is a distinct service from these medical services. The purpose of health insurance is to mitigate the financial consequences associated with the risk of being diagnosed with financially expensive diseases or suffering financially expensive accidents.

Explicitly defining these services emphasizes that many healthcare services (such as routine checkups or the purchase of low-cost, generic medicines to treat common sicknesses) are not insurable events. If the

goal is to empower patients and encourage greater healthcare entrepreneurship, then patients need to directly control the expenditures made by payers on their behalf for non-insurable healthcare services.

To see why this transformation is important, Figure 4 presents patients' out-of-pocket expenditures as a share of total healthcare expenditures between 1960 and 2018. While patients directly controlled nearly half of all healthcare expenditures back in 1960, this control has consistently eroded. As of 2018, patients only paid 10-cents on the dollar directly. The caveat "directly" is imperative to recognize. Patients ultimately pay for all of the healthcare services through the thousands of dollars in premiums they pay (either by them or on their behalf by their employers or the government). However, health insurers and other payers control these expenditures.

**FIGURE 4**
OUT-OF-POCKET EXPENDITURES AS A SHARE OF NATIONAL HEALTH EXPENDITURES 1960—2018 (SELECTED YEARS)



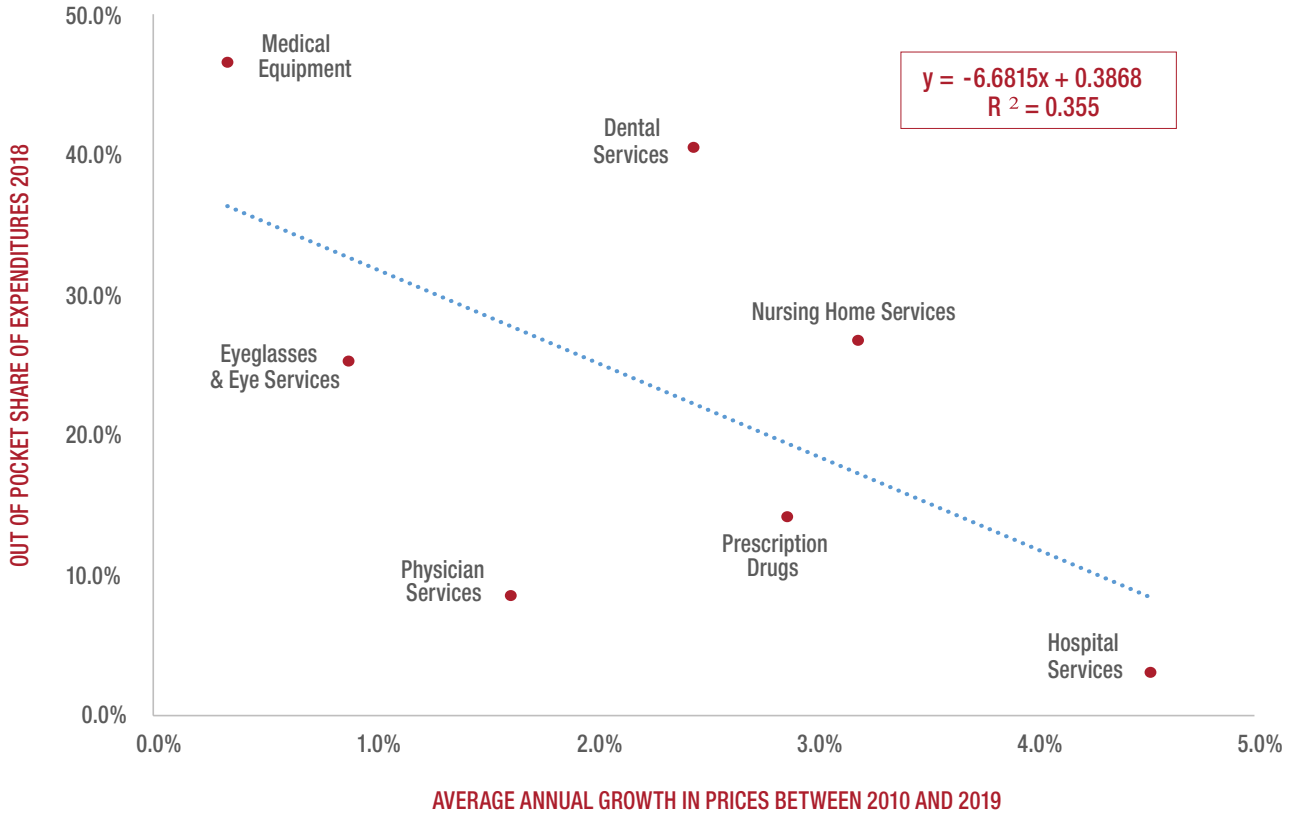

*Source: Author calculations based on NHE data*

Rising costs and the absence of healthcare entrepreneurship are just a few of the consequences of this transformation. Figure 5 presents the evidence in support of the impact on costs. Figure 5 compares the share of expenditures covered by patients through out-of-pocket payments to the growth in costs. The y-axis in Figure 5 is the share of total healthcare expenditures taken up by out-of-pocket expenditures for the service in question. The data is as of 2018. For instance, out of the total expenditures on hospital services in 2018, patients' out-of-pocket payments covered 2.9 percent; for eyeglasses and eye services, total out-of-pocket expenditures covered a much higher 26.6 percent of all spending.

The x-axis in Figure 5 is the average annual change in inflation between 2010 and 2019 for each healthcare service area. The average annual rate of inflation for hospital services, for example, was 4.5 percent; the average annual rate of inflation for eyeglasses and eye services was a much smaller 0.9 percent. As the

downward sloping line in Figure 5 illustrates, this pattern holds more broadly across the different types of healthcare services—when patients funded a greater share of the total healthcare costs out of pocket rather than through premiums, the growth in costs was less.

**FIGURE 5**
AVERAGE ANNUAL GROWTH IN INFLATION ACROSS SELECTED HEALTHCARE SERVICES COMPARED TO OUT-OF-POCKET EXPENDITURES SHARE OF SPENDING FOR SELECTED SERVICES




*Source: Author calculations based on Bureau of Labor Statistics and NHE data*

The lesson from Figure 5 is that policy changes can harness the same competitive processes that help Wal-Mart better serve customers to address the problems plaguing the healthcare system. Reforms that expand the scope and reach of Health Savings Accounts (HSAs) are an essential part of the solution to this problem. Ideally, HSAs should be open to all individuals and both employers, employees, and the self-employed should be able to contribute to the account. The owner of the HSA should have wide latitude to use the funds to pay for healthcare costs including daily expenses, health insurance premiums, and co-insurance costs. Account holders should be able to save any money that is not used during the year it was contributed for use in future years or (if never used) as part of their retirement income.

The benefits from HSAs are often couched in terms of empowering consumers to seek more affordable healthcare services and avoid unnecessary care (over-utilization). And, these are important benefits. HSAs are also an important demand-side reform that will addresses one of the constraints diminishing the amount of healthcare entrepreneurship that could beneficially reform the practice of medicine.

Leveraging the resources in their HSAs, patients are able to financially reward those providers who provide healthcare services in a new or innovative manner helping ensure that the health care services reflect their values and needs. Within such a system, there are stronger incentives for entrepreneurial providers to serve these preferences of consumers and adopt innovative new technologies and healthcare delivery models.

Changes to the delivery model also hold great potential for improving the quality of healthcare. The predominant delivery model currently is the fee-for-service model that traces its roots back to Title XVIII and XIX of Social Security Act (which established Medicare and Medicaid) in 1965.[46] Typically, under the fee for service model, payers (insurers or government programs) reimburse physicians and healthcare providers based on the number of services provided or procedures performed.

The fee for service model has distinct disadvantages. For instance, the fee for service model creates an incentive for providers to focus on the volume of patients seen, and discourages a wholistic approach to patients' care. In response to these shortcomings, other delivery models are emerging. For instance, under the capitation payment model, patients pay providers a flat fee in return for providing defined healthcare services based on the quality of care. Entrepreneurial ventures are also introducing other value-based payment models, such as pay for performance. While there are different variations of these models, effectively they connect payments to meeting specific care benchmarks.

> "Entrepreneurial ventures are also introducing other value-based payment models, such as pay for performance.

There are important advantages to these alternative payment models because they sever the link between payment and the quantity of care. Instead, the focus is on improving the quality of care. These models also better align the incentives of patients and payers. Widespread availability of flexible HSAs is important for encouraging these alternative payment models because such a system empowers patients to choose the payment models they believe will provide the most value to themselves and their families.

By empowering patients to separate out their purchases of routine healthcare services from the need to purchase insurance to protect against the financial consequences of specific healthcare risks, HSAs can also improve the functionality of the health insurance markets. The current health care insurance system is readily available to cover routine health care expenditures, such as most of the costs for checkups or the $25 it costs to purchase generic penicillin. These relatively smaller expenses do not create financial risks for most patients. However, when patients require major surgeries or must manage devastating diseases, health insurance often fails to adequately reduce the financial risks. Yet, these are the true health care risks that patients face, and covering these financial risks is the ultimate purpose of having health insurance.

The system fails health insurers as well. Nearly one-half of the population is covered by employer-sponsored health insurance.[47] Since the average tenure of an employee is less than five years,[48] this means that health insurers face a great deal of turnover, making it very difficult for them to effectively manage patients' lifetime health care costs. Health insurers will be able to focus less on defining what healthcare services patients can access and, instead, focus on minimizing patient financial exposure to true health risks—the actual purpose of insurance.

Separating out these functions liberates insurers to focus on emerging issues. Paramount among these emerging issues are implementing payment reforms to support new technological innovations entrepre-

neurial companies are bringing to market (e.g. the Apple-type entrepreneurial innovations). The current issues surrounding gene therapies exemplify the possibilities and the problems.

The large health benefits from gene therapies were discussed earlier (in the section *the Benefits of an Entrepreneurially Focused Healthcare System*). Unfortunately, the current payment system can make it more difficult for patients to access these therapies, potentially discouraging their development. Just like organ transplants, which can cost over a half million dollars per transplant or more,[49] gene therapies can cost millions of dollars. The current payment system is not equipped to make such expensive therapies widely available. Essentially, the system is asking insurers to pay the high upfront costs for gene therapies even though they will not likely benefit from the lower future prescription, hospitalization, and physician costs.

HSAs combined with comprehensive catastrophic coverage policies help reduce the obstacles to a vibrant gene therapy sector. HSA portability will help insurers establish a more stable insured population because people who like their current health insurance providers will be able to keep them regardless of whether they switch jobs or not. This stability will help insurers benefit when future health insurance costs decline, better aligning the interests of insurers and patients. The greater stability also helps health insurers manage risks, and should be supported with greater use of re-insurance or high-risk pools to effectively manage the truly exceptional costs.

With respect to the costs that patients must still cover, since the health benefits are received over the long-term, it makes sense that the costs should be incurred over time. Flexible HSAs empower patients with the resources to take advantage of innovative financing structures such as health care installment loans. Health installment loans are the equivalent of mortgages for large health care expenses that would let patients finance their share of the costs over time, and would be contingent on the success of the therapy.[50]

When combined with the reforms to the supply-side of the healthcare system discussed in the next section, payment reforms incentivize greater healthcare entrepreneurship that will improve overall healthcare quality while reducing its cost.

## Supply-Side Obstacles—It's the Regulations

While payment reforms are necessary, such changes are insufficient if the goal is to significantly encourage entrepreneurial innovations in the healthcare space. Significant supply-side constraints also exist that need to be addressed in tandem with the demand-side reforms—after all, an efficient market requires a healthy demand- and supply-side. Unfortunately, as Graboyes (2014) noted the current healthcare debate "underplays questions of supply—how innovation can alter the very nature of the health care delivery system."[51]

It is well documented that innovations like telehealth, 3D-printed devices, and point-of-care devices are poised to revolutionize the way health care is delivered.[52] And, as emphasized in the demand-side considerations, reforms to the practice of medicine that implement new ways to deliver medicine more effectively are needed. However, in addition to the demand-side constraints, the supply-side of the healthcare system is hampered by excessive, and inappropriate, regulations that restrict how healthcare providers can implement innovative reforms.

Telemedicine exemplifies both the potential benefits and the regulatory restraints limiting the realization of this potential. Telemedicine is a broad term that refers to healthcare professionals providing medicare care at a distance through the use of information technologies such as video conferencing, remote moni-

toring, online prescriptions, emails, and telephone services. There are many potential health benefits from telemedicine.

During the COVID-19 pandemic, telemedicine has been an effective means for patients to connect with healthcare providers while still practicing social distancing. Many emergency departments (ED) at hospitals are finding telemedicine "a 21st-century approach to forward triage that allows patients to be efficiently screened".[53] But, we are just scratching the surface of the potential benefits. Telemedicine can help connect specialists with facilities that lack their expertise (e.g. small rural hospitals), connect patients with providers 24/7, and even substitute for in-person office visits if the condition does not require it.

Before the COVID-19 pandemic, regulatory impediments severely limited the deployment of telemedicine. Starting with federal impediments, Medicare's narrowly construed payment policies have been a major obstruction. According to the Center for Connected Health Policy,

> telehealth restrictions in the Medicare program include limitations on where telehealth services may take place, both geographically and facility-wise, the limited number of providers who may bill for services delivered via telehealth, a limited list of services that can be billed, and restricting, for the most part, to only allowing live video to be reimbursed."[54]

At the state level, telemedicine parity laws exist in a majority of the states. Telemedicine parity laws require this care to have the same repayment requirements as in-person care. These requirements remove one of the major benefits telemedicine offers and impedes widespread deployment.[55] Adding to these problems, state credentialing barriers, prescribing regulations, and licensing laws are additional obstacles that diminish the potential value telemedicine could provide patients.[56] For example, the majority of states require doctors to obtain licenses in every state where he or she wants to practice medicine. This requirement imposes a costly, and time-consuming, burden on physicians that exacerbate local doctor shortages and make responding to emergencies more difficult. In recognition of these large costs, efforts to create an interstate licensure compact were growing prior to the COVID-19 pandemic.[57]

In response to the pandemic, the Department of Health and Human Services (HHS) relaxed many of the regulatory barriers to make it easier for doctors to provide telehealth services including providing HIPAA flexibility during COVID-19; relaxing restrictions on people enrolled in Medicare, Medicaid, and Children's Health Insurance Program (CHIP) to receive telehealth services; expanding (temporarily) the types of services that can be covered under telehealth services; adjusting the requirements on cost sharing and billing for providers; and, waiving the inter-state licensing restrictions on doctors.[58]

As noted above (in the section *The Benefits of an Entrepreneurially Focused Healthcare System*), in response to the relaxation of these restrictions and the spike in demand due to the pandemic, the use of telemedicine has increased dramatically. Building from the current suspension, these burdens should be permanently eased. Maintaining this lower-regulated environment going forward will significantly expand the entrepreneurial nature of the healthcare system allowing innovative providers to use telemedicine services as a means to better serve patients and control costs.

Regulations also disincentivize entrepreneurship by placing arbitrary restrictions on the healthcare sector's ability to invest in needed infrastructure. One of the more onerous regulations is predicated on the belief that government planners can reduce costs by restricting supply. These state laws, which are effective in 35 states and the District of Columbia, are known as Certificate of Need (CON) laws.[59] CON laws re-

quire healthcare providers to obtain the government's approval before expanding its capacity or making capital expenditures. Ostensibly, CON laws help ensure that healthcare providers do not create too much healthcare capacity thereby controlling healthcare inflation, ensuring the financial viability of the current facilities, and ensuring access to facilities for at-risk populations.

The logic of CON laws is economically flawed. Essentially, proponents of CON laws are arguing that artificially restricting supply lowers prices and improves patient quality. Not only does such a supposition contradict fundamental economic logic, it is also inconsistent with the empirical outcomes. Summarizing the research led by Thomas Stratman, Mitchell (2017) noted several adverse impacts for the states with CON regulations compared to those without these barriers.[60] These include:

- Having 99 fewer hospital beds per 100,000 people and 131 fewer hospital beds per 100,000 people for those CON programs that regulate acute hospital beds
- Reducing the number of hospitals with MRI services
- Increasing the need for patients to travel out of the county to receive the appropriate healthcare services
- Having 30 percent fewer rural hospitals per 100,000 people
- Having higher mortality rates from treatable conditions including the complications, and following surgery, heart failure, and pneumonia.[61]

In reviewing the literature on the impact on costs, Mitchel (2017) found that the majority of the research found that CON regulations increase overall spending.[62] Essentially, the CON law research illustrates that the supply-side of the healthcare system responds to incentives in the same manner as other sectors of the economy.

The ill-advisability of overly burdensome regulations does not only apply to investments in technology, equipment, and healthcare facilities. It also applies to many non-physician healthcare professionals. In addition to relaxing the unnecessary regulatory restrictions on physicians discussed above, the regulatory environment prevents many non-physician practitioners from providing the healthcare services they are qualified to provide. As Graboyes (2019) explained in testimony to the Committee on U.S. House Ways and Means, Rural and Underserved Communities Health Task Force,

> Many medical services require a physician's attention. However, countless tasks can be performed just as well by nonphysician professionals, such as nurse practitioners (NPs), physician assistants (PAs), nurse anesthetists, psychologists, and pharmacists, especially when it comes to delivering primary care services. Allowing them to practice to the full extent of their qualifications would increase access to care and help alleviate the consequences of the current (and looming) physician shortage. …
>
> Easing restrictions on nonphysician practitioners who are able to perform tasks currently performed by doctors can free up doctors' time, thereby lowering costs and expanding access. Of course, nonphysician providers should not engage in care beyond the extent of their training.[63]

Just like with doctors, the experience and training of non-physician healthcare providers can be used more effectively if the regulatory environment would permit these innovations to be implemented.

# Conclusion

The U.S. healthcare sector has fundamental contradictions. It is plagued with waste, inefficiencies, low productivity growth, and a stagnant delivery model. But, it also benefits from technological innovations and dedicated health professionals that have led to substantial improvements in patient health outcomes.

Advocates calling for single payer healthcare, or the creation of a single public option, focus on the former problems claiming that only the government can fix them. But, Medicare's higher per-patient administrative costs and its uneconomical reimbursement rates belies these arguments. When coupled with the long-lines, low innovation, and doctor shortages that plague countries with single-payer systems, it is clear that expanding the government's control over the healthcare system is not the answer. This paper argues that a more effective way to address the healthcare systems' problems is to empower patients and the healthcare professionals who, despite the current obstacles, are still driving innovations and improvements in health outcomes.

> "An entrepreneurially focused healthcare system can leverage the knowledge and experience of millions of healthcare professionals to devise the innovations that could improve our health outcomes.

An entrepreneurially focused healthcare system can leverage the knowledge and experience of millions of healthcare professionals to devise the innovations that could improve our health outcomes. Put differently, the healthcare entrepreneurs who could fundamentally improve the quality of healthcare in the U.S. while simultaneously driving down its costs already exist. Reaping these benefits simply requires the removal of the systemic obstacles standing in their way.

The current payment model is a large obstacle that discourages innovations and prevents patients from expressing their preferences regarding which services they value. Without the valuable input from patients, the ability of entrepreneurs to improve the delivery of healthcare services is restricted. Further restricting healthcare entrepreneurs is an overly burdensome regulatory environment at the state and federal level. These regulations prevent healthcare professionals from fully leveraging their expertise to better serve patients. All of these problems are inextricably linked to the manner in which the federal and state governments provide the income support services for healthcare (e.g. Medicare and Medicaid) that further distort both the supply-side and the demand-side of the market.

Reforms that empower patients and healthcare entrepreneurs establish a healthy market process that rewards healthcare professionals for implementing productivity enhancing innovations that patients' value. The result will be a higher-quality, lower-cost, and more accessible healthcare system.

# Endnotes

1 Advocates for a public option or single payer healthcare will cite the data that shows Medicare's administrative expenses are a lower share of total spending compared to private insurers. This comparison ignores the fundamental difference in healthcare use between people over 65 and people under 65. People over 65 use significantly more healthcare services meaning, by definition, administrative expenses a smaller share of total spending. These percentages are not applicable to the under 65 population that would be covered by a single-payer or public option healthcare program, however. The per enrollee spending level is the appropriate comparison.

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