Chapter 6

Innovative Policies to Improve All Americans' Health

There are many determinants of health, but recent U.S. government health policy has mainly focused on one: expanding health insurance coverage through implementation of the Affordable Care Act (ACA). The ACA expansion covered fewer people than anticipated, and most of them gained coverage through Medicaid, which provides small, uncertain benefits and limited access to care. Moreover, the ACA imposed costly mandates and regulations that raised costs, diminished people's choices, and forced them to buy insurance they neither wanted nor needed.

Health insurance is a positive factor in the lives of Americans, providing financial protection and peace of mind in case of serious illness. But the evidence shows that health insurance provided through government expansions and the medical care it finances affect health less than is commonly believed. Determinants of health other than insurance and medical care—such as drug abuse, diet and physical activity leading to obesity, and smoking—have a tremendous impact and have exacerbated recent declines in life expectancy, despite the ACA's increased coverage.

Health policy that is predominantly focused on expanding insurance coverage risks missing other policies that can improve the health of our citizens. This Administration is focused on reversing the harm caused by the ACA by fostering competition, choice, and innovation while also addressing the many factors beyond insurance that influence health. The Administration is particularly concerned about the opioid crisis that exploded during the ACA expansion. The CEA finds that the economic cost of the opioid crisis—as much as $504 billion

in 2015, or 2.8 percent of gross domestic product—is far higher than previous estimates. The Administration has taken substantial steps to decrease the supply of prescription and illicit opioids and to increase treatment options. Additional government actions and private innovation may be needed to make further progress against opioid abuse and other behavioral health problems such as obesity and smoking.

Innovation often reduces the price of health over time by providing previously unavailable treatments at patent-protected prices that fall as competing brands, and eventually generic products, come on the market. Nevertheless, as the prices of new specialty drugs have demonstrated, the initial prices of innovative products can sometimes be so high that people struggle to pay for them. The Administration is committed to bringing down the price Americans pay for healthcare, especially drug prices, while preserving and improving incentives to innovate. This chapter outlines the Administration's efforts to move beyond government insurance expansions that provide uncertain benefits to only a small segment of the population and instead pursue initiatives that lower costs and improve the health of all Americans.

Health is an extremely valuable good, because it is a prerequisite for fully enjoying life's many activities. Although improving health is an important goal in itself, it is also important because better population health will increase productivity and economic growth. This chapter discusses the Administration's initiatives to enhance Americans' health and how these efforts differ from previous policies.

Over the last eight years, health policymakers focused on expanding insurance coverage, primarily through the Medicaid expansion and exchange subsidies in the Affordable Care Act (ACA). Health insurance is a positive factor in the lives of Americans, providing financial protection and peace of mind in case of serious illness. But the ACA expansion had a limited effect on health and many downsides. The ACA only expanded coverage to, at most, an additional 6 percent of the population. In addition, most of these people gained coverage under Medicaid, which provides limited access to care and uncertain, and at most modest, health benefits. Moreover, the ACA imposed costly and

cumbersome mandates and regulations that raised costs, decreased people's choices, and forced them to buy insurance that they neither wanted nor needed. The lack of competition and choice inherent in the ACA approach was not the most efficient way to provide coverage and medical care for the poor and uninsured, and thus resulted in higher health insurance premiums and spending.

By focusing primarily on expanding insurance coverage through the ACA, the health policy community lost sight of other important policies that can improve the health of a larger share of our citizens. Extensive economic and medical literature shows that while public insurance coverage expansions increase the amount of healthcare used, they generally improve health less than is commonly believed. Indeed, there is substantial evidence that other determinants of health outside of insurance and medical care, such as diet and physical activity, smoking, and drug abuse, impact health enormously. For example, for the first time in over 50 years, life expectancy in the United States declined for two consecutive years—in 2015, and again in 2016 (CDC 2016a, 2017a). This negative health outcome occurred despite the ACA coverage expansion, suggesting that other factors are causing population health to deteriorate.

This chapter focuses on the Administration's goal of reversing the harm caused by the ACA while taking a broader perspective—with a focus on fostering competition, choice, and innovation—in order to improve the health of the entire population in the most cost-effective way possible.

We first assess the evidence about the small and uncertain, positive effect that government insurance expansions have on health. Government expansions in general, and the ACA in particular, often replace uncompensated care with insurance coverage that provides limited access to low-benefit care and imposes requirements that are ineffective. The ACA exacerbated this by imposing mandates and price controls that resulted in an unstable market and rapidly rising premiums. We document the policies the Administration has adopted to restore competition and choice to the insurance market.

We next discuss three important determinants of health other than insurance and medical care—opioid abuse, obesity, and smoking—that have an outsized influence on the most common and costly illnesses. The Administration has focused on confronting the opioid epidemic, which exploded through the period of ACA expansion, leading to immense social and family disruption along with loss of life and human dignity. The Surgeon General lists substance abuse, including the opioid epidemic, among the nation's top health priorities (HHS 2017). The opioid problem has reached crisis levels in the United States, and is partly responsible for declining life expectancies—in 2016, over 42,000 Americans died of a drug overdose involving opioids. We highlight a study by the Council of Economic Advisers (CEA 2017), which finds that previous estimates greatly underestimate the economic cost of the opioid crisis by

undervaluing the lives lost to overdoses. This study found that in 2015, the economic cost of the opioid crisis was as much as $504 billion, or 2.8 percent of gross domestic product (GDP) that year. We enumerate the Administration's efforts to address the crisis and its negative health effects.

For some behaviors that drive population health, private sector medical innovation may be a more effective way of decreasing the negative consequences of these health behaviors than traditional government interventions like public health measures and raising prices through taxation. In particular, the private sector has recently delivered many innovative new products and procedures to treat everything from HIV, heart disease, cancer and hepatitis C. These innovations can be seen as lowering the effective price of better health by providing previously unavailable treatments—and thus, from an economist's perspective, prohibitively expensive treatments—at patent-protected price levels that decline over time as competitors, and eventually generic substitutes, come to market.

But innovations that improve population health are unhelpful if people cannot afford them. The Administration is focusing on two essential goals: first, to decrease the price Americans pay for healthcare and especially expensive drugs; and second, to keep lowering the effective price of better health in the future by spurring medical innovation. We discuss how these two goals can be achieved through a combined strategy to reduce inefficiently high prices at home while at the same time reducing free-riding abroad.

Administration policies that promote market competition and choice will deliver innovative solutions to these and other health problems, as opposed to top-down, government approaches. A more holistic approach to health policy beyond a singular focus on low-quality coverage expansions for a small part of the population will improve health, increase productivity, and lead to greater economic growth.

Healthcare Insurance and Spending, and the ACA

During the last eight years, the health policy community focused on the Affordable Care Act, which set out to improve health by expanding health insurance coverage while also decreasing healthcare spending. The ACA failed on both fronts: it ended up insuring fewer additional people than projected (CBO 2017)—only 6 percent of the population, most of whom gained coverage under Medicaid (Uberoi, Finegold, and Gee 2016), a program with historically small and uncertain effects on health outcomes and limited access to care. The remainder of newly insured people were forced to buy more expensive and elaborate insurance than many wanted, or else be subject to a penalty. Not only were the ACA's ostensible cost control features ineffective, but they also led to market consolidation, decreased competition, higher premiums, and a clear increase in inefficient healthcare spending.

The Impact of the ACA and Health Insurance on Health

Expanding health insurance coverage provides protection against financial catastrophe in the case of serious illness. Mazumder and Miller (2016) found that personal bankruptcies declined and credit scores improved when Massachusetts expanded health coverage in 2006. Other research indicates that fewer medical bills went into collections and fewer people went into medical debt after expansions of Medicaid coverage (Baicker et al. 2013; Hu et al. 2016). Insurance coverage also provides covered people with the peace of mind that comes from alleviating the fear of possible financial distress.

Although increasing financial security is important, most initiatives to expand health insurance coverage and access to healthcare are undertaken with the goal of improving the health of insured people. Though the evidence is clear that gaining health insurance increases healthcare utilization and spending, it is less clear that government coverage expansions improve people's health.

One of the first attempts to study the effect of health insurance on health was the RAND Health Insurance Experiment. In the 1970s, participants were randomly assigned to multiple levels of coinsurance, ranging from free (no coinsurance) up to 95 percent coinsurance. The study found that as the amount of coinsurance decreased, utilization of medical care rose. However, with the exception of improved hypertension control, dental care, and vision care for the poorest patients assigned free care, there were no health improvements for the average person receiving more generous insurance (Newhouse 1993; Brook et al. 2006). Hanson (2005) observes that because the researchers conducted 80 tests by health indicators, 4 positive health results could appear by chance alone, given a 5 percent significance level. Unfortunately, the RAND study did not compare insurance with not having any insurance.

A careful examination of the literature by Levy and Meltzer (2008) found that although many studies purport to find that insured people have better health outcomes than uninsured people, most of these studies did not establish a causal relationship between health insurance and health. Observational studies, which make up the vast majority of studies, did not adequately address the problem of the endogeneity of health insurance—that observed differences in health outcomes might be driven by unobserved differences between the insured and uninsured. Results from quasi-experimental studies, where endogeneity is less of a problem, were inconclusive. Levy and Meltzer concluded that increases in health insurance increased the consumption of medical care and might modestly improve self-reported health. Although insurance can improve some health measures for some population subgroups, especially vulnerable ones like children, there is little evidence that insurance significantly affects the health of most people.

Perhaps the best recent evidence of the effect of insurance on health comes from the Oregon Medicaid expansion experiment (Baicker et al. 2013). People selected at random for Medicaid coverage from a waiting list of uninsured people were compared with a control group of those who were not selected. Both groups were followed for two years. The covered group gained improved financial security, which was reflected in less medical debt as well as less borrowed money to pay bills or skipped payments. They increased their use of medical care—ambulatory care, emergency department visits, preventive visits and services, prescription drugs, and hospitalizations all increased. Medicaid enrollees also reported an improved sense of physical and mental health. Yet, other than improved depression outcomes, the group gaining coverage did not show improvement in health outcomes. There was no significant improvement in blood pressure, cholesterol level, diabetes control, or mortality.

In a recent review of the effect of insurance coverage, Sommers, Gawande, and Baicker (2017) asserted that insurance improves health. They cited a single quasi-experimental study showing that insurance improves health outcomes. That study (Cole et al. 2017) only found improvement in four of eight "quality measures," and three of the four were process measures, not outcome measures. Blood pressure control was the only outcome improvement, a finding that is contrary to the finding of no improved blood pressure control in the randomized Oregon experiment. Sommers, Gawande, and Baicker (2017) also claimed that insurance lowers mortality. They cited two quasi-experimental studies showing a 6 percent reduction in mortality over 5 years in three States that expanded Medicaid in the early 2000s as compared with neighboring States that did not expand Medicaid (Sommers, Baicker, and Epstein 2012), and reductions in mortality in Massachusetts after its 2006 health reform as compared with mortality in demographically similar counties nationally (Sommers, Long, and Baicker 2014). These studies, as the authors acknowledged, were susceptible to unmeasured confounding. Finally, they asserted that the positive effect on self-reported health seen in the Oregon study predicts reduced mortality over a period of 5 to 10 years. They relied on two earlier studies (Miilunpalo et al. 1997; DeSalvo et al. 2006) that reported a correlation between perceived poor health at a point in time and mortality. These studies may be accurate, but neither one sought to answer how changes in self-reported health brought on by gaining insurance affect eventual mortality.

Multiple studies cited by Sommers, Gawande, and Baicker (2017) had short-term follow-up. In contrast, a recent 20-year observational study of the near elderly (age 50–61 years), which took pains to counteract the deficiencies of earlier observational studies by using a more complete set of covariates, found that insured people use more healthcare services, but there was little or no effect of insurance on health and mortality (Black et. al. 2017).

A study by Richard Kronick (2009)—who worked on ACA implementation as HHS Deputy Assistant Secretary for Health Policy (2010–13) and as Director of the Agency for Healthcare Research & Quality (2013–16)—found that on almost every characteristic measured, uninsured people have higher risk factors compared with privately insured people; this study had a follow-up period of 16 years. When adjustment was made for high-risk characteristics, being uninsured was not associated with an increased risk of mortality. Although cautioning about the difficulties of inferring causality from an observational analysis, Kronick concluded that "there would not be much change in the number of deaths in the United States as a result of universal coverage."

Why the ACA Expansions May Have Limited Health Effects

There are at least four reasons why health insurance, particularly through government coverage expansions, may have a smaller effect on health than anticipated. The first three of these reasons—that the uninsured were often able to obtain care before coverage, access problems for patients who gain Medicaid coverage, and mandated insurance benefits that have a minimal impact on health—are particularly salient when examining the results of the ACA coverage expansion.

First, care has been available for many who have no insurance coverage. The 1986 Emergency Medical Treatment and Labor Act requires anyone coming to a hospital emergency department to be stabilized and treated, regardless of their insurance status or ability to pay. Moreover, physicians in private practice have historically been willing to care for some uninsured or poorly insured patients, although recent increases in operating costs and declines in insurance reimbursements have decreased willingness to provide charity care (Zinberg 2011). Finkelstein and McKnight (2008) explained their finding that in its first 10 years after passage in 1965, Medicare had no discernible impact on elder mortality, in part because before Medicare, elderly individuals with life-threatening, treatable conditions sought care even if they lacked insurance. Finkelstein, Hendren, and Luttmer (2015) found that in the Oregon experiment, Medicaid enrollees only valued each additional $1 of government Medicaid spending at $0.20 to $0.40. Most of the benefit went to doctors and hospitals, who would have otherwise provided uncompensated care to these enrollees. Similarly, a study of how many enrollees dropped out when charged higher premiums for Medicaid-like coverage on Massachusetts' low-income health insurance exchange found that most enrollees valued coverage at less than half the cost of coverage. The availability of uncompensated care for low-income uninsured people explained the gap between enrollee value for Medicaid below the program cost (Finkelstein, Mahoney, and Notowidigdo 2017). In fact, the ability of low-income, uninsured people to declare bankruptcy serves as an implicit form of high-deductible insurance (Mahoney 2015).

Second, about three-quarters of the ACA's net coverage increase came from people who were newly covered by Medicaid (Uberoi, Finegold, and Gee 2016), a type of insurance that is associated with limited access to care. When there are public coverage expansions, demand prices (copays and premiums) fall for those who are subsidized, but supply prices set by the government (reimbursements) are usually lower than commercial rates. This leads to excess demand and a limited supply of willing providers to serve those covered by the low reimbursement rates under the public expansion. The Kaiser Family Foundation (2016) reported that State Medicaid programs pay physicians an average of 72 percent of Medicare fees, and Medicare fees are often lower than commercial rates. The reimbursements are even lower (66 percent of Medicare) for primary care physicians who are regarded as the key points of access into the healthcare system. Low Medicaid reimbursement rates mean relatively low physician participation in the program (Decker 2013). A study of appointment availability found that every $10 change up or down in Medicaid fees led to a 1.7 percent change in the same direction in the proportion of patients who could secure an appointment with a new doctor (Candon et al. 2017).

Office-based physicians' willingness to accept new patients varies, depending on a potential patient's type of insurance. Nearly 85 percent of physicians will see a new patient if they have private insurance, and 84 percent will see a patient with Medicare; but just 69 percent will accept new Medicaid patients (CDC 2015). Moreover, the percentage of physicians accepting Medicaid varies vastly among States. Three of the most populous States in the Nation have significantly lower percentages of accepting physicians than the 69 percent national average—California (54 percent), New York (57 percent), and Florida (56 percent) (CDC 2015). If Medicaid coverage did not improve outcomes in the Oregon experiment, where the proportion of physicians accepting Medicaid (77 percent) was higher than the national average, it suggests that expansion in these States would have only a marginal effect. Not surprisingly, Miller and Wherry (2017) found no difference in the health outcomes of individuals in States that expanded Medicaid under the ACA compared with nonexpansion States, no significant improvement in self-reported health status, and an increased probability of delay in obtaining care because no appointments were available or waiting times were too long for those in expansion States.

The third reason public coverage expansions have a small effect on health is that government rules, associated with public expansions, may produce inefficient healthcare utilization. The ACA, for example, mandated that preventive care and annual office visits be covered at no cost to the patient, even though the benefits of preventive care and screening are modest. A review by the Stanford Prevention Research Center of randomized trials and meta-analyses of the efficacy of available screening tests for diseases where death is a common outcome found that "reductions in disease-specific mortality are

uncommon and reductions in all-cause mortality are very rare or nonexistent" with these tests (Saquib, Saquib, and Ioannides 2015). Cancer screening can generate health benefits when used for appropriate populations, but it is performed far more commonly in this country than elsewhere and is often overly intensive, of low value, and potentially harmful (Zinberg 2016). Even Dr. Ezekiel Emanuel (2015), one of the ACA's architects, acknowledged that routine annual physicals—visits for general healthcare that are not prompted by any specific complaint or problem—do not decrease mortality, waste resources, and may lead to harmful additional testing and unnecessary treatments. By mandating the provision of low-value medical care measures at little or no cost, the ACA may inefficiently allocate scarce medical resources, because low-value measures could crowd out high-value ones.

Fourth and finally, public coverage may have limited or possibly negative effects on health because of its long-run impact on innovation. Many governments, particularly in Europe, have paired large coverage expansions with the imposition of price and spending controls. These centralized controls may have an adverse impact on medical innovation and make healthcare less effective and more costly to obtain in the future. Therefore, a complete assessment of the impact of government insurance expansions on health requires a long-run perspective. In sum, though health insurance is undoubtedly a major positive factor in the lives of many Americans, health policy focused predominantly on expanding insurance runs the risk of crowding out other policies that could better contribute to improved health outcomes for our citizens. Box 6-1 describes the Administration's initiatives to restore choice and competition to healthcare in America.

The ACA's Impact on Spending

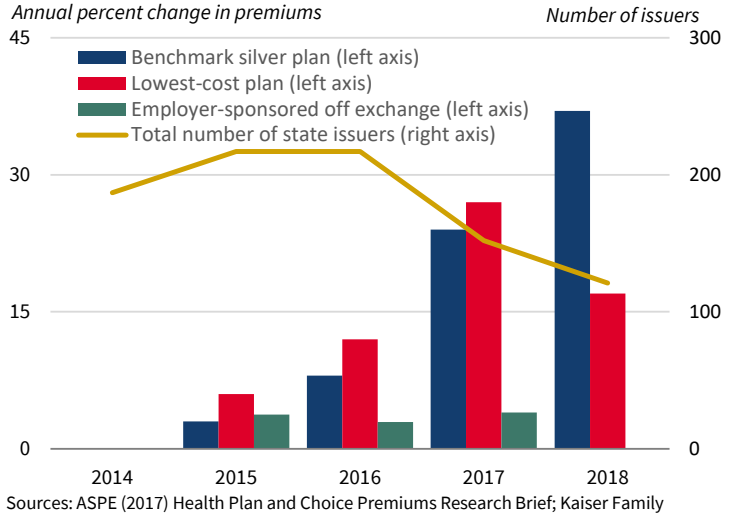
The share of GDP attributable to healthcare expenditures has increased sharply over time, rising from 5 percent of GDP in 1960 to 17.4 percent in 2010, when the ACA was enacted (CMS 2017a). This spending growth represents increased quantities of services, increased prices for these services, or a combination of both. Economic research finds that factors contributing to spending growth include increasing income, the aging of the population, and the increased extent of insurance coverage. However, new technologies have perhaps been the central driver, contributing between 27 and 48 percent of spending growth since 1960 (Smith, Newhouse, and Freeland 2009). The growth in real per capita health expenditures slowed worldwide after 2002, well before the enactment of the ACA in 2010, largely as a result of the two recessions in the last decade (Sheiner 2014), but has recently turned upward.

Despite promises to "bend the cost curve" and purported cost control provisions in the ACA, real national health spending per capita rose 3.0 percent a year, on average, from 2013 to 2016, compared with 1.5 percent from 2003 to 2013, according to the Centers for Medicare and Medicaid Services (CMS

Box 6-1. The Trump Administration's Actions to Restore Choice and Competition to Healthcare

The ACA imposed costly benefit requirements and regulations on the insurance market that limited people's options and raised premiums. The individual mandate required people to buy insurance whether they wanted it or not, and the ACA's minimum essential benefit requirement mandated a more costly and comprehensive package of benefits than what many people preferred. This requirement, combined with the ACA's restrictions on premium variation, has driven premiums up in the insurance market for individuals and small groups. Far fewer people signed up on the ACA exchanges than expected (CBO 2017). Young, healthy patients have largely shunned the overpriced insurance coverage—in effect, refusing to subsidize lower premiums for elderly, sick patients (Antos and Capretta 2016). As a result, many insurers have incurred substantial losses and have fled the exchanges (Cox et al. 2016). In 2018, 51 percent of counties had only one carrier participating in their healthcare exchange (CMS 2017d). The average number of insurers participating in each state's ACA marketplace declined from 5.0 in 2014 to 4.3 in 2017 and to 3.5 in 2018. In 2018, eight states have only a single ACA insurance provider (Semanskee et al. 2017). Insurers that have remained in the market increased premiums by 25 percent, on average, for benchmark silver plans for plan year 2017 (rates were determined during the fall of 2016), and by even more for 2018 (figure 6-i).

Figure 6-i. Federal Marketplace Premiums and Issuers, Plan Years (PYs) 2014–18



Sources: ASPE (2017) Health Plan and Choice Premiums Research Brief; Kaiser Family Foundation and Health Research and Eduational Trust Employer Health Benefits 2017 Annual Survey.
Note: States using HealthCare.gov in all five PYs. Premiums set in September of prior year.

The President has addressed the ACA's key problems from the beginning of his tenure. Within hours of being sworn in on January 20, 2017, he signed Executive Order 13765, directing the Secretary of Health and Human Services and the heads of other agencies to take all actions consistent with the law to minimize the ACA's economic and regulatory burdens, to provide greater flexibility to the States, and to promote the development of a free and open interstate health insurance market.

President Trump also signed Executive Order 13813 to promote healthcare choice and competition by expanding affordable coverage options. The order directs the Department of Labor to lower the barriers preventing small businesses from forming Association Health Plans (AHPs), so these firms can gain the regulatory benefits that large employers now receive. For example, as AHP members, small businesses would gain bargaining power to negotiate more affordable insurance and avoid some of the ACA's costly requirements, as large companies already do for their employees. A total of 11 million Americans lack employer-provided insurance because they or a loved one work for a small business or sole proprietorship that does not offer insurance. On January 4, 2018, the Department of Labor proposed a rule on AHPs that would give employers greater ability to form AHPs and to allow sole proprietors to join these plans.

Executive Order 13813 also calls for the consideration of new regulations to expand the availability, duration, and renewability of Short-Term Limited Duration Insurance. These plans are exempt from the ACA's rules, offer greater choices of coverage, and are significantly cheaper than ACA exchange plans. They were previously available for terms of up to one year, but were limited to 90 days without renewability by a late 2016 regulation. The Executive Order also seeks to expand the availability and the use of Health Reimbursement Arrangements—employer-funded, tax-advantaged accounts that reimburse employees for deductibles, copayments, premiums, and qualified medical expenses in plans or other arrangements that best suit them.

Finally, Executive Order 13813 directs the Secretary of Health and Human Services to provide a report detailing how existing State and Federal statutes and regulations limit Americans' healthcare options, decrease competition, and raise costs. State rules and regulations—such as certificate of need laws, narrow scope of practice rules, and restrictions on telemedicine—are government-erected barriers to entry that benefit established providers, allowing them to charge higher prices and reducing incentives for them to produce higher-quality, lower-cost goods and services. This spring, HHS will release a report detailing recommendations to reduce government-erected barriers to entry, thereby expanding choice and competition in healthcare markets.

On the legislative front, the Administration's tax reform will eliminate the ACA's individual mandate.

2017a). In part, this was due to a rapid rise in Medicaid spending, as enrollment rose from 54 million in 2010 to 71 million in 2016 (CMS 2017a). In addition, spending per expansion enrollee in Medicaid expansion States was far higher than projected (CBO 2017). By 2016, health expenditures accounted for 17.9 percent of GDP (CMS 2017a).

In addition, the ACA's signature cost control provisions were ineffective and had unintended consequences. Accountable Care Organizations (ACOs) were supposed to give providers incentives to become more efficient, but they have not produced overall savings as implemented. In fact, after accounting for bonus payments to ACOs that were awarded for keeping costs down—and for the fact that most ACOs were in one-sided risk arrangements, whereby they shared savings but were not liable to the government for losses—the Medicare Shared Savings Program ACOs actually increased Medicare spending by $216 million in 2015 and by $39 million in 2016 (Capretta 2017). The initial belief that ACOs would curb spending growth, and their subsequent failure to do so, follows a long history of such payment reforms not altering spending growth. The market essentially was taken over by health maintenance organizations and their more generous cousins, preferred provider organizations, while spending kept growing at the same rate. The same was true for capitation payments and disease management programs.

The ACA also imposed a penalty on hospitals that have high rates of readmissions within 30 days of discharge, in an effort to cut costs and improve quality. Although hospitals cut readmissions, part of the effect was due to hospitals' decreasing admission rates for returning patients, whom they would normally have admitted, in order to avoid penalties (Gupta 2017). A study of Medicare patients hospitalized for heart failure found that implementing the hospital readmission reduction program was associated with a subsequent increase in 30-day and 1-year risk-adjusted mortality (Gupta et al. 2018).

Instead of relying on consumer choice and competition to control costs, the ACA encouraged healthcare providers to combine into larger health systems and to take on financial risk, based on the unproven assumption that this would incentivize providers to decrease unnecessary services, cut costs, and improve outcomes. However, excessive consolidation in the market may enable producers to use their market power to raise prices, lower quality and innovate less than they would in a competitive market.

ACA-mandated cuts in hospital payments and new regulatory burdens made it difficult for smaller institutions to go it alone. Small physicians' groups and solo providers could not afford to purchase and maintain electronic medical records and comply with government reporting requirements. As a result, hospital mergers are booming, leading to horizontal integration, and large hospitals are buying up physicians' practices and outpatient service providers to form large, vertically integrated healthcare networks. Hospital mergers and acquisitions averaged 97.8 per year (ranging from 88 to 102 a year) in the

five years after the ACA was enacted (2011–15), compared with 58.8 per year (ranging from 38 to 83 a year) during the 10 years preceding the ACA (2001–10) (AHA 2016). After significant consolidation, Cutler and Morton (2013) found that almost half of hospital markets are highly concentrated, with one or two large hospital systems dominating many regions across the country. Cooper and others (2015) found that hospital prices in monopoly markets are 15 percent higher than those in markets with four or more hospitals, after controlling for several demand and cost factors. Baker, Bundorf, and Kessler (2014) found that vertical integration led to an increase in market share, which was associated with higher prices and increased spending. These cost increases due to consolidation are exacerbated by many State regulations, such as certificate-of-need laws and rules about narrow scopes of practice, that serve as barriers to entry, particularly for lower-cost alternatives.

To free the market from these mandates and constraints on competition—pursuant to the President's October 12, 2017, Executive Order—the Administration will release a report in the spring of 2018. It will identify Federal and State government policies that reduce competition and increase consolidation and provide recommendations to mitigate these policies. The literature is clear that hospital competition leads to lower prices and higher quality (Gaynor and Town 2012). This is consistent with the Administration's deregulatory agenda, which has already withdrawn, made inactive, and delayed hundreds of economically destructive regulations.

Improving People's Health by Limiting the Effects of Unhealthy Behavior

In industrialized countries, health behaviors—actions and inactions by individuals that affect their own health or the health of others—are more important determinants of health than insurance coverage and the medical care it finances. A review of the literature has identified five key determinants of health in industrialized countries: health behaviors, genetics, social circumstances, environmental and physical influences, and medical care. Health behaviors appear to be the most important, making a relative contribution of 30 to 50 percent to health, according to various studies, while medical care accounts for only 10 to 20 percent (Gnadinger 2014). The second most important relative contribution to health, at 20 to 30 percent, is made by genetics. The government cannot and should not directly affect people's genomes, but here it does have an important function: to set ethical and regulatory guardrails for the development and use of genetic testing and therapies.

Using mortality as an indicator of health, Schroeder (2007) finds that up to 40 percent of premature deaths in the United States are due to unhealthful behaviors like smoking, poor dietary habits, and sedentary lifestyles. Now, deaths resulting from the escalating opioid abuse crisis are adding to this

self-inflicted toll. Although life expectancies in different geographic areas have a negative correlation with poor health behaviors like smoking, they are not correlated with access to healthcare (Chetty et al. 2016).

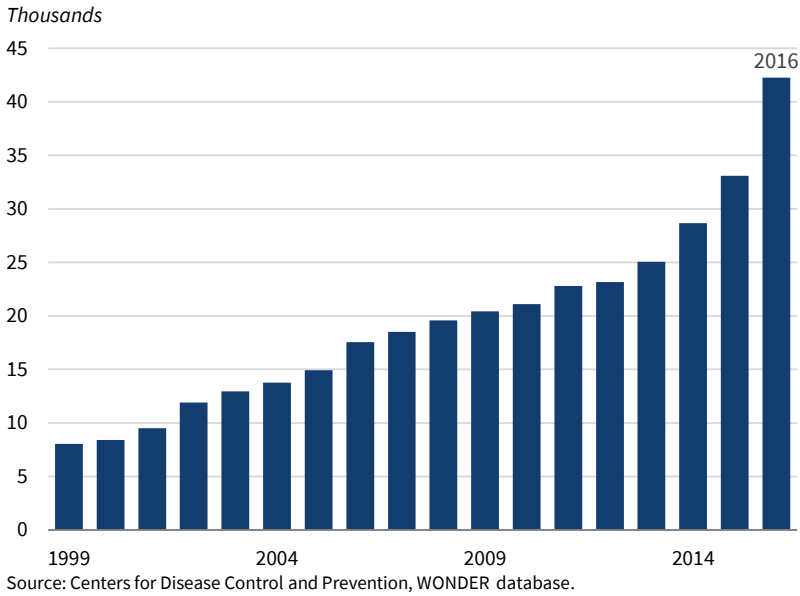
Poor health imposes economic costs in three ways: direct health care spending; the costs of premature deaths resulting from poor health; and productivity losses from illnesses that keep people out of the labor force or cause absenteeism and "presenteeism"—that is, decreased worker productivity while at work—for those who are in the labor force. The Commonwealth Fund estimated that in 2003, 18 million people between the age of 19 and 64 were out of the labor force because of illness, and that if their lost work time was valued at the minimum wage, the nation lost $185 billion in economic output (1.6 percent of GDP) (Davis et al. 2005). Another 69 million workers lost 407 million sick days, which cost $48 billion, if valued at actual wages. Finally, they estimated there were 478 million days when illness reduced workers' productivity, resulting in a loss of $27 billion if they were working at "half capacity." The share of prime-age employees citing poor health as the main reason for staying out of the labor force has increased significantly during the past two decades, and it is higher among those with less education. During the second quarter of 2017, 5.4 percent of prime-age individuals (those age 25 to 54) reported being too sick or disabled to work in the labor force, 1.6 percent more than two decades ago. If this trend were reversed, it could increase the workforce by up to 4 million people and add about 2.6 percent to GDP (Terry 2017).

In this section, we focus on three behaviors—opioid abuse, poor diets and sedentary lifestyles that lead to obesity, and smoking—that severely exacerbate our most costly illnesses and impose enormous related economic and social costs.

Improving Health by Combating the Opioid Epidemic

As debates focused on expanding health insurance coverage during the past eight years, an opioid epidemic was ravaging the country, devastating the lives of those struggling with addiction, and the lives of their loved ones. The consequences for the health of Americans—most important, a skyrocketing death toll—have been enormous (see figure 6-1). In 2016, almost as many people died of an opioid-involved drug overdose (42,249) as died of HIV (43,115) at its peak in 1995 (Mendell, Cornblath, and Kissel 2001). And since 1999, over 350,000 people have died of opioid-involved drug overdoses, which is 87 percent of the 405,399 Americans killed in World War II (DeBruyne 2017). The staggering opioid death toll has pushed drug overdoses to the top of the list of leading causes of death for Americans under the age of 50 and has cut 2.5 months from the average American's life expectancy (Dowell et al. 2017). This subsection documents the immense economic toll the opioid epidemic has taken on the United States, and thus, the importance of Administration actions that have been undertaken to reduce these costs and save lives.

Figure 6-1. Opioid-Involved Overdose Deaths, 1999–2016

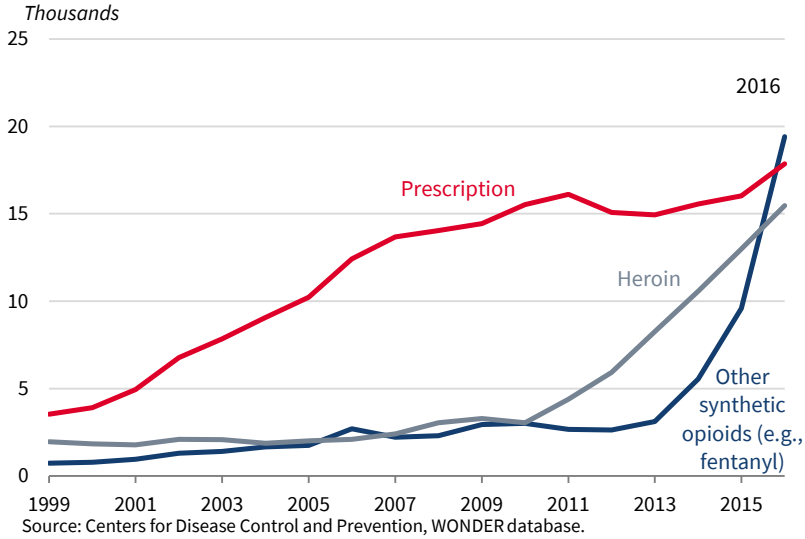


Source: Centers for Disease Control and Prevention, WONDER database.

The opioid epidemic evolved with three successive waves of rising deaths due to different types of opioids, with each wave building on the earlier one (Ciccarone 2017). In the late 1990s, in response to claims that pain was undertreated and assurances from manufacturers that new opioid formulations were safe, the number of opioid prescriptions skyrocketed (CDC 2017b). What followed was an increase in the misuse of and deaths related to these prescriptions (figure 6-2). As providers became aware of the abuse potential and addictive nature of these drugs, prescription rates fell, after peaking in 2011. Deaths involving prescription opioids leveled off, but were followed by a rise in deaths from illicit opioids: heroin and fentanyl. Heroin deaths rose first, followed by a rise in deaths involving fentanyl—a synthetic opioid that is 30 to 50 times more potent than heroin and has legitimate medical uses but is increasingly being illicitly produced abroad (primarily in Mexico and China) and distributed in the U.S., alone or mixed with heroin. In 2015, males age 25 to 44 (a core group of the prime-age workers whose ages range from 25 to 54) had the highest heroin death rate, 13 per 100,000. Fentanyl-related deaths surpassed other opioid-related deaths in 2016.

The CEA estimates that the opioid epidemic's economic cost was $504 billion in 2015, or 2.8 percent of that year's GDP (CEA 2017). This estimate dwarfs estimates from previous studies for several reasons—most important, previous studies undervalued the cost of the lives lost to drug overdoses. For example, some studies focus mainly on healthcare costs and find that prescription opioid abusers utilize significantly more healthcare resources

Figure 6-2. Overdose Deaths by Type of Opioid Involved, 1999–2016



Source: Centers for Disease Control and Prevention, WONDER database.
Note: "Prescription" denotes the combined data for methadone and natural/semi-synthetic opioids.

than nonaddicted peers (e.g., White et al. 2005, 2009; McAdam-Marx et al. 2010; McCarty et al. 2010; Leider at al. 2011; Johnston et al. 2016; Kirson et al. 2017). Others account for additional costs, including forgone earnings from employment and higher costs for the criminal justice system (e.g., Birnbaum et al. 2006, 2011; Hansen et al. 2011; Florence et al. 2016). A recent estimate by Florence and others (2016) found that prescription opioid overdoses, abuse, and dependence in the United States cost $78.5 billion in 2013; but they did not account for the costs of illicit opioids.

Although previous estimates are informative about certain types of costs, they only partially account for the damage caused by the opioid epidemic. They do not account for the costs associated with the escalating abuse in recent years of illicit opioids, such as heroin and fentanyl, and the resulting increase in deaths. Evidence also suggests that fatality statistics understate the number of opioid-related deaths (Ruhm 2017). But most important, previous studies fail to fully account for the value of the lives lost to overdoses. Studies that only include healthcare expenditures typically capture none of the value of the lives lost, and studies that account for earnings losses among those who die account for only a fraction of the loss from such mortality. Extensive research indicates that people value fatality risk reduction far beyond the value of lost earnings due to premature death, because earnings do not take into account other valuable activities in life besides work. Using conventional estimates of the losses induced by fatality routinely used by Federal agencies—in addition

Table 6-1. Comparison of Estimated Costs of Opioid-involved Overdose Deaths, CEA and Other Studies

Study	Study year	Opioids included	Fatal costs	Adjustment for under-counting	Cost (billions, 2015$)	Ratio of CEA estimate to study estimate
Birnbaum et al. (2006)	2001	Prescription	Earnings	No	11.5	43.8
Birnbaum et al. (2011)	2007	Prescription	Earnings	No	61.5	8.2
Florence et al. (2016)	2013	Prescription	Earnings	No	79.9	6.3
CEA (2017)	2015	Prescription and illicit	VSL	Yes	504.0	1.0

Sources: Birnbaum et al. (2006); Birnbaum et al. (2011); Florence et al. (2016); CEA (2017).
Note: Each of the studies listed includes healthcare, criminal justice, and employment costs in nonfatal costs. CEA nonfatal costs are calculated by applying Florence et al. (2016) estimates of the per-person average nonfatal costs of prescription opioid disorders to individuals with prescription opioid and heroin disorders in 2015. CEA fatal costs are calculated by applying the age-dependent value of statistical life to drug overdose deaths involving any opioid in 2015.

to making other adjustments related to illicit opioids, more recent data, and the underreporting of opioids on drug overdose death certificates—the CEA study found that the overall loss imposed by the crisis is several times larger than previous estimates (table 6-1). (The CEA uses an age-adjusted value of statistical life measure to estimate the cost of lives lost to opioid-involved overdoses; see CEA 2017.)

It is important to note that though the fatal costs of the opioid epidemic ($432 billion) are the major component of its total costs, its nonfatal costs ($72 billion) are also important. Florence and others (2016) estimate that in 2013, prescription opioid misuse increased healthcare and substance abuse treatment costs by $29.4 billion, increased criminal justice costs by $7.8 billion, and reduced productivity among those who do not die of an overdose by $20.8 billion (in 2015 dollars). To arrive at our nonfatal cost estimate of $72 billion, the CEA adjusts these costs upward, adding in illicit opioid use and also the greater number of opioid abusers in 2015. Other research has shown that opioid abusers miss twice as many days of work compared with other employees (Benham, Goplerud, and Hodge 2017; Ruetsch 2010). They are also significantly less productive while at work because the drugs can induce drowsiness, cause mental confusion, impair attention and focus, and reduce creativity or reliability.

By any measure, the opioid epidemic is exacting a massive and growing toll on the United States. Death rates continue to skyrocket, while nonfatal

Box 6-2. The Trump Administration's Actions on Opioids

The Administration has taken a series of actions, including creating the President's Commission on Combating Drug Addiction and the Opioid Crisis and declaring a public health emergency under the Public Health Service Act. These additional actions have been taken:

To prevent prescription opioid abuse:

- The Centers for Disease Control and Prevention (CDC) launched the Rx Awareness Campaign to increase awareness of the risks of prescription opioid use by telling the stories of people recovering from addiction.
- The CDC awarded $28 million in new funding for prescription drug monitoring programs, so prescribers and pharmacists can monitor how many opioid prescriptions patients have received and prevent duplicate prescriptions, diversion, and abuse.
- The Food and Drug Administration (FDA) has worked to educate prescribers about safer pain management to reduce unnecessary prescribing.
- The Centers for Medicare and Medicaid Services (CMS) delinked pain management scores from provider evaluations to decrease pressure to prescribe opioids.
- The Department of Justice (DOJ) established an Opioid Fraud and Abuse Detection Unit to crack down on prescription opioid use for nonmedical reasons.
- The Department of Health and Human Services (HHS) and DOJ conducted the largest ever healthcare fraud enforcement action, by the Medicare Fraud Strike Force, in 2017. More than 120 people were charged with fraudulently billing public and private insurance programs for prescribing and distributing opioids.

To improve access to and quality of treatment for those already addicted:

- HHS awarded $485 million to States for prevention, treatment, and recovery services under the newly created State Targeted Response to the Opioid Crisis grant program.
- Another $144 million was awarded for treatment and other opioid-related costs by the Substance Abuse and Mental Health Services Administration.
- Significant funding has also been directed to mental health and substance abuse service centers, rural health organizations, physician training programs, and other entities that will support treatment and recovery using evidence-based practices.
- The Administration is cutting the red tape that hinders States' ability to use Federal funding as effectively as possible. The CMS announced in November 2017 that Medicaid would grant waivers from a decades-old statute so funds can be used to pay for treatment in facilities with more than 16 beds.

To encourage innovation in addressing the opioid epidemic:

- The National Institutes of Health (NIH) is partnering with innovative companies to develop nonaddictive pain therapies, new addiction treatment regimens, and overdose-reversal drugs.
- The Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome study will evaluate neonatal abstinence syndrome treatments for opioid-dependent newborns.
- An $81 million research partnership between HHS, the Department of Defense, and the Department of Veterans Affairs was announced to support pain management research for the military and veterans.

To disrupt the supply of illicit opioids:

- President Trump signed the Interdict Act in January 2018 to equip Border Control Agents with better technology to intercept illicit, synthetic opioids at the border.
- DOJ shut down AlphaBay, the largest online criminal marketplace and major source of illicit drugs and indicted two Chinese manufacturers of illicit fentanyl.
- The U.S. Postal Inspection Service seized increased amounts of fentanyl shipped through the mail, and the Department of State is working with international partners in reducing the production and shipment of fentanyl from abroad.

costs to productivity and the healthcare and criminal justice systems increasingly hurt the economy. This does not mean that opioids themselves have no beneficial effects—they are largely effective for their main prescribed uses of reducing acute pain and as anesthesia during surgery. But the epidemic of misuse and abuse—along with their often deadly consequences—is a health crisis many years in the making that requires urgent attention. Fortunately, the Administration has taken concrete steps to begin to stem the costs of this epidemic, and with sustained action, can make continued progress in addressing it (see box 6-2).

Obesity

Obesity has become a major health problem, leading to large direct medical expenditures, significant premature mortality, and large productivity losses.[1] It raises the risk of all-cause and cardiovascular mortality (the leading cause of death in the U.S.) and the risk of morbidity from hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and other respiratory problems, and some cancers (Jensen

[1] Obesity is medically defined as the height-adjusted weight measure—Body Mass Index (BMI)—greater than 30. BMI is defined as a person's weight in kilograms divided by the square of his or her height in meters.

et al. 2014). Stewart and others (2009) estimated that an 18-year-old with a BMI increasing by the historical average, 0.5 percent a year, would lose 1.02 years in life expectancy due to obesity alone.

The Centers for Disease Control and Prevention's National Center for Health Statistics reports that obesity rates among U.S. adults 20 and older rose from 22.9 percent in the years 1988–94 to 38 percent in 2013–14 (CDC 2016b). Another 33 percent of U.S. adults were overweight (i.e., have a BMI between 25 and 30). Obese patients incur 46 percent higher inpatient costs, 27 percent more physician visits and outpatient costs, and 80 percent higher prescription drug spending than normal-weight patients (Finkelstein et al. 2009). In 2006, they spent an average of 42 percent more (an average of $1,429 a year) than normal-weight patients, resulting in a total cost of medical care associated with obesity in the United States of $147 billion in 2008 dollars (Finkelstein et al. 2009).

Obesity also decreases the productivity of those still in the workforce through absenteeism and presenteeism (Goettler, Grosse, and Sonntag 2017). An estimate of annual obesity-related absenteeism and presenteeism costs among full-time U.S. employees in 2008 was $59 billion, in 2015 dollars (Heidenreich et al. 2011).

Rising obesity is an unintended consequence of technological progress (Philipson and Posner 1999). Welfare-improving technological change has lowered the cost of consuming calories through improved agricultural production, while raising the cost of expending calories by making work, both on the job and at home, more sedentary. People now need to pay for gym memberships to exercise and forgo leisure to replace decreased physical activity at work and in the home. Unfortunately, people do not exercise enough during their leisure time to make up for the exercise they formerly obtained at work and home—which, when combined with increased calorie intakes, has resulted in rising obesity (Lakdawalla, Philipson, and Bhattacharya 2005).

The U.S. government inadvertently contributed to this problem beginning in the 1970s when it, along with major professional nutrition organizations, recommended that Americans eat a low-fat/high-carbohydrate diet. During the succeeding decades, Americans, adhering to these recommendations, replaced fat calories with even more carbohydrate calories. Total calorie intake increased substantially, and the prevalence of obesity rose, in part, as a consequence. Researchers eventually recognized that fat was less of a problem, and by 2015, the U.S. Department of Agriculture's Dietary Guidelines for Americans essentially removed the upper limit on the recommended fat intake (Ludwig 2016).

Smoking

Tobacco use is the leading cause of behaviorally induced disease and death in the United States, even after recent declines in tobacco use during the last few

decades. Cigarettes are the most commonly used tobacco product among U.S. adults, partly causing more than 480,320 deaths per year in the United States, including more than 41,000 deaths resulting from secondhand smoke exposure (CDC 2017c). They account for about 30 percent of all cancer deaths in the United States, including about 80 percent of all lung cancer deaths—the leading cause of cancer death for both men and women (American Cancer Society 2015). Smoking is also a risk factor for cancers of the mouth, larynx, pharynx, esophagus, kidney, liver, bladder, and stomach. It is also strongly associated with many significant diseases other than cancer, including cardiovascular and respiratory diseases. The largest numbers of smoking-attributable deaths were from lung cancer (124,800), coronary artery disease (82,000), and chronic obstructive pulmonary disease (64,700) (Kiszko et al. 2014).

Goodchild, Nargis, and d'Espaignet (2017) estimate that the total economic cost attributable to smoking is between $418 and $514 billion. Only 40 percent of the cost is due to direct spending on healthcare, with the remaining amount due to indirect costs of the economic loss of morbidity and mortality due to diseases attributable to smoking. They estimate indirect economic losses using the human capital method, which calculates the present value of labor productivity lost due to morbidity and mortality. This estimate, like others, suggests that health spending attributable to smoking amounts to between 5 and 10 percent of national health expenditures. This is consistent with earlier estimates that smoking accounted for about 7 percent of total annual healthcare spending for noninstitutionalized U.S. adults from 2000 to 2008 (CBO 2012) and 8.7 percent of annual U.S. healthcare spending, nearly $170 billion, in 2010 (Xu et al. 2015).

A 2014 report by the U.S. Surgeon General found that, for the years 2005–9, the value of lost productivity attributable to premature death from smoking, based on the 19 diseases associated with smoking, was $107.6 billion annually—with cancers accounting for $44.5 billion, cardiovascular and metabolic diseases accounting for $44.7 billion, and pulmonary diseases accounting for $18.4 billion. Using all-cause mortality, the value would be $150.7 billion—$105.6 billion for men and $45.1 billion for women (HHS 2014). Additionally, the value of lost productivity due to premature deaths caused by exposure to secondhand smoke was estimated to be $5.7 billion. Because these figures account only for lost productivity due to premature mortality and not for lost productivity due to morbidity that living smokers and former smokers experience, they significantly underestimate the full value of lost productivity from smoking.

Bunn and others (2006) found that current smokers and former smokers both had higher losses from absenteeism and presenteeism than people who had never smoked, suggesting that former smokers have lingering health problems. Using an average hourly rate of $34.25, the annual amount of health-related absenteeism was estimated to be $1,206 for nonsmokers, $1,343 for

Box 6-3. The Administration's Actions to Combat Smoking

Despite significant reductions in the number of smokers, smoking remains the Nation's largest behavioral source of premature death. The Trump Administration, through the FDA, has taken the following measures:

- The FDA is exploring initiatives to lower nicotine levels in cigarettes to nonaddictive levels (FDA 2017).
- The FDA continues to investigate the safety and health effects of e-cigarettes and vaping (NASEM 2018).
- On December 11, 2017, the FDA announced "Every Try Counts," a two-year education and advertising campaign to encourage adult smokers to quit, even if they have been unsuccessful in the past.

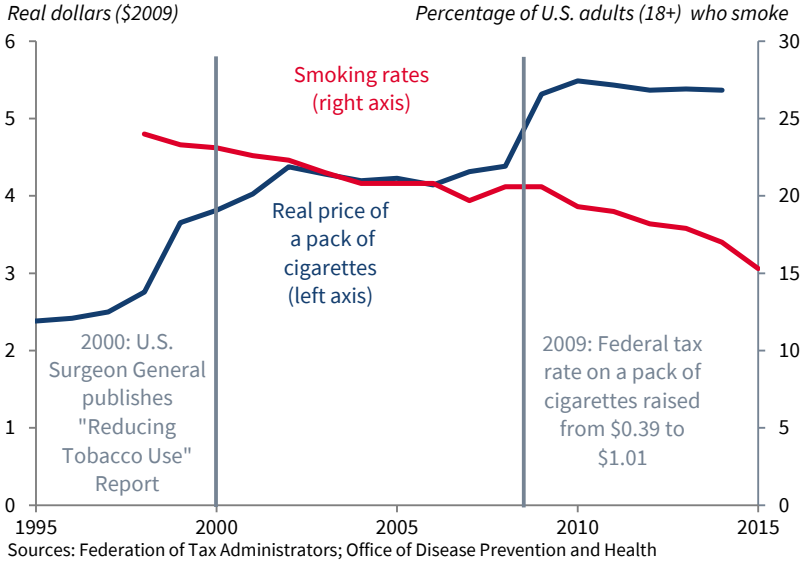
former smokers, and $1,836 for current smokers. Health-related presenteeism was estimated to be $1,466 for nonsmokers, $1,918 for former smokers, and $2,620 for current smokers. In total, absenteeism and presenteeism cost employers $2,672 for nonsmokers, $3,261 for former smokers, and $4,456 for current smokers (see box 6-3).

Policy to Address Health Behaviors

Public health measures and higher tobacco taxes have cut the number of smokers and decreased tobacco's toll on health (Mader et al. 2016). Excise taxes (both State and Federal) raised the monetary cost of smoking, and time and place restrictions raised the nonmonetized cost by making smoking more inconvenient. Taxes effectively raise tobacco's price, although smuggling can avoid some of the higher State taxes. Because many smokers were used to smoking throughout the day, time and place restrictions could effectively limit their consumption (Fichtenberg and Glantz 2002) and nonsmokers' exposure to secondhand smoke (Hartmann-Boyce et al. 2016). The health and economic gains from reducing smoking were enormous. It is estimated that tobacco control efforts led to 8 million fewer tobacco-related premature deaths than were expected if smoking had continued unabated. Life expectancy in the 50 years since the Surgeon General's 1964 report on smoking and health increased 7.8 years for men and 5.4 years for women, of which tobacco control is associated with 2.3 years of the increase for men and 1.6 years for women (Holford et al. 2014). These gains dwarf any health improvements resulting from increased insurance coverage. Nevertheless, although the smoking rate has plummeted (figure 6-3), smoking remains a leading cause of death and morbidity.

It is less clear that the behaviors that are factors in causing obesity can be addressed through taxes and public health measures. Studies of the economic and social approaches to preventing obesity that have been employed to date—such as taxes on sugary foods, wellness programs, menu labeling, and financial rewards for weight loss—are inconsistent and show only modest,

Figure 6-3. Smoking Rates and the Price of Cigarettes, 1995–2015



Sources: Federation of Tax Administrators; Office of Disease Prevention and Health Promotion; CEA calculations.

long-term effects on weight (Cawley 2015). A recent review of the literature concluded that "there is an abundance of evidence that suggests calorie labeling, as it is currently being implemented, has no impact on overall food purchases or consumption for the population as a whole" (Kiszko et al. 2014). This is not that surprising when we consider that eating is an ingrained behavior, food is readily available for most people, and it is hard to pass up pleasurable foods or engage in difficult physical activity now for the promise of lower weight and better health sometime in the future.

Wellness programs have the potential to reduce healthcare costs and productivity losses from absenteeism (Baicker, Cutler, and Song 2010). Unfortunately, not every employee is willing to participate, and current incentives may be inadequate. The ACA encouraged employers to offer workplace wellness programs but limited the incentives that could be offered. There has been rapid growth in these programs, which now cover about 50 million people. However, a new, large randomized study found that the workers who chose to participate in the workplace wellness programs that sprung up after the ACA tend to be self-selected—they had lower medical expenditures and healthier behaviors before joining the program than nonparticipants. Moreover, the study did not find significant causal effects of participation on total medical expenditures, health behaviors, employee productivity, or self-reported health in the first year (Jones, Molitor, and Reif 2018). Relaxing the limitations on incentives that can be offered may attract a wider range

of participants, including those who could benefit the most, and make these programs more effective.

It may be difficult for taxes to significantly affect opioid abuse, particularly because the recent spike in deaths is being fueled by illicit opioids (heroin and fentanyl) that defy conventional approaches. Forty-nine States and the District of Columbia have started Prescription Drug Monitoring Programs—Statewide electronic databases to monitor opioid prescriptions and dispensing—which have had some success in limiting prescription opioid diversion and abuse (Reifler et al. 2012). Unfortunately, initiatives that have decreased prescription opioid abuse have led some abusers to turn from prescription opioids to cheaper, more available heroin (Muhuri, Gfroerer, and Davies 2013). For example, a 2010 reformulation of a commonly abused prescription opioid to make it more abuse-resistant had the unintended consequence of increasing heroin deaths (Evans, Lieber, and Power 2017; Alpert, Powell, and Pacula 2017). The increased availability of cheap, ultrapotent fentanyl and fentanyl analogues, used alone or mixed with heroin, has exacerbated this problem. Hence, future policy will need to continue and strengthen the programs that have limited prescription opioid abuse and add new efforts to deter and control illicit opioid abuse. NIH and HHS have announced efforts to improve access to opioid reversal agents, support research on pain and addiction and on developing new addiction treatments, and improve access to treatment and recovery services (NIDA 2017a). (Box 6-2 above outlines other Administration initiatives.)

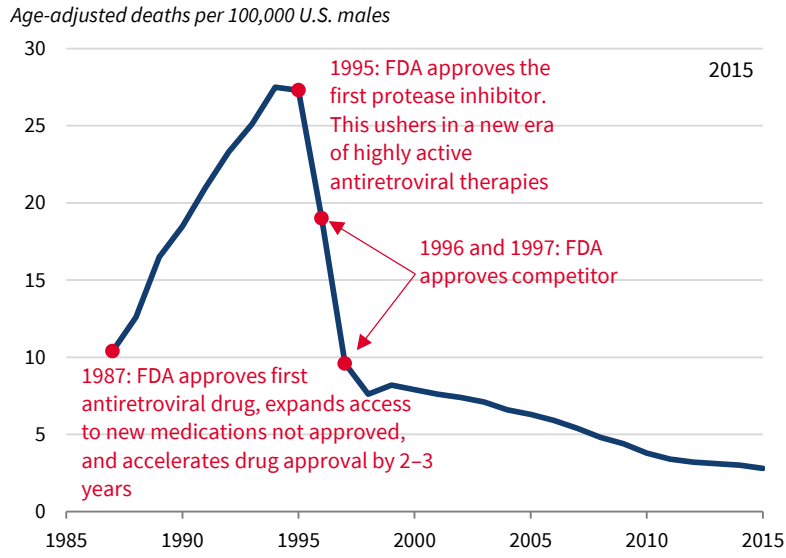
Intensive, State-based efforts to increase treatment availability and social supports have ameliorated the effects of addiction (Brooklyn and Sigmon 2017; Rembert et al. 2017), but they do not deter new abusers. Accordingly, a key policy focus for the Administration is to interrupt the supply chain to decrease availability and effectively increase prices in order to deter new users and make it more difficult for current abusers to continue abuse.

On January 10, 2018, President Trump signed the Interdict Act, which will increase the number of chemical-screening devices available to U.S. Customs and Border Protection officers in order to intercept imports of fentanyl and other synthetic opioids. This should decrease the supply and increase the prices of these opioids, and, when combined with the other measures described in box 6-2 above, will lead to decreased abuse and fewer deaths.

Improving People's Health through More Access to Medical Innovations

People's health can also be improved through new technologies. Innovations produced by the private sector, aided by public policy, may be the most efficacious way to make cost-effective progress against the behavioral determinants of health that have resisted more standard tools like public health measures

Figure 6-4. U.S. Male Deaths Caused by HIV Disease, 1987–2015



Source: National Center for Health Statistics, National Vital Statistics System.

and taxation. Although some raise a concern that new technologies increase healthcare spending, it is important to distinguish the price of healthcare from the price of health. Some new treatments have high initial prices, but they often bring down the price of health over time.

To illustrate, consider the history of HIV/AIDS (figure 6-4). Despite much publicity about the cause and transmission of HIV and public health measures, the infection and death toll continued to rise until 1995, when the Food and Drug Administration (FDA) approved the first protease inhibitor and ushered in the era of highly active antiretroviral therapies. Before the new drugs, longer life could not be purchased at any price. Once new innovative and effective treatments were approved, the price of health for HIV-positive individuals decreased to the price of the new, patented drugs. The price of health fell even further as competing drugs and cheaper generics became available. More than 100 antiretroviral therapies have been approved since then, including generic drugs in 2005 (HHS 2016). The lower price of health for HIV-positive individuals increased spending on healthcare, but beneficially so, because the gain in health was much larger than the new spending.

Valuable medical innovations can reduce the current and future real prices of health. Profitable new drugs attract competitors into the market. Prices fall closer to costs as patents expire and generic medicines come on the market. The FDA data show that when generics become available, prices will fall below 50 percent of branded prices after the second generic is approved and to 20 percent of branded prices when large numbers of generics are approved

(FDA 2015). Future populations will use generic versions of today's high-priced therapies. The vast majority of the World Health Organization's Essential Drugs today are off patent, allowing poor people here and around the world to enjoy what were innovations in the past. Generic drugs now account for 9 out of 10 prescriptions dispensed in the U.S., and saved the U.S. healthcare system $1.68 trillion from 2005 to 2014 (Woodcock 2016).

Innovations, whereby mortality and morbidity gains exceed costs, are not always expensive. Cutler and McClellan (2001) found that the value of decreased morbidity and mortality rates resulting from technological changes in the treatment of heart attacks, low-birthweight infants, depression, and cataracts far exceeded the increase in spending on these conditions. The costs of treatment of heart attacks rose by $10,000 in real terms, but life expectancy increased by about a year—in other words, a bargain. Similarly, survival gains across all cancer patients in the U.S. between 1983 and 1999 cost on average only $8,670 per year of life gained (Philipson et al. 2012).

In recent years, however, many of the breakthroughs have been specialty drugs—large, complex molecules—many of which are efficacious but initially very expensive. The 2013 introduction of novel drugs to treat hepatitis C (HCV)—a chronic viral infection that leads to cirrhosis, liver failure, liver cancer, and death—helps to further illustrate the dramatic reduction in the price of a healthier life. In 2012, therapies to treat HCV were expensive, had low cure rates, and resulted in various side effects. In contrast, new drugs have cure rates well over 90 percent and fewer side effects. Although the list price for a course of the first available treatment was $84,000, negative public reaction to the high price led to discounting and rebates (Bruen et al. 2017). Within a few years, several competing drugs from multiple companies came on the market, further driving down prices (Toich 2017). Medicaid officials report discounts and rebates of 40 to 60 percent off HCV drug list prices (Bruen et al. 2017). The most recently approved drug is highly effective, treats all six genotypes of the virus, and has a list price of $26,400 for a course of treatment (Andrews 2017), less than the discounted prices of the earlier drugs. Prices will fall further when generics become available.

Of course, not every new drug or technology is more cost-effective than older treatments. Utilizing robotic surgery as opposed to standard laparoscopic surgery for rectal cancer surgery and kidney surgery, for example, was not associated with any improvement in outcomes but was associated with prolonged operating time and higher hospital costs (for the kidney surgery) (Jeong et al. 2017). Additionally, physicians often overuse cancer drugs that have small marginal benefit but high financial, physical, and psychological costs (Zinberg 2015). Physicians, hospitals, and both private and public payers are increasingly recognizing the importance of evaluating the value of treatments both new and old (Porter 2010) and utilizing these assessments in treatment decisions.

Chandra and Skinner (2012) organize healthcare technologies into three groups: high-cost, "home run" innovations that are cost-effective for nearly everyone, for example, the HIV medications discussed above; treatments that are highly effective for some but have declining marginal benefits for others, such as coronary angioplasty and stents; and "gray area" treatments with modest or uncertain clinical value, such as arthroscopic surgery for osteoarthritis of the knee. Even home run technologies span the price spectrum; HIV medications were initially expensive, sterile surgical gloves are cheap, and antibiotics, possibly the biggest home run of them all, range from cheap to moderately expensive.

It often takes time to establish the value of new technologies and treatments as compared with other treatments, especially when it is in an area of active research and product development. For instance, coronary artery bypass grafting (CABG) was popularized in the years following 1967. Despite being expensive ($20,000–25,000 per operation in 1983; Stason and Weinstein 1985), CABG, as compared with the best medical therapy of the time, completely or partially relieved angina (chest pain on exertion) in patients with severe angina (McIntosh and Garcia 1978; Rahimtoola 1982) and improved longevity in patients with a particular type of coronary artery occlusion—severe left main artery disease (Takaro et al. 1982). For patients with severe angina, the estimated net cost per quality-adjusted year of life gained from CABG ranged from $3,800 for left main disease to $30,000 for single vessel disease. For patients with left main disease, life expectancy increased by 6.9 years (Weinstein and Stason 1982). Not every patient with coronary artery disease benefited from CABG. Improvements in medical therapy shortly after the popularization of CABG meant that patients with stable angina and coronary artery disease less severe than left main coronary artery disease (e.g., single- or two-vessel disease) had equivalent survival rates from medical and surgical treatment. The subsequent introduction of newer techniques—such as percutaneous coronary artery angioplasty, coronary artery stents, and drug eluting stents—made cost-effectiveness determinations for coronary artery disease a moving target.

Unfortunately, policymakers and potential innovators do not know what will prove successful in advance. It is imperative to preserve the incentive to innovate so new treatments will become available for evaluation, and, if they represent a good value, can be adopted. Innovators and entrepreneurs are motivated to undertake research and development (R&D) by the potential return on investment provided by temporary, patent-protected prices. High patent prices are also linked to the cost of capital to fund R&D for the pharmaceutical industry. Large pharmaceutical firms do not typically borrow to finance R&D, probably because capital markets are reluctant to invest in lengthy and risky drug development—only 1 in 10 drug candidates are eventually approved, the process takes over a decade, and the total cost per drug approval (inclusive of failures and capital costs) is about $2.6 billion (DiMasi, Grabowski, and

Box 6-4. The Administration's Efforts to Facilitate Innovation

The Administration is committed to rolling back regulations that impede innovation and competition. One of President Trump's earliest actions—on January 30, 2017—was issuing Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs. Shortly afterward, on February 24, he issued another Executive Order directing agencies to appoint regulatory reform task forces to determine which rules and regulations are too expensive, burdensome, or unnecessary so that they can be simplified or repealed.

The new tax law allowing immediate expensing and lowering the corporate tax rate will increase investment and innovation, including in the healthcare field. Current profits encourage R&D by signaling future profits and by providing the current capital on which many pharmaceutical firms rely (U.S. Department of Commerce 2004). Chapter 1 of this *Report* reviews the evidence that a decrease in taxes on corporate profits decreases the before-tax rate of return required for the marginal product of new physical assets to exceed the cost of producing, increasing firms' desired capital stock. Grabowski and Vernon (1990) found that the return on R&D for new drugs is equivalent to the industry's cost of capital. Lowering the cost of capital will increase R&D intensity, given that projects would require lower return on investment. The ability of innovative pharmaceutical, biotechnology, and medical device firms to immediately expense equipment and pay a lower marginal tax rate will increase spending on capital, which in turn will increase innovation.

The FDA has moved to facilitate the approval of new, innovative therapies to improve health and hold down prices by increasing competition. In 2017, the FDA approved the highest-ever number of generic drugs (1,027), the most-ever novel drugs and biologics (56), the most-ever novel medical devices (95), and the first-ever gene therapies (Gottlieb 2018).

Hansen 2016). Instead, they mostly rely on internal funds—in short, profits—to finance R&D (U.S. Department of Commerce 2004) (see box 6-4).

Encouraging Innovation, and Making It Affordable

Innovations are of limited utility if people cannot afford them. As noted above, many of the newest treatments are high-priced specialty drugs. Table 6-2 provides a range of annual per-patient costs for treating a condition with some of these high-priced drugs. As an extreme example, the annual cost of drugs that treat genetic diseases can reach almost $800,000 for a single patient (AHIP 2016).

The affordability of healthcare and biopharmaceutical drugs is a top concern for Americans, regardless of political party (figure 6-5). It is often asserted

Table 6-2. Summary of Annual Per-Patient Drug Expenditures, 2015

Condition	Range of annual per-paitent drug expenditures ($)	
	Low	High
Genetic diseases (including hereditary hypercholesterolemia)	73,431	793,632
Cancer, hemotalogical malignancies	12,897	540,648
Immune system disorders (including Multiple Sclerosis)	12,856	462,384
Cystic Fibrosis	40,546	368,688
Infectious Diseases	13,440	226,800
Cancer, solid tumors	27,144	220,320
Pulmonary Arterial Hypertension	103,464	196,560
Hereditary Angioedema	14,292	98,040
Cancer, supportive care agents	14,183	41,576
Growth hormone deficiency	30,064	38,944
Organ transplant	15,528	38,765
Ophthalmic disorder	13,320	29,256

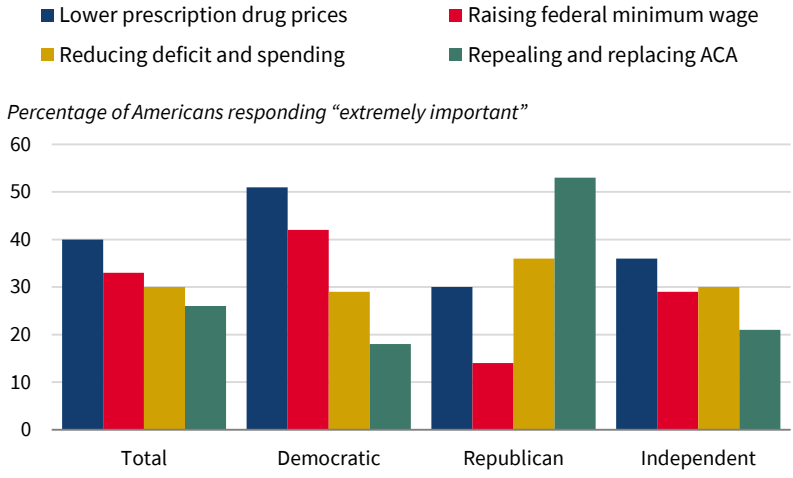
Source: America's Health Insurance Plans, High-Priced Drugs: Estimates of Annual Per-Patient Expenditures for 150 Specialty Medications.
Note: Based upon average wholesale prices as of September 30, 2015; the "Low" entries above represent the medication with the lowest annual per-patient expenditure for the disease state while the "High" entries represent the medication with the greatest annual per-patient expenditure.

that promoting innovation and affordable drugs are conflicting goals. New innovations, however, often provide improved health that was not previously available at any price or obviate the need for more costly care. They thereby lower the effective price of health down to the price of the patented drugs, and later down to the price of generic drugs. Federal policies that affect drug pricing should satisfy two goals. First, domestic drug prices paid by Americans should be reduced. Second, the price of better health in the future should also be reduced by spurring medical innovation. This section considers policy options to simultaneously advance these two seemingly conflicting goals.

Reducing the drug prices that Americans pay means recognizing that many artificially high prices result from government policies that prevent, rather than foster, healthy price competition. Drug prices, for example, are sometimes artificially high due to government regulations that raise prices. This section discusses changes to the Medicare and Medicaid programs that could help lower domestic prices, as well as reforms to the FDA that could encourage more robust price competition.

Preserving incentives for biopharmaceutical innovation can be achieved while still promoting lower prices for Americans. Global financial returns from product development drive innovation. But these returns are unfairly low today. This is because most foreign governments, which are the primary

Figure 6-5. Politico / Harvard Polling on Americans' Top Priorities for Congress, 2017



Sources: Politico / Harvard; Americans' Top Priorities for Congress Through the End of 2017.
Note: Poll of U.S. adults open August 30 to September 3. ACA is the Affordable Care Act.

buyers in their respective pharmaceutical markets, force drug manufacturers to comply with pricing rules to gain market access. Through this leverage, foreign governments are able to set drug prices below those that prevail in the United States and erode the returns to innovation that manufacturers might otherwise see from selling in their markets. Among the OECD's members, the United States accounts for only 34 percent of the OECD's combined GDP (at purchasing power parity), yet the CEA estimates that Americans pay more than 70 percent of patented biopharmaceutical profits (CEA 2018; OECD 2016). In short, pharmaceutical innovators—and foreign governments—around the world rely on America's patients and taxpayers to finance critical research and development.

The objective of government in biopharmaceutical policy is to ensure that the private sector competes and invests in meaningful innovations that lower the price of healthcare, rather than incentivizing market exclusivity and high prices for products. The two goals of reducing American prices and stimulating innovation are consistent, and they can be achieved through a combined strategy that corrects government policies that hinder price competition at home while at the same time limiting free-riding abroad.

Why Americans Pay High Prices for Biopharmaceutical Products, and How to Lower Them

In a well-functioning, competitive market, the price of a good is driven down to the cost of production of the firms producing it. This principle applies to

all markets, including the market for pharmaceutical drugs. However, various factors often preclude competition from driving down prices in U.S. pharmaceutical markets.[2] In the case of patent-protected monopolies for new drugs, the lack of competition and associated higher prices are necessary to preserve incentives for innovation. What has been less emphasized is that government policies and public insurance programs have unintended consequences that prevent, rather than foster, healthy price competition and induce artificially high prices. To promote patient welfare, government policy should induce price competition. However, in the two main Federal insurance programs, Medicaid and Medicare, current policies dampen price competition, thereby artificially raising prices.

Medicaid. Manufacturers that choose to enter the Medicaid Drug Rebate Program are required to offer State Medicaid programs their prescription medications at a price that either includes a minimum rebate or, if lower, the best price the manufacturers offer to any other purchaser. In exchange for these discounted rates, States are then required to cover the manufacturer's drugs in their Medicaid programs. The practice of tying public prices to private ones is partly beneficial, because it allows the private market to set market prices, based on value and competition, that then get imported into the government reimbursement. Although this basic approach of using market prices is sound as currently implemented, the Medicaid Best Price program can create artificially high prices in the private sector under certain conditions. If a large share of a given drug's market is enrolled in Medicaid (e.g., for HIV or mental health drugs), a pharmaceutical firm has an incentive to inflate prices in the private sector so that it can collect higher postrebate prices from its large Medicaid customer base. Similarly, the mandated price discrimination implicit in this program prevents price discounts for lower-income patients in the private sector. Lower-income, private patient populations cannot be charged low prices, because they would jeopardize the Medicaid price. Reforms could help prevent the inflated private sector prices the program induces while at the same time allowing the government to use pricing information from the private sector to determine value (see box 6-5).

Medicare. As the Federal program providing health insurance for the elderly and the disabled, Medicare delivers outpatient drugs administered by health providers through Part B and prescription drugs through Part D. In the Medicare Part B program, drugs are reimbursed based on a 6 percent markup (now 4.3 percent, due to the sequester) above the Average Sales Price (ASP) that manufacturers receive, net of any price discounts. As is true in any cost-plus reimbursement environment, this mutes the incentive for providers to

[2] It should be noted that there are various prices of pharmaceutical drugs, including the manufacturer price, pharmacy sales prices, and patient price. Even within these categories, prices can vary depending on rebates, markups, and insurance coverage. Each price is important, and we focus on these different prices throughout this section.

Box 6-5. The Trump Administration's Improvements to Medicaid

The Trump Administration has proposed a demonstration to allow up to five State Medicaid programs to use more competitive drug formularies and negotiate with drug manufacturers. Meanwhile, patients will be able to appeal for access to nonformulary drugs when medically necessary.

prescribe cheaper drugs and, therefore, for manufacturers to engage in price competition. Though there may be higher costs to providers for prescribing more expensive drugs—such as storing expensive drugs and the lower probability of collecting reimbursement—these costs are routinely handled in other healthcare markets without resorting to distorted cost-plus reimbursements. And though some private payers have responded to this type of perverse incentive problem with alternative reimbursement procedures for drugs delivered in clinics, similar reforms have not been made for the Medicare Part B program (see box 6-6).

Medicare Part D has several provisions that artificially raise costs for patients. The government has previously interpreted the Social Security Act's requirement to include drugs within each therapeutic category and class to mean the inclusion of at least two drugs. This requirement eliminates the ability of Part D sponsors to negotiate for lower prices when there are only two drugs on the market because drug manufacturers know that the CMS must cover both. Changing this requirement could lower prices for taxpayers and patients.

Another problem resulting from Medicare Part D is the inefficient overpricing of low-value drugs. The Social Security Act §1860D-14A stipulates cost-sharing amounts for low-income subsidy enrollees that vary by income and are adjusted by projected program cost growth. The use of formulary tier-based cost sharing is prohibited for low-income enrollees, which eliminates the ability of plan sponsors to price and discount drugs according to their value to patients. Low-income subsidy enrollees and plan sponsors should have incentives to use high-value drugs. The Medicare Payment Advisory Commission (MedPAC 2016) has highlighted this problem by reporting that 17.3 percent of low-income subsidy enrollees are high-cost, compared with just 2.8 percent of other enrollees.

Another problem occurs because the Medicare Part D program breaks payment liability into three phases that incentivize beneficiaries to utilize expensive brand drugs over generics. In the initial phase, beneficiaries are responsible for 25 percent of drug costs up to an initial coverage limit ($3,750), at which point they enter the coverage gap, popularly known as the donut hole. The Coverage Gap Discount Program requires drug manufacturers to provide a 50 percent discount to enrollees on brand name drugs while in the coverage

Box 6-6. The Trump Administration's Improvements to Medicare Part B

To improve Medicare Part B and lower drug prices for patients, the Trump Administration will remove perverse incentives for prescribing higher-priced drugs and instead provide an incentive for doctors to prescribe less expensive drugs, putting competitive pressure on manufacturers to reduce their prices. Thus, the Administration will:

- Provide the Secretary of Health and Human Service with the authority to cover certain drugs in Part D that are currently covered under Part B, where there are savings to be gained through increased price competition.
- End the "gaming" in reporting drug price data that is driving up Part B prices for patients. This is important because not all drug makers are required to report data on all the price concessions they offer, which results in Medicare setting payment rates higher than would otherwise apply under statute. For new drugs that do not have much sales data, the provider's payment will be cut to attenuate the incentives.

gap. The plan sponsor pays 15 percent. Even though the beneficiary pays no more than 35 percent of the price for a brand name drug, 85 percent of the price (35 percent plus the 50 percent discount) is counted as a beneficiary out-of-pocket payment toward reaching the out-of-pocket threshold ($5,000) and entering the catastrophic plan phase. In contrast, beneficiaries pay 44 percent of drug prices for generic drug prices used in the coverage gap and only the amount beneficiaries actually pay counts toward reaching the out-of-pocket threshold and the catastrophic phase. Once in the catastrophic phase, the beneficiary only pays 5 percent, the plan's sponsor pays 15 percent, and Medicare pays 80 percent. With such discounts, beneficiaries may have an incentive to use brand name drugs and reference biologics to get through the coverage gap to the catastrophic phase as quickly as possible, despite less expensive generics and biosimilars being available, because the 50 percent manufacturer discount counts toward the true out-of-pocket costs.

This Part D benefit structure creates perverse incentives for plan sponsors, which often receive large discounts from branded drug manufacturers, to generate formularies that favor high-price, high-rebate branded drugs that speed patients through the early phases of the benefit structure where plans are most liable for costs. Revisions to the benefit structure that eliminate the inclusion of manufacturer discounts from the calculation of beneficiaries' true out-of-pocket costs would eliminate this misaligned incentive. Additionally, increasing plan liability in the catastrophic phase from 15 to 80 percent would provide the appropriate incentives for plans and pharmacy benefit managers to manage beneficiary drug costs throughout the entirety of the benefit (see box 6-7).

Box 6-7. The Trump Administration's Improvements to Medicare Part D

The Medicare Part D program has unintended consequences that have resulted in higher drug prices for consumers. Solutions to overcome these problems include:

- Requiring plans to share some of the drug manufacturers' discounts with patients at the point of sale. The remainder of the discount would help offset plans' costs and help keep premiums low, as has been the case under the current law.
- Allowing plans to manage formularies to negotiate better prices for patients.
- Eliminating copayments on generic drugs for low-income beneficiaries.
- Increasing Part D plan sponsors' liability in the catastrophic phase of coverage.
- Discouraging plan formulary design that speeds patients to the catastrophic coverage phase of the Part D benefit and increases overall spending.

Cutting High Prices Resulting from Price Manipulation

The high prices of many drugs are a result of monopoly power controlling the production of drugs that treat severe diseases with price-insensitive demand. Being the sole supplier allows monopolists to set high prices due to the inelastic demand often associated with more severe or life-threatening diseases. Monopoly pricing in a class is as damaging to patients who cannot afford the drug as having no innovation at all. The problem is not confined to branded, patent-protected drugs. Several recent episodes have illustrated the ability of firms to legally take advantage of their position as the sole source for old but important drugs by rapidly increasing prices. Competitors that want to produce drugs that are off patent still face economic, regulatory, and temporal barriers to market entry.

Unlike most markets, where new products can enter easily and cut prices, in the biopharmaceuticals market, the FDA acts as a strict government gatekeeper for new pharmaceutical products. The evidence is clear that generic drug competition rapidly drives down the cost of drugs. After the 1984 Hatch-Waxman Act went into effect, researchers found that market entry of generic manufacturers resulted in generic prices falling to between 17 and 25 percent of the pre-expiration patented price within 24 months (Caves et al. 1991; Grabowski and Vernon 1992). A more recent study by Berndt and Aitken (2011) estimates that U.S. generic prices fell to 6 percent of patented prices after 24 months of generic entry. Olson and Wendling (2013) account for the endogenous entry of new generic competitors and find even larger decreases in drug prices after two and three competitors enter the market. Yet even generic drugs face barriers to entry. Generic drug applications to the FDA

(known as Abbreviated New Drug Applications, or ANDAs) to make the same drug can cost applicants millions of dollars and can take several years. The FDA reports that it is devoting more resources to lessening review times and this backlog (Woodcock 2016).

A valuable policy option might be changing the criteria for expedited reviews to include new molecular entities that are second or third in a class, or second or third for a given indication for which there are no generics. This would serve as a new pro-competition pathway that would enhance therapeutic price competition by providing expedited entry into monopoly markets. To avoid imposing policies retroactively on the industry, this policy change could be phased in slowly, so the current manufacturers of single-source drugs would retain the value of their efforts to be the first in a given therapeutic space.

In later subsections, we discuss FDA reforms that may enhance faster drug price competition. The FDA Reauthorization Act of 2017 currently authorizes the FDA to designate a drug as a "competitive generic therapy" upon request by an applicant when there is "inadequate generic competition"—that is, when there is no more than one approved abbreviated new drug application (ANDA) for the patented reference product (not including discontinued products).[3] This designation allows for improved communication, advice from the FDA, and a 180-day exclusivity period with no additional ANDA approvals available for other applicants.

Enhancing Price Competition in the Pharmacy Benefit Manager Market

Pricing in the pharmaceutical drug market suffers from high market concentration in the distribution system and a lack of transparency. Pharmacy benefit managers (PBMs) act as buying intermediaries between drug manufacturers and health insurance plans and their beneficiaries. They negotiate rebates off manufacturers' list prices and then pass on some of the benefit to health insurance plans and beneficiaries. However, the PBM market is highly concentrated. Three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves. More than 20 percent of spending on prescription drugs was taken in as profit by the pharmaceutical distribution system (Sood et al. 2017). The size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret. The system encourages manufacturers to set artificially high list prices, which are reduced via manufacturers' rebates but leave uninsured individuals facing high drug prices. Policies to decrease

[3] ANDAs or generic drug applications generally do not have to include preclinical and clinical data to become approved. A generic drug is one that is comparable to a novel drug product in intended use and effectiveness.

concentration in the PBM market and other segments of the supply chain (e.g., wholesalers and pharmacies) can increase competition and further reduce the prices of drugs paid by consumers (Sood et al. 2017).

Raising Innovation Incentives and Decreasing Free-Riding to Reduce the Price of Better Health

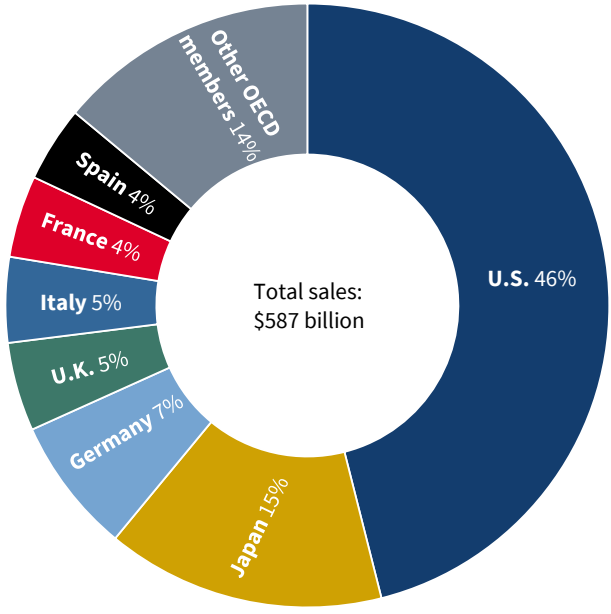
It is important to continue cutting the price of health by encouraging innovation. This can be accomplished by increasing the reward for innovation by limiting inefficient underpricing, both in foreign countries and at home, and by decreasing the cost of R&D through FDA policy.

Limiting underpricing and free riding in foreign countries. Worldwide profits drive innovation incentives, but when worldwide profits are partially determined by centralized pricing by governments, this induces unique free-riding issues (Egan and Philipson 2014). Drug prices in the United States are less publicly financed than in other countries; governments set prices in most foreign countries. It is in each country's interest to have other countries provide the returns to fund innovation through generous reimbursement. Smaller markets that do not significantly affect world returns, such as those in Europe, have an incentive to set low prices without a discernible impact on the flow of new products their citizens enjoy. The problem is that in the aggregate, these free-riding actions of many small countries have a substantial negative impact on worldwide profits. Put simply, providing innovative returns is a global public good problem that leads to classic underprovision through government free-riding.

The United States is the engine of worldwide pharmaceutical innovation, accounting for an estimated 46 percent of OECD patented pharmaceutical sales. Figure 6-6 shows patented pharmaceutical sales by country. The U.S. market for pharmaceuticals is about three times larger than the second-largest country for both total sales (China) and patented sales (Japan). Although the U.S. market provides a disproportionally large share of global pharmaceutical sales, it accounts for an even larger share of world pharmaceutical profits because profit margins are much larger in the United States. In a white paper, "Reforming Biopharmaceuticals at Home and Abroad," the CEA (2018) estimates that the variable profit margins of patented pharmaceuticals sold in the U.S. are 4.1 times higher than in other developed countries.[4] Using the estimated profit margins and sales, the CEA estimates that the share of OECD-patented pharmaceutical profits earned in the United States is about 78 percent, despite the fact that the United States makes up only 34 percent of the OECD's GDP at purchasing power parity (CEA 2018; OECD 2016).

[4] The developed countries included were the United Kingdom, Canada, France, Germany, Italy, Spain, Japan, Brazil, and Mexico.

Figure 6-6. OECD Patented Pharmaceutical Sales, 2016



Sources: U.S. Department of Commerce, Business Monitor International.

In a study using data from the late 1990s, Vernon (2003) found a similar ratio of profit margins for patented pharmaceuticals between the U.S. and other developed nations. Using a different method with novel firm-level data that reflect the margins of the world's top 20 firms for products sold in the United States and the rest of world, Vernon found that drugs sold in the United States had pretax operating profit margins that were, on average, 3.9 times those of the more regulated markets of France, Germany, Italy, Japan, and the United Kingdom. With this estimated profit margin ratio, the CEA estimates that the United States has a 77 percent share of OECD profits. More recently, Goldman and Lakdawalla (2018), using a different methodology, estimated the U.S. share of world profits to be 71 percent (midrange), as opposed to OECD profits. The fact that this world share estimate is only modestly smaller than the OECD share estimated by the CEA may potentially be due to the fact that the OECD countries account for almost all world profits. Taken together, these studies suggest a conservative profit share of the United States among the OECD countries above 70 percent.

Although U.S. consumers and taxpayers finance more than 70 percent of estimated OECD profits on patented biopharmaceuticals during a single year, this does not account for the fact that these drugs are often sold in the United States before they enter other markets. Drug manufacturers usually pursue market access in the United States before other markets due to the higher

Box 6-8. The Trump Administration's Steps to End Global Free-Riding in Biopharmaceuticals

Reforms are needed to address the global free-riding that takes unfair advantage of American innovation, through enhanced trade policy or policies that tie public reimbursements in the United States to prices paid by foreign governments in foreign free-riding countries. To combat this unfair free-riding by foreign markets, the Trump Administration will:

- Analyze the drug prices in the United States compared with those in the other OECD member countries, to better understand the unfair disparity and support the U.S. Trade Representative.
- Make regulatory changes and seek legislative solutions to put American patients first.
- Change the incentives for foreign, developed nations that can afford to pay for novel drugs, to price novel drugs at levels that appropriately reward innovation.

prices in the United States. Danzon, Wang, and Wang (2005) find evidence that the United States gains access to drugs sooner and has earlier drug launches compared with other developed countries. For example, the United States had several times more drug launches than Japan in the 1990s, and those launches that occurred in the United States were on average 19 months earlier. This implies that if the U.S. government pays for the initial years of sales (i.e., those discounted across fewer periods and therefore producing a higher present value), an even larger share of the return on innovation is paid for by the United States.

Because the OECD countries do not face a trade-off between prices and innovation, given that innovation is not substantially affected by their pricing, most OECD nations employ price controls in an attempt to constrain the cost of novel biopharmaceutical products—for example, through cost-effectiveness or reference pricing policies. In essence, in price negotiations with manufacturers, foreign governments with centralized pricing exploit the fact that once a drug is already produced, the firm is always better off selling at a price above the marginal cost of production and making a profit, regardless of how small, than not selling at all. Thus, the foreign government can insist on a price that covers the marginal production cost—but not the far greater sunk costs from years of research and development—and firms will continue to sell to that country (see box 6-8).

Limiting underpricing domestically. Reducing inefficient pricing domestically could help to realign incentives for pharmaceutical firms to innovate. The Medicaid Drug Rebate Program, discussed above, had the unintended consequence of far fewer voluntary discounts from drug manufacturers to certain safety net health providers because the discounted price would become the

Box 6-9. The Trump Administration's Improvements to the 340B Program

The goal of the 340B Drug Pricing Program is to provide affordable pharmaceutical drugs to low-income patients, not to pay economic rents to hospitals. In November 2017, CMS reduced the amount Medicare pays hospitals for drugs acquired through the 340B program. It will lower Medicare beneficiaries' coinsurance and save them an estimated $320 million in 2018 alone (CMS 2017e). The Trump Administration will create more precise eligibility criteria and modify hospitals' payments for drugs acquired through the 340B drug discount program to reward them based on the charity care they provide and to reduce payment if they provide less than 1 percent of their operating expenses for uncompensated care. When facilities do not provide charity care, they should not get a discount for serving the most vulnerable populations in society.

"best price" for all remaining Medicaid patients. Congress created the 340B Drug Pricing Program, in part, to exempt discounts for safety net health providers from the Medicaid best price formula. The 340B Drug Pricing Program requires manufacturers that want to have their drugs covered under Medicaid to sell outpatient drugs at a discount to safety net healthcare providers serving vulnerable populations (Baer 2015).

The 340B program has expanded dramatically in recent years due to loosened eligibility requirements under the ACA (Stencel 2014). Safety net providers and their affiliated sites spent more than $16 billion to purchase 340B drugs in 2016, six times the amount spent in 2005 (Vandervelde and Blalock 2017). Two significant problems have emerged in the 340B program. First, the imprecise eligibility criteria have allowed for significant growth of the program beyond its intended purpose. Second, providers can earn significant profits by qualifying for the program, buying heavily discounted drugs, and then selling them to Medicare and private patients at higher prices. Furthermore, there is no requirement that hospitals use the money they earn from the 340B discounts to benefit low-income patients. These large incentives distort provider organizations' decisions in attempts to qualify for the program, which is simply a form of rent seeking (see box 6-9).

Reducing the cost of innovation through change at the FDA. The fixed costs of developing and bringing a drug to market are typically large compared with the small marginal costs of producing additional pills or doses. Thus, the incentive to innovate is driven by whether expected profits exceed these fixed R&D costs, and FDA policies have a major influence on the size of these fixed costs.

It is widely accepted that the fixed cost of bringing a new, patented drug to market has risen rapidly over time. The Tufts Center for the Study of Drug

Development has estimated that the average pretax industry cost in 2013 dollars per new prescription drug approval (inclusive of failures and capital costs) is about $2.6 billion (DiMasi, Grabowski, and Hansen 2016). Moderating this cost growth requires an understanding of the drug development process.

The most time-intensive steps for developing drugs are clinical trials involving human subjects (80.8 months) and the FDA review (16 months), which has fallen with each reauthorization of the Prescription Drug User Fee Act.[5] Because clinical trials and FDA review are the most time- and resource-intensive steps, reforms that significantly reduce the fixed costs of entry must focus on these areas. Although the FDA's drug review and approval times have generally been shorter than those of regulatory agencies in other countries, over the years the FDA has attempted to speed up the process (Downing et al. 2012; CIRS 2014). In particular, the FDA has four separate programs to expedite the development and approval process for drugs that address an unmet medical need in the treatment of a serious or life-threatening condition. Although these programs have been put in place to speed up market entry for therapeutic drugs, there is still room for improvement—an average time of more than 10 years for the development and entry of new drugs is too long.

Reforms reducing the cost of innovation raise price competition. Drug development reforms could lower the cost of entry and enhance price competition vis-à-vis new innovations. Reforms that lower prices after patents expire are also important. Generic drugs have been highly successful in driving down drug prices—as more generics come on the market, prices drop rapidly, to nearly half after just the second generic introduction. Faster generic drug approvals could decrease the cost of entry, and thus lower drug prices even further. The current approval process for generic drugs is based on the 1984 Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act). Generic drugs go through an abbreviated approval process, in which applicants are only required to prove bioequivalence (showing that the active ingredient is absorbed at the same rate and to the same extent as the patented drug) to an already-approved drug. Tests to prove bioequivalence are much less costly than tests to prove safety and efficacy. In addition, the Hatch-Waxman Act allows applicants to start clinical testing before the patent on the original drug expires. The result was that after the act took effect, the lag between patent expiration and generic entry for top-selling drugs dropped from more than three years to less than three months (CBO 1998). Nevertheless, the time until approval (and associated cost) for most generic drugs is far greater. As several recent, well-publicized episodes have shown—the rapid price increase for epinephrine auto-injectors, for example—some manufacturers are willing to exploit their monopoly positions. The FDA is undertaking needed regulatory actions to streamline and speed up the process

[5] PDUFA, reauthorized in 2017, allowed the FDA to collect fees from manufacturers during fiscal years 2018–22 to fund the new drug approval process.

Box 6-10. The Trump Administration Expedites Drug Approvals

In August 2017, President Trump signed the Food and Drug Administration Reauthorization Act (FDARA) into law, reauthorizing the Generic Drug User Fee Amendments (GDUFA) to empower the FDA to collect user fees for generic drug applications and consistently process applications in a timely manner. In 2017, a record number of generic drugs were approved.

The Trump Administration has prioritized the approval of more generic drugs to bring down the cost of pharmaceuticals (FDA 2018). Last year, the FDA announced the Drug Competition Action Plan (DCAP) to expand access to safe and effective generic drugs. Efforts have focused on three key priorities to encourage generic drug competition: (1) preventing branded companies from keeping generics out of the market, (2) mitigating scientific and regulatory obstacles in gaining approval, and (3) streamlining the generic review process. The FDA has already released guidance that outlines for companies and FDA staff members the specific steps to reduce the number of review cycles and shorten the approval process. Some of the actions that the FDA has taken under the DCAP include:

- New policies to expedite review of ANDAs where there are limited approved generics for a given product.
- Publication of a "List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic," which will receive expedited review if an ANDA for the product is submitted.
- New guidance for industry on submitting ANDAs.
- Product specific guidance to support generic development of small-molecule complex generics.
- Guidance for the industry for evaluating the abuse deterrence of generic solid oral opioid drug products.

President Trump's fiscal year 2019 budget proposal will end so-called first-to-file gaming. When a first-to-file generic application (and therefore one eligible for 180 days of exclusivity) is not yet approved due to application deficiencies, the FDA would be able to tentatively approve a subsequent generic application, which would start the 180-day exclusivity clock, rather than waiting an indefinite period for the first-to-file applicant to fix its application. Triggering the start of this 180-day exclusivity period for first-to-file applicants who "park" their exclusivity would speed the delivery of generic drugs and provide substantial cost savings to American patients.

whereby generics are approved. Inefficient gaming of the regulations that distort the industry away from the intended goals of the regulations of lowering drug prices for patients can be further reduced.

The Trump Administration also supports increasing competition for biologics—complex biological treatments made in living cells—by encouraging the approval of competing biologics, known as biosimilars, that have the

same clinical safety and efficacy as the first FDA-approved biologic. As more biosimilars are approved, it is estimated that the price for these advanced treatments could decrease, saving an estimated $44 billion over 10 years (Mulcahy, Predmore, and Mattke 2014). Unlike conventional and easily replicated small-molecule drugs, biologics and biosimilars are highly sensitive to the living systems in which they are created, requiring significant scientific expertise (Palmer 2013). Biosimilars can take 8 to 10 years and hundreds of millions of dollars to gain approval (FTC 2009); see box 6-10. The FDA approved five new biosimilars in 2017, more than the approvals during the two previous years, which include novel treatments for cancers (FDA 2018).

The Government's Role in Reducing Prices and Stimulating Innovation

The two seemingly inconsistent goals of reducing American prices and stimulating innovation can be achieved only with a combined strategy to reduce high prices at home while at the same time reducing free-riding abroad. The role of government is to ensure that firms invest in meaningful innovations that lower the price of healthcare, rather than provide incentives that dampen competition between firms pursuing innovations. It is also government's role to help solve international problems, such as global free-riding on drug innovation, that harm U.S. citizens. The Administration's policies as outlined in this chapter can lower prices in the United States, foster innovation, and limit foreign free-riding on the U.S. biopharmaceutical industry and American consumers and taxpayers. Preserving the U.S. biopharmaceutical industry and encouraging it to innovate, while making drugs that are more available and affordable for all Americans, is an attainable goal.

Conclusion

A vital role of government is to promote a healthy and productive society. A main premise of the ACA—if not its central premise—was that more insurance would mean better health. For years following the ACA's passage, proponents measured the success of the law by the number of people who were covered by health insurance. Unfortunately, the ACA never expanded coverage as much as anticipated—only about 6 percent of the population gained coverage—and its gains largely came through expanded Medicaid coverage, which gives limited access to care. Moreover, the ACA imposed costly and cumbersome mandates and regulations that raised costs, decreased people's choices, and forced them to buy insurance that they neither wanted nor needed.

The Trump Administration is committed to reducing the harm caused by the ACA by decreasing unnecessary regulations and mandates, and by restoring competition and choice to the insurance markets. Instead of focusing solely on insurance expansion, which the evidence indicates has less

impact on health than commonly believed, the Administration plans to take a more holistic approach by addressing all the determinants of health, including individual behaviors that greatly influence health. Despite the increase in insurance coverage during the last several years, life expectancy in the United States declined in 2015, and again in 2016 (CDC 2016a, 2017a). Such a decrease in life expectancy has not occurred since the early 1960s, suggesting that health behaviors are causing people's health to deteriorate. The poor health and illnesses resulting from these behaviors impose significant economic costs through direct medical spending, premature deaths, and reduced productivity. Effectively addressing these behaviors can improve health, productivity, and economic growth.

The Administration has already taken important steps to address the opioid epidemic that has ravaged our society and led to skyrocketing deaths while the ACA expansion was ongoing. The Administration has declared a public health emergency under the Public Health Service Act and has taken concrete actions to prevent prescription opioid abuse, interdict the supply of illicit opioids, improve access to treatment for those already addicted, and encourage innovative new treatments. Additional government actions and private innovation will be necessary to further address the opioid epidemic and other important problems, such as smoking and the lack of physical activity and poor diets that lead to obesity.

Medical innovations that improve people's health can be expensive initially, but they have the potential to bring down the price of healthcare over time. Yet innovations are unhelpful if people cannot afford them. The President shares the American people's concern over high drug prices. The Administration has laid out a strategy to accomplish the two seemingly inconsistent goals of reducing American drug prices and stimulating innovation by correcting government policies that hinder price competition at home while reducing free-riding abroad.