Worthy

Why are prescription drugs so expensive and what can we do about it?

Ensure that drug prices are tied to actual value and that the discovery and development of new drugs is efficient

PART SEVEN

Introduction

Imagine if you were only allowed to work in one professional field for 10 years. Perhaps you decided to become a teacher or a firefighter or a nurse but could only work in that job and in that field (academia for the teacher, community safety for the firefighter, healthcare for the nurse) for a decade. Then after that, you needed to find a job and make a living in another field altogether. You couldn't just change schools if you were a teacher or go from being a nurse to being a physician's assistant; you'd literally have to go into a completely different line of work.

For some adventurous souls, this might feel invigorating and liberating, but for most of us it would likely be stressful. It would also probably trigger some healthy and unhealthy behaviors.

On the healthy side, it would force us to think hard about the kind of work we like to do, what other possibilities are out there for us, which people we should meet to help find a future new job, and how to develop "marketable skills" for a new future career that we know is coming. On the unhealthy side, we might be tempted to insist on expanded job responsibilities before we are truly ready, act in a more aggressive manner to get a promotion that we don't have time to wait for, job hop frequently to the highest bidder and/or demand higher pay as soon as possible to maximize our income, and minimize or avoid investing time in activities such as mentoring or helping colleagues.

While this is certainly an imperfect metaphor, it hopefully gives you a sense of the life of a pharmaceutical company. Granted, some pharmaceutical companies have other businesses such as distributing over-the-counter drugs, but typically their core business deals with developing new therapeutics, for which competitors are prohibited from copying and selling that therapy for a certain period of time (it ranges depending upon a number of factors including the type of compound but generally is between 10 and 15 years). Under our current system of laws and regulations governing drug development, running a pharmaceutical company is a high-wire act and just like in the metaphor, leads to both positive behavior and behavior that is detrimental to the healthcare system.

So, in this segment, I'm going to:

- Provide a simplistic overview regarding how the system currently works
- Summarize the "good" and the "bad" behaviors the current system elicits
- Summarize the changes we should make

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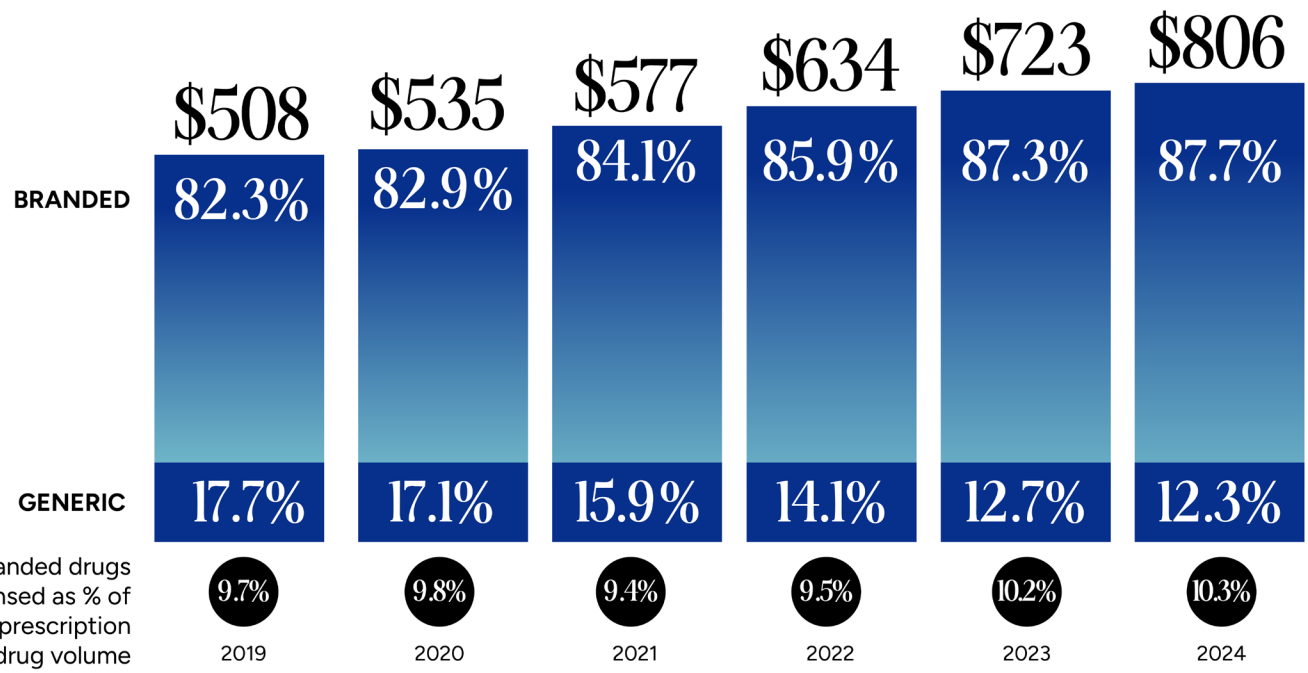
Overview of current system

Drug discovery and development works under a complex system of patents and other rules such as market exclusivity. If you are interested in learning more details on how these work see these links: (FDA, Commonwealth Fund, Congress.gov). To keep things simple and avoid mischaracterizing details, I'm going to focus on drug development, pricing, use, and patent protection. With this in mind, there are a few important things to understand about the current system:

- When a company discovers a new drug, completes all the clinical trials for it, and gets approved by the Food and Drug Administration the company receives a patent and gets a period of time in which no other organizations are allowed to produce and sell that specific "brand" drug. This period varies but typically lasts at least a decade.
- While the patent protects the specific drug discovery a company made for a period of time, it does not prevent other companies from going through their own scientific discovery process to find different therapies that treat the same condition(s). As a result, even with a patent that protects their intellectual property, drug companies sometimes face competitive alternatives, although often after a period of time with limited competition.
- Once the patent expires, other companies can produce and sell the same drug as a "generic" or a "biosimilar". Typically, the introduction of this kind of competition eventually reduces the price of the drug dramatically. As a result, there are usually a small number of branded drugs – and increasingly a small number of "specialty" branded drugs – that drive the vast majority of pharmacy costs. As you can see in the chart below, 10.3% of the prescriptions were for branded drugs in 2024 but they represented 87.7% of the costs.

Annual U.S. branded v. generic drug sales, $B, % of total sales[1]



[1] Total prescription drug spend published year-over-year by AJHP. Split of generics v. branded drug sales and costs based on IQVIA data published by the Association for Accessible Medicines (AAM) SOURCE: AAM, AJHP, AJHP, AJHP, AJHP, AJHP

- The U.S. government and various academic centers fund a great deal of research that often serves as the foundation for drug development.
- Despite this important research support, drug discovery is costly, takes a long time (it often requires a decade of development and clinical trials before coming to market), and has a high failure rate. See these reports for more information (ScienceDirect, DIA Global Forum, Economist).
- Increasingly, smaller research teams and start-up companies are doing a lot of initial drug discovery while the large pharmaceutical companies are acquiring or investing in the most promising of these drugs. This was the case with Sovaldi, the Hepatitis C drug treatment we will highlight later.
- As a result, actually taking a drug to market is almost exclusively financed by private and public for-profit companies which are heavily influenced by the ability to earn a financial return commensurate with the cost and risk of developing a drug.
- It is worthy of note that physicians will sometimes prescribe a drug for a use that it was not approved which is also known as "off label" prescribing.

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How does the current system influence behavior? The good.

Americans and people around the world have benefited from this system in many ways. By offering patent protection for a period of time, we have created the ability to financially reward innovative new therapies which, in turn, has prompted various companies to invest heavily in research and development to pursue them. Even large pharmaceutical companies, which do not always invest much directly in research and development, are constantly scouring the environment to see how research is advancing in other companies and on academic campuses and medical centers — always on the lookout for promising ideas that they could invest in or acquire.

As a result, there have been some inspiring examples of innovative treatments that have saved lives and dramatically improved others. There is no way to provide a comprehensive list but let me provide you with a couple of relatively recent examples.

Hepatitis C is a viral infection that primarily affects the liver. The infection is generally passed through the blood from one person to another, which is why people who use or share intravenous needles are at a particularly high risk for infection. The range of reactions to hepatitis C can vary dramatically from person to person and over time. For example, infected people can go their entire lives without experiencing serious symptoms, whereas others can have a relatively short, manageable acute episode, and still others can eventually develop a serious, lifelong chronic condition that ultimately may require a liver transplant (people in this last category are referred to as having "chronic hepatitis C"). Hepatitis C also has different "genotypes" but for the purpose of keeping this example simple and succinct (not to mention avoiding having a non-doctor get too deep into medical explanations), I won't be talking about those distinctions.

The Centers for Disease Control and Prevention estimated that 2.4 million Americans had hepatitis C in 2020, although given that people can be infected without realizing it, the numbers could be higher. Up until 2013, there were some very expensive drug therapies available that helped treat symptoms of chronic hepatitis C, however, they rarely cured the patient of the disease, often had nasty side effects and usually required long treatment periods, e.g., 6-12 months.

As a result, these drugs were used in a limited fashion, often because patients couldn't tolerate the side effects for such a long period of time. That meant the patients with the most serious and advancing symptoms required ongoing treatment and ultimately a liver transplant. It also meant that the percentage of the people taking the drugs who were eligible to do so was quite low.

But late in the year 2013, all of that changed because Gilead Sciences launched a "direct-acting antiviral" drug called Sovaldi. It and its more advanced successors that were released shortly thereafter provided drug options with much shorter treatment periods (often 3 months), less frequent and more manageable side effects, and ultimately a cure for the disease (in 95% or more cases for some genotypes).

These drugs were truly an amazing innovation and breakthrough! They actually offered a cure for the vast majority of people with a potentially lifelong and life-threatening illness. They also shortened the treatment period and made it far more pleasant for the patient, leading to much higher and more effective usage than any of the other drugs available before.

Another more recent example is glucagon-like peptide-1 (or GLP-1) drugs such as Ozempic, Wegovy, Mounjaro and Zepbound that can treat diabetes and obesity. These drugs had impressive results in clinical trials including weight loss (averaging around 15% of body weight), reduced Hemoglobin A1C (blood sugar) levels, reduced cardiovascular events, and improvements in blood pressure, cholesterol, and other health risks. There were also side effects from the drugs including nausea and vomiting, and the majority of patients gained back the weight that they lost within a year of stopping taking the drug. Also, as these drugs have been made available more broadly, many patients stop taking them within a year due to the costs of the drugs and their side effects and so weight loss appears to be below the averages in the clinical trials (we'll share more on this later). That said, based on real-world, clinical trials and evidence, these drugs hold a great deal of promise to improve health and, in the process, potentially reduce other healthcare costs.

There are certainly other examples of therapeutic innovations, and this is not meant to be an exhaustive list. The point of all this is that because of the system we have today in the United States, pharmaceutical companies feel compelled to aggressively and proactively seek out innovative new therapies which can save lives and help make us healthier. The biotech and pharmacy industry has an impressive track record of doing just that, and so any reform of this system should preserve its pursuit of innovative new therapeutics because we want treatment options that are Worthy of us all.

Of course, we also want treatment options that are sustainably affordable — and that is where our current system is failing us.

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How does the current system influence behavior? The bad. →

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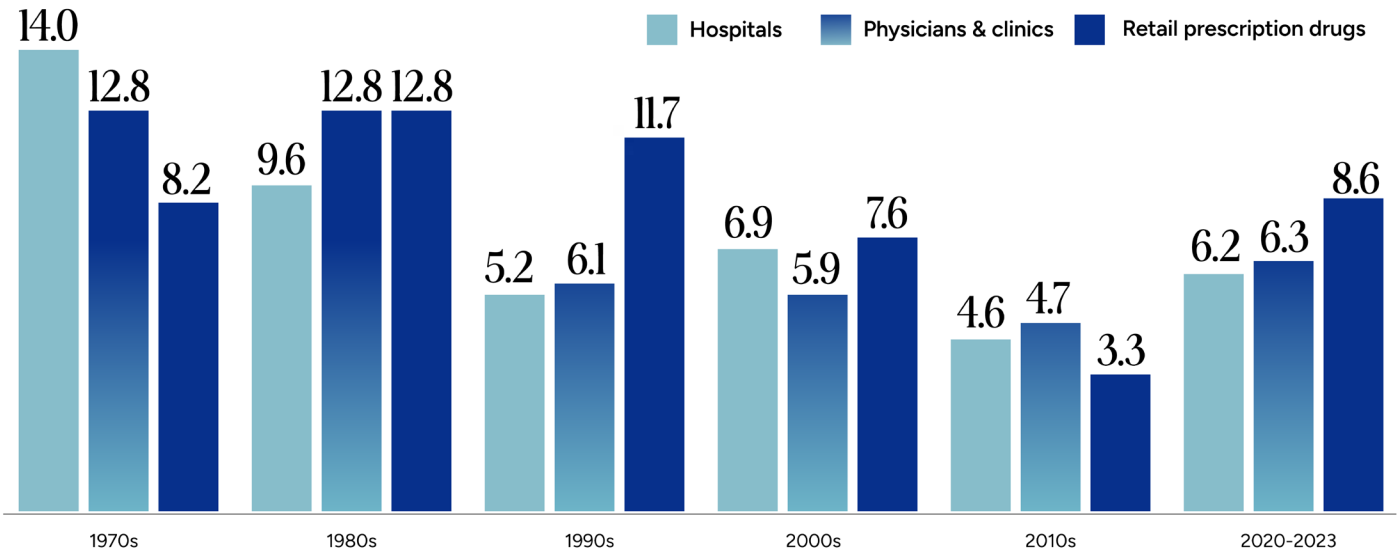
How does the current system influence behavior? The bad.

There is a dark side to this forced system of reinvention. The same desperation that can drive companies to seek new innovations, can also drive them to set prices at "maximum" levels, stifle and/or delay competition, and aggressively try to create demand for their drugs in a manner that increases their profit and the cost of healthcare, but doesn't necessarily improve patients' health. In fact, pharmaceutical costs — particularly brand-name prescription drugs — have been the largest or second largest contributor to higher healthcare costs for at least the last 6 years and are projected to be for the foreseeable future (chart from KFF).

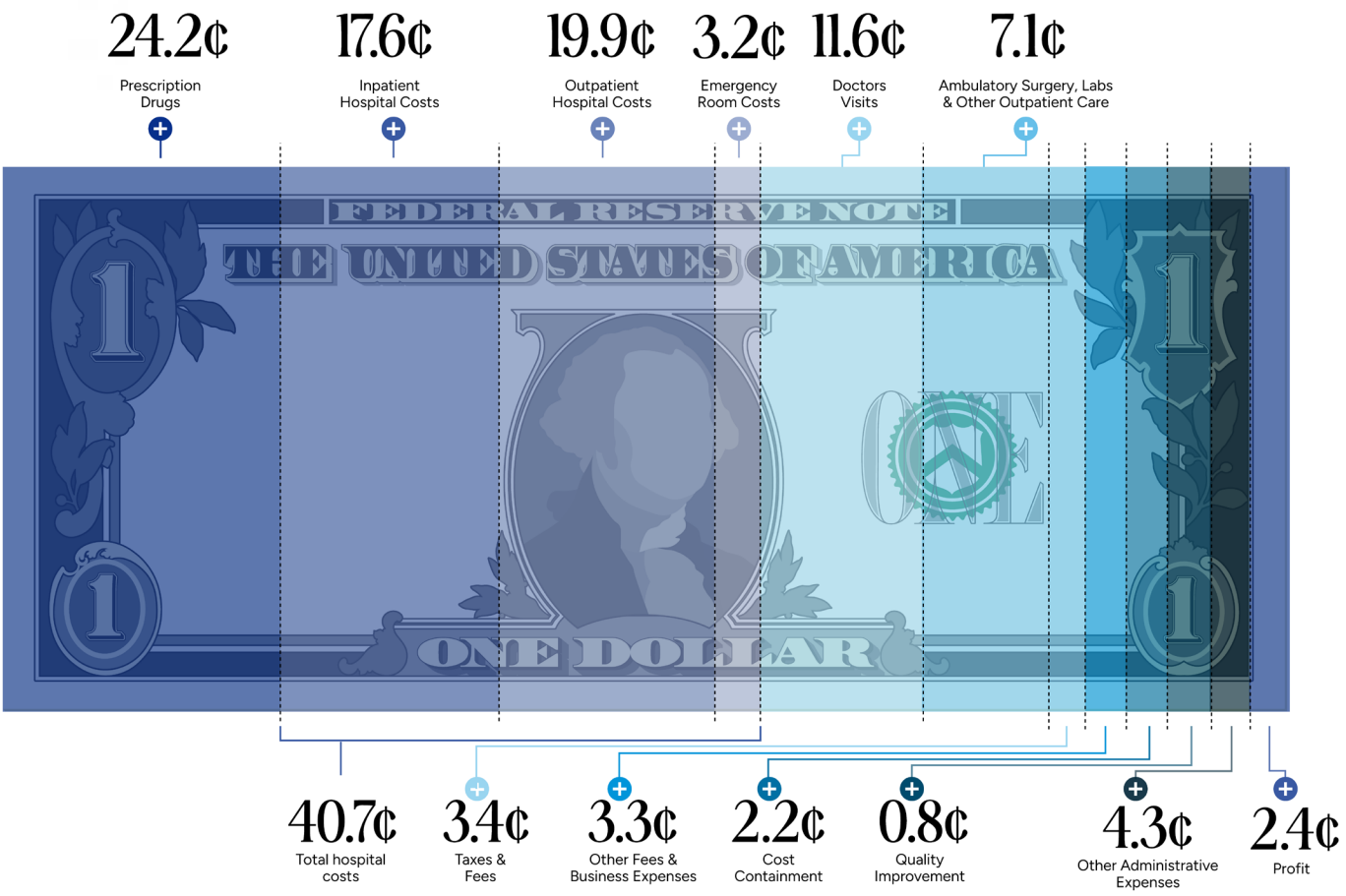
Average annual expenditures growth rate for select service types, 1970-2023



More recent and future pharmaceutical trends are even higher than these historical numbers. In 2024, overall pharmaceutical expenditures in the US grew 10.2% vs. 2023, to $806B. From 2024-2025, overall prescription drug spend was projected by the American Journal of Health-System Pharmacy to increase by an additional 9-11%. This trend will likely continue for the foreseeable future (AJHP).

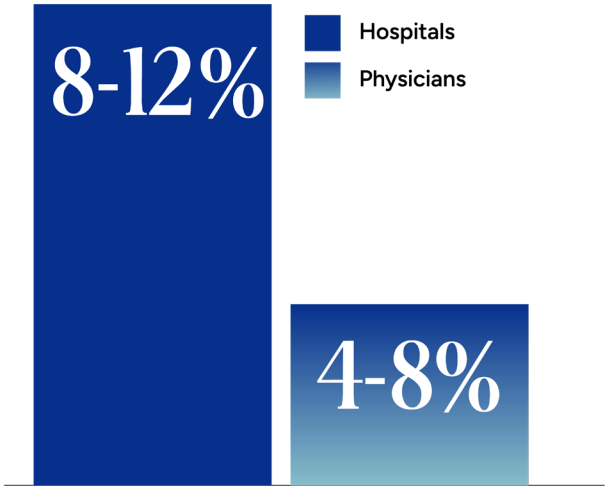
⚠ Nerd Alert!

People that work in the pharmaceutical industry like to say that prescription drugs only represent 9%-11% of healthcare costs in the country and so therefore they are a very small part of the healthcare affordability problem. While this is a common talking point, the fact is that total spending on pharmaceuticals typically represents anywhere from 20-30% of a health plan's total healthcare costs and are trending at about 10% per year. It is worth explaining how some people and organizations significantly understate total spending on prescription medicine.



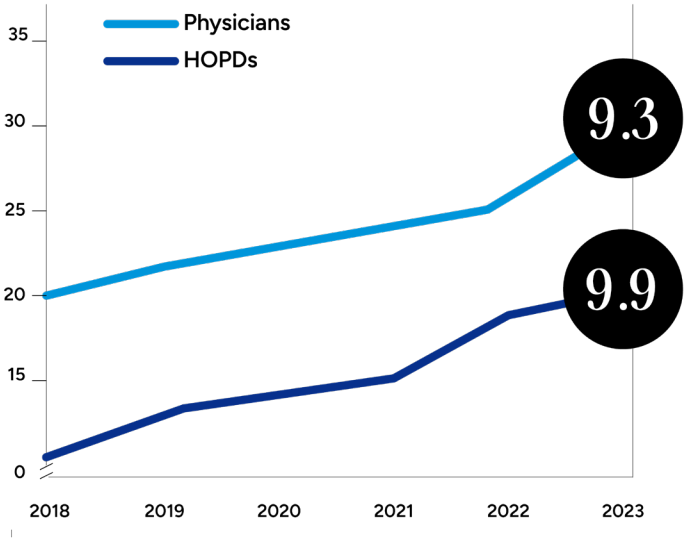
Essentially, the lower number represents only "retail" drugs administered at a pharmacy and excludes spending on "specialty" drugs administered in a hospital or physician setting — which are the most expensive drugs growing at the fastest rate. It is common to aggregate healthcare costs into categories based on who is billing for the cost. For example, when a health plan receives and pays hospital claims, all of those costs generally get categorized as "hospital costs" even though a very large and growing part of those costs is for drugs that the hospitals buy and then bill the payor for reimbursement (usually at a very high profit margin). The same is true for drugs administered by physicians. As you can see in the chart below, a substantial amount of the cost of healthcare that is attributed to "hospital" or "physician" spending is actually drug costs. Specifically, ~8-12% of "hospital" costs and ~4-8% of costs for "physicians" on average are actually for drugs these providers administer to patients.

Average spend on prescription drugs as share of total costs for hospitals and physicians, %, 2024[1]



[1] Other categories of spend include compensation, benefits, supplies, and overhead costs. Figures could vary by individual provider
SOURCE: AHA, MGMA, MedPAC

Medicare spending for Part B drugs provided by physicians and hospital outpatient departments (HOPDs), $B, CAGR, %



⚠ Nerd Alert Complete

California has set a long-term target of keeping annual healthcare costs and health insurance premium increases to an average of 3% per year; in-line with the pace that wages and other prices are increasing. However, the current and forecasted increases in pharmacy costs alone will likely create a 2-3% increase in total healthcare costs to health plans (a 10-11% increase on 24.2% of total healthcare costs shown in the nerd alert represents a 2.4%-2.5% total cost of healthcare increase). If this holds true, it would mean all other healthcare costs, e.g., for physicians, hospitals, would have to either not increase at all or increase at a maximum rate <1% per year in order to make healthcare affordable. Put another way, we need to address pharmacy costs and trends in order to make healthcare affordable.

Let's take a look at each of the potential negative side effects of our current system of pricing drugs, specifically:

- A "maximum" pricing philosophy
- Efforts to stifle or delay prospective competition
- Efforts to drive demand for drugs that do not necessarily improve healthcare for patients

"Maximum" pricing

As an example of "maximum" pricing, let's go back to the examples of Sovaldi and GLP-1 drugs, both amazing innovations in their own rights. While these are just two examples, they are highly illustrative of what I believe is a common approach to pricing new drugs.

It is important to note that these examples are meant to highlight industry-wide behavior rather than call out the specific drug/drug class or the companies that produced them. I chose these drugs as examples for multiple reasons:

- They are truly major medical breakthroughs and represent some of the best of what our pharmaceutical companies do.
- The introduction of these drugs has forced governments and others to make difficult decisions about which patients could actually get access to them.
- In the case of Sovaldi, a Senate committee published the results of an investigation of the pricing of the drug and its successors, which gives a much more detailed view of the internal decision-making process and dialogue than we would usually see.

When Sovaldi was first introduced, its list price was $84,000 for a 12-week treatment, which included taking one pill per day. That made the list price $1,000 per pill.

From Gilead's perspective, the company that put Sovaldi on the market, you can see their rationale. The alternative therapies on the market had similar prices and were far less effective, with far more severe and frequently experienced side effects. Pricing a superior drug at a similar level as the currently available but inferior drugs seemed like it should be considered a good deal.

For the most part, it wasn't seen as a good deal by those who had to pay for it. One of the problems with pricing at that level was that Sovaldi's potential market was nearly all the ~2.4 million potential patients with chronic hepatitis C. Because it effectively created a cure for such a broad spectrum of patients and genotypes, and because it didn't have severe side effects, far more people were likely to use the new drug — particularly in comparison to the current treatments. Therefore, while the price was similar, the total potential cost wasn't similar at all. In fact, if you do some simple math by multiplying the list price at the time of launch ($84,000 per treatment) by the total potential patient population (2.4 million people), you get to a total cost exceeding $200 billion. Just to put that in perspective, the entire country spent $271 billion for all prescription drugs in 2013.

Because people can experience no symptoms for a long time, it is possible that the total prospective patient number was actually higher than this estimate. The costs were more than hypothetical. In 2014, Medicaid spent $1.3 billion treating only about 2.4% of hepatitis C-positive enrollees. The state of Indiana alone spent $40 million treating just 462 people. As a result, when Sovaldi launched, many Medicaid programs restricted coverage, e.g., to patients with advanced liver disease, and while Medicare covered the drug it required high out-of-pocket copayments from patients which made access for some very challenging.

The pricing of Sovaldi prompted a serious outcry from a lot of different sources. It ultimately led to a bipartisan U.S. Senate Committee on Finance investigation of Sovaldi pricing, co-chaired by Senator Ron Wyden, a Democrat from Oregon, and Senator Chuck Grassley, a Republican from Iowa. The investigation took 18 months, reviewed over 20,000 pages of documents, conducted many interviews with experts and analyzed Medicaid data extensively. The committee concluded that Gilead Sciences deliberately set Sovaldi's price at the $1,000 per pill level, with the primary goal of maximizing revenue rather than ensuring affordability or accessibility for patients. Gilead's own internal analyses, which were highlighted in the report, showed that

lower pricing would dramatically increase patient access, but the company chose to price at a higher level anyway.

There were multiple quotes from Gilead executives included in the report, but one sums up the mindset of the company even after they started to get external pressure about their pricing decision. As one Gilead executive vice president put it, "Let's not fold to advocacy pressure in 2014. Let's hold our position whatever competitors do or whatever the headlines."

The study did share that there was a lot of analysis that went into the pricing decision, but it seemed to reflect an attempt to rationalize the highest possible price rather than an objective assessment of the actual value of the drug. In the case of Sovaldi, one of the analytical arguments made was that the drug's price was much less expensive than the cost of a liver transplant. That is absolutely true, however, in 2012 there were approximately 2.4 million people with chronic hepatitis C, and only 415 of them had liver transplants, according to Lippincott, Williams, and Wilkins.

In my experience, these kinds of misleading arguments about how much "savings" occur in other parts of the healthcare system are usually not grounded in solid facts or analysis, and are simply designed to rationalize what the company wants to charge. These companies also tend to incorporate 100% of their calculated value of the drug into the price, despite the fact that there are other factors and costs required for the drug to be effective, including:

- An accurate diagnosis and appropriate prescription by the treating physician
- Timely, appropriate delivery and administration of the drug
- Patient compliance with the drug regimen
- The drug actually working for that particular patient (for nearly all drugs, they have a success rate of less than 100% even when all the conditions above are met)
- The importance of ensuring a substantive portion of the value created should go back to the customer, particularly the federal government whose research grants helped create the knowledge that has supported a lot of drug development

The proprietary "analysis to rationalize a price" approach is ironic given the level of discipline, precision, and objective science — math, chemistry, biology, genetics, and medicine — required to do drug development. The gap between the objective analytical rigor of the research pharmaceutical companies do, as compared to the work done to determine the value and pricing of a drug, is massive.

In the case of Sovaldi, there was an attempt by a nonprofit organization called the Institute for Clinical and Economic Review (ICER) to set a value for Sovaldi. While no methodology or approach is perfect and ICER has been critiqued by many in the pharmacy industry, their methodology was transparent and their team had no financial conflicts of interest. Their conclusion was that instead of being priced at $84,000 per treatment, the total cost of the Sovaldi would need to be $34,000-$42,000 in order to represent good value to the American public.

If you adjust the highest Sovaldi value proposed by ICER and incorporate the factors and costs highlighted above — e.g., the need for a timely and accurate prescription, patient adherence, etc. — then the price of Sovaldi probably should have been between $20,000 and $30,000 in

order to ensure it was priced commensurate with the value it was creating. Priced at this level, Sovaldi and its successors would have created a huge financial return for its investors and likely would have treated a lot more people.

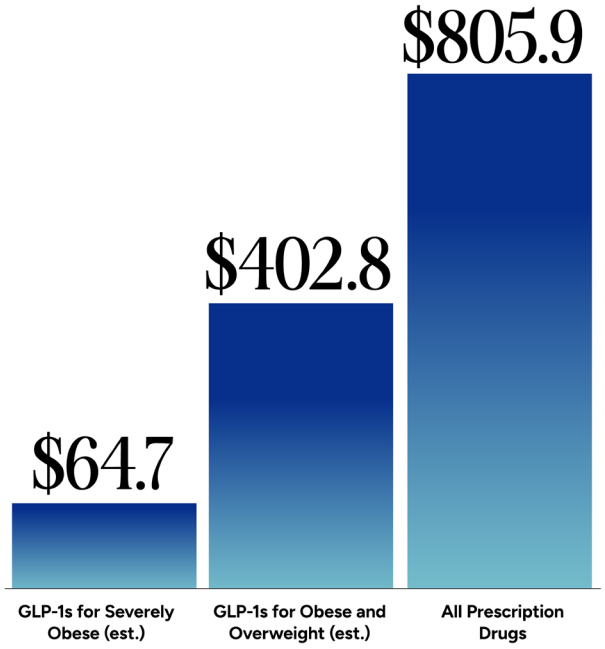
It is also true that while Sovaldi and its successors were under patent protection, other companies such as AbbVie and Merck, created their own direct acting anti-viral drugs to treat Hepatitis C. This prompted Gilead Sciences to offer rebates off their $84,000 list price (effectively lowering the total price/cost). This dynamic is not uncommon and many in the pharmacy industry point to this as competition/ the market working to moderate prices. While it is true that competition moderated the initial price in this case, it is also true that even at a reduced level these drugs were priced well above the ICER estimated value for much if not all of their respective patent periods. In other words, when there is competition, it is not fully ensuring drugs are priced commensurate with their value in all scenarios.

Another more recent example are the GLP-1 drugs mentioned earlier. While they hold a lot of potential to improve health, they are also putting significant pressure on health insurance premiums everywhere — and from the analysis below, it is easy to see why. The Food and Drug Administration has approved these weight-loss drugs for people who are severely obese, which means they have a Body Mass Index of 40 or higher. According to the Centers for Disease Control, this is true for over 22 million Americans. That means that even at the recent price that the federal government negotiated for one of these drugs (Zepbound) of $245 per month, if everyone for whom the drug is approved took it, the resultant healthcare costs would be approximately $65 billion per year. There are an additional 114 million Americans who are obese or overweight and if the Food and Drug Administration ever approved these drugs for all of those individuals, the annual cost at this price would be just over $400 billion annually, or approximately half of the total amount of money spent on all pharmaceuticals in 2024.

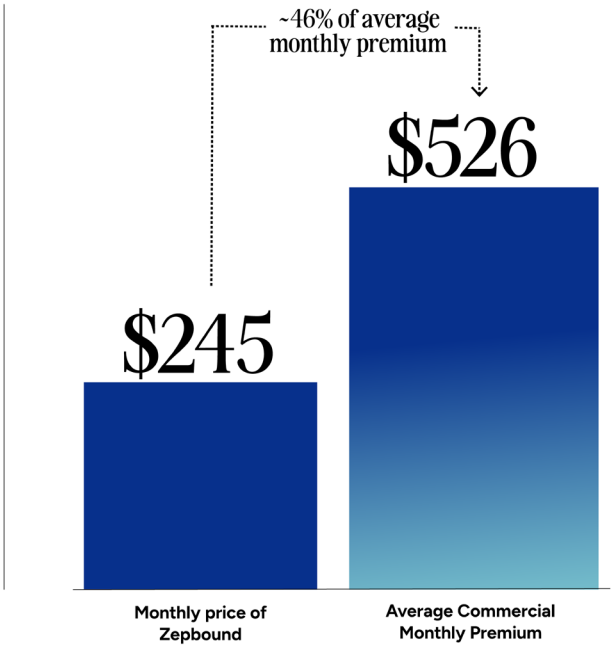
As noted in the earlier description, the majority of patients who stopped taking the drug regained the weight they had lost within one year. This means, based on what we know today, it is expected that individuals will have to continue taking the drug to get the benefits — so this $400 billion has the potential to be a recurring healthcare cost every year.

See the following charts showing the cost of GLP-1s as compared to all prescription drugs and as share of monthly average commercial health insurance premiums:

Annual cost of GLP-1s v. all prescription drug costs, 2024, $B[1]



Monthly price of Zepbound v. average premium, 2024, $[2]



[1] Number of severely obese individuals (~22M) and obese and overweight individuals (~137M) multiplied by $245 per month (monthly price of Zepbound negotiated by federal government) compared to total 2024 prescription drug spend of $805.98 as published by AJHP. [2] Monthly negotiated price of Zepbound ($245 per month) compared to average commercial insured premium collected by health plans per member per month (PMPM). Used average premium (PMPM) for comprehensive hospital and medical plans published by NAIC. SOURCE: CDC, AJHP, AARP, NAIC

While these projections may seem extreme and alarmist, the fact is that only 13 of 50 state Medicaid programs cover GLP-1s for obesity treatment; others have chosen not to cover these drugs at all and/or put severe restrictions on patients' ability to access them. Most large employer firms do not cover GLP-1 drugs for weight loss, and coverage in the Affordable Care Act marketplace plans is limited. Medicare does not cover GLP-1 drugs currently; however, the Trump administration has been pursuing pilot programs and has negotiated deals to lower GLP-1 costs. The rationale across these stakeholders is that the drugs simply are not affordable.

The challenge is that this effectively leads to a two-tiered system. Individuals with the financial means to afford the drug themselves can access it and its potential benefits. While those without the financial means — who make up most people in the United States — either cannot access the drug at all or can do so only with great difficulty due to the restrictions mentioned above. All of this means that even if an individual drug has wonderful potential health benefits, it will not improve the quality of care for the general population unless we can afford it. That is also why you can have innovative breakthroughs in drug therapies, while not improving quality of care for the broader population.

The pricing of GLP-1s suffers from the same flawed logic as described above with Sovaldi. That is, it does not take into account all the other factors required for the drug to deliver value. One example of this is that roughly half of patients that start taking these drugs stop taking them within a year, mainly due to the cost of the drugs as well as their side effects (Cleveland Clinic Reasons to Quitting GLP-1s). In those situations, someone is paying full price for the drug but only getting benefits from it with roughly half the patients.

It is also worth noting that the $245 per month price negotiated by the federal government and cited above is substantially lower than the initial pricing of these drugs and there are now at least two companies, Eli Lilly and Novo Nordisk, who offer versions of them. So, competition is reducing the initial price but not enough to make the drugs affordable.

Finally, it is well documented and much discussed that the prices the United States pays for branded drugs are higher and often much higher than other developed countries. This has led to proposals, such as most favored nations pricing, to try and address that issue. It only seems fair for pricing levels to be much more egalitarian across the developed world than they are today, however, the most fundamental issue when it comes to drug prices in the United States is to ensure they are actually commensurate with the value that the drugs provide.

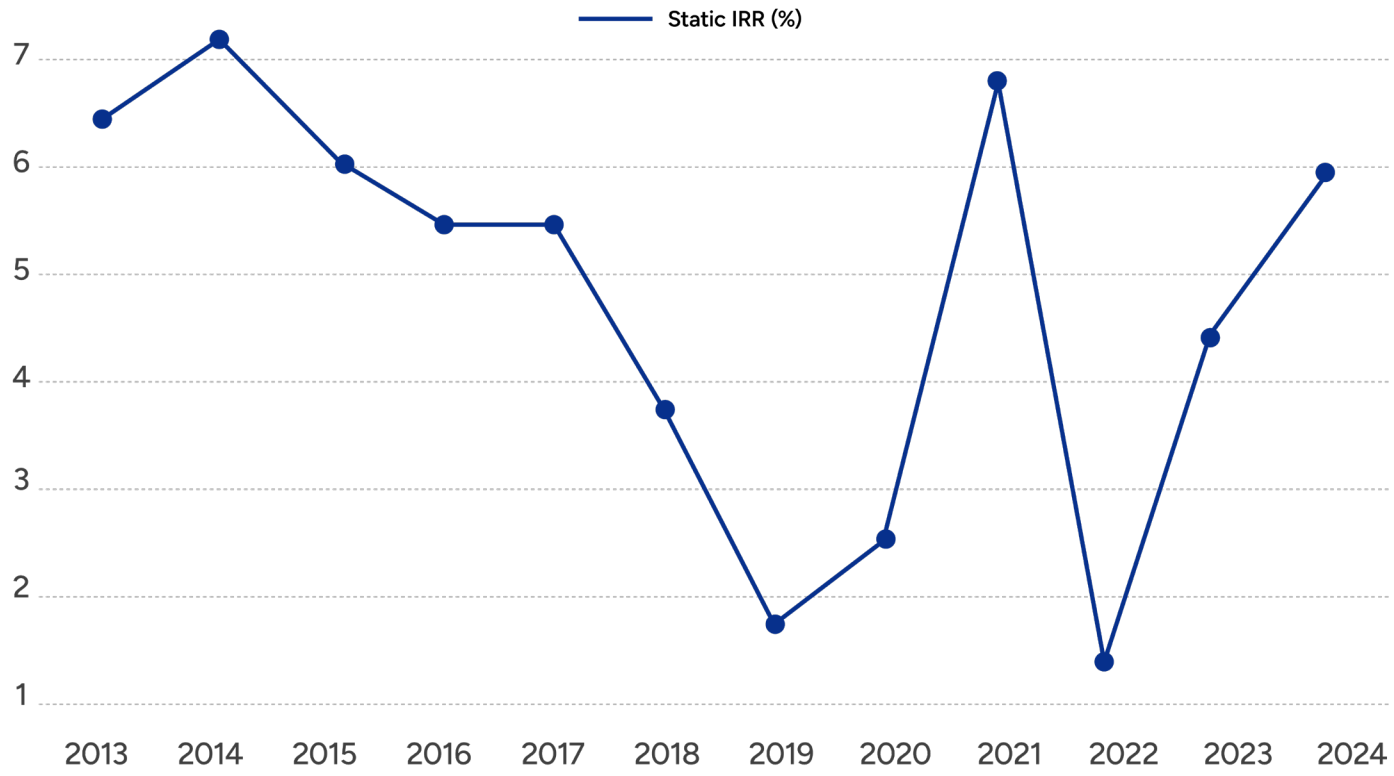
While it may be tempting to just ask pharmaceutical companies to change their pricing behavior and do more to prioritize affordability and access, it is important to remember the points made in the overview about the companies creating these drugs:

- Almost all of them are for-profit organizations that need to attract substantial capital for often risky financial investments, e.g., in 2011 Gilead paid $11 billion for Pharmasset, the company that was developing Sovaldi, before the drug was approved for use and while the prospects were very promising, success was not guaranteed
- They are often publicly traded, and the financial community that covers their performance generally pushes leadership teams to ensure they are not leaving any proverbial money on the table when pricing drugs

- They have probably experienced multiple failed drug development attempts and cannot be sure when the next successful attempt will happen
- They feel the clock ticking on their patent expiration date
- They face uncertainty as to whether reducing the price will actually improve access and increase volume because they don't know whether lowering prices will reduce government and payor restrictions, e.g., not covering the drug, requiring prior authorization requirements and/or high patient copayments
- They understand that drug discovery has been getting more expensive, which is both pressuring financial returns and making them more volatile (see analysis below)

In the chart below from Deloitte's "Be brave, be bold" report, you can see the volatility and inconsistency of the internal rate of return on pharmaceutical research and development (Deloitte).

Internal rate of return of late-stage pipeline, 2013-2024



In other words, all the structural pressures in the current system push pharmaceutical companies and their leadership teams to maximize pricing, and there is no systemic incentive to do otherwise. Therefore, it is not surprising that this is a common practice and will be for the foreseeable future unless we change the system.

Stifle/delay competition

When a drug patent expires, it is often referred to in the industry as a "patent cliff." This is because of a projected sharp drop in revenue for the company, as competitors offering generic or biosimilar alternatives enter the market, typically with much lower prices. Not surprisingly, pharmaceutical manufacturers prefer to avoid such a sudden drop, so they have developed tactics to extend the time after the patent ends, during which they can sell their products at a much higher price than if full-blown competition had started immediately after the expiration. These tactics include:

- "Pay for delay": This is a practice whereby the company with the expiring patent makes direct payments to prospective generic drug manufacturers to delay their entry into the market with competitive alternatives. These deals are not explicitly prohibited by law but can be illegal in some circumstances, and they have come under much heavier antitrust scrutiny over the past decade.

- Patent extensions and thickets: Companies with a soon-to-expire patent will file additional patents related to the drug to preclude competitive generic or biosimilar versions of it coming to market. For example, a company might make minor modifications to the drug's formulation, dosage, or delivery system to obtain new patents or protections. They may then aggressively sue competitors that attempt to enter the market for patent infringement, even after the original patent should have expired. Even if these efforts are ultimately unsuccessful, drug companies can effectively keep prospective competitors at bay for years and/or raise the legal costs and risks for those companies trying to enter the market.

If you are interested in more detail about how pharmaceutical companies use patent thickets, you can read more about them here. In the meantime, here are a few examples of pharmaceutical manufacturers using patent thickets to delay competition and extend their patents:

- AbbVie filed 250+ patents for its rheumatoid arthritis drug Humira, of which 130+ were granted by the US Patent and Trademark Office (USPTO). AbbVie leveraged these patents to extend its intellectual property rights for the drug for 7 years from 2016 – the year of primary patent expiry – to 2023.

- Merck filed 180+ patents for its melanoma drug Keytruda, of which 78+ were granted by United States Patent and Trademark Office (USPTO). Merck used these patents to extend its intellectual property rights for the drug for 8 years from 2028, the expected year of primary patent expiry, to 2036.

- Bristol-Myers Squibb (BMS) / Celgene filed 200+ patents for its multiple myeloma and myelodysplastic syndromes therapy Revlimid, of which 100+ were granted by USPTO. These patents enabled the company to extend its intellectual property rights for the drug for 7 years from 2019, year of patent expiry, to 2026.

- BMS / Pfizer filed 48 patents for Eliquis — used to treat atrial fibrillation and venous thromboembolism — of which 27 were granted by USPTO. These patents enabled the company to extend its intellectual property rights for the drug for 9 years from 2022, year of patent expiry, to 2031.
- There have been several notable examples of pharmacy companies making small tweaks to delivery mechanisms to extend their patents, including:
    - AstraZeneca's Prilosec lost its patent in 2001 but its "new and improved" successor, Nexium, allowed for continued sales with a patented tweak to the same active ingredient.
    - At a lower dose, Pfizer's Viagra doubled as Revatio for pulmonary hypertension and facilitated the company securing fresh patents.
    - Sanofi turned Lantus insulin into Toujeo, a longer-acting version, and helped the company earn continued patent protection on the drug.

Using rebates and fees to maintain market share

We shared the example of Humira in the pharmacy distribution reform segment, whereby a full year after Humira's patent ended, the drug with a list price of nearly $7,000 and a net price of $2,100 had 90% market share as compared to biosimilar alternatives that cost < $600. By paying large rebates and fees to the distribution system, pharmaceutical companies can convince the system to keep prioritizing their drugs over much lower-priced competitive alternatives.

The problem with all of this is that it financially benefits the companies selling the drugs, while hurting the patients who need access to them and the customers who pay for them, including federal and state governments. It does not help the quality of care and, in fact, it probably hurts it in those instances where the cost of the drug becomes a barrier for a patient choosing to get treatment.

Aggressively drive demand

There are multiple ways that pharmaceutical companies attempt to maximize the consumption of their drugs. You may be wondering why this is concerning: Since every other company markets their products to prospective customers, why shouldn't pharmaceutical companies do the same thing?

The reason that the practices described below are concerning is that prescription drugs with a patent are selling powerful, regulated medications in a market that is neither free nor fully competitive. My understanding of competitive markets is somewhat informed by studying Economics in school. My own, perhaps oversimplified, view of a competitive market is that it has many willing buyers, many willing sellers, and a good flow/availability of information such that buyers and sellers promote the overall good of society by acting in their own self-interest. By way of example, when a company is trying to make a living selling a product but its price is higher than most of the other companies selling a similar product and buyers are aware of this, then that company needs to find a way to lower its price and/or offer a distinctive product that is valued more by potential buyers. In either case, the company's pursuit of its own self-interest benefits society by ultimately offering a product that has a lower price and/or greater value.

For the most part, none of these criteria for a competitive market exist with a drug that has patent protection:

- By definition, at least initially, the company is the only one offering that specific drug and so there is one seller. Sometimes other companies use their own discovery process to develop a different drug that can treat the same condition as a competitive alternative, but even in those cases there are typically a very small number of companies offering a product rather than "many."
- The buyers of the drug (Medicare, Medicaid, employers, health insurers) are typically not the users of the drug (the member/patient is the user).
- The users of the drug are not legally allowed to make an independent decision to acquire the drug. A physician or other qualified clinician needs to write a prescription for that to happen.
- As we have seen in the prior section on drug distribution, almost no one can seem to find out what the actual price of a drug is without serious investigation, i.e., there is not clear, easily available information.

As a result, these aggressive tactics to increase demand are not the same as a company trying to sell a product in a truly competitive market, e.g., like the market for cellular service. These tactics have a tendency to increase demand, revenue, and profit for the pharmacy company, and cost of healthcare overall, but not necessarily improve the health of patients.

Let's look at some examples.

Direct-to-consumer advertising

If you use an electronic device, it is almost impossible to avoid seeing advertisements for prescription drugs. Pharmaceutical companies spend billions of dollars on this every year. Interestingly, the United States — and, to a more limited extent, New Zealand — are the only countries in the world that allow direct-to-consumer drug advertising (Harvard Health, 2017).

All other developed countries, e.g., European countries, Canada, Japan, do not allow it mainly because they believe that medical experts, e.g., physicians, should be the primary source of information and guidance when it comes to prescribing such powerful medications. For these countries, there is a worry that direct-to-consumer advertising can lead to increased and potentially inappropriate prescription drug use, as well as confusion and misinterpretation of information by consumers.

Based on the evidence in the United States, they are right to be worried.

- Drug companies benefit from these ads
- Channels for advertising have increased, and the FDA's capacity to enforce drug advertising regulations seems to have substantially weakened

Subsidizing patients (and only patients)

A number of pharmaceutical companies have created financial "patient assistance programs," whereby they offer to pay for most, if not all, of an insured patient's copayment for their drugs. While benefit designs can vary substantially from plan to plan, if a drug is covered, it is common for a health plan to pay more than 75% of the cost of

the drug. For the really expensive drugs, however, even paying for 10% of the cost can make it prohibitively expensive for the patient. So instead of reducing the total price to make the drug more affordable, pharmaceutical companies offer to subsidize just the portion of the payment for the insured members who qualify. If the patient owes 10% of the cost, the drug company covers all the patient's costs — which effectively provides a 10% discount on their drug — but the company gets substantially more volume at 90% of their expected price.

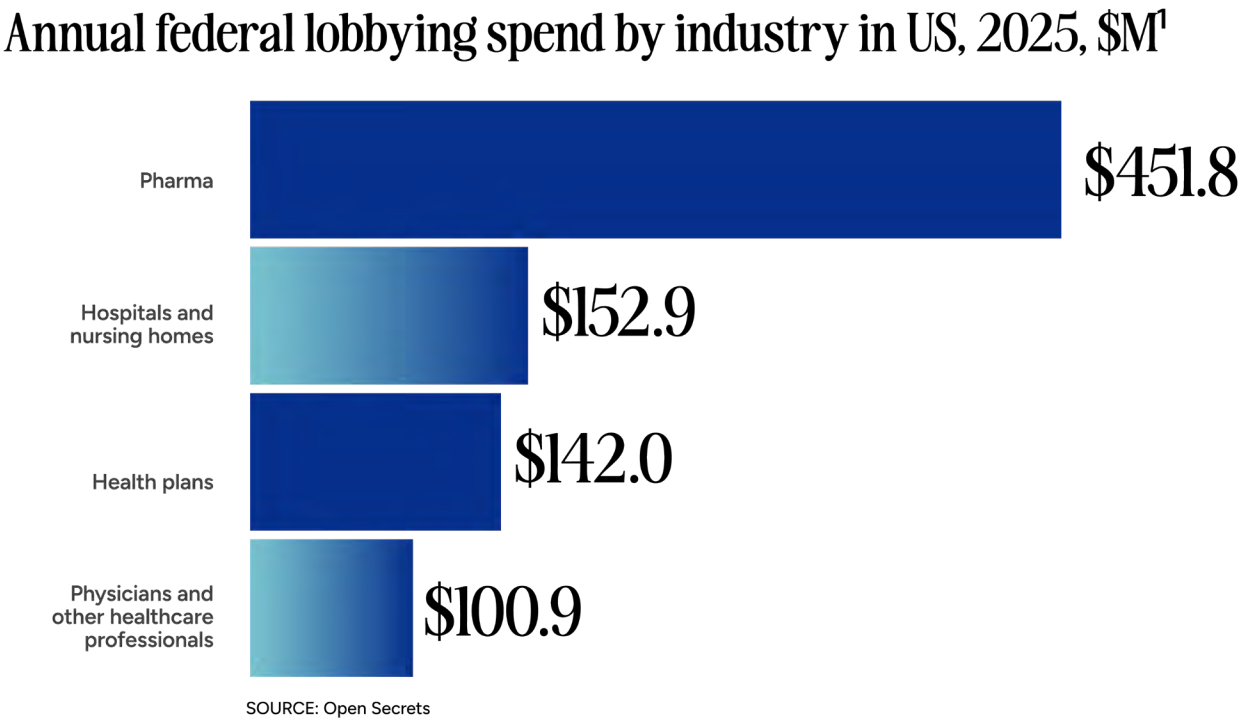
There is an appropriate and healthy debate going on about what the right level of cost sharing is for members to ensure there is appropriate access and use of healthcare services. If everything is free, health services get overused and, for example, emergency rooms can be overrun with patients who don't have to pay anything to visit the emergency room.

On the other hand, copayments that are too high can create a barrier to patients' accessing needed services and medications (PhRMA, JAMA Network). I'm not going to dive into that debate in this segment, however, I will make a proposal about this in a future segment and in the meantime suffice to say that when health plans price their products, they do so assuming that the member will pay for their portion of the bill. Health plans understand that payment will impact the use of services, and so subsidizing patients' copays increases costs and ultimately the price of health insurance. By making a drug available at no cost/free, it can also lead to over-consumption.

Company	Description	Source / Link
Biogen	Offers a program for dimethyl fumarate (a multiple sclerosis drug) that caps copays at $10 per month	MSAA
Dendreon	Covers up to $6,000 of patients' copays, coinsurance, and deductibles for sipuleucel-T (a prostate cancer treatment)	Provenge
Amgen SupportPlus	Offers a copay program for ENBREL	Enbrel
Abbvie	myAbbvie Assist provides copayment assistance and financial support to qualifying patients, including those limited or no coverage and who demonstrate qualifying financial need	Abbvie
Pfizer	Pfizer provides copayment assistance and financial support to eligible patients who are uninsured or underinsured and cannot afford copayments	Pfizer

Lobbying for laws that will increase consumption

Pharmaceutical companies are active lobbyists. In 2025, these companies spent $425M on political contributions and federal and state lobbying efforts — dramatically more than other sectors of the healthcare industry.



There is nothing illegal about lobbying, and the resources cited above are used for a lot of different efforts aimed at influencing federal and state governments. The focus here is on lobbying efforts aimed usually at state governments to increase demand for specific drugs. Often this comes in the form of advocating for laws that prohibit the ability of a payor to require physicians and/or patients to take steps prior to having a drug covered. For example, to approve the use of a drug, payors will sometimes use a process called "step therapy" in which a member must try other, usually more conservative, treatments before being approved for the drug/treatment requested. Pharmaceutical companies will work with other interest groups to advocate for laws that eliminate the ability to use step therapy for their specific drug.

Direct to physician marketing (detailing)

Once a new drug has been developed, it is important to educate those that can prescribe the medicine, namely physicians. Not surprisingly, pharmaceutical companies invest heavily in this practice and much of this can be helpful in ensuring the medical community is aware of new discoveries.

However, when physicians, clinics, and hospitals can also engage in spread pricing or “buy and bill” practices that were described in depth in the previous Worthy segment on the distribution of drugs, this practice can become problematic because it can unintentionally become a sales pitch on how these providers can make more money as opposed to simply sharing clinical information on a new treatment. It’s all the more reason to adopt the changes in the system recommended in our previous segment on how we need to reform the pharmacy distribution system.

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Proposed changes to the system – what we need to eliminate →

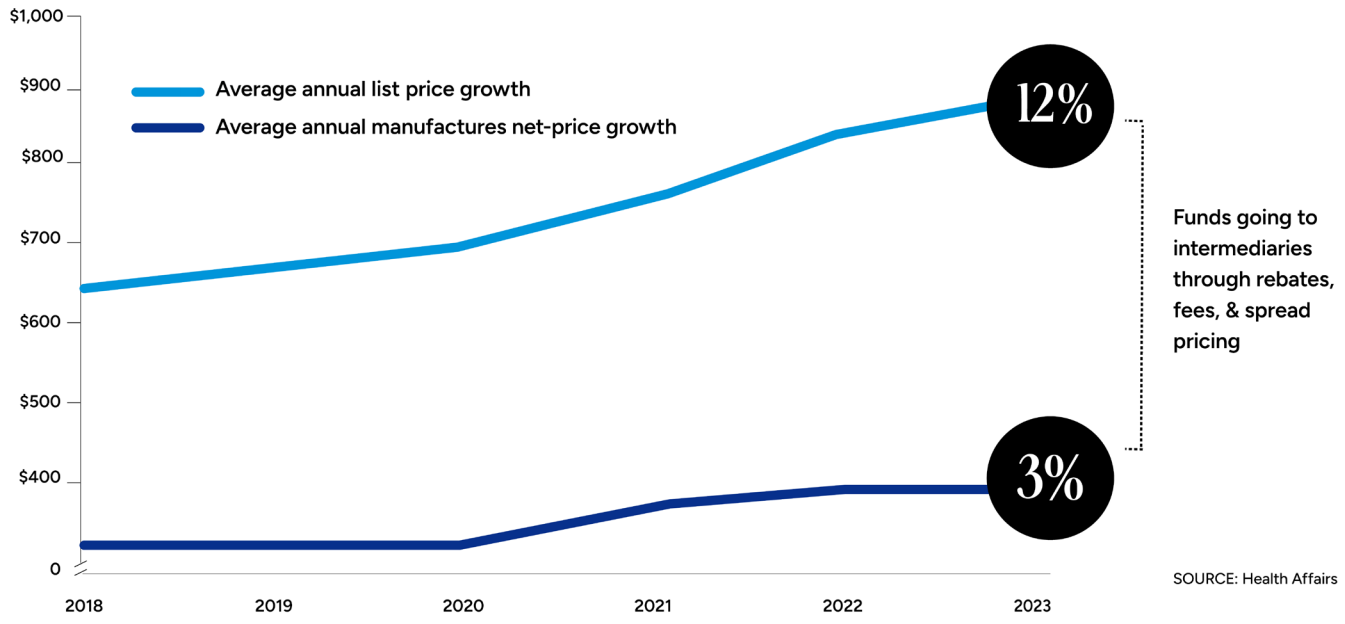
PART SEVEN

Proposed changes to the system – what we need to eliminate

In the context of prescription drugs, care Worthy of our family and friends and sustainably affordable means that we want our loved ones to get the right drug, at the right time, in the right place in the most cost-effective and convenient manner possible. The objective of these proposed changes is to create a system where that happens consistently for everyone.

It is critical to note that we must adopt the proposed changes to the pharmacy distribution system before making the additional changes proposed here (the pharmacy distribution model changes were proposed in an earlier segment and can be accessed here). Otherwise, the pharmacy benefit managers and other intermediaries between the pharmaceutical company and the patient will nullify the potential benefits of these changes by continuing to push the distribution and administration of drugs to those that generate the most profit. The best example of this was in the (Health Affairs Scholar) study cited in the Worthy pharmacy distribution segment that indicated the gap in rate of increase for the "list price" of drugs as compared to the "net price" or the increase price actually collected by the pharmaceutical company (see chart below).

Average annual list-price markup v. manufacturing net-price growth, 2018-2023, $B



SOURCE: Health Affairs

With that said, let's start with addition by subtraction. The first thing we need to do is eliminate the ability of pharmaceutical companies to:

- Extend patents, or create barriers to entry for competitors after patents have expired by creating "patent thickets" and filing lawsuits
- Pay incentives to potential competitors to delay launching alternatives (pay for delay)
- Market drugs directly to consumers
- Offer subsidies or discounts on only the consumer's portion of the cost of the drug

These are pretty simple concepts, but let's walk through each of them one at a time.

Eliminate patent thickets and extensions

The easiest way to do this is to simply say that the period when a drug is protected from market competition starts after the drug is approved by the FDA and that period is fixed. The length of the protection is not dependent on the length of the FDA approval process nor does it matter if the company comes up with some variation in the way the drug is administered, e.g., through a different, more efficient inhaler or in a pill form instead of an injectable form. Once the period of protection from market competition ends for that drug, other competitors can enter the market without delay.

This should give pharmaceutical companies and their investors knowledge and confidence regarding the period of time that they have to generate a return, eliminate patent thickets and extensions, and give companies developing generic and/or biosimilar drugs certainty as to when they can begin offering competitive alternatives. The law should also be clear that there are no exceptions for patent extension. The date is the date.

Eliminate pay for delay

Pass a law that clearly makes it illegal to pay another company not to produce a competitive alternative. While this can potentially get more complicated when payments are made to firms outside the United States, I am confident that those more steeped in international law can help figure out a way to prohibit this inappropriate practice increasing prices/costs that Americans pay for drugs.

Change tax and financial treatment of direct marketing to consumers

Ideally, drug advertising directly to consumers in any form would be prohibited as it is in most of the rest of the world. Pharmaceutical companies should be allowed to market to physicians and other qualified healthcare providers who can prescribe their drugs, but not to the consumers who lack the medical training and knowledge to fully understand how the drugs work and what the risks are (no matter how many potential side effects are mentioned as part of required disclosures).

Given that some have or will argue that such a prohibition is unconstitutional and it is unclear whether such arguments would be successful in court, a safer strategy would be to eliminate the tax deductibility of direct-to-consumer advertising, i.e., for the purposes of calculating income tax, the expense of direct-to-consumer marketing could not be deducted as a standard business expense. In addition, all the annual direct-to-consumer marketing expenditures should be deducted from the "threshold price" recommended in the next section.

Eliminate patient only subsidies

Like any company, pharmaceutical companies can decide to reduce their price. In this proposal, drug companies will only be able to reduce their price to a consumer if they proportionately reduce the total price of the drug to all paying parties. In other words, a pharmaceutical company could not reduce the cost sharing for a drug without a corresponding reduction in the total cost of the drug. Otherwise, drug companies will continue to increase the total cost of their drugs to offset any foregone cost-sharing, which drives up the cost of insurance for everyone.

There are legitimate, charitable organizations that provide financial support to patients to help pay their out-of-pocket health expenses, including premiums and copayments. These organizations should be allowed to continue to do their work. However, as you can see from the links below, there are for-profit companies that have tried to use charitable organizations to further their business interests.

- Lawsuit claims DaVita steered patients to commercial plans to boost profits (2017)
- DaVita faces another probe over ties to kidney care charity (2023)

Therefore, as part of this change, it will be important to ensure that any charity providing this kind of financial support is free of conflicts of interest, including having major donors that have a vested financial interest in financially supporting certain patients or products.

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Proposed changes to the system – what we need to add →

Proposed changes to the system – what we need to add

We need to do more than just subtract from our current environment. There are multiple steps we should add to the current system of developing and pricing pharmaceuticals. Specifically, we should:

- Require all new drugs with a potential cost above 1% of annual national pharmacy costs (which would be a little less than $1 billion per year at current cost levels) and/or >$1 million per patient per year to go through an external, objective, qualified third-party review, also known as a "Health Technology Assessment." That review would establish a threshold price that can be charged for that drug in order to maintain patent protection and ensure unfettered patient access to the drug.
- Develop a process to objectively and accurately track, using real-world data, the impact individual drugs actually have on the quality of health and costs, and adjust the threshold price described above in accordance with this performance.
- Create new processes to improve the speed and efficiency of drug discovery.

Once again, we'll expand on these one at a time.

Set a threshold price and provide powerful financial incentives to price within it

This proposal would require an objective third-party Health Technology Assessment process to set a "threshold price" for any drug that has the potential to increase the total cost of drugs nationally by 1% or more (at 2025 levels that would be ~$900 million in annual sales) or cost more than $1 million per patient per year. To be clear, this is highly complex work and requires subjective judgment and assumptions that should be rigorously and transparently debated, e.g., how much should we value a drug that typically extends life by 3 months? There are also many examples of countries and organizations doing this type of work that have not all garnered the trust of the industry, e.g., in some cases they may be perceived by some as simply a tool to rationalize a price rather than a genuine attempt to measure value. Therefore, setting up this process will not be easy and it may make sense to have more than one qualified organization do the work and find an appropriate way to triangulate their work to reach a conclusion. Whatever the final process is, the organization(s) that do this work should meet some key criteria, specifically, any organization doing this work should:

- Be a nonprofit organization with no financial incentives tied to the outcome

- Have no organizational or individual employee conflicts of interest
- Have a staff of qualified people who are educated and skilled at doing sophisticated health analytics
- Foment trust from everyone (see more on this below)

For the organization(s) that do this work, the process has to be open, transparent, and build trust with the public, government agencies, and all the major players in the industry. That does not mean that everyone will agree with the conclusions of the work, but everyone has to be confident that the analysis was done consistently with a clear, credible methodology and using appropriate data and methods.
To that end, the third-party process must make publicly available its:

- Methodology for determining a threshold price
- Data and methods used in the analysis
- Key assumptions that have the biggest impact on the threshold price
- Detailed approach so that others can replicate their work

The work also has to be completed in a timely, efficient manner, and give the public and key industry players the opportunity to provide feedback before the analysis is finalized. The methodology must take into account the value that people and entities other than the pharmaceutical company add to the process, e.g., provide an accurate diagnosis, help the patient stay in compliance, and recognize that a prescribed drug has a positive impact less than 100% of the time.

To facilitate all of this, the pharmaceutical company whose drug is being assessed must provide timely, accurate and comprehensive data to the third party doing the work.

Once the third-party work is completed, a "threshold price" will be established for the drug in question. The next step is to create powerful financial incentives for the pharmaceutical companies to price at or below that threshold price as this will ensure that new drugs are priced commensurate with their value. How much of an incentive and whether the incentive should be positive (a "carrot") or negative (a "stick") or both can certainly be debated. As I've reflected on my experience in the industry, behavior is most likely to change when there are both big positive and big negative potential financial consequences.

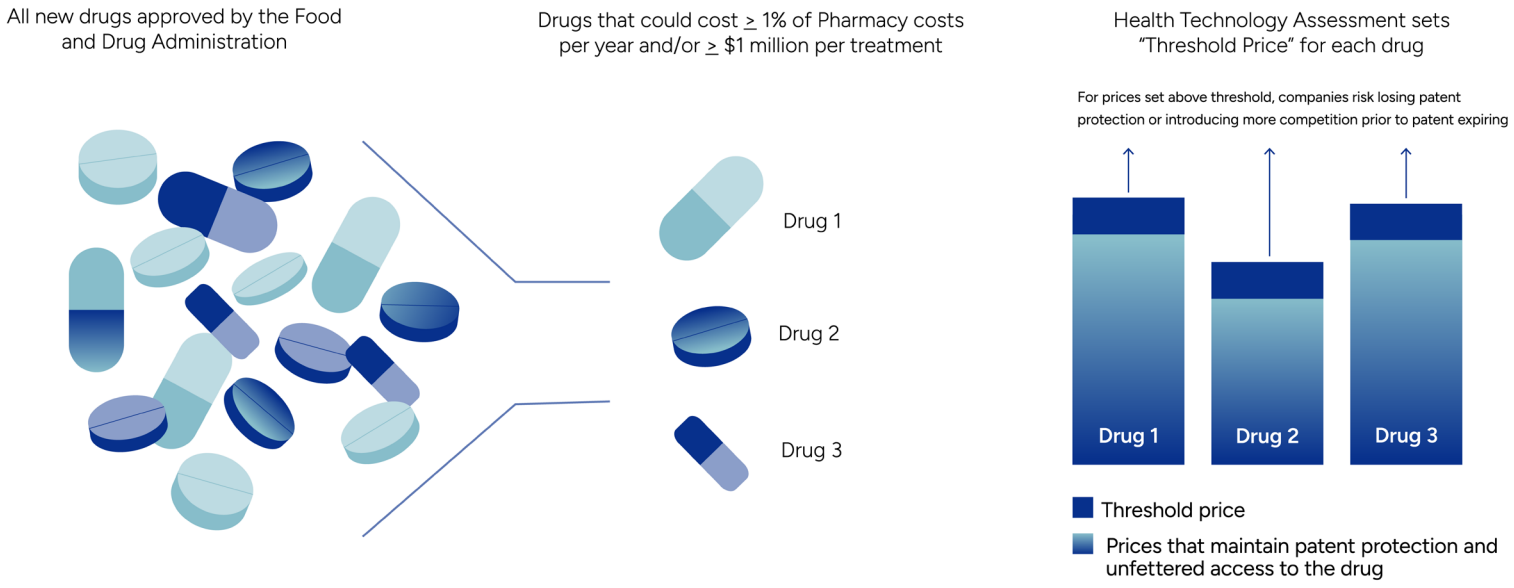
Therefore, what I'm proposing is that the pharmaceutical company can price the drug at any level that they want. However, if they price below the "threshold price", then any time their drug is prescribed for its FDA approved indications, it will be made available to Medicare, Medicaid, and commercial patients without restrictions. In other words, payors cannot keep it off their formulary, subject it to prior authorization, or charge unusually high copayments for that particular drug. Since it has gone through a rigorous objective process and been determined to deliver value commensurate with that price, we should ensure it is available for the indications/conditions that it was approved to treat. This, combined with the known, fixed patent period described earlier, should create a strong positive financial incentive for pharmaceutical companies to set their prices below the threshold level.

While incentives should be helpful in getting pharmaceutical companies to price at a more reasonable level, there also should be strong disincentives for these companies to continue pricing at whatever price they choose. The policy levers for not following the value-based price could range from the immediate surrender of patent protection to giving the government some ability to invite competition on a more limited basis depending on how far the drug diverges from the value-based price. Whatever the policy, we need a strong stick to create a meaningful financial incentive not to exceed the threshold.

While figuring out the value a new drug brings to the world is far from a perfect science and can be a distasteful process for some, it is something we can and need to do as a society, as it is the best way to ensure that the pricing of new, innovative therapies is both rewarded and affordable. We need to encourage innovation by financially rewarding it. At the same time, pharmaceutical companies must be required to price drugs at a level society can afford if they want to have their intellectual property rights protected.

I've attempted to illustrate this process in the chart below.

Process for Setting Threshold Price



Given the crucial importance of the Health Technology Assessment work and how technically complex it is, the ideal scenario would be if the healthcare industry worked together to establish this process. However, if it doesn't happen via industry initiative, then it should be established via a new law.

Develop a process to objectively track performance

While the third-party organization(s) that develops a threshold price do not have to be the organization(s) that track(s) actual performance, they probably *should* be the same, as it would be much more efficient. Whichever organization(s) do the work, they should follow the same standards described above to develop a level of public and industry trust in their work.

Ultimately, we will be asking the third-party organization(s) to track the actual performance of the drugs subject to the threshold price requirement with updates at least annually. When setting the threshold price, certain assumptions were made, e.g., what percentage of patients will have a positive health impact when taking the drug, what benefits they will have after taking the drug, and how much other healthcare costs will be reduced as a result of taking the drug. The point of this work is to track what actually happens in comparison to those assumptions. Is the drug working roughly as expected? Better? Worse?

If the actual performance over an extended period of time with sufficient data is significantly different than that was projected when setting the threshold price, then the threshold price can be revisited (higher or lower). Maintaining this analysis over time provides the industry and the public an objective, credible perspective on the actual impact of a drug. It also uses this work to feed a process for potential pricing changes, ensuring that the value of a drug stays tethered to its price. It also provides pharmacy companies plenty of motivation to ensure their new drugs deliver value. As a result, it maintains the benefits described above over time.

Make drug development more efficient

Developing new drugs takes a long time and costs a lot of money. While some of that cost is unavoidable, both the time and the cost could be reduced through coordinated industry efforts that are much more likely to happen if the reforms described above are adopted. Doing so creates the possibility of offering drugs at a lower price while still generating financial returns that make investing in drug discovery worthwhile.

For example, pharmaceutical and biotech companies are already using Artificial Intelligence (AI) to help them more rapidly and efficiently find promising new therapies and potentially increase the percentage of those pursued that end up going to market. If we appropriately allow access to larger data sets (more on that below), AI tools could increase the speed and improve the hit rate even more.

Conducting human clinical trials is one of the last steps a drug has to go through to be approved. While there are various steps in this process, it usually requires a large number of patients in order to provide substantial evidence of effectiveness. By mandating the creation of comprehensive, real-time digital health records for every American (as recommended in the "Digitize, Simplify, and Automate" segment), there will be a rich patient data set. With the appropriate safeguards to ensure consumer consent, privacy and security,

this information could be aggregated and used to track the actual experience of a large volume of randomly selected patients with a specific condition. This could improve the efficiency of finding patients by:

- Reducing the cost of recruiting patients for clinical trials by identifying a large group that could be offered the opportunity to participate
- More efficiently establish a comparison group
- Facilitating some phases of clinical trials to be run in parallel rather than in sequence
- Support finding promising areas of exploration for new drugs faster and more efficiently

It is important to note that this data sharing would have to be compliant with all applicable privacy and security regulations, and that no private company should be able to charge for the data, other than covering modest and reasonable administrative costs for providing it. Consumers should be able to get reimbursed for their data as they sometimes are for clinical trials today. The rules around the sharing and use of these data for research purposes and enforcement of those rules could be managed by a federal government agency or a non-profit, charitable organization with appropriate government oversight.

That said, there is a substantial opportunity for the industry to work together to make drug discovery faster and more efficient. This is just one example, and those who do drug discovery for a living certainly have a lot more ideas as to how to improve the speed and efficiency of the process. The point is that if we can change the rules around pricing drugs to ensure they are priced commensurate with their value, then everyone in our industry and in our country should want to support faster, better clinical innovations, including new drug discovery.

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Conclusion and summary →

PART SEVEN

Conclusion and summary

We have all witnessed some amazing, life-changing innovations from the companies that discover new drugs — and we want them to keep going. If we are going to have a healthcare system that is Worthy of us all and sustainably affordable then we want to have hope that there could be cures for some of the most debilitating and deadly illnesses out there. We want to believe that the length and quality of life of our loved ones won't be cut painfully short.

We have also watched pharmacy costs grow faster than any other healthcare costs over the past three years (2021-2024), with no end in sight for these unsustainable trends. Prescription drugs along with hospital costs are the biggest contributor to the rapidly rising cost of healthcare. Some pharmacy prices are so high that they are creating a two-tiered system where only the people with the financial means can access them.

So, we need to discover the power of **"and"** when it comes to our system of pricing drugs. We need to be able to price drugs that provide financial incentives to support continued drug discovery **and** ensure those drugs are affordable.

Fortunately, that is possible if we:

- First, adopt all of the recommendations described in an earlier segment to change the pharmacy distribution system
- Eliminate current practices that add to cost but not necessarily to quality, including stopping the ability to:
  - Pay incentives to potential competitors to delay launching alternatives (pay for delay)
  - Extend patents, or create barriers to entry for competitors after patents have expired by creating "patent thickets" and filing lawsuits
  - Market drugs directly to consumers on a tax and financially advantaged basis
  - Offer subsidies or discounts on only the consumer's portion of the cost of the drug
- Establishing a clear, fixed period of patent protection for new drugs

- Require all new drugs with a potential cost above a specific cost threshold to go through an external, objective, qualified third-party review (a "Health Technology Assessment") to set a threshold price with substantial financial incentives attached to pricing below that level and substantial disincentives to price above it
- Develop a process to objectively and accurately track the actual performance of new drugs
- Make the process of drug discovery more efficient

All of this should help lead to a much better system of developing, pricing and distributing drugs by:

- Ensuring that new drugs are priced in a way that is directly tied to their actual value
- Eliminating practices that add a lot of cost to healthcare but do little or nothing to improve the quality of health
- Making patent periods highly consistent and predictable for everyone
- Tracking the actual impact/benefit a drug has after it has been approved
- Making the discovery and development of new, innovative drugs more efficient and effective

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