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Chairman Alexander, Ranking Member Murray and members of the HELP Committee, my name is Gerard Anderson. I am a professor at Johns Hopkins Schools of Public Health and Medicine and Director of the Johns Hopkins Center For Hospital Finance And Management.

This summer, I will have the opportunity to teach our 250 entering MPH students a course on public health policy, and Senator Barbara Mikulski will be giving them a lecture based on her years of experience on the HELP committee.

I do not receive any financial support from pharmaceutical companies; entities involved in the pharmaceutical supply chain, or health insurers. I am also not testifying on behalf of Johns Hopkins University, but in my role as a professor at Johns Hopkins University.
Today, I will cover three topics.

First, my main concern about high drug prices is that they are limiting access to essential drugs. Innovation is wonderful, but people need to be able to afford the innovative drugs. I begin by showing how high drug prices are affecting access to care. I will focus on four areas where people are having the greatest difficulty accessing drugs.

1. Patients with chronic diseases who cannot afford all of their medicines.
2. Patients prescribed very expensive specialty drugs.
3. Patients prescribed off patent drugs whose prices have recently skyrocketed due to a lack of competition.
4. Patients on public programs where the public program cannot afford to purchase the drug**.**

Second, I will attempt to summarize how drug prices are set and how this process can affect patients' access to these medications.

Third, I briefly present a series of recommendations for increasing the level of price competition, revising regulations and legislation, lowering pharmaceutical prices, and improving patients' access to essential drugs, while still providing healthy returns and incentives for innovation.

How High Drug Prices Affects Access to Care

While many patients have some level of difficulty paying for their drugs, patients taking a large number of drugs or very expensive drugs face an even greater health challenge.

Almost half of all Americans have one or more chronic conditions. Perhaps less well known is that one-quarter of all Americans have multiple chronic conditions, and there are about five million Medicare beneficiaries with five or more chronic conditions. Many of these chronic conditions require people to take multiple drugs, and having access to the drugs to treat these conditions is critical for patients to remain healthy.

The problem is that many people taking these drugs cannot afford to fill their prescriptions. As a result, they are forced to make choices between paying the rent, purchasing food, caring for their children and being able to afford the drugs that will keep their chronic illnesses from becoming even worse. A December 2016 Kaiser Family Foundation poll found that one in five Americans did not fill a prescription last year because of cost and one in six Americans cut pills in half or skip doses in the prior year. This is rationing based on price.

I am working with an organization called Patients for Affordable Drugs, an organization that has been collecting stories from over 7000 people who are having difficulty paying their prescription drug bills. Its founder, David Mitchell, told me that the most challenging stories that he gets every day are from people with chronic conditions that cannot afford to purchase their drugs or need to split pills or skip doses in order to have the prescription last longer. High drug prices are impeding their access to essential medicines that directly affects their health.

A woman from Schenectady, NY wrote him: "I am a 53 year old diabetes patient who was diagnosed with bipolar disorder. I have also suffered 8 strokes in the last 20 years. As I've gotten older, controlling my blood sugar has become harder and harder. I had never had a problem paying for my daily medications until a year and a half ago. The diabetes supply that I need are [she lists five drugs] and other supplies such as a blood meter, needles, test strips, etc. Combine that with the costs of the other 10 drugs I take to control my other medical issues, co-payments, [and] hospital tests needed; I am unable to afford these increasing monthly costs. Under my Part D coverage with Medicare and Humana, my monthly supply of these drugs will cost me approximately $1,700 monthly." She is one of the millions of patients who are unable to afford drugs to treat chronic conditions in spite of having health insurance coverage.

Other patients struggle to afford their treatment because they have been prescribed an extremely expensive specialty drug. Recently, a number of very effective new drugs have entered the market offering complete cures or ways to maintain a high level of functioning. These are the kinds of innovations that will improve health status and increase life expectancy. The problem is that many of these drugs are so expensive that most people cannot afford them.

One of my colleagues at Johns Hopkins who treats babies with genetic neuromuscular defects was thrilled when he learned that the FDA had approved the first drug to help these babies. The drug, a new molecular entity, essentially repairs the genetic defect and will allow the baby to live a normal life. The treatment is only truly effective if it is given immediately following birth before the generic defect leads to muscular deterioration. A month later, the doctor was mortified to learn that the drug company set the price at $750,000 for the first year of treatment, and $375,000 per year after that for the rest of the child's life. Who wants to hear that your newborn has a genetic defect and then learn that your young family will need to raise $750,000 in the next two weeks in order for your infant to progress normally? If the insurance company initially denies the payment, then the appeal will almost always require more than two weeks. It is hard to imagine the stress that young families feel when faced with this situation.

The Senate Finance Committee conducted a study of the pricing of one of these specialty drugs. Gilead was the first drug company to develop a cure for hepatitis C. This was a major clinical innovation offering a cure for an infectious disease. Hepatitis C is the infectious disease responsible for the greatest number of deaths in the United States every year – even more than HIV/AIDS. However, the drug company set a price that few could afford, and Gilead did this knowing that not every one with hepatitis C would be able to afford the drug. Let me simply quote one line from the executive summary of the Senate Finance Committee's report: "Gilead's own documents and correspondence show its pricing strategy was focused on maximizing revenue —even as the company's analysis showed a lower price would allow more patients to be treated."

While we do not have exact numbers of the percent of people with hepatitis C that have been treated, the best estimate is that less than 20% of people with hepatitis C have been treated for a potentially fatal, but curable infectious disease. Even after the drug has been on the market for three years and two additional competitors have entered the market, still less than 20% of hepatitis C patients have received treatment.

Apparently, simply having competition for branded drugs is not sufficient to bring the price down to a level that most people can afford. The United States should have prices that allow everyone to have access to these life saving drugs. While we need innovation, we also need access and high drug prices set by the drug companies should not ration access.

The Kaiser Family Foundation conducted a study of Medicare beneficiary cost sharing for specialty drugs. For Medicare beneficiaries with Part D coverage, out-of- pocket costs averaged $7000 for drugs to treat hepatitis C, $6000 for drugs to treat multiple sclerosis, $4000 for drugs to treat rheumatoid arthritis and $8000 for drugs to treat certain types of cancer. For a social security recipient earning $26,000 per year, these out-of-pocket costs represent 16% to 32% of the person's total income for the year and clearly are prohibitively expensive. At these prices, it is not surprising that many Medicare beneficiaries with Part D insurance cannot afford these drugs.

Even for off patent drugs, high prices can still create access problems.
Much of the recent attention has focused on the rapid increases in prices of off patent drugs that do not have any competitors. The generic drug industry works reasonably well when there are three or more competitors selling the same drug. Since the drugs are interchangeable, competition works to keep prices affordable.

However, problems occur when there are no competitors (or even just one or two). When there is little competition for off patent drugs, companies can raise the prices without fear that consumers will choose a lower priced competitor. This is exactly what Martin Shkreli did with his drug. He took an off patent drug that had been on the market for many years, raised the price by 3500%, and created mechanisms to prevent other competitors from entering the market.

Analysis by Senator Susan Collins and the Senate Aging Committee staff showed how Martin Shkreli and others have been able to keep competitors from entering the market. First, the company acquired a "sole-source drug, for which there was only one manufacturer, and therefore faces no immediate competition, maintaining monopoly power over its pricing." Second, "the company ensured the drug was considered the gold standard—the best drug available for the condition it treats, ensuring that physicians would continue to prescribe the drug, even if the price increased." Third, "The company selected a drug that served a small market, which were not attractive to competitors and which had dependent patient populations that were too small to organize effective opposition, giving the companies more latitude on pricing."

Fourth, the company created a closed distribution system to stifle competition. As the report notes, "The company controlled access to the drug through a closed distribution system or specialty pharmacy where a drug could not be obtained through normal channels, or the company used another means to make it difficult for competitors to enter the market." Without access to the drug, a competitor cannot conduct bioequivalence studies in order to submit a drug application to the FDA. Increasingly, drug companies are using these closed distribution systems to stifle competition. This is an area that Congress could address, as I will discuss later.

The Senate Aging Committee concluded by stating, "Lastly, the company engaged in price gouging, maximizing profits by jacking up prices as high as possible. All of the drugs investigated had been off patent for decades, and none of the four companies had invested a penny in research and development to create or to significantly improve the drugs. Further, the Committee found that the companies faced no meaningful increases in production or distribution costs."

There have been hundreds of stories written about the problems created by these rapid price increases in off patent drugs without competition. Let me quote from another email that Patients for Affordable Drugs received: My wife "has seen [her drug's] price increase by over 3600% since 2014." Again, this is for an off patent drug. "Today her medications cost $283,000 per year or about $200 per dosage - from the 1980-'s to 2006 [drug name

eliminated for confidentiality reasons] was $1.00 per dose/$1500 per year." People simply do not have the resources to afford these drugs and often the cost sharing is prohibitively expensive.

Finally, public programs cannot afford these expensive drugs. States and the federal government have budget constraints and high prices are forcing public programs to make very difficult life or death decisions.

For example, the state of Louisiana wants to expand treatment for hepatitis C, but cannot afford to offer the care to everyone at current prices. According to the Secretary of Health in Louisiana, it would cost $764 million dollars at current prices to cover the 35,000 uninsured and Medicaid recipients with hepatitis C in the state. Louisiana simply does not have these resources, without dramatically reducing spending for things like education or public safety.

We, at Johns Hopkins, are working with the Secretary of Health in Louisiana to help her develop ways so that Louisiana can afford to purchase the drugs and prevent the spread of an infectious disease. Similar concerns about the affordability of certain drugs have been expressed by other states and by federal agencies such as the Veterans Administration and the Indian Health Service.

A woman from Alabama writes to Patients For Affordable Drugs: "My husband and I are currently doing without needed medication because of the cost. We recently lost our health coverage. With the high cost of medication, we simply cannot afford to fill our prescriptions. My daughter is in the same position, however she is on Medicaid. She has numerous health conditions and without her needed prescriptions, which Medicaid won't cover due to the cost, she ends up being forcibly hospitalized for treatment." States must make difficulty choices. And simply telling them to cover everyone that needs a drug ignores the fiscal realities.

How Drug Prices Are Set and Why This Matters to Patients

The establishment of the initial drug price, how this then gets translated into the price that the pharmacy or hospital pays to acquire the drug, and how it ultimately impacts the price that the patient pays to obtain the drug is extremely complicated. Much of the process is not transparent. My summary by necessity is an oversimplification of the process. A full description would consume a book.

It begins with a drug company setting a list price for the drug. There are no regulatory or market forces that determine the list price that the brand name drug company can set, and the drug company has full discretion and market power to set whatever list price it chooses when the drug is launched or to change the list price at any point of the life cycle of the drug.

It is important to recognize that the branded drug company has patent and market

exclusivity periods that prevent other drug companies from manufacturing the drug. These are government given monopolies that protect the intellectual capital of the drug company and make it profitable for the branded drug company to engage in research and development.

However, any economist can tell you the dangers when a company has a monopoly; the drug companies are able to set the price that maximizes their profit. The monopoly price is not the price that allows everyone to get access to the drug. They set a price that is much higher than they would set in a competitive environment.

There are a number of factors that go into the drug company setting the list price. One factor is the cost of research and development. However, the list price is typically not based on the research and development that went into developing that specific drug; instead, the company looks at their entire portfolio of drugs to determine the profits they will require to create the next generation of drugs. Even using the pharmaceutical industry's own data, it is clear that branded drug companies typically spend less than 25% of their revenues on research and development, and far more on advertising and marketing.

Many people have argued that the list price is irrelevant because few entities actually pay the list price. However, the list price is often used to determine the amount of cost sharing that many patients will pay. Since the list price is the only price that is publicly announced, it becomes the basis for many cost-sharing agreements. Thus, patients are harmed when the list price goes up.

Most people with health insurance have their drug benefits determined by pharmaceutical benefit managers (PBMs), who negotiate prices with drug companies on behalf of health insurers or large employers. Only three PBMs control 80% of the market, which is troubling from a competitive vantage point.

Increasingly, it is being reported that PBMs are responsible for some or even most of the price increases. While they do have a role in the price increases, PBMs also serve to negotiate lower prices because of their tremendous buying power.

PBMs earn the majority of their profits by negotiating rebates off of the list price. The greater the list price, the greater the difference between the list price and the actual transaction price, and the greater the profit the PBM can earn. As a result, there is a financial incentive for the PBMs to try to get the drug company to increase the list price to show the insurance company or the large employer that they are getting a larger discount. However, this also serves to maximize the PBM's own rebates. For example, if the list price is $100 instead of $50, and if the actual transaction price is $30, then the discount appears much greater when the list price is $100. Also the PBM's rebate might be greater. Neither the size of the rebate nor the actual transaction price is transparent. Congress might want to use its subpoena power to investigate.

The fact that a higher list price can result in greater sales for the drug company is contrary

to all economics principles. In nearly all markets sales decline when prices increase. However, for drug pricing, higher list prices and the greater rebates can help drugs get better placement on the formulary and hence more sales. The challenge is to change the rebate structure for PBMs a topic that I discuss later in the testimony.

Wholesalers bring the drug from the manufacturer to the pharmacy or hospital. The profit margins of the large wholesalers add only 1-2% to the price of the drug.

Pharmacies and hospitals sell the drug to the patient after they negotiate a price with the drug manufacturer and add a dispensing fee. Doctors, pharmacies and hospitals can get rebates from drug companies for using their drug as well. These rebate arrangements are almost never disclosed to patients.

Most patients pay something out-of-pocket for the drug. The exact amount is based on their insurance coverage. Insurance companies and PBMs determine the price that the patient will pay out of pocket by placing drugs on different tiers with different levels of cost sharing. PBMs and the branded drug companies negotiate aggressively on tier placement and this also helps determine the amount of the rebate. Again, all of these negotiations are confidential and the patient cannot understand how the cost sharing amounts are set. As a result, there have been calls for greater transparency in the pharmaceutical supply chain.

What we have recently learned is that some PBMs have instituted gag clauses with the pharmacy that prevent the pharmacy from telling their patient that if the patient paid cash instead of using their insurance card the price would be lower. Placement of the drug on a cost-sharing tier where the drug has a very high list price and low transaction price could mean that paying the cost sharing based on the list price is greater than the cash price. Pharmacies have reported this occurs quite often.

However, it is important to note that it all starts with the drug company setting the list price. Brand name drug companies have complete discretion on the price that they set and can raise it at any time. The government does not determine or limit the price. In fact, the government gives the branded drug company a government issued monopoly to set the price. Off patent drugs face market competition if there are multiple competitors. The problem in the off patent market occurs when there is only one or two off patent drug companies making a drug.

Policy Options to Increase Competition, Decrease Drug Spending, and Improve Patient Access While Encouraging Innovation

We are examining policy options for the HELP committee to consider. We have divided them into two categories

1. Policies that increase the level of competition
2. Policies designed to increase access to pharmaceuticals

Initiatives to Increase the Level of Competition

1. Curb Use of Limited Distribution Networks that Restrict Ability of Generic Companies to Copy Drugs and Submit ANDAs to FDA

   Generic drug companies need access to brand and off patent drugs in order to demonstrate bioequivalence to the FDA for abbreviated new drug applications (ANDAs). However, some brand and off patent drug companies are putting their drugs in limited distribution networks, making it virtually impossible for a generic drug company to access the drug. Hearings at the Senate Aging Committee and House Government Oversight Committee have shown how Martin Shkreli and others have used this tactic to stifle competition for old and off-patent drugs. Requiring drug companies to make their drugs easily available to generic firms would accelerate the introduction of generic drugs in the market and could save $2.8 billion, according to the Congressional Budget Office.

2. Include Drugs in Bundled Payments and ACOs

   This is a potential game changer. Most drugs are still paid under a fee-for-service model. Payment reform is moving towards value based purchasing; however, drugs are typically not included in these approaches. Including drugs in reforms like bundled payments and Accountable Care Organizations (ACOs) would allow the physicians and other providers to make allocation decisions that include tradeoffs between a drug and other treatment modalities. Including drugs in bundled payments and ACOs would fundamentally disrupt the drug purchasing process and lead to more transparent pricing and put doctors in charge of deciding which drugs the person receives instead of the PBM or insurer. The doctor would have the financial incentive to make the decision that is in the best interest of the patient. Drugs are already included in the Medicare DRG payment that hospitals receive; this would simply expand the scope to value based purchasing arrangements.

3. Eliminate Rebates in PBMs and PDPs

   PBMs earn most of their profit by getting rebates from the drug companies. The rebate is based on the difference between the list price and the transaction price. Increasing the list price therefore results in greater rebates, which totally distorts the pricing system. The higher list price also means greater cost sharing for patients because cost sharing is typically based on the list price. Forcing the PBMs and indirectly the prescription drug plans (PDPs) to pass on all of the rebates to the government, health plan or self-insured company would eliminate the market distortions, reduce prices, and should be used to reduce premiums or patient cost sharing. The PBMs would earn a fee for their services instead of a portion of the rebate. Giving the rebate to the patient--although it sounds good in principle--serves to distort the market since the patient would no longer be affected by the price and the drug company could increase the price even further. Some "skin in the game" for patients is needed to keep prices down, as long as it does not prevent access.

4. Restrict Pay for Delay Behavior

Branded drug companies have used a variety of mechanisms to prevent generic drug companies from entering the market, including paying them to delay the introduction of a competitor generic drug. While the courts have continually said this is illegal, some abuses continue. Litigation is time consuming and allows the branded drug company to continue to earn substantial profits while the case is still being litigated. An alternative is to penalize the generic company that applies to be the first entrant into the market after the patent expires, but then does not actually manufacture the drug. Congress could, for example, give the FDA the authority to keep the generic manufacturer from making an ANDA application for a second drug until it has actual sales on its first application. Generic drug companies would be motivated to get the drug to market as soon as possible and pay for delay would be eliminated.

5. Restrict Use of Patient Assistance Programs

While public programs like Medicare and Medicaid do not permit drug coupons, they do permit patient assistance programs that provide billions of dollars in financial support to Medicare and Medicaid beneficiaries. Some of the largest foundations in the US are now patient assistance programs sponsored by drug companies, with several of them giving out almost a billion dollars a year. The problem with patient assistance programs is that they allow drug companies to raise prices while keeping patients immune from all cost sharing. A recent Wall Street Journal analysis suggests for every $1 million funneled to patient assistance programs by drug companies resulted in $21 million in increased drug sales. This is problematic considering the IRS considers patient assistance program donations to be charitable deductions. Again, some "skin in the game" for patients is necessary, as long as it does not harm access.

6. Reduce Abuse of Orphan Drug Designations

Some branded drugs have multiple orphan drug approvals that extend their period of market exclusivity and give them significant tax advantages. While the Orphan Drug Act had good intentions, the legislation needs revision to prevent companies from applying for multiple orphan drug designations and receiving multiple approvals and therefore market exclusivity extensions for the same drug. Revision of the law would lower prices by moving branded drugs to the generic market sooner.

7. Restrict Mergers of Generic Drug Companies

The Hatch Waxman Act effectively controls drug prices for generic drugs when there are three or more generic competitors manufacturing the drug. However, the generic industry has undergone a series of mergers that have reduced the number of competitors and lessened price competition. Recently, the largest and the third largest generic manufacturers merged. Because generic drugs are responsible for almost 90% of drug sales in the US, Congress and the FTC need to take a careful look at the level of competition in the

generic market to make sure there are more than three competitors for all generic drugs. The recent mergers have lessened the level of competition in the generic market.

Additional Initiatives to Improve Access to Pharmaceuticals

1. Revise Medicare Catastrophic Drug Spending Rules

   The main reason for the rapid increase in Medicare Part D spending is the advent of the high priced specialty drugs costing more than $7000, for which the Medicare program pays 80% of the cost. In spite of paying 80% of the cost, Medicare is prohibited from negotiating these drug prices. MedPAC has proposed shifting 80% of the cost to the PDPs and dropping the Medicare proportion to 20% so that the PDPs have a greater incentive to negotiate lower drug prices for these specialty drugs. However, this could cause the PDPs to discriminate against people with multiple chronic conditions (who take lots of drugs). Instead, Medicare should be able to negotiate prices directly for these high priced specialty drugs. If negotiation fails, Medicare could use reference pricing, binding arbitration or value based pricing to set prices.

2. Enact Price Gouging Legislation

   This year, the State of Maryland enacted bipartisan legislation to empower the Attorney General to take legal actions against drug companies enacting "unconscionable" price increases for off patent drugs with fewer than three competitors. It is designed to keep people like Martin Shkreli from raising prices on an off patent drug for which there is the only one manufacturer. It is the first legislation to address the problem of rapid price increases for off patent drugs. Congress could consider similar legislation to stop actions by people like Martin Shkreli.

3. Allow One Single Federal Agency to Negotiate Drug Prices

   Currently many different government agencies negotiate drug prices, with each federal agency paying very different rates with different or no formularies. Looking at those 30 drugs for which we can directly compare prices, the Medicare program pays 30% higher prices than the DOD. Considering the similarities in the drugs needed by these agencies, the federal government would have a better procurement process if there was only one federal agency purchasing drugs. Because the prices are highest in the Medicare program and Medicare beneficiaries pay the highest cost sharing, Medicare beneficiaries are the biggest losers when government agencies pay different prices. While some federal agencies might pay more in one price arrangement, the entire federal government could pay less. Savings would be dependent on where the single federal entity set the price – at the highest level (Medicare), the lowest (DOD), or at the weighted average.

4. Use 1498 Authority To Negotiate Drug Prices

   The federal government has the existing authority (28 U.S.C. § 1498) to take away the

patent of a company, such as a pharmaceutical company; provide reasonable compensation to the drug company for the use of the patent, and allow a generic manufacturer to manufacture the drug. The Department of Defense, the National Gallery of Art and many other federal agencies have used this authority to purchase patented materials at reasonable prices. Health and Human Services Secretary Tommy Thompson threatened to use 1498 authority to purchase Cipro following 9/11 and Bayer lowered its price in response. The state of Louisiana is currently considering asking Secretary Price to use his authority under 1498 so that Louisiana can purchase hepatitis C drugs for the uninsured and Medicaid populations.