Testimony for the Record
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"Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines"

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Senators Collins, McCaskill and members of the Senate Aging Committee, thank you for inviting me to speak this afternoon. My name is Gerard Anderson and I am a professor of health policy and management, medicine, and international health at Johns Hopkins University. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

Several years ago, I had the privilege of testifying before the Senate Aging Committee about the problems faced by millions of Medicare beneficiaries with chronic conditions. This hearing on drug prices is related to my prior testimony because Medicare beneficiaries with 5 or more chronic conditions (about 15 percent of the Medicare population) fill an average of 50 prescriptions during the year.

In my testimony today, I will discuss how millions of Americans, and especially those millions of Medicare beneficiaries with chronic conditions, are affected by high drug prices. In keeping with the focus of the hearing, I will concentrate my testimony on those generic drugs that have shown very rapid price increases in the last few years and the adverse impact they are having on people with chronic conditions.

Pharmaceuticals have the potential to significantly improve health when people have access to the appropriate drugs. Innovation in the drug industry is something that needs to be supported. However, it must be noted that generic drug companies do not sponsor innovation because they do not undertake research and development (R&D).

At Johns Hopkins, my colleagues and I are conducting a series of studies demonstrating how high drug prices affect access to drugs. The reasons are very different for generic and brand name drugs. I would like to share with you some of our preliminary findings and how the recent price increases are adversely impacting millions of people.

Problems with Access to Generic Drugs

For many years, the generic drug market worked reasonably well. Prices for generic pharmaceuticals were relatively inexpensive in the US and almost everyone could afford them.

Numerous empirical studies found that having more generic pharmaceutical competitors in the market significantly lowers the price of generic drugs[1]. Generic companies compete exclusively on price since each company has to use the exact same chemical compound as the brand name drug when they manufacture the drug. When a new generic competitor enters the market, it must offer a lower price in order to attract business. When there were 3 or more generic companies selling the same drug, it was quite common for the generic companies to sell drugs at 25% of the brand prices – and I have seen generic drugs with 99% discounts off of the price of the brand drug when there are multiple competitors.

[1] Berndt E, et al. Authorized generic drugs, price competition, and consumer welfare Health Affairs, 26.3 (2007): 790-799

Generic drug companies can still earn a profit at these prices because the cost of actually producing most drugs is pennies per pill. You can easily see this in the pricing algorithms of generic companies – a 100-milligram dose is often the same price as a 200-milligram dose or maybe a penny cheaper. This is because the cost of actually manufacturing the product is small for nearly all drugs. Unlike brand name drugs, generic companies do not have any R&D expenses and since each generic drug is selling the exact same chemical compound as the brand product there are no marketing expenses.

Because of this robust price competition, the prices for generic drugs were often lower in the US than they were in other industrialized countries. **Senator Hatch, a member of this committee, deserves considerable credit for these lower generic drug prices. The bill he coauthored in 1984 (Hatch Waxman) was landmark legislation to promote price competition in the generic drug market.** After over 30 years, it is time for Congress to revisit the issue of the generic market place and how generic drugs prices are determined.

Several years ago, Wal-Mart began selling generic drugs for $5.00 and people with health insurance paid nothing or very little out of pocket for most generic drugs. Access to generic drugs was reasonably good, although some Americans still had problems accessing certain generic drugs.

Price Competition Begins to Break Down in the Generic Drug Market

Unfortunately, in the last 5-10 years, the competitive market for generic pharmaceuticals has begun to break down. The Turing example of a several thousand percent price increase is only the tip of the iceberg. Many other generic companies are doing the same thing - their price increases are just not quite as egregious and so they do not get quite as much media attention.

The prices began to increase as the generic pharmaceutical industry started to consolidate. Mergers and acquisitions of generic drug companies have been common in the last 5-10 years-which is still happening today with Allergan's $40 billion spinoff of its generic division to Teva Pharmaceuticals[2]. The consolidation has resulted in less price competition, higher prices and increased shortages for generic drugs.

A second concern about consolidation within the generic drug market is harder to substantiate and is something the Aging Committee should investigate. Generic drug companies recognize that greater competition is not beneficial to them. It is better for the generic companies if there are fewer generic companies selling the drug. If they can reduce the amount of competition, then they all can earn higher profits.

For example, if my generic drug company competes with your company on a product then your company earns a lower profit. If your generic drug company competes with my company then my company earns a lower profit. With only a few generic drug companies in the market, the decision not to compete on certain drugs is much more likely to occur. Recently, we are seeing many generic companies choosing not to enter certain drug markets. The Turing example shows what happens when there is no competition in the generic drug market. This is something for the Aging Committee to consider as it considers options.

The first indication of a market failure in the generic market was drug shortages.[3] Several years ago, hospitals, physicians and patients suddenly found it almost impossible to fill certain prescriptions for generic drugs. These drugs had been available for many years without shortages. Without multiple competitors there can be spot shortages. The problem is most likely to occur when there is only one manufacturer and that manufacturer has a production problem. When a person relies on a specific drug for their health and suddenly that drug is unavailable, there is a personal and a public health crisis. Consolidation in the generic drug industry has resulted in less competition and more solo manufacturers of a generic drug. The Aging Committee could examine why only one generic drug company is

[2] Koons, C. (2015, August 5). *Teva's Just the Start as More Generic Drug makers Poised to Merge.* www.bloomberg.com

[3] Chabner, BA. "Drug Shortages – a critical challenge for the generic-drug market" NEJM 365 (23), 2147-2149

manufacturing a specific drug. Is it simply a small market for that drug or are generic companies cooperating with each other? Are certain markets too small to permit two companies manufacturing the drug?

The second indication of a problem in the generic market is the recent price increases. When patients have limited access due to high prices, they often end up in the hospital with worsening of their medical condition. At Johns Hopkins Hospital, a patient contracted a brain infection that rendered her confused and unable to communicate. Her treatment regimen included the anti-parasite drug, pyrimethamine, the drug made by Turing. For four years she was on the drug and all of a sudden the price increased several thousand percent. Because of the price increase and a change in distribution she was unable to get the drug. The patient's infection returned and she was hospitalized again. Fortunately after an extensive hospital stay, the patient recovered fully. Her own cost and the cost to the health system, however, were enormous. This does not even consider the pain and suffering she endured.

Time and again escalations of prices and shortages of generic drugs have been observed for common medications such as doxycycline (for infections), propofol (anesthesia), digoxin (heart failure), pravastatin (high cholesterol) and naloxone (antidote for heroin abuse) significantly affecting both morbidity and mortality.

The drug shortages and the recent increases in drug prices are most likely related. Following a series of shortages, the generic companies realized that they could raise their prices – there would be no competition entering the market. The hearings today are a response to these price increases.

The reason for both the shortages and the price increases are essentially the same – a growing lack of price competition in the generic drug industry because of the recent consolidation. It is hard to remember a recent month when one or more generic drug companies were not in merger discussions or acquisition negotiations[4].

Larger generic drug companies means less price competition. Generic companies could argue that larger generic companies have economies of scale – larger firms can produce the drugs more efficiently. However, as noted earlier, the cost of producing a pill is only pennies so economies of scale play only a small factor. It appears the main reason for the mergers is to reduce the level of price competition.

A second problem with the recent consolidation is that the larger generic companies appear to be less likely to enter smaller drug markets. Many of the larger generic companies do not choose to sell products with less than $100 million in annual sales. Turing, for example, found a generic product in a relatively small niche market with no competitors and they used this market failure to raise the price for that drug by several thousand percent. A large generic company like Teva is less likely to enter a market with less than $100 million in total sales. Companies like Turing look for markets that the larger generic companies are not likely to enter. With fewer generic companies overall and larger generic companies, it becomes easier for companies like Turing to find these market niches. The Aging Committee could ask the larger companies why many of them do not compete in the drugs with less than $100 million in sales.

While your company is the only seller of the drug, you can set the price. This can happen until another generic drug company is able to go through the FDA process of getting their drug approved for sale. However, the regulatory burden cannot explain the rapid increases in generic drug prices or the rapid change in the market. In markets where sales are less than $100 million, the administrative cost of going through the FDA process might be a sufficient barrier to restrict entry.

In addition to mergers/acquisitions and the size of generic markets monopoly can be created when companies divert their resources towards drugs whose patents have recently expired because the profit margins are greater. This leaves behind older generics in the hands of fewer companies. Not only does it create price hikes; fewer companies are also not able to handle the volume of demand leading to shortages.

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[4] Wieczner J. "The real reasons for the pharma merger boom." Fortune magazine July 28,2015

A Possible Solution: An Expedited Review Process for Generic Drugs Where There is Little or No Price Competition

There are many ways to further increase competition in the generic industry. One option is for DHHS to establish a priority review process for generic drugs when there is little price competition for that generic drug. The process would be similar to the process the FDA offers to brand name drug companies. Under current law, they can get a priority review if there is the possibility of significant clinical benefit**.** However, instead of significant clinical benefit, the system for generic companies would apply if there were significant economic benefit. The priority review would be triggered if there were little or no price competition for that generic drug. If the federal government determined that approval of a particular generic drug would help the market become more competitive then an expedited review would be triggered.

The evaluation should be made by an agency outside the FDA since the FDA typically does not have the expertise in economic evaluation. One possibly entity to conduct the review is the Assistant Secretary for Planning and Evaluation in DHHS.

It is relatively easy to see what drugs do not have competition. The drugs with two or more competitors will be subject to a federal upper limit (FUL) established by the federal government or maximum allowable costs (MAC) established by the states. FULs and MACs are calculated when there are 2 or 3 more generic drugs competing for business so it is easy to identify drugs where there is competition.

Unresolved questions

There are several questions that as an academic researcher that I cannot answer because they require data from the generic drug companies. They are important questions, however in order to understand the behavior of the generic drug industry.

The first question is how big the generic market needs to be before it can support competition? Some drugs are sold to only a few patients and only one manufacturer is economical in that space. There may be natural monopolies in the generic market and something will need to be done when this naturally occurs because of the small number of patients taking a specific drug. This is where shortages and price hikes are most likely to occur.

The second question is what causes a generic firm to enter a specific market? There are many different considerations including the cost of getting FDA approval and the uncertainty of know if other competitors will enter the market as well. There is very little information about how generic firms decide to enter the market and which markets they decide to enter.

About all that we seem to know is that larger generic companies are less likely to enter small markets. If we want to know how to increase competition in the generic drug market we need to know what causes firms to enter the market.

What we think we know (but more work needs to be done) is that the cost of production is not significant (pennies per pill) and that retooling the product to produce a new drug is relatively small expense. The reasons for not entering a market do not seem to be based in the cost of manufacturing the product but more in the uncertainty of who else will enter the market and the cost of regulation.

Restoring Price Competition in the Generic Drug Industry While Promoting Greater Access

Congress and the Federal Trade Commission should take a careful look at the recent consolidation in the generic drug industry. One possibility is to severely restrict any new mergers or acquisitions until there is more competition in the generic industry. The recent consolidation are already having an adverse impact on access and allowing generic companies to raise prices. In addition, the Congress should consider giving the

FDA the flexibility to a conduct priority reviews when there is evidence of limited price competition in the generic industry.

Pricing in the Generic Drug Industry

In addition to restoring competition in the generic drug industry, it is also important to examine the method for setting generic drugs prices. Even when there is robust price competition, the pricing system for generic drugs needs significant revision.

It is difficult to think of a pricing system that is more opaque than for generic drugs. **It begins by the generic drug company announcing a high price that no one actually pays.**

Surprisingly, the generic company announcing a higher price for its drug typically means greater sales for its product – something contrary to most markets. This is called marketing the spread in the generic drug industry. The spread is the difference between what the insurer pays and the actual price the pharmacy pays to acquire the drug.

This can be quite large because what the insurer pays is partially based on the price that generic company announces which is always larger than what the pharmacy actually pays. Thus a higher announced price results in a larger spread. The reason for this strange behavior is how health insurers like Medicare, Medicaid and most private insurers pay for drugs. It is partially why Turing announced a very high price and is now unwilling to lower the price.

While pricing for generic drugs is very complicated, I will try to simplify the way that generic drugs are paid by health insurers. It is important to understand this in order to understand why the generic companies are raising their prices. **The payment incentives in the generic industry require close examination by the Aging Committee.**

Most insurers want to reimburse pharmacies based on the price they paid to acquire the drug plus a dispensing fee. The insurer wants to pay the pharmacy for its acquisition cost. This assumes the insurer knows the actual acquisition price the pharmacy actually pays.

However, the insurer does not know the actual acquisition price because it is not what the generic company says it is. For reasons described below, when the generic company announces a higher price it allows the pharmacy to earn a greater profit on selling its generic drugs. Because the pharmacy can earn a greater profit selling a generic drug from one generic drug company than another company, the pharmacy chooses to buy that drug from the generic drug company that gives them the highest profit. Since all the drugs made by different generic drug companies have the same chemical compound and the manufacturing prices are low and the costs to manufacture the drugs are similar, the spread becomes a deciding factor on which generic drug to select. This is why generic drug companies set a high price and then market the spread between the announced price and the actual price.

Since the insurers are likely to use the higher price announced by the generic drug company as the starting point for paying the pharmacy they end up overpaying for the drug. The generic drug company with the highest published price is likely to get more business because the profits (the difference between what the insurer thinks the pharmacy pays and what the pharmacy actually pays) are greater when the announced price is greater. This is most striking when two generic drug companies sell the same drug at exactly the same price. The generic company with the higher announced price gets the business because the spread is larger.

The process begins by the generic drug company announcing something called the average wholesale price (AWP). Generic drug companies need to announce prices in order to sell their drugs. This price is typically published in a compendium and everyone in the pharmaceutical industry uses this information. If you apply the literal meaning of the term average wholesale price it is the price that the pharmacy pays the wholesaler for the generic drug. Generic drug companies sell the drug to wholesalers who then sell the drugs to the pharmacy.

The problem is that the average wholesale price announced by the generic drug company is not the actual price that the pharmacy pays for the generic drug. Often it is not even close – sometimes off by a factor of 10 or more. So the important question is – why would a generic drug company announce a price that no one actually pays?

The answer is that because the AWP is not the actual price; the insurer must guess the price the pharmacy is actually paying. When the insurer guesses too high, then the pharmacy is able to earn a profit on the acquisition cost. By setting the AWP price higher than the actual price the generic company allows the pharmacy to earn a profit when the insurer bases the payment on the AWP. Since all the generic companies selling the same drug will have the same compound, the only reason for a pharmacy to choose a drug from a specific company is the potential profit to the pharmacy. This is known in the drug industry as marketing the spread and is pervasive in the generic industry.

Medicare, Medicaid and most private insurers use the published price or average wholesale price to determine how much they will pay the pharmacy for many drugs. Unfortunately, there is no relationship between the actual sales price and the AWP for generic drugs. There are all sorts of arrangements in the generic drug industry called chargebacks, rebates, stocking allowances and many other discounts. These are all confidential arrangements between the drug company and the purchaser that preclude the health insurers from determining the actual prices that the pharmacies are paying. Because of the actions of the generic drug companies submitting false prices, a perfectly good system of determining prices the AWP results in marketing the spread.

Estimating the actual acquisition cost is extremely difficult for insurers like Medicaid. Federal law requires the state Medicaid programs to pay estimated acquisition cost.[5] The states typically look at a variety of sources to find the true prices. These prices are hard to find since the arrangements between the generic companies, the wholesalers and pharmacies are hidden in confidential agreements. The Wisconsin Medicaid program went so far as to use information on what veterinarians in Wisconsin were paying for the same drugs to determine an actual sales price. Other insurers have similar problems determining the prices that are paid.

As mentioned earlier, when there is robust price competition, the actual price for generic drugs is on average only 25% of the published price, but it varies from drug to drug. For some generic drugs it might be 50% of AWP and other drugs 5% of AWP. Insurers cannot use one markdown number to determine the actual price because the relationship between the actual price and AWP varies considerably from drug to drug. Because these deals are confidential no insurer knows exactly the price that is being paid for any specific drug. When the insurers use the AWP to set the prices they pay pharmacies they are relying on the prices established by the generic drug companies. Companies with the highest announced prices get the most business.

This is a game the generic drug companies' play that costs the public billions of dollars. State Medicaid agencies have been suing the generic drug companies for years over this practice and recovering billions of dollars in overcharges from the generic companies. Other insurers have done the same. If the whole process for determining how much to pay for a generic drug sounds complicated it is because it is. **The entire generic drug pricing is designed to earn profits for the generic drug company and the pharmacy.**

This very strange way of pricing should be investigated by Congress. Generic drug companies are routinely announcing AWPs that are two to 10 times their actual price. The local grocery store could not remain in business if it adopted this pricing model and neither would Apple computer.

<u>How Can Congress Increase Price Transparency for Generic Drugs?</u>

The obvious question is why insurers don't simply ask the pharmacies for the actual prices that they are paying. The insurers want to pay the pharmacies their actual acquisition cost plus a dispensing fee. First of all, pharmacies are

[5] CFR447.502. An estimate of the price paid by providers for a drug.

under no legal obligation to provide this information to private companies. This applies to insurers in the Medicare Part D program since they are private companies.

Recently, state Medicaid programs have begun surveying the pharmacies for the prices they actually pay. While this seems reasonable for each Medicaid program to try to learn the actual prices that are being paid by the pharmacies in their state, it is a huge cumbersome undertaking for the Medicaid program. There are over 50,000 different drugs that are sold when you consider each dose, manufacturer and means of administration as a unique drug. Each one of these 50,000 drugs has its own price and the prices can change daily. Surveying pharmacies to determine the actual price for each drug is tremendously time consuming. More importantly, a survey is going to reflect prices that were paid weeks or months ago. Using a survey to determine prices is not a good approach – but it may be the best option for states unless something else is done. Clearly a better approach is to have the generic companies announce true prices not fictitious prices when it first enters the market and every time there is a material change in the price.

A Potential Solution to the Generic Pricing Problem

Congress could compel generic drug companies to announce their actual average wholesale prices**.** By this I do not mean the price that a specific company like Wal-Mart pays to a generic drug company for a specific generic drug. This would seriously interfere with the market place since every pharmacy would want to get the prices that Wal-Mart or some other larger retailer gets.

The DHHS Office of Inspector General told the generic drug companies to publish the real prices in 2002.[6] The key section of the OIG report is entitled "Integrity of data used to establish or determine government reimbursement." The OIG guidance says that the "manufacturers reported prices should accurately take into account price reductions, cash discounts...." Unfortunately this is only OIG guidance and does not have the force of law or regulation. **Congress should determine if it wants to legislate that generic drug companies report the actual prices that are paid or some fictitious price that no one pays.**

Congress could compel the generic drug company to publish the average price it actually receives for that drug. Fortunately this information is already available. In the drug company pricing terminology this is known as the average manufacturers price or AMP. Years ago the Congress told the drug companies how to calculate AMP and DHHS has issued regulations for calculating the AMP.

States are required to pay estimated acquisition costs under federal law. The problem is that while the state Medicaid agency has this information, the state cannot actually use the AMP to determine the rates it pays to pharmacies. **Federal law prevents state Medicaid programs from actually using the AMP to set rates.** These rates are a very close approximation of the actual transaction prices and the generic drug prices would be transparent if the AMPs were made public.

If states were permitted to use the AMP prices to set rates, then the states would not have to guess the prices that the pharmacies are paying. They would save considerable money since they would be paying actual acquisition cost and not making a guess at the acquisition costs.

A huge added advantage is that announcing the AMP publicly would make the prices transparent and other insurers could use the information to set their rates. Patients and insurers would know the average prices that pharmacies are paying to purchase the drugs and the insurers could pay actual acquisition costs to the pharmacies. There would be no marketing the spread.

There has been general agreement that price transparency in health care is beneficial and allowing the Medicaid programs to use pricing information they already have to set prices would enhance price

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6 DHHS Office of Inspector General. "Compliance Program for Pharmaceutical Manufacturers". October 5, 2002.

transparency in the pharmaceutical industry. Other insurers could also use the information if it was publicly available.

How would this increased price transparency improve access to care? Consumers would be able to actually compare true prices of the various drugs and would be able to choose the least expensive generic drug. The current system makes this impossible. A company like Turing would not be able to increase the price several thousand percent and then give discounts to only a selected few purchasers.

I am happy to answer any questions.