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Mr. Waxman and members of the Oversight and Government Reform Committee, thank you for inviting me to testify this morning. I am Gerard Anderson, a professor of Health Policy and Management, Professor of International Health and Professor of Medicine at Johns Hopkins University. I also direct the Johns Hopkins Center For Hospital Finance and Management.

In preparing my testimony today, I examined the problems federal and state governments encounter when they purchase drugs. My analysis suggests that most government programs have two common problems: (1) some government programs do not know the prices they actually pay for drugs and (2) each government program pays a different price for most drugs and it appears that the Medicare Part D plans are paying much high prices for certain types of drugs compared to other government programs. In light of these findings, I have three recommendations for the Committee to consider.

- 1) Each government program should know the actual price it pays for specific drugs
- 2) Drug prices should be compared across government programs to find out which government programs are paying the highest prices for specific drugs.
- 3) Congress should examine whether the federal government should pay different prices for the same drug and whether a more consolidated approach should be considered.

Each Government Program Should Know The Price It Pays For Drugs

My first recommendation is that each government program should know the price it actually pays for each specific drug. Unfortunately, many government programs do not know the prices they pay for drugs. One reason is that the systems the some government agencies use for determining the prices they pay for drugs is so complicated. In other cases, the data is available but not analyzed.

Let me begin with the largest federal purchaser of drugs – the Medicare Part D program. Medicare beneficiaries can go on the Medicare.gov web site and find out how much each Part D plan charges for each drug in their formulary.

However, the Secretary of HHS, the CMS actuaries, CBO, CRS, GAO, etc. do not know the prices the Part D plans actually pay for these drugs. The data is available, but it has not been analyzed by any of the Congressional agencies or the CMS actuaries.

The Secretary of HHS and the Congress should know the prices Part D plans pay for each of the 4300 drugs on one or more of the Part D formularies in order to determine if the Part D market is working. The legislation the House recently passed (HR 4) will require the Secretary of HHS to know the actual prices that the Part D plans are getting. This is a necessary first step before the Secretary knows where to negotiate.

In my opinion, the Secretary does not need to negotiate prices for each of the 4300 drugs. Instead, the Secretary should only negotiate prices where there is market failure and where Part D plans are paying relatively high prices. Let the market work where the market is working effectively; the Secretary should intervene only where there is market failure. This will permit the Secretary to focus attention on the drugs where the market is not working and Part D plans are paying relatively high prices.

The Secretary of HHS should compare the lowest price any Part D plan is getting for each drug to the prices that Medicaid, VA or Canada are paying for the same drug. In making this comparison, it is not necessary to report the prices that every Part D plan is paying. All that needs to be reported is the lowest price that any Part D plan could obtain for each drug because this represents the lowest price the marketplace can obtain. The Secretary of HHS can then concentrate his/her efforts on negotiating lower prices where there is market failure.

The Secretary should compare the lowest price obtained in the marketplace to the VA price because the VA Secretary has negotiated drug prices with pharmaceutical companies. Medicaid prices are an appropriate comparison because this government program has been operating for many years and because Medicaid programs have an extensive formulary. Canada's prices are a relevant comparison because it will show what another country is paying for drugs. Also, if there is a large differential between the Canadian and US prices for drugs, this will cause a substantial number of American seniors to obtain drugs from Canada.

340 B Programs

Many government programs experience difficulties determining the prices that they are actually paying for drugs because the formulas are so complicated. This is particularly true in 340B programs operated by HRSA.

An October 2005 report by the DHHS Inspector General found that HRSA does not know the prices it pays for drugs in the 340 B program. The three major findings of the report were:

- 1) HRSA needs an accurate record of 340 B ceiling prices to verify that entities receive the discount to which they are entitled by law.
- 2) HRSA lacks the oversight mechanisms and authority to ensure that 340 B entities pay below the 340 B ceiling price.
- 3) Participating entities cannot independently verify that they receive the correct 340 B discount due to confidentiality provisions.

In other words, the entities participating in the 340 B program do not know if they are paying the correct prices.

Medicaid Programs

A series of reports by the DHHS Inspector General found a variety of problems with the prices the Medicaid programs were paying for drugs. The reason is that the formulas are very complicated and there is tremendous price variation across the states. As a result CMS cannot monitor if the states are paying the correct price.

One report examining price variation paid by Medicaid programs found that “On average, the highest paying state paid 477 percent more per drug than the lowest paying state”. CMS should investigate this large variation and help the states that pay the most.

Another report found that the Medicaid program was overpaying pharmacies to dispense drugs because the formula used by most Medicaid programs is flawed. The problem is that Medicaid reimbursement to pharmacies is based on discounts from average wholesale prices rather than on actual sale transactions. It is difficult for states to determine average wholesale prices. The DHHS Inspector General’s Report found that the average sale prices were 49% lower than average wholesale price and yet most Medicaid programs were obtaining discounts substantially less than 49% of average wholesale price under current rules. This gives the pharmacies additional profits because the pharmacies can purchase drugs cheaper than the Medicaid thinks they can and the pharmacies can pocket the difference.

A third report examined the Medicaid federal limit calculation and found that certain drugs were inappropriately excluded resulting in additional spending by the Medicaid program. The report found that “58 new drug products that met all

statutory and regulatory requirements were not added to the Federal upper limit test due to inflated published prices” and this cost the Medicaid program over “100 million per year.”

In 2005, Congress passed the Deficit Reduction Act requiring each drug manufacturer to enter into a rebate agreement with CMS and pay quarterly rebates to the state Medicaid program. The problem is that the pharmaceutical manufacturers set the price and then they pay rebates off the price that they set themselves. Another report by the DHHS Inspector General argues that the “existing requirements for determining certain aspects of AMPs [Average Manufacturer Price] are not clear and comprehensive, and manufacturer’s methods of calculating the AMPs are inconsistent.” The lack of consistency results in fewer rebates being paid to Medicaid program.

In summary, it is clear that the Secretary of HHS does not know the prices the Part D plans are paying for drugs, HRSA does not know the prices that it is paying for 340 B programs and CMS does not understand the prices that the Medicaid directors use to pay for drugs. The problems are that the formulas are so complicated and/or the data is not being compiled.

Price transparency is a virtue in most circumstances. Drug pricing in many government programs is so complicated that many government agencies do not know the actual prices they are paying. The Committee should make sure that the various government agencies know the prices they pay for drugs. This also applies to the Medicare program which should know the prices the Part D plans pay for specific drugs.

II. Comparing the Prices the Various Government Entities Pay

Once the various government agencies learn the actual prices they pay for each specific drug (including discounts, rebates, price concessions, etc), it should be possible to actually compare the prices the various government programs pay. This has been attempted with incomplete data and should be repeated once the pricing data is more reliable and the Part D data becomes available.

Using incomplete data, various organizations have tried to estimate the rates that various government agencies pay. All of the studies suggest wide variations in the amounts the various government agencies pay and that the Part D plans are paying the highest rates for some types of drugs.

Families USA and Consumers Union have recently compared the prices paid by the VA and Part D plans and both studies found that Part D plans were paying substantially higher prices than the VA for drugs.

The Families USA study found that “The price differential between the lowest VA-negotiated price and the lowest price available from a Part D private plan is

often substantial. For example: for Zocor (20 mg), a lipid-lowering agent, the lowest VA price for a year's treatment is \$127.44, while the lowest Part D plan price is \$1,485.96—a difference of \$1,358.52, or 1,066 percent.” The report listed numerous other examples of commonly prescribed drugs where the differentials in prices were nearly as large.

Consumers Union compared the drug prices for 6 drugs in Broward County Florida. Their study found that “VA prices were 54 percent lower than “full-cost” prices under Part D plans. The average per drug VA price for the six drugs surveyed was \$22.06 per drug; the average “full-cost” price under the Medicare Part D plans in Broward County was \$48.38. Full-cost price refers to that paid by beneficiaries who fall into the “doughnut hole” coverage gap.”

Both studies have been criticized on methodological grounds, however, in my opinion; both studies are the best that can be done using available data. Of course, having actual data would eliminate much of the methodological debate. I would also note that the price differences are very large and any methodological issues are going to have only a small impact on the differences. Finally, the critics of these studies have not presented any alternative evidence.

Various government agencies have produced studies comparing the prices paid by different government agencies but I have not identified a study that compares the actual prices paid by Part D plans to the prices paid by government agencies. This should be a priority.

In 2005, The Congressional Budget Office made an attempt to compare the drug prices various government agencies pay for drugs at the aggregate level. I emphasize “made an attempt” for two reasons. The first section of my testimony emphasizes that some federal agencies do not know the actual prices they are paying. This makes price comparisons difficult. I also emphasize “at the aggregate level” because the CBO comparison did not look at the price variations for specific drugs and there is reason to suspect that there is more variation for certain types of drugs than other types of drugs. Finally this report was written in June 2005 and did not examine the prices paid by Part D plans.

The CBO report shows significant variations in aggregate drug prices across the various government programs. The report compared the discount that various federal agencies received to the average wholesale price (AWP). Average wholesale price is the “publicly available, suggested list price for sales of drugs by a wholesaler to a pharmacy or other providers.” CBO selected the average wholesale price “as the reference price for the analysis because it is commonly used in pharmaceutical transactions”. CBO noted that the pharmaceutical companies will often provide discounts, rebates, and other price concessions and so the average wholesale price is not the actual price the wholesalers pay. It is also not the price that most patients pay.

CBO estimated that average price paid by the Medicaid program was 51% of average wholesale price and the 340 B ceiling price was also 51% of AWP. In comparison, the VA paid only 42% of the average wholesale price and the DOD military treatment facility average price was 41% of AWP. In contrast, the average manufacturer price (the price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies) was 79%.

The CBO report calculates the discounts other government programs receive.

Because of provisions in the Medicare Modernization Act, data on the actual prices that Part D plans pay for drugs is not publicly available. CBO cannot compare prices obtained by the Part D plans because the data is buried somewhere in Baltimore at CMS headquarters and the CMS actuaries, CBO, CRS, GAO have not examined the data. At the present time, CBO and CRS are not even authorized to review the data.

I was interested in estimating the prices that Part D plans are paying for drugs to see if they are getting reasonable prices. In order to estimate the actual prices paid by the Part D plans, I relied on numbers produced by the CMS actuaries.

(Table 1 is from the CMS actuaries report) In their 2006 report on the projected costs in the Part D program, the CMS actuaries assume a 21 percent reduction in average wholesale price and a 6 percent rebate for a total of 27 percent reduction from the average wholesale price. **It appears that the CMS actuaries assume that the Part D plans pay 73% of the average wholesale price.**

First, it should be noted that the price reduction obtained by Part D plans is considerably less than what the VA or Medicaid have obtained. The 73% number is comparable to the 51% reduction by the Medicaid program and 42% reduction by the VA. **In other words, Part D plans are paying 22 percent more than Medicaid and 31 percent more than the VA.**

The CMS actuaries assume that Part D spending will exceed \$1 trillion dollars in the 2006 to 2015 time period. **A 22 percent or a 31 percent reduction in drug prices would save the Medicare program \$200 to \$300 billion dollars during this time period.**

Second, it is important to notice in Table 1 that the **CMS actuaries do not anticipate that the Part D plans becoming any more effective over the years in negotiating price reductions from the pharmaceutical companies.** In the CMS projections, the discounts are constant over the years from 2006 to 2015. **Between 2006 and 2015 Part D expenditures are forecast to increase 10.3 percent per year on average.**

There is confirming evidence to suggest that Part D plans are paying high rates for drugs. One comparison is the prices states were paying for drugs for the dual eligibles. The Medicare Modernization Act moved millions of dual eligibles from Medicaid to Medicare for prescription drug coverage.

One simple way to estimate the higher prices that Part D plans are paying for drugs is to compare the CBO estimates of the discounts that the Medicaid program and the private sector receive for “brand name” drugs. According to the CBO report, the average manufacturer price is 79% of the average wholesale price. The average manufacturer price is the “average price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies”. The CMS actuaries’ then subtract an additional 6% discount for rebates. This suggests that the Part D plans are paying 73% of average wholesale price. However, Medicaid was paying only 51% of average wholesale price. **This suggests that Medicare is now paying 22 percent more than Medicaid was paying for the same drugs for the same dual eligibles.**

There is further collaborating evidence of the Medicare part D plans paying higher rates based on the pharmaceutical companies’ own reports to the financial industry. Pharmaceutical companies are required to file 10Ks and 10Qs with the Securities and Exchange Commission whenever a major event occurs that could influence the stock price. There are indications in some of the 10Ks and 10Qs filed by the pharmaceutical companies that they are getting higher prices from Medicare than they did from Medicaid. For example, Pfizer acknowledged that they paid fewer rebates, price concessions and gave fewer discounts due “to the impact of the Medicare Act”. Specifically on page 34 of their 10Q report dated October 1st 2006, Pfizer states that “Our accruals for Medicaid rebates, Medicare rebates, contract rebates and charge backs totaled \$1.5 billion as of October 1, 2006, a decrease from \$1.8 billion as of December 31, 2005, due primarily to the impact of the Medicare Act”. There are similar examples in other 10K and 10Q submissions by the pharmaceutical industry.

III. Understanding The Variations in Drug Prices And A Suggested Remedy

Once the price data has been validated and the price comparisons conducted, Congress should consider three questions:

- 1. Are the price variations across the government agencies across the board or mostly for certain types of drugs?*

The theory and limited available data suggests that most government entities are paying similar prices for generics and widely different prices for “brand name” drugs. Orphan drugs and drugs without therapeutical equivalents may be special cases and show even greater variation across

government programs. It is important to know what categories of drugs are responsible for most of the variation.

Without the actual data we can not know if most of the variation occurs in certain types of drugs, however, there are some indications that it does.

In 2004, I coauthored a paper that was published in the peer reviewed journal Health Affairs. In the paper we compared the prices for the 30 most commonly sold drugs in the United States to the prices for the same 30 drugs in Canada, the United Kingdom and France in 2003. What we found was that the United States was paying substantially higher prices for the market basket of the 30 most commonly prescribed drugs. We assumed that the private sector would obtain a 20% reduction from the average wholesale price (AWP). **We then calculated that the United States consumer was paying 52% more than people in the United Kingdom, 67% more than people in Canada, and 92% more than people in France for the market basket of 30 drugs.**

However, in conducting the analysis, we also found that the markups were not uniform across the 30 drugs. This illustrates why it is important to analyze the relative prices for each individual drug.

Table 2 compares the prices in the US to the prices in the other countries for each of the 30 drugs. For example, in 2003, **10 doses of Lipitor cost 36% more in the US than Canada, 86% more than in France and 65% more than in the UK. 20 doses of Zocor cost 42% more in the US than Canada, 190% more than in France, and 69% more than in the UK.** Sometimes the US gets the lowest price (Viagra) and in most cases the US pays the highest price.

2. What explains the variations in prices?

Each of the government agencies has a somewhat different approach to determine the price that will be paid for each drug. As a result price variations are to be expected. Some of the government agencies use a formula, others use negotiation, and others rely on the market price. It will be interesting to learn which of the approaches is able to obtain the lowest overall prices and which approach can get the lowest prices for different types of drugs.

My expectation is that the price differences will vary by whether the drug is generic or brand name and whether it is an orphan drug or a drug without a therapeutic equivalent. My expectation is that the generic drugs will show the least variation and the most unique drugs will show the most variation.

3. Should the federal government consolidate its approach to purchasing drugs?

Most other industrialized countries have a single entity that purchases drugs for the government. This may be a more effective way for the federal government to pay for drugs. As shown earlier, the US pays the highest prices for most drugs. Having multiple purchasers of drugs within the government could make the US a less effective purchaser of drugs if the objective is to pay the lowest price for drugs.

More important, the current system of each component of the federal government purchasing drugs independently does not seem to be working. This testimony has relied on numerous studies suggesting that several government programs such as 340 B plans and Medicaid do not know the actual prices they are paying for drugs. The Medicare program does not know the prices that the Part D plans are paying for drugs. There are numerous studies documenting fraud, abuse, and waste in the purchase of drugs. Finally the limited data that is available suggests that there are substantial variations in how much federal government agencies are paying for drugs.

Given the likely variation in prices the different government agencies pay for drugs, I wonder if there is any rationale for the variation in prices across government agencies. I have trouble finding a rationale.

I have trouble understanding why certain government programs should pay more for drugs than others. Should the Medicare program pay more than the Veterans Administration? Should the military pay more than community health centers? Should Medicaid programs pay more than the Indian Health Service? The question becomes what government entity and ultimately what government beneficiary is entitled to pay the lowest price for drugs because they are most deserving.

Currently it seems that the Military and the VA are paying the lowest prices. Both Secretaries negotiate for drug prices.

Because I cannot answer the question of which government program should pay the lowest price, **I believe the Congress should consider greater consolidation of government drug pricing.**

Thank you for the opportunity to testify this morning and I would be happy to answer any questions.

Table 1

Key Factors for Part D Expenditure Estimates

Calendar Year	Annual Per Capita Drug Cost Increase	Cost Management and Discounts	Manufacturer Rebates	Plan Administrative Expenses
Intermediate estimates				
2006	7.1%	21.0%	6.0%	12.5%
2007	7.2	21.0	6.0	11.8
2008	7.3	21.0	6.0	11.9
2009	7.4	21.0	6.0	11.6
2010	7.5	21.0	6.0	11.5
2011	7.5	21.0	6.0	11.3
2012	7.6	21.0	6.0	11.1
2013	7.7	21.0	6.0	10.9
2014	7.7	21.0	6.0	10.7
2015	7.7	21.0	6.0	10.4

Source: CMS Actuaries, 2006 Report

Table 2 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003

Product	Dose	US: Canada	US: France	US:UK
Lipitor	10	1.36	1.86	1.65
Lipitor	20	1.64	.	1.49
Lipitor	40	1.63	1.41	2.13
Lipitor	80	1.67	1.89	1.64
Zocor	20	1.42	2.90	1.69
Zocor	40	1.80	1.79	1.75
Zocor	10	1.00	.	1.30
Zocor	80	1.27	.	1.24
Zocor	5	1.46	1.78	.
Prevacid	30	1.59	.	.
Prevacid	15	1.47	.	.
Paxil	20	1.60	2.48	2.07
Paxil	40	.	.	.
Paxil	10	1.62	.	.
Paxil	30	1.52	.	1.21
Zoloft	100	1.45	.	1.21
Zoloft	50	1.27	1.96	1.62
Zoloft	25	3.41	2.56	.
Celebrex	200	2.29	2.06	2.14
Celebrex	100	2.95	2.65	2.75
Celebrex	400	.	.	.
Norvasc	5	0.96	1.58	1.26
Norvasc	10	1.09	2.63	1.46
Norvasc	2.5	.	.	.
Neurontin	300	1.21	1.38	1.08
Neurontin	100	1.29	1.86	1.09
Neurontin	400	1.24	1.42	1.12
Neurontin	600	1.13	1.36	0.89
Neurontin	800	1.03	1.32	0.94
Effexor	75	1.23	.	1.27
Effexor	37.5	1.94	2.75	1.69
Effexor	25	.	4.08	.
Effexor	100	.	.	.
Effexor	50	.	2.76	1.22
Pravachol	40	2.00	1.93	1.93
Pravachol	20	1.45	2.00	1.16
Pravachol	10	1.74	.	2.15
Pravachol	80	.	.	.
Vioxx	25	2.46	1.73	1.76
Vioxx	12.5	2.07	1.60	1.59
Vioxx	50	.	.	.

Table 2 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003 (Continued)

Fosamax	70	1.68	1.22	1.22
Fosamax	35	.	.	.
Fosamax	10	1.24	1.34	1.25
Fosamax	5	1.62	1.32	1.18
Fosamax	40	1.50	.	.
Wellbutrin	75	.	.	.
Wellbutrin	100	2.39	.	.
Zithromax	250	1.59	2.03	1.61
Zithromax	600	1.40	.	.
Zithromax	500	.	.	1.71
Zithromax	1000	.	.	.
Zithromax	250	.	.	.
Singulair	10	1.32	1.42	1.41
Singulair	5	1.97	1.44	1.43
Singulair	4	2.13	.	1.39
Ambien	10	.	9.62	9.01
Ambien	5	.	.	9.98
Levaquin	500	2.02	.	.
Levaquin	250	2.00	.	.
Levaquin	750	.	.	.
Viagra	100	0.89	0.78	0.78
Viagra	50	0.89	0.93	0.95
Viagra	25	0.93	0.99	1.04
Premarin	0.63	6.27	3.39	3.28
Premarin	1.25	5.16	2.85	3.63
Premarin	0.3	5.36	.	.
Premarin	0.9	4.18	.	.
Premarin	2.5	.	.	5.71
Claritin	10	3.64	5.43	5.37
Augmentin	875	2.95	.	.
Augmentin	500	3.46	4.13	.
Augmentin	250	2.54	3.17	.
Toprol	50	2.99	.	9.10
Toprol	100	2.66	1.21	8.34
Toprol	25	.	0.79	.
Toprol	200	4.29	2.27	5.60
Synthroid	0.08	5.70	.	.
Synthroid	0.1	6.65	.	.
Synthroid	0.05	8.84	.	.
Synthroid	0.13	6.68	.	.
Synthroid	0.15	7.98	.	.
Synthroid	0.03	4.94	.	.
Synthroid	0.11	5.84	.	.

Table 2 Comparing US Prices to Canada, UK, and France for the 30 Most Commonly Prescribed Drugs in the US in 2003 (Continued)

Synthroid	0.2	8.55	.	.
Synthroid	0.18	6.84	.	.
Synthroid	0.3	6.34	.	.
Ortho-tri-cyclin	0	2.98	3.19	.
Allegra-D	60	3.02	.	.
Glucotrol	10	.	1.61	.
Glucotrol	5	.	1.68	.
Glucotrol	2.5	.	.	.
Zestril	20	2.74	0.99	1.12
Zestril	10	1.11	.	1.22
Zestril	40	.	.	.
Zestril	5	1.41	2.81	1.55
Zestril	30	.	.	.
Zestril	2.5	.	.	1.34
Amoxicillin	500	.	0.72	0.74
Amoxicillin	250	.	.	0.70
Amoxicillin	875	.	.	.
Atenolol	50	.	0.32	0.66
Atenolol	25	.	.	0.74
Atenolol	100	.	0.29	0.99
Flonase	---	2.41	3.90	2.36