Hearing: Medicaid and AWP Hearing: Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much
December 7, 2004

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CHAIRMAN JOE BARTON: The sub-committee will come to order. Today we're going to hold a hearing on Medicaid prescription drug reimbursement and why the government pays too much. We've got a number of panels and a number of witnesses. This is a very important hearing. Medicaid is a program for the poorest and sickest in our country. We in the Congress have the responsibility to make sure that every possible dollar available under the program goes to those who need it the most. We also have an obligation to make sure that the American taxpayer gets what he or she is paying for. Unfortunately the current system by which we reimburse providers for prescription drugs under Medicaid flies in the face of both of these principles. The system is broken and it needs to be fixed. The government pays far too much for many prescription drugs under Medicaid, primarily because most states continue to use a system that is called Average Wholesale Price – AWP – is the basis for their reimbursement. For example, during our investigation, the committees obtained documents showing that during the summer of 2002, one drug manufacturer's direct sales price of 2000 20 Mg. capsules of fluoxetine, the generic version of the popular antidepressant Prozac was $82.62, while the Average Wholesale Price was more than 5,300. Let me repeat that. The generic version, $82.62, but the Average Wholesale Price was $5,300.

I'd like to commend the former subcommittee Chairman, Mr. Jim Greenwood, and the current Vice-chairman, Mr. Greg Walden, who is sitting to my right for their work on this issue over the last year. What they've done is very, very important. Chairman Greenwood in particular was tenacious in the pursuit of Average Wholesale Price reform, first in Medicare, where we did change the system, and now in Medicaid, which so far we have not. In fact, today's hearing is an outgrowth of committee's prior work on AWP-based drug reimbursement under Medicare. During a hearing back in September 2001, Chairman Greenwood noted that the tern AWP could just as easily be an acronym for Ain't What's Paid. Apparently this remains true today. As you will hear shortly, the federal government, and ultimately the American Taxpayer could save hundreds of millions or even billions of dollars a year if states would bring drug reimbursements more in line with what they actually cost the pharmacy and other healthcare providers to purchase these drugs. Today's hearing, which is the culmination of an extensive investigation by subcommittee staff on a bipartisan basis will focus on systemic problems with the structure and administration of prescription drug expenditures under Medicaid, as well as abuses of the system. The committee's prior AWP work ultimately led to important changes in last year's landmark Medicare Modernization Act, MMA, changes that

will save the Medicare program $15 billion over the next ten years. It is my profound hope that this hearing, by exposing some of those same problems and abuses, will set the stage for similar Medicaid reform on a bipartisan basis in the upcoming Congress.

Medicaid is supposed to reimburse pharmacists the estimated acquisition costs of the drugs plus a reasonable dispensing fee. Over the years that ABP has emerged as a proxy for estimated acquisition costs. Currently all but eight states rely on AWP as a basis of Medicaid reimbursement. Unfortunately, all too often the AWP bears little or no resemblance to what providers really pay, particularly in the generic marketplace, where multiple manufacturers compete to sell identical drugs that are for all intents and purposes a commodity. During the course of this investigation, the committee has uncovered evidence that several manufacturers either inflate their AWPs or actively market their products, not based on the lowest price, but on the difference between the price and the reimbursement amount, better known in the industry as the spread. Although the manufactures practice to marketing the spread appears to have waned in recent years, due in large part to litigation and the heightened scrutiny generated by the work of this committee and others, the existence of substantial spreads remains a fixture of Medicaid prescription drug

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reimbursement. Let me say that again: The existence of substantial spreads remains a fixture of Medicaid prescription drug reimbursement.

Generic manufacturers initially set up the AWP of their products at 89.9 percent of the brand name's AWP, and in the words of one manufacturer, we set it, and forget it. Meanwhile, fierce competition drives down the actual sales price of these generics, therefore increasing the spread, often dramatically. I want to be clear here that the price competition is a good thing. Generic drugs have a critical role to play in controlling drug costs. Concern, however, is that because of AWP, Medicaid program all too often misses out on these cost savings. Medicaid's use of AWP corrupts the market and turns what would otherwise be a positive development, namely price competition, into abuse that deprives Medicaid of the benefits. The primary beneficiaries of the current reimbursement structure are the retail pharmacies. Data obtained by the committee from five of the largest retail pharmacy chains reveals that during the period of July 1, 2002 to June 20, 2003, the average acquisition costs for seven widely prescribed generic drugs was 22 cents, while the average Medicaid reimbursement just for those drugs alone was 56 cents, more than double the cost, and you can see that on the chart that's up on the overheads. Indeed, evidence gathered by the committee suggests that Medicaid

reimbursement is more generous than that of most private payers.

The pharmacies do not deny that they reap substantial margins on certain prescription drugs under Medicaid. Their argument is that any overpayments for the prescription drugs are necessary to offset Medicaid dispensing fees, which they assert do not cover the true cost of the services that they provide to the Medicaid population. This situation is analogous to position administrated drugs in Medicare. In the new Medicare law, we have attempted to make significant changes in the way physicians administer drugs are reimbursed, scrapping AWP in favor of a new market-based average sales price, and increasing payments for physician services. A recent Government Accountability Office study released just last week shows that the appropriateness of the new payments. Here as in Medicare, I believe that we should pay providers fairly for their services. I've got absolutely no problem increasing dispensing fees if that's what we need to do, but we should pay them accurately so that we can achieve cost savings while ensuring that Medicaid beneficiaries will continue to have access to critically important drugs.

In this context, I'm especially pleased to welcome David Batland from the Texas Health and Human Services Commission and Patrick O'Connell from the Texas Attorney

General's Office. Texas is one of the states on the forefront of Medicaid reform and the approach that the State of Texas has taken to address these problems, an approach that should serve as a model to other states, in my opinion, is one of flexibility, transparency and fairness. Texas has imposed and aggressive reimbursement formula and requires manufacturers to provide transaction data as a means of verifying acquisition costs, while at the same time having one of the highest dispensing fees of any state. These reforms have resulted in substantial cost savings for both the state and for the federal government, yet not one pharmacy has left the program as a result of underpayment. This is work that was begun under then Attorney General John Cornyn who's now one of our senators from Texas, and I want to commend him for his work in that area. As Texas Attorney General in 1999, Senator Cornyn identified Medicaid fraud as a priority and created a special section devoted entirely to this issue. Senator Cornyn was invited to testify here today, but due to a scheduling conflict he's not available.

I want to thank all of our witnesses at today's hearings. I think the amount of money we're spending on prescription drugs under Medicaid program, it's important that we identify reforms to get the biggest bang for the buck. I want to thank the committee staff on both sides of the aisle for the strong work that they've done over the last

year and a half on this issue, and I look forward to this being one of the landmark hearings of this subcommittee. With that I would—Oh, Senator Cornyn has submitted a written statement for the record and we'll put that into the record. Now I want to recognize my distinguished friend from Massachusetts, one of the members who's been a real watchdog on this subcommittee. Mr. Markey of Massachusetts for an opening statement.

REP. ED MARKEY: Thank you, Mr. Chairman, very much, and thank you for having this very important hearing today. We're going to hear from the Department of Health and Human Services' Inspector General, indicating that the federal government is paying far too much for prescription drugs under the Medicaid program. This is not the first time that such concerns have been raised. We have been getting reports of these overpayments since the 1990s, yet the Centers for Medicare and Medicaid Services have continually failed to address their internal mismanagement and the systematic problems that enable drug companies and pharmacies to commit fraud and inflate the prices of their drugs. Prescription drugs are one of the fastest growing expenses for Medicaid. Between 1992 and 2002 expenditures for prescribed drugs increased by 19 percent per year and by 2003, the Medicaid program spent over $31 billion on prescription drugs alone. If we do not address the rising costs of prescription drugs,

it will drain the Medicaid program of the funds needed to provide healthcare to our nation's most vulnerable populations.

There are three problems with the current system that I hope to hear more about in today's hearing. The first is that CMS has been slow to implement simple cost-saving measures within the agency. The second problem is that the price the states pay has nothing to do with the actual costs of the drug. The third problem is that the federal government is not allowed to use its market power to negotiate lower prices for our consumers.

The Inspector General has identified several simple ways that CMS could save money if they were more diligent in their administration of the problem. Putting qualified drugs on the federal upper-limits list as soon as they are approved, for example, could save over $100 million. Unfortunately, not all of Medicaid's problems can be solved so easily. We also have to address the fact that the current reimbursement system practically begs to be exploited. The fact that numerous pharmacies and drug companies have plead guilty to overcharging Medicaid, lying about the costs, taking kickbacks and submitting false claims show the vulnerability of the system. We currently have a system where companies are simply asked to make up the price that the states will pay for their drugs. This price, called the

Average Wholesale Price has not relationship to the actual cost of the drug, and the companies that set that price do not have to provide the states any information about the real costs of manufacturing the drugs. It's like being asked to pay $50 for a T-shirt without having access to any information about what others have paid for the same T-shirt. If the vendors tell you that it is a fair price, but doesn't have to give you any evidence that it is reasonable, you have no choice but to trust that seller that that seller is being honest.

When it comes to spending taxpayer money, we cannot base our decisions on trust; we need to base them on evidence. In order to ensure that states are not overpaying for prescription drugs, they should have access to pricing information and the actual costs of the drug. We will hear today about the new program that has been successful in actually reducing spending on prescription drugs. In April, HHS allowed Michigan, Vermont, New Hampshire, Alaska and Nevada to form a purchasing pool. By combining their programs, they were able to increase their market power and to negotiate better drug prices. At a time when drug prices were rising at a rate of almost 20 percent for year, Michigan's drug prices actually declined about one percent in the first year of their pooling program. In response to their success, administrator Mark McClellan stated that "pools are

a proven legal and safe way to lower drug costs". However, if evidence suggests that pools work and CMS acknowledges that they are an effective way to lower costs, then why is the federal government forbidden from creating one large pool and using its market power to negotiate the best price for Medicaid and Medicare beneficiaries with the drug companies across our country? Today, we are going to hear from WalMart about how they're reducing costs through the purchasing power of their Sam's Clubs. But why can't we establish and Uncle Sam's club that can link up all the states to pool their enormous purchasing power of the federal and state governments to further drive down the costs of prescription drugs for every ordinary American in our country? Why are they forbidden from pooling their resources in order to help those most dependent upon prescription drugs, who are in fact being picked upside-down and having money shaken out of their pockets to pay for prescription drugs that every American knows is overpriced to those vulnerable consumers of needed prescription drugs?

In order to preserve this critical healthcare program we need to find ways to curb the costs of prescription drugs. Instead of wasting taxpayers' dollars on overinflated drug prices, Medicaid funds could be spent on providing better healthcare to our country's most vulnerable populations, the children, the elderly, the poor and the disabled. I look

forward to hearing from the recommendations from the IG, the states and other witnesses, and I compliment you on having this hearing, Mr. Chairman.

CHAIRMAN JOE BARTON: Thank you, Mr. Markey. We now ask our distinguished Vice-chairman of the subcommittee, Mr. Walden for an opening statement.

REP. GREG WALDEN: Thank you very much, Mr. Chairman. Let me begin by saying that I too share the concerns that the states and federal government are spending too much for drugs dispensed to our nation's poorest individuals on the Medicaid program. I look forward to learning more about what we can do to remedy this situation.

In September 2001, as you mentioned, this committee held a hearing that addressed similar problems with prescription drug reimbursement under Medicare. The systemic problems and abuses brought to light in that hearing helped pave the way for significant reforms under the Medicare Modernization Act, scrapping Medicare's reliance on the flawed Average Wholesale Price, or AWP. I noted your comment about Mr. Greenwood saying AWP was paid, I think it was Always Worst Price, at least when it comes to the government. We now turn our attention to Medicaid. Despite differences between the two programs, there is one common denominator, and that is AWP. We've allowed a system to develop where AWP, a number not defined by statute or regulation has become the

reimbursement standard for the vast majority of Medicaid prescription drug programs. Because AWP is not, in many cases, reflective of actual market prices, it opens the door for the abuses that we will hear about today. At the very least, it serves to deny the taxpayer the full benefit of price competition in the generic marketplace.

Let me give you an example. Ipratropium bromide is a popular inhalation drug, used to treat patients with respiratory problems, like bronchitis, emphysema and asthma. Data obtained by this committee during this investigation reveals that between 1998 through 2003 the AWP for most generic manufacturers in the marketplace for a particular size and strength of the drug remained constant at $44 while the sales price dropped from the mid-teens to the low single-digits. In mid-2000, however, another competitor entered the market with an AWP of $56 for that same drug, and internal drug company documents show that the existing manufacturers immediately began to lose business because pharmacies could make more money off of the higher AWP. Data obtained by the committee from five of the largest retail pharmacy operations also show how the Medicaid program failed to capture the cost savings. In fiscal year 2000, the average cost to these pharmacies for a single unit of this particular ipratropium bromide product was roughly 20 cents while their average Medicaid reimbursement was 41 cents for the same product, not

including any dispensing fees. And by 2002 the average cost had dropped to 13 cents, but the average Medicaid reimbursement remained at 41 cents.

We will hear today from the Department of Health and Human Services Office of Inspector General about the substantial cost savings, perhaps totaling hundreds of millions of dollars that could be achieved by eliminating AWP as a reimbursement standard, as well as by placing drugs on the Federal Upper Limit in a more timely fashion. I'm also pleased that Edward Stratameyer, former Vice President of Legal Government Relations and Public Policy at Aventis Pharmaceuticals, a manufacturer of brand name drugs has agreed to appear before the committee to discuss problems that he and his former employer have identified with the use of AWP as a reimbursement standard and the need for AWP reform. Medicaid prescription drug costs are enormous, we all know that. And they continue to rise. In the fiscal year 2002 total Medicaid expenditures for prescription drugs exceeded $23 billion. The Office of the Actuary at CMS projects that Medicaid prescription drug expenditures will increase at an average of 12.7 percent through 2011. In a recent report from the National Association of State Budget Officers predicts that in 2004 states will for the first time spend more on Medicaid than any other program, including education. In light of these soaring drug costs under Medicaid, it is

imperative that the federal and state governments do everything possible to ensure that drug reimbursement is adequate and fair not only to the taxpayers, but also to the pharmacies dispensing the drugs. To date the solution adopted by many state Medicaid programs to the problem if bloated AWP has simply been to modify their reimbursement formulas with larger discounts off of AWP. This is a Band-Aid, not a long-term solution. A discount of a bad number is still a bad number, and at what point does it simply become nonsensical? AWP minus 15 percent? AWP minus 50 percent? AWP minus 80 percent?

As in the case of Medicare, I recognize that as we consider how to reform prescription drug reimbursement under Medicaid we must also consider the impact on the service providers, so let me say up front that no one expects pharmacies or any other healthcare providers, for that matter, to serve the Medicaid population at a loss. If the pharmacies are in fact, underpaid for their services, then let’s examine that issue more fully, analyze the relevant data and take steps to make sure they’re reimbursed fairly for their services and expenses. The answer is not to proceed with the status quo, however, making up shortfalls in one area through overpayments in another, and hoping that at the end of the day everything comes out in the wash. I would point out, however, that according to figures obtained by the

committee, Medicaid dispensing fees are far more generous than those that the pharmacies receive from their largest private payers.

I would also like to thank all the witnesses for appearing here today, and I hope this hearing will serve as a springboard for meaningful Medicaid reform in the near future. AWP is a convention that has long outgrown its usefulness and it is time for us to adopt a reimbursement standard for Medicaid that's more reflective of actual market costs. AWP, we're told, has been described as the devil we know. I guess I'd prefer not to dance with this devil at all. Thank you Mr. Chairman.

CHAIRMAN JOE BARTON: Thank you, Mr. Walden. The chair would note that we have in order of appearance the distinguished member from California, Mr. Waxman and the equally distinguished—well, that was my question. Which of the distinguished members do we want to recognize? They're both equally distinguished. One is the ranking member of the full committee, however. We will recognize Mr. Dingell, for an opening statement.

REP. JOHN DINGELL: Thank you, Mr. Chairman, and I thank my colleague. I think he is overly kind to me, and I want to express my respectful appreciation to him and also to you, Mr. Chairman. This morning we're having a very interesting hearing in which we're trying now to figure out

what it is that is going to happen in the future with [inaudible] to drug prices under the legislation enacted during the last Congress with regard to Medicare and Medicaid and prescription pharmaceuticals. The situation is not one in which we can look forward with any particular comfort. This committee has been addressing the use of AWP or the Average Wholesale Price, as the basis of reimbursement for federal and state prescription drug programs for several years. As we will learn today, the current reimbursement system for Medicaid is built on layers of artificial price structures, most of which in no way reflect actual costs. It has also created the environment that puts providers in situations where they can charge higher drug prices to federal and state governments and also to insurers.

There have been piecemeal efforts to address this flawed system and reduce prices. There's a rebate program which covers $7 billion a year of the $30 billion spent for Medicaid prescriptions. Since 2001 aggressive US Attorneys and state's Attorney's General with the assistance of whistle-blowers such as the ones we will hear from today have uncovered efforts to game the system and have recovered over $1 billion in Medicare and Medicaid overcharges and fines. These lawsuits will continue in New York City and the State of Pennsylvania filing the most recent ones. The states are taking their own steps to reduce drug prices. My own state of

Michigan has been a leader in pooling its bargaining power with other states to get lower prices, and I welcome Paul Reinhart, the head of Michigan's Medicaid program to this hearing, and I look forward to his testimony.

In the Texas drug program, or the Texas vender drug program, which contains actual drug acquisition prices from vendors has recently recommended by an attorneys' panel as one that the Center for Medicare and Medicaid Services, CMS, should consider implementing nationwide. I would ask at this time, Mr. Chairman, that the report by ABT [misspelled?] for Associates be placed in the record.

CHAIRMAN JOE BARTON: Without objection, so ordered.

REP. JOHN DINGELL: Thank you, Mr. Chairman. We also look forward to learning more about this program and from our witnesses from Texas. But these measures alone are not going to solve the healthcare problems of our poorest citizens, nor will taking away health insurance from the poor to reduce the Medicaid rolls. Medicaid is not an essential part of the nation's healthcare system. In 2003 there were 40.4 million persons covered by Medicaid for their health needs, or 13.6 percent of our population. If this program did not exist, almost one third of this nation's total population would be totally uninsured. We need to be stepping up our assistance, and billions of dollars in tax cuts should not come at the basis of the health of our most vulnerable citizens.

We're also here to look at what the Medicare Modernization Act (MMA) will do to the states and the elderly poor. Mr. Reinhart will tell us that Michigan may pay more under MMA for drugs than it ever did before. And on Sunday the New York Times ran a disturbing article about the unworkability of the new Medicare drug plan for the 1.5 million Americans who live in nursing homes, many of them in different stages of dementia or receiving drugs through feeding tubes, people obviously able to come to a judgment about what plan it is will serve their interests best. These people are not on the Internet studying the various drug cards. Nor are they able to. It appears that CMS has no strategy for serving these people. But I look forward to inquiring of CMS about these matters at a suitable time. We must address this critical issue then, in the next Congress at the earliest time. Mr. Chairman, I commend you and I thank you for continuing to focus on the Medicaid drug pricing issues, and I look forward to the testimony from all the witnesses.

CHAIRMAN JOE BARTON: We thank the distinguished gentleman from Michigan and ask our distinguished subcommittee chairman of the Health subcommittee, Mr. Bilirakis from Florida for an opening statement.

REP. MICHAEL BILIRAKIS: Thank you Mr. Chairman. Good morning to all. Today's hearing, obviously by now, focuses on

an issue of great importance, Medicaid prescription drug reimbursement. Prescription drug payments are one of the fastest growing healthcare costs. In 2001 alone, Medicaid spend approximately $20 billion on drugs and from 1997 to 2001 federal Medicaid expenditures—federal Medicaid expenditures, I emphasize—grew at more than twice the rate of total Medicaid spending. The Medicaid program is the largest payer for prescription drugs nationally, representing about 14 percent of the market. The federal government contribution ranges from, as we know, 50 to 83 percent in matching payments depending on the states' per capita income. Examining the amount of money the federal government pays for drugs is a new issue for the Energy and Commerce committee. In both the Medicaid and Medicare programs there have been concerns that the federal government is paying too much for drugs. Congress addressed some of these concerns, hopefully in the Medicare Modernization Act that was signed into law last year, but there's still more work to be done to ensure that prescription drugs are reimbursed at an accurate rate.

Medicaid reimbursement for prescription drugs is complicated as is already obvious to all of us, and as we will see here today, varies greatly from state to state. The federal government sets the maximum reimbursement limit, but within those federal parameters each state establishes its own estimated acquisition costs formula. This calculation is

based on data from published drug prices, Average Wholesale Price info and wholesale prices. However, states do not necessarily have access to the actual price paid for drugs, as has already been state. According to a recent Department of HHS Inspector General Report, the difference between the highest and lowest state Medicaid drug payments ranged between 12 to 4,073 percent. At a glance, this definitely seems odd, doesn't it? However, there are many complicated factors as to why state reimbursement policies vary, the most visible being the acquisition price formula, but there are other factors as well. This subject, is as I think, again, obvious to all of us, will be a top priority for this committee in the 109th Congress. We all look forward to hearing what our witnesses have to say, and I believe and hope that the information that they share with us will help us to move forward in the next Congress. Thank you, Mr. Chairman.

CHAIRMAN JOE BARTON: Seeing no other members present, the Chair would ask unanimous consent that all members not present—Oh, I'm sorry. I forgot Mr. Waxman. Mr. Waxman's distinguished gentleman from California is recognized for an opening statement.

REP. HENRY WAXMAN: Thank you very much. I'm pleased that the subcommittee is holding this hearing today on issue involving Medicaid prescription drug reimbursement. Medicaid,

as you know, is a critical program for over 52 million low-income families and children, and aged, blind and disabled people who rely on it for their healthcare services. It's a program that is costly and it's a program that strains the budgets of the states, who are struggling to meet the needs of their citizens. It is a program that needs better tools to control costs and spend dollars efficiently, and is a program that frankly, needs increased fiscal support from the federal government. While members of this subcommittee might disagree on the best ways to improve and strengthen Medicaid, what surely all of us can agree on is that our scarce dollars be spent effectively. We should not be wasting dollars by overpaying for prescription drugs.

First, of course, in this program as in Medicare, we should be taking all the steps we can to lower the price of prescription drugs, we should be using the bargaining power of negotiation in order to get better prices. Medicare represents millions of people, Medicaid represents millions of people, as does private insurance. We ought to be using that collective buying clout to get better buying prices for the prescription drugs in both programs.

Interestingly enough, Medicaid in some ways has been a leader in this effort. In fact, it was 1990 when we established that Medicaid be given the greater of the best price for brand name drugs or minimum rebate of dollars off

the average manufacturer's price, or AMP. Years before Medicare took similar action, we broke away from the concept of accepting the Average Wholesale Price, or AWP, as the price the program should pay. It was an early recognition that the AWP was an essentially bogus price that bore little relationship to the actual acquisition price of drugs. Further, we attempted to assure competition if there were three or more generics on the market, by limiting the price the program would pay.

But we made a critical mistake when these policies were developed. Even then, the drug industry was powerful, and they succeeded in securing a provision in the basic legislation that kept the best price and the AMP information a secret. Can you imagine that? The federal government knew this information, but we kept it a secret from the states. This has proved to be a costly error. Without this crucial piece of information, states, who were after all, responsible for establishing the reimbursement rates for prescription drugs could not set their reimbursement rates appropriately. AS a result, they continued to rely on the Average Wholesale Price minus some arbitrary amount, simply because they did not have the information needed to set a more appropriate reimbursement rate.

Well, we at the federal level bear responsibility for this, but we can remedy it. We need to make the information

on the AMP and the best price available to the states. I would hope this administration would ask for the authority to do this, and that members of the majority party would support it, even though the pharmaceutical companies might well oppose it. It might mean taking on these drug companies, who seem opposed to transparency, but it makes a lot more sense to save money this way than to slash the federal commitment to the people who depend on Medicaid.

As we will learn today, some states have been very aggressive in attempting to get this information and requiring drug companies to provide it. Too often they have found that the federal government has undercut their ability to do this. There is a further irony in the fact that the so-called claw-back provision of the recently passed Medicare prescription drug bill are designed so that the states that have spent the last few years in aggressive efforts to control increases in prescription drug expenditures will be disadvantaged for their efforts. They will have their fiscal obligation to the federal government grow at a higher rate than would have been the case if their prescription drug price control efforts had continued. This is also wrong, and we should fix it.

I hope this hearing today will shed some light on these issues and help show us a way to save money in Medicaid that will in the end benefit, not hurt the millions of

Americans this program is designed to serve. Thank you, Mr. Chairman.

CHAIRMAN JOE BARTON: Thank you, Mr. Waxman. Not seeing any other members who've not yet made a statement, the chair would ask you now to consent that all members of the subcommittee not present have a requisite number of days to put their written statement in the record. Hearing no objection, so ordered.

We now want to welcome our first panel. We have Mr. Mark Jones, who's President of Venacare in Florida. And we have Dr. John Lockwood, who's Vice-President of that same company, also in Florida. Gentlemen, we welcome you. Your statements are in the record in their entirety. We'll recognize you, Mr. Jones, and then you, Dr. Lockwood, for seven minutes to elaborate on your statement. Welcome to the subcommittee.

MR. MARK JONES: Mr. Chairman [inaudible], my name is Mark Jones. . .

Excuse me, this is an oversight. I have to ask this. I'm not used to doing hearings where I have to swear people in. It is the tradition of this subcommittee since it's an oversight and investigation subcommittee to take all testimony under oath. Do either of you gentlemen oppose testifying under oath? You also have the right under the Constitution to be represented by counsel during your

testimony. Do either of you have counsel here that you wish to advise you during your testimony? Would you then, each of you, stand and raise you right hand?

MALE SPEAKER: Do each of you swear that the testimony you're about to give is the truth, the whole truth, and nothing but the truth, so help you God? Be seated.

CHAIRMAN JOE BARTON: I'm sorry. Now, we can start with you, Mr. Jones. Seven minutes.

MR. MARK JONES: My name is Mark Jones. I'm the President of . . .pardon? Try it again. My name is Mark Jones. I'm President of Venacare of the Florida Keys. I wish to thank you for the opportunity to appear before you today to discuss a matter of vital importance to the government healthcare benefit programs such as Medicaid. Before I go on, this is Dr. John Lockwood. He's the Vice-President of Venacare, as well.

Today's hearing focuses on excessive reimbursement for pharmaceutical products by the states' Medicaid programs. Deceptive price reports by some drug manufacturers are causing hundreds of millions of dollars of damages to our country's joint state and federal healthcare programs for the poor. The inflated reimbursements resulting from deceptive reports of prices have a corruptive effect on our healthcare system. Venacare has learned this firsthand, when it suffered economic retaliation for its refusal to enter into a business

arrangement where inflated reimbursements were used to enrich positions in order to induce them to increase their orders or expensive drug therapies. The HHS OIG has reminded drug manufacturers that reporting deceptive price information to government programs is unlawful. The OIG said the following in its 2003 program compliance guidance for pharmaceutical manufacturers about the integrity of data used to establish or determine government reimbursement: The OIG said, “Many federal and state healthcare programs establish or ultimately determine reimbursement rates for pharmaceuticals either prospectively or retrospectively using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent or misleading information is actionable.”

The difference between the amount a provider is reimbursed for a drug and the provider’s cost is the spread. In the context that we are addressing today, it means the difference between the cost to the pharmacy or other provider, and the amount Medicaid reimburses for the cost of the drug. The greater the spread, the greater the profit. When a manufacturer reports a price that exceeds the price at which its drug is selling for in the marketplace, that states Medicaid programs determine reimbursement amounts that are

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higher than the government sends. Participating manufacturers then engage in conduct known as marketing the spread by mens such as the following: Some manufacturers take action to increase reimbursement by further inflating their reported prices in order to persuade customers to buy their drugs. Some manufacturers train their sales personnel to pitch the higher reimbursement spread on their drugs as compared to their competitor's drugs. The reimbursement on manufacturer's drugs is routinely marketed through software programs and data provided by wholesalers and group purchasing organizations that show the pharmacy the comparative spreads on manufacturer's drugs so that that pharmacy can choose the drug with the greatest spread.

Not withstanding explicit warnings from the OIG, the drug manufacturer executives who report inflated prices and direct their subordinates to market the spread often contend that their deceptive conduct should be blamed on the government reimbursement programs themselves. They argue that their reported prices are no more than list prices and need not be good faith representations of what their drugs actually sell for in the marketplace. Executives and other representatives from these companies have actually contended that it is the industry standard for them to make up any price they choose and report it for use by government reimbursement programs, even if the reported prices are ten

times the true prices they know are generally and currently available in the marketplace.

Such assertions have been rejected by the courts. For example, in a recent case involving the drug Lupron, United States District Court Judge [inaudible] Stearns spoke directly to such preposterous assertions by the drug company defendants. Judge Stearns wrote, “Defendants repeatedly assert that they had no duty to disclose what was publicly known to everyone, that is, that the Lupron AWP was a sticker price and never intended to reflect the drug’s wholesale price. In support of this argument, defendants cite a number of government reports acknowledging that published AWPs for prescription drugs often exceed their acquisition cost. The argument is ultimately unpersuasive. There is a difference between a sticker price and a sucker price.” Judge Stearns then addressed an argument often made by drug manufacturers who are caught reporting inflated prices. They argue that the United States Congress actually condones and even encourages such deception. Judge Stearns wrote again, “The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual.”

It’s my hope that my testimony as well as the information gathered through this committee’s investigation will illuminate certain factors and concerns which I believe

are critical to understanding the Medicaid reimbursement problem. They are: Drug manufacturers choose to have their drugs covered by Medicaid, they are not required to do so. Drug manufacturers know that the state Medicaid programs rely on the prices the manufacturer reports directly or through the price reporting compendia. As with any system of government reimbursement, pharmaceutical reimbursement is based upon trust, in this case, trust the drug companies will report their prices in good faith. The root of the problem for Medicaid reimbursement for pharmaceuticals lies with those drug manufacturers that choose to deceive rather than tell the truth about their prices. The excuse that a company will lose market share if it reports prices truthfully should not be accepted from pharmaceutical manufacturers. Other industries, such as banking, communications, electrical power and defense manufacturers have been faced with similar integrity issues. Any legislation directed at improving the Medicaid reimbursement system should not inadvertently produce a potential defense through which manufacturers may argue that Congress has somehow absolved them from their passed defalcations. Judge Stearn’s decision, quoted above illustrates that the manufacturers who have participated in this scheme seek to misconstrue the intent of Congress as somehow approving their deceptive conduct.

In closing, I would ask that this committee consider

the insidious damage that such deceptive practices have on our free market system. The contention by drug manufacturers that deception is somehow justified when it becomes widespread in their industry reveals a serious and fundamental integrity flaw that, if left unaddressed, threatens the taxpayer, the patient and the industry itself. Mr. Chairman and members, thank you for the chance to appear before your committee. Dr. Lockwood and I are happy to answer questions.

CHAIRMAN JOE BARTON: Dr. Lockwood, you don't have a statement that you—?

DR. JOHN LOCKWOOD: No, I don't.

CHAIRMAN JOE BARTON: Okay. The Chair would recognize himself for five minutes, ten minutes. Dr. Lockwood and Mr. Jones, explain in layman's term what Average Wholesale Price should be. What should it mean?

DR. JOHN LOCKWOOD: Average Wholesale Price has been a benchmark for the industry for over 30 years, and for brand drugs, AWP is a fairly reliable benchmark. About 80 percent—at least, based on our studies and government studies and talking to Medicaid program directors—about 80 percent of the Medicaid dollars are paid on brand drugs and are fairly accurately reimbursed.

I don't want to know what the tradition is. I want to know in layman's terms, Average Wholesale—I'm trying to

think, if I go out and I grow cotton, I know what it cost me for the seed, I know what it cost me for the tractor, I know what it cost me to own the land, if I'm paying on it or to rent the land if I don't own it, and when that cotton crop is ready to go to market, I've got a pretty good idea what my costs are, and I add some profit margin, which is a little bit based on the market and demand and supply, and that's my Average Wholesale Price, I think. So in drugs, all these different manufacturers who tend to be running around like, "We don't know what Average Wholesale Price is. It's some number that we can stick out there, and the higher the better, because it increases the spread that we can then discount to encourage the pharmacies to use our drug, because they get a bigger markup on it." What should it be? And how, if we wanted to set some sort of a federal standard in law for Average Wholesale Price, what should it be? That's my question.

DR. JOHN LOCKWOOD: We believe that Average Wholesale Price should be a number that's reflective of the underlying marketplace that the drug manufacturer sees when they look at their own books. And, because AWP is not defined, but they've sometimes interpreted average to mean usual. The average or usual wholesale price. Traditionally, it has been 20 percent higher than the invoice price that the wholesaler gets, so that when a drug manufacturer sells to a wholesaler. There's

an invoice price.

CHAIRMAN JOE BARTON: So you're saying it's not a cost-based price? It's not based on the cost of the manufacturer of the drug to actually produce and market that drug. It's not a cost-based price, it's a market-based demand price.

DR. JOHN LOCKWOOD: It's a market-based price. We in this country have never instituted price controls, and my partner and I are certainly capitalists, and we don't believe in price controls. We believe drug companies should be able to set their own prices, but we think those prices should be reflective of their underlying marketplace. We don't want to get into the business of manufacturers. If they can produce something for a dollar, and sell it in the market for ten, that's their business. But the shouldn't report to the government that when they're actually selling it for ten, that they're selling it for 100, and that's what's happening with AWP. They're saying this drug costs $100, when everyone in the market is buying it at ten.

CHAIRMAN JOE BARTON: So we ought to do away—I mean, if it's okay for the manufacturer to set the price wherever they want, what we should do from the federal government perspective is whatever you actually sell it for is what you report it for. If you sell it for $1000, you report it. If you sell it for ten cents, you report it, but don't say, "I'm

gong to sell it for 1000, and I'm really selling it for $10."

DR. JOHN LOCKWOOD: Correct. We believe in capitalism. We think drug companies should be able to set their prices. They just need to report them in an accurate and fair and responsible way, much like the OIG has recommended in their compliant—

CHAIRMAN JOE BARTON: The people that are setting this Average Wholesale Price, is that the manufacturer, or is it a middleman that sets that price?

DR. JOHN LOCKWOOD: Well, there's been argument about that, but I don't think anyone argues that the compendia certainly use prices they get directly from manufacturers to calculate AWP. In some circumstances, manufacturers send the AWP to the compendia and tell them that is their price. In other circumstances they send their price that they know the compendia are going to mark up 20 percent, for instance, which has been a common industry amount. So they know that when they send a price of $100 that the compendia are going to make an AWP of $120. There's no confusion there. What's more, our investigations have shown that all the compendia send a report to the drug manufacturers every year and ask them to verify that the prices they're reporting are in fact correct, accurate and appropriate, and if they're not right, they need to be changed.

CHAIRMAN JOE BARTON: Well, if we have some

manufacturers testify later, and I ask them, what's wrong with reporting what your true selling price is, what is wrong with that? What is it that is so scary or so negative toward their continued existence as a for-profit entity that they can't report what the real selling price is?

T **DR. JOHN LOCKWOOD: T**he transparency seems to scare them dramatically. Exactly why, you may need to ask them. I could speculate, but—

CHAIRMAN JOE BARTON: Well, speculate!

DR. JOHN LOCKWOOD: We believe that the real market prices may actually become lower as a result of transparency. My point being, that if you have a drug that you're selling at a high AWP, you may actually be able to sell that drug for more money than your competitor, because you have a better spread. I don't want to confuse you, but if you're selling a drug for $10 and your AWP is 100, you might go and get $10, whereas another company might be selling the drug for $5, but because their AWP is 50, nobody's buying their drug. So that, high AWP's help drag up, in some circumstances, the transaction prices.

CHAIRMAN JOE BARTON: But if we switch to a system where they actually report the real selling price, and document and verify, not price controls, but some sort like we have in the natural gas market or the oil market, or any other market where there's buy and sell and some sort of a

commodity function over time, everybody's going to know what the true prices are, at least the selling price, not the proprietary costs, but the actual selling price, and the best win, right?

DR. JOHN LOCKWOOD: Absolutely. We believe that's fair and appropriate. We think they have that obligation now. There's some disagreement on that. But we believe that the government should be benefitting from transparency in price transactions. That will lead to a true marketplace. Currently, Medicaid, Medicare—until you recent bill—and consumers are price shielded from true competition that's occurring in the marketplace. We're seeing these AWPs but not seeing the real marketplace.

CHAIRMAN JOE BARTON: But if we did that, if we went to a requirement for true price reporting, gave some flexibility on the dispensing fee for pharmacies so that if their costs for dispensing the prescription for Medicaid is truly high or something, they get reimbursed for that, implement that, have a transition period, year, two years, go from the old system to the new system, is there any reason that that wouldn't work and result in significant savings to both the state and federal coffers for Medicaid and to the consumer's for on the copayment side if they have a Medicaid copayment?

DR. JOHN LOCKWOOD: We believe it will work, and we

believe it’s ideal. It preserves capitalism in the marketplace and it fosters competition, and it’s what should be happening in this market.

CHAIRMAN JOE BARTON: Anything I haven’t asked you that I should in the next ten seconds before my time expires? [LAUGHTER?]

DR. JOHN LOCKWOOD: We need more than ten seconds, probably.

CHAIRMAN JOE BARTON: Okay. My time’s expired. I recognize the gentleman from Massachusetts, Mr. Markey for ten minutes.

REP. ED MARKEY: Thank you, Mr. Chairman, very much. So what you’ve got here is a situation where a drug company makes a drug. They’re selling 100 pills for $100 wholesale, and so it looks like the price is $100 for 100 pills, but actually there’s a ten percent discount to the wholesaler, so it’s really only $90 for 100 pills to the wholesaler. And then the wholesaler can further try to make a profit as a wholesaler on their sale down the chain. Meanwhile, the report to Medicaid is that it actually cost $125 for the 100 pills, which is then the price which the federal government and the taxpayer has to pay, although we know that the actual price is $90 for 100 pills, because that’s the real world. The made up number, the Average Wholesale Price is the price that we have to pay, Americans have to pay for these pills.

How do they make up this Average Wholesale Price, which is perhaps 35 percent higher than the actual cost to an actual wholesaler to purchase these drugs? How do they make up that number?

MR. MARK JONES: I think more importantly than how they make it up is what they're doing with it. Basically in the generic marketplace right now manufacturers are always in control of their prices. They own every price that's ever published. It's theirs. They are taking those published prices, using the difference between what they're selling it for and what the end buyer is going to bill the program, gets reimbursed for, as their marketing tool to sell their drugs. So that's called the spread. A manufacturer reports price, $125 is the AWP, Medicaid uses that $125 to reimburse whoever's billing it, yet they sell if for $90. Well, the difference between $90 and $125 is the spread. That's the financial incentive that these companies use to sell their drugs, because you're talking about a generic market. You're talking about marketplace in general where there's seven or eight manufacturers of the same drug.

REP. ED MARKEY: Okay. Well, we held our first hearing on Average Wholesale Price in 2001. The drug companies have paid over $2 billion in fines, penalties and reimbursement to the federal and state governments. Now, that's a lot of money. But has anything really changed in the

marketing of prescription drugs to the retailer since 2001.

MR. MARK JONES: Well, I think for those manufacturers who have participated in paying that money, a lot has changed! I mean, obviously—

REP. ED MARKEY: How about for the marketplace in general?

MR. MARK JONES: No, I think the marketplace obviously has an awareness of what they're doing. Maybe a little anecdotal evidence here. Over the time period that we've been investigating this, we've heard drug manufacturers first claim that they didn't know where AWP came from, it wasn't their number, and then that evolved into, "Yes, we set the AWPs," and then we heard drug manufacturers say, "We don't know anything about marketing the spread. We're not interested in marketing the spread. We're only interested in the price that we charge our customer." But we finally evolved into, "Yes, there is a spread out there, and yes, we do market it." And now we're at the point with this industry where they're saying, "Look, it's so messed up, everybody wants to buy drugs based solely on the spread value, and we can't stop it even if we want to."

REP. ED MARKEY: So has the spread between the Average Wholesale Price paid by their retailers been reduced, or is the Average Wholesale Price as false as it always was?

MR. MARK JONES: Well, obviously depending on the

drugs, because different drugs have different methods of pricing. But I think—

REP. ED MARKEY: Which drugs still have a false price?

MR. MARK JONES: The generic industry drugs, basically your generic drugs. That's how they're marketing them in this country right now.

REP. ED MARKEY: So the industry [inaudible] that they still need a very high Average Wholesale Price, whether it is openly marketed or not, is that correct?

MR. MARK JONES: Yes. That's their argument.

REP. ED MARKEY: Now, is it a justified argument?

MR. MARK JONES: Absolutely not.

REP. ED MARKEY: Why not?

MR. MARK JONES: Because they're using precious government funds as the incentive for selling their drugs, to market their drugs with.

REP. ED MARKEY: So, one of the witnesses on the third panel will testify that the real acquisition costs for wholesalers it the reported wholesale acquisition costs plus five percent. Is that a good base price to use for reimbursements?

DR. JOHN LOCKWOOD: Well, for some brand drugs, that is an accurate number. But for a whole host of other drugs, the wholesale acquisition costs has been altered over time

and is not longer an accurate number. We discovered that in Texas, certainly. Texas is paid of a price to the wholesaler, and we found essentially that there's fraud in the WAC marketplace as well.

REP. ED MARKEY: So what is your view of the Federal Upper Limits set up by CMS by the federal government? Do they reflect the real costs of the drug.

DR. JOHN LOCKWOOD: The Federal Upper Limit has been an attempt by the government to ensure prudent purchasing in generic drugs, and they essentially are saying, this is a ceiling price. We're not going to pay anything more than this. The problem with the FUL is that it's based on reported prices, and that if a manufacturer or a whole host of manufacturers are reporting inflated prices, whether it be WAC, direct price or Average Wholesale Price. If those are inflated, the resulting FUL is inflated.

REP. ED MARKEY: FUL means?

DR. JOHN LOCKWOOD: Federal Upper Limit. It's an upper limit price that CMS creates, the limit reimbursement on generics, so that the lowest generic price reported, if it's $100, the FUL basically says, We're not ever going to pay more than $150.

REP. ED MARKEY: A markup of a spread of 25 to 35 percent seems incredibly high and unreasonable to me for a markup in a commodity marketplace, don't you agree?

DR. JOHN LOCKWOOD: We agree with that. We are proponents of average sales price.

REP. ED MARKEY: So if every wholesaler is able to reap a 25 to 35 percent spread, doesn't that suggest that there isn't real price competition in the prescription drug market?

DR. JOHN LOCKWOOD: Well, in fact, wholesalers don't receive those kinds of benefits. Generally speaking, wholesalers are probably making one or two or three percent.

REP. ED MARKEY: What about the pharmacies?

DR. JOHN LOCKWOOD: The pharmacists are then taking advantage of those spreads. And you know, we're not against paying pharmacists appropriately and fairly.

REP. ED MARKEY: Do the pharmacies deserve to get a 25 to 35 percent markup in the price of drugs to Grandma who is standing there in front of the counter? Do they deserve that kind of markup?

MR. MARK JONES: Medicaid is trying to estimate acquisition costs. Thirty percent markups over acquisition costs are not realistic in the Medicaid program.

REP. ED MARKEY: So, what's the fix then? How do you make sure that Grandma isn't digging through her pocketbook standing there trying to pay a 25 to 35 percent markup for a drug that we all know is nowhere near that cost in terms of its manufacture and delivery right to that counter? So why

should she, knowing that she's going to have to take that pill in half and hour, have to pay that money, and how do we fix that problem at that counter?

DR. JOHN LOCKWOOD: In fact, your 25 and 30 percent is very low. If we could bring up Slide #6 perhaps? This will give you an idea, and it's in your binder under #4. If you'll look at it, you'll see that there are huge spreads involved in some of these common generic drugs. In the case of fluoxetine, we're talking about an AWP of $259.85, and the current cost last week is, $4.25 for that bottle, for the whole thing. And even the FUL isn't capturing this, okay?

REP. ED MARKEY: So, we've got a situation here where the pharmacist is saying that poor Grandma, that is the federal government or the states have to pay 25 to 35 percent more for the drugs, but the states could be using that money to lower the costs for Grandma to be in a nursing home, to lower the costs for more children to be covered by a medical program that would increase the health of the children in that state, and yet the pharmacy is saying, "We won't give this drug to Grandma unless you give us this 25 to 35 percent markup.

So what we need from you in 30 seconds, is how you fix that? [LAUGHTER.] What do you recommend to fix that at that counter to make sure that the drugs are a price that they should be so that all the rest of the money could be

used to help Grandma and the children in that community to have a higher healthcare?

CHAIRMAN JOE BARTON: The gentleman's time has expired. We'll let the witnesses answer the question and go to Mr. Walden.

DR. JOHN LOCKWOOD: I think we like average sales price. The GAO just came out, I think six days ago, has verified that average sales price is an effective way of estimating drug costs, and then by all means, taking care of the pharmacies. Paying them a reasonable dispensing fee for their services. They have to make a profit. They have to stay in business. They have to distribute our drugs.

REP. ED MARKEY: In other words, use the Medicare system to determine the price, rather than this system that Medicaid is now using, because the Medicaid system allows for the taxpayer and Grandma to get ripped off in terms of the benefit they receive, is that correct?

DR. JOHN LOCKWOOD: We like the ASP system, yes.

You like the Medicare system better than the—

DR. JOHN LOCKWOOD: The new Medicare system, yes, sir.

CHAIRMAN JOE BARTON: I'd like to point out before we recognize Mr. Walden that we have changed in Medicare to the Average Sales Price in this MMA, the Medicare Modernization Act. CBO says that should save about $15 billion over the

next ten years, so I'm not saying we got it right in Medicare, but we're moving in the right direction, and the purpose of this hearing is to see if we can't do a similar thing in Medicaid, and we obviously see that there are lots of areas that we can improve in. With that, we recognize Mr. Walden for ten minutes.

REP. GREG WALDEN: Thank you, Mr. Chairman. Before I start asking questions, I'd just like to ask that the documents that are contained in the exhibit binder be made a part of the official record. Thank you Mr. Chairman. You know, gentlemen, it seems to me like this is the proverbial $500 toilet seat of Medicaid, the AWP is, and I'm wondering what the FUL is, because if you look at your chart there, the Federal Upper Limit doesn't seem to be a standard that works either, compared to the price that's actually being paid. Is that correct?

MR. MARK JONES: Unfortunately, it's a price that's determined off of the manufacturer's reported prices, so it's as vulnerable to price manipulation as any other.

DR. JOHN LOCKWOOD: Could we bring up Slide 8?

REP. GREG WALDEN: I was just going to go to Slide 8. Indeed. We could go to Slide 8. there you are. All right, go ahead.

DR. JOHN LOCKWOOD: This Slide is based on current prices and the ASB plus 6 from the second quarter of 2004, so

I don’t, we are mixing apples and oranges a little bit here. The current cost price is listed in the column.

REP. GREG WALDEN: So let’s take ipratropium. Three dollars and fifty cents is the current price?

DR. JOHN LOCKWOOD: Yes, sir.

REP. GREG WALDEN: As of when?

DR. JOHN LOCKWOOD: Oh, about three days ago.

REP. GREG WALDEN: And the Federal Upper Limit is as of, a year ago?

DR. JOHN LOCKWOOD: Yes.

REP. GREG WALDEN: And why is that price from November 2 or ’03?

DR. JOHN LOCKWOOD: Well, that was the date the FUL was changed, and I—

REP. GREG WALDEN: Isn’t that another issue that we face, is updating the FUL list?

DR. JOHN LOCKWOOD: Yes, we do, but I don’t know if the recorded prices have changed or not. In fact, they may not have changed in the past year. If the manufacturers are continuing to report the same prices they did at that time, the FUL won’t change.

REP. GREG WALDEN: Well, I think there’s also an issue in the IG’s report about how often these prices get adjusted once they’re determined generics on the market. There’s a continuing problem there that may date back a

decade, it seems like, or at least a half a decade, if not more. Well, how current is the AWP? Is that the same issue?

DR. JOHN LOCKWOOD: The AWPs are current now.

REP. GREG WALDEN: So the $4.10 for ipatroprium is a current price?

DR. JOHN LOCKWOOD: Yes, Sir.

REP. GREG WALDEN: So you're looking at more than ten times the price. The spread is more than ten times the actual price.

DR. JOHN LOCKWOOD: Yes, Sir.

REP. GREG WALDEN: And who's pocketing that difference?

DR. JOHN LOCKWOOD: In general, the pharmacies, the providers.

MR. MARK JONES: The manufacturers are also benefitting by the market and market share.

REP. GREG WALDEN: So there's a marketplace working here, isn't there?

DR. JOHN LOCKWOOD: Absolutely.

REP. GREG WALDEN: It's just not working for the benefit of the person paying the bill. And generally in America, the marketplaces that we like are the ones that benefit the buyer. Isn't that how you foster competition?

MR. MARK JONES: The consumer's not benefiting here.

REP. GREG WALDEN: The consumer's losing, the state's

losing, the federal government is losing, people in between are making at least what would appear to be a tidy profit. Now, we also have to recognize that this AWP isn't necessarily the price being paid, right?

DR. JOHN LOCKWOOD: That's correct, there's usually a discount.

REP. GREG WALDEN: Because they will discount off of that.

DR. JOHN LOCKWOOD: And it would be all to the FUL for most state Medicaid programs.

REP. GREG WALDEN: And are these FUL, current cost, AWP prices, are they fairly representative of all the drugs or are these the worst case examples?

DR. JOHN LOCKWOOD: These are not the worst cases. In fact, I have included a couple of charts.

REP. GREG WALDEN: Do you want to reference those?

DR. JOHN LOCKWOOD: A wide range of drugs that's in your binder under #4. And these represent drugs that are antidepressants, inhalant drugs, antibiotics, cancer drugs, such as tamoxifen, used in breast cancer, and high blood pressure drugs, so this is over virtually the entire drug marketplace. It's not just one little niche where this is occurring.

REP. GREG WALDEN: You're seeing some—I'll probably not pronounce this correctly—ranitidine?

DR. JOHN LOCKWOOD: Ranitidine.

REP. GREG WALDEN: I got that wrong.

DR. JOHN LOCKWOOD: It's a drug used to control stomach acid that's now actually over the counter.

REP. GREG WALDEN: And we're paying 44—Well, the current cost is 44.92 over the counter?

DR. JOHN LOCKWOOD: That's for a bottle for 1000 pills. The current cost is $44.92.

REP. GREG WALDEN: And the AWP is $1480?

DR. JOHN LOCKWOOD: Yes, sir.

REP. GREG WALDEN: And that's a current AWP?

DR. JOHN LOCKWOOD: Yes sir.

REP. GREG WALDEN: All right. Have you done any analysis of how good a job these Federal Upper Limits do in capturing cost savings?

DR. JOHN LOCKWOOD: Well, they certainly reduce, as you can see in that drug, if the government's paying $341 instead of $1480, that's a significant cost savings, but when you compare the FUL, if you look at the FUL spread on that column, you can still see that there's a huge, huge profit involved there. And it's because the FUL is based on reported prices that manufacturers seem to do what they want with.

REP. GREG WALDEN: What I struggled with is why this isn't considered some sort of fraudulent billing practice.

DR. JOHN LOCKWOOD: I believe we consider it fraud.

REP. GREG WALDEN: Why?

DR. JOHN LOCKWOOD: Because of—actually the OIG probably did a much better job of explaining it than I could. I'm not an attorney, but the OIG really set down the guidance to manufacturers in 2003 and they point out that these type behaviors may be actionable under the false claims act and under the anti-kickback statute. And I'm no attorney, but I'm relying on them.

REP. GREG WALDEN: Several drug manufacturers have asserted in their written statements that the current Medicaid reimbursement system effectively puts them between a rock and a hard place. They can't lower their AWP to make it more reflective of actual market prices without losing all of their business. How do you respond to that argument, and I've got some e-mail traffic that indicates very clearly that there's enormous market pressure to raise the AWP or you'll lose market share.

MR. MARK JONES: Certainly they use the reported prices to gain market share in the generic marketplace. Off the top of my head when I think about that statement, they corrupted the system. They're the ones that are responsible for reporting the prices. Those prices come from them and the selling prices come from them. So now they find themselves in that untenable position of not being able to adjust or correct a system that they've already corrupted.

DR. JOHN LOCKWOOD: They can't stop the fraud.

MR. MARK JONES: They did too good a job educating the consumers who were going to bill the program, the pharmacists or the doctors or whomever is receiving the benefit of selling that drug. They've educated them so well, I mean—

REP. GREG WALDEN: They're marketing the spread.

MR. MARK JONES: Absolutely.

REP. GREG WALDEN: And the idea is that the bigger the spread, the more the take.

MR. MARK JONES: The higher the utilization in certain circumstances.

DR. JOHN LOCKWOOD: Manufacturers will tell you they can't stop doing this unless everyone stops at once. They'll tell you they can't quit doing it unless everyone stops at once.

REP. GREG WALDEN: Which is why it's up to us to make that change, isn't it.

DR. JOHN LOCKWOOD: Because if there's a half a dozen companies in the market and one of them stops

REP. GREG WALDEN: They're out of business.

DR. JOHN LOCKWOOD: They're out of business. Now, Avick Laboratories did some significant price changes in 2001 that significantly lowered their prices in the marketplace, and it think they should be commended for it.

REP. GREG WALDEN: And what was the impact of that?

DR. JOHN LOCKWOOD: Well, they lowered AWPs on a whole host of drugs enormously. Now, I don't have that information in front of me, but they made a substantial change in their price reporting on a whole host of drugs.

REP. GREG WALDEN: Can you turn to Tab 5 in your binder, there please, sir? It's in the final minute and a half I have here. This exhibit is information on pricing from a company called Innovatix? Innovatix? Your home infusion specialists. And I'm intrigued because this would seem to be a document available how? Through subscription service or something?

DR. JOHN LOCKWOOD: To members it's available over the Internet.

REP. GREG WALDEN: Members of?

DR. JOHN LOCKWOOD: Innovatix.

REP. GREG WALDEN: Okay. And it lists the AWP spread, the AWP. It's pretty hard to read on this graph. And then the contract price, right?

DR. JOHN LOCKWOOD: Yes, sir.

REP. GREG WALDEN: Doesn't this give us the data where we could make more informed decisions about actual costs of drugs being sold out on the market? These reflect prices in the marketplace, and isn't that what Medicaid and Medicare and other consumers should be paying, based on that?

MR. MARK JONES: Absolutely.

DR. JOHN LOCKWOOD: We believe that.

REP. GREG WALDEN: There are some who make an argument that if you just add a percentage to this price, say, you know, a contract price plus six percent for overhead, you're going to distort the market as well, and just continue to drive up price to get the higher percentage. How do we wrestle with that?

DR. JOHN LOCKWOOD: Those are difficult issues. It's hard unless you have a prospective payment program like Medicare has for hospitals to control every cost. I think our effort has been to get the real market prices and then deal with that.

REP. GREG WALDEN: Because what we don't want to do here is create another AWP, another system that functions in an inverted way, if you will, so—I appreciate your testimony today. Thank you Mr. Chairman.

CHAIRMAN JOE BARTON: Before we go to the next one, the key, though, is the government reimbursement rate has got to be based on an actual price that somebody pays, not on some artificial posted price.

DR. JOHN LOCKWOOD: Yes, sir, we do.

CHAIRMAN JOE BARTON: We've got to change like we have in Medicare, from some sort of—I won't say a made up price, but a sticker price, to what somebody who's actually

going to use the drug is paying.

MR. MARK JONES: Something that has a basis in reality and the marketplace.

CHAIRMAN JOE BARTON: Yeah, and that has to be transparent. It has got to be verifiable and there has to be some ability for willing buyers and willing sellers to have some degree of certainty that that is a real price available to anyone that meets the conditions of quantity and deliverability and things like that.

We want to thank you for your testimony. There may be some written questions for the record, and we would ask that you reply as quickly as possible, because we are going to attempt to legislate in the next Congress.

MALE SPEAKER: Sort of like, trust but verify.

CHAIRMAN JOE BARTON: Trust but verify. I've heard that somewhere. But thank you gentlemen. You are excused. And now I'd like to have our second panel come forward. We have Mr. George Reed, who is the Assistant Inspector, Centers for Medicare and Medicaid Audits. He's accompanied by Mr. Robert Vito, the Regional Inspector General for Evaluations and Inspections for the Philadelphia region. We also have Mr. Dennis Smith who's the Director for the Center for Medicaid and state operations, Center for Medicare and Medicaid Services here in Washington. We have Mr. Patrick O'Connell who's the Assistant Attorney General for Civil Medicaid Fraud

in the Texas Attorney General's Office in Austin, Texas, Mr. David Deland, who is the Associate commissioner for Medicaid and CHIP, the Texas Health and Human Services Commission in Austin, Mr. Paul Reinhart, who's the Medicaid Director for the State of Michigan in Lansing, Michigan. Welcome, gentlemen. It's the tradition of this subcommittee to take all testimony under oath. Any of you object to testifying under oath? You also have the right to be advised by counsel during your testimony. Do any of you have counsel with you that you wish to also swear in? Will you all please rise and raise your right hand?

MALE SPEAKER: Do each of you swear that the testimony you're about to give is the truth, the entire truth and nothing but the truth, so help you God?

MALE SPEAKERS: I do.

MALE SPEAKER: Be seated.

CHAIRMAN JOE BARTON: Your testimony's in the record in its entirety. We're going to start with you, Mr. Reinhart, and we're just going to go right down the row and give each of you gentlemen that wish to elaborate on your testimony seven minutes to do so. So, welcome to the subcommittee, Mr. Reinhart.

MR. PAUL REINHART: Thank you. Good morning Mr. Chairman, and members of the subcommittee. Thank you for this opportunity—

CHAIRMAN JOE BARTON: Pull that microphone directly towards you, sir, please.

MR. PAUL REINHART: Good morning Mr. Chairman, and members of the subcommittee. Thank you for this opportunity to discuss Medicaid prescription drug policies. My name is Paul Reinhart and I'm the Director of the Michigan Medicaid program.

While we work very hard to constrain cost increases in all areas of the Medicaid program, Michigan's pharmacy cost containment efforts have been particularly effective. Unfortunately, one aspect of the Medicare Modernization Act will increase pharmacy costs, at least in the short term. Michigan Medicaid program utilizes many strategies to hold down the costs of the pharmacy benefit.

The three major initiatives we have used in Michigan are our preferred drug list, the multistate drug purchasing pool and limiting reimbursements to pharmacists to their actual acquisition drug costs. These strategies have been quite successful and have produced savings not only for Michigan, but also for the federal government. In fiscal year 2003, the first year of our preferred drug list program, prescription cost increases declined to four percent from the 11 percent increases that routinely occurred in prior years. Similarly in fiscal year 2004, the first year of our multistate purchasing initiative, per beneficiary costs for

prescription drugs actually declined by about one percent. We believe our aggressive cost containment programs saved us $130 million in fiscal year 2004.

The Michigan Medicaid program, like a growing number of states, uses a preferred drug list, or PDL to discourage physicians from prescribing high-cost drugs when lower-cost but equally effective drugs are available. Here's how the PDL works: A committee of physicians and pharmacists and Medicaid staff uses evidence-based information and costs to decide which drugs will be included on the preferred list. Drugs not on the list are available, but the prescribing physician must secure prior authorization from our pharmacy benefit manager. This program has substantially increased the use of low-cost generic drugs.

The ability of the preferred drug list to generate savings is enhanced by out multistate purchasing program. When Governor Grandholm began her term in January 2003, she directed the Medicaid agency to develop a multistate pharmaceutical purchasing program. She believed that manufacturers would be willing to give state Medicaid programs a better price for their products in exchange for access to a larger market, and she was right. In mid-2003, Michigan and Vermont began a joint purchasing program for Medicaid prescription drugs and asked the Centers for Medicare and Medicaid Services for permission to add

additional states to the program. After a series of delays, in April of 2004, CMS finally authorized Michigan, Vermont, Nevada, Alaska and New Hampshire to create an even larger pool and jointly negotiate better prices from pharmaceutical manufacturers. This larger pool will save Michigan an additional $13 million this year. CMS has also recently authorized Minnesota and Hawaii to join the pool, which should increase savings even more.

We have also generated substantial savings in Michigan by limiting Medicaid payments to pharmacists to their actual acquisition costs. We do this by significantly discounting payments for brand name drugs and daily adjustments of our payments for generic drugs to the best price available that day from pharmaceutical distributors.

Finally, while the Medicare Modernization Act certainly has many positive aspects, one component for that Act is likely to increase costs for states that have effectively managed the benefit for dual-eligibles. Michigan has been able to hold down the rate of growth in pharmacy spending to well below five percent, but the MMA's mandatory state contribution will be determined using much higher inflation factors. Even after adjusting for the declining contribution percentage we estimate that the claw-back will increase Michigan's costs by about $20 million in fiscal year 2006 and $30 million in fiscal year 2007.

In conclusion, I hope my remarks today demonstrate that at least in Michigan we are not paying too much for the pharmaceutical products used by Medicare beneficiaries.

CHAIRMAN JOE BARTON: Thank you. Mr. Smith.

MR. DENNIS SMITH: Thank you, Mr. Chairman. I appreciate the opportunity to appear before the subcommittee today. I have a full statement for the record. I did also want to provide for the subcommittee maybe a broader picture of the Medicaid drug purchasing as a whole. We are providing to the subcommittee a number of charts that show that indeed, there is variation state by state within drug classes, et cetera. We hope this information will be helpful to the subcommittee as it is looking at the issues of Medicaid prescription drugs.

There are a number of sort of underlying assumptions that we all are faced with in terms of looking at the costs of prescription drugs in the Medicaid program, first that the states themselves operate within federal reimbursement overall framework for reimbursement. We have a large number of pharmacies that participate in the Medicaid program. States are looking at guaranteeing access to coverage for low-income individuals, many of them with special needs. We have great participation rates among the nation's pharmacies in the Medicaid program, so the states and the federal government are looking at balancing different interests

between access for the Medicaid beneficiary and being prudent purchasers of the services themselves.

So, first we start off with that Medicaid is a matching program, a shared cost between the states and the federal government, and as the first line, when the state has its dollars at risk, they indeed have a basic incentive to be prudent purchasers for the Medicaid program. The framework sort of broadens from there from the different options that the Medicaid program has to set prices for prescription drugs, including the Federal Upper Limit, which we've focused on a lot here this morning already, and I know that that's something the subcommittee is very much interested in. The states also have an option to adopt what is called the maximum allowable cost, or a MAC and a number of states do that. Those MACs are generally more stringent than the Federal Upper Limit, so again, we're looking at a federal framework that says that the states cannot pay more than this amount, but the states have great flexibility underneath those amounts as I mentioned again, in relation to other types of payers, as well. The federal statute that was adopted, I believe was alluded to earlier, back in 1990. The statute requires manufacturers who want coverage of their products to enter into an agreement with CMS to provide rebates for the prescription drugs through the rebate plan. So again we have a different way of getting the best price

and the lowest price, the best value for the taxpayers for the Medicaid program. The acquisition of the drug itself if part of it, but the rebate is another part of it, as well. Obviously in the Medicaid program there are a number of different types of both purchasers and providers involved in the decision making itself. When you're looking at the overall costs of the Medicaid program. Obviously, pharmacies, physicians and the consumers themselves all have a role in ultimately determining what the price that Medicaid will pay for a prescription. Approximately 550 pharmaceutical companies participate in the rebate program itself and in fiscal year 2003 the manufacturers paid rebates of about $6.4 billion for outpatient drugs.

In terms of the focus over the last few years of how CMS is helping states to find ways to be more prudent purchases of prescription drugs, our focus has been through the various state plan amendments which Mr. Reinhart alluded to. Again, states have adopted a variety of approaches with the help of CMS in terms of we have more states than ever before that are negotiating supplemental rebates with the manufacturers. There's the national rebate, and states are negotiating further rebates on top of that. More states than ever before are doing those supplemental rebates.

Other tools, such as prior authorization is an important key for at the point of access with the physician,

to help educate physicians about being price sensitive through the Medicaid program. A number of states have adopted prior authorization in recent states as well, so again, the focus has been on several different areas, not just one particular area of helping states to negotiate lower prices for the Medicaid program. Mr. Reinhart referred to the purchasing pool. Again, had never existed before this administration approved of that purchasing pool, and expanded the purchasing pool to help states pool the lives that are involved in order to get deeper discounts for the programs. Again, I think that a lot of the discussion this morning, much of this is about information, and I think we are taking further steps, steps that had not been taken ever before about making that information available to the general public as a whole. The prescription discount card, under Medicare. The Administration took the unprecedented step of actually putting on the website price comparisons to give the general public access to information. We believe that that information, indeed, is an important component. Again, in the marketplace, people having access to that information is obviously very important part to make it successful for the marketplace to work. I see my time is ready to expire, so again, I appreciate the opportunity to appear before this subcommittee and ask that my entire statement be included in the record.

CHAIRMAN JOE BARTON: It will be. Thank you, Mr. Smith. Mr. Reed, thank you for being with us.

MR. GEORGE REED: Good morning, Mr. Chairman. I'm George Reed. I'm Assistant Inspector General for the Centers for Medicare and Medicaid Audits within the HHS Office of Inspector General. Robert Vito, Inspector Regional Inspector General for Evaluations and Inspections in Philadelphia accompanies. We appreciate that opportunity to appear before you today.

In short, the Medicaid program continues to pay too much for prescription drugs. My written statement describes the OIG's work, showing- that the Medicaid drug program could save money if it is improved on four particular fronts. First, states need better methods for estimating pharmacy acquisition costs. Second, CMS must ensure that qualified drugs are placed on the Federal Upper Limit list in a timely manner. Third, states must do a better job of accounting of their billing and collections of the rebate from the rebate collection process. And fourth, we believe CMS should seek legislation to correct the inconsistencies which exist between the rebate and the reimbursement calculations.

Most states have used and continue to use the Average Wholesale Price list made pharmacies acquisition cost of drugs. The published AWPs the states use to establish their Medicaid drug reimbursements generally bear little

resemblance to the prices incurred by retail pharmacies to purchase drugs. In prior audit reports that we issued in 2001 and 2002 we estimated that pharmacies' actual acquisition costs for brand name drugs in 1999 was an average of 21 percent below AWP and for generic drugs was an average of 65 percent below AWP. The effect of the difference between the pharmacy invoice cost and the amount Medicaid would have paid for those drugs was about $1.5 billion, a spread from which the states could have derived savings through better reimbursement methods. After additional analyses based on both state and industry interests, we recommended that if states continue to use the reimbursement system based on AWP, they should consider adopting a four-tier payment system that's described in my written statement.

Next I'd like to mention our findings with regard to the Federal Upper Limit Program. for multiple-source drugs, Medicaid limits reimbursement to Federal Upper Limit amounts if at least three generic equivalents are available, and certain other requirements are met. Medicaid misses savings opportunities when qualified drugs are not placed on the Federal Upper Limit in a timely manner. In a report we issued in February this year, we estimated that Medicaid could have saved an additional $123 million ini 2001 if CMS had just added 55 more products to the Federal Upper Payment list. As a followup to that report, your committee requested that OIG

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conduct additional work on this subject. Today we are releasing the results of that work. Again, we found that qualified drugs needed to be added more timely to the Federal Upper Limit list. Delays in adding the drugs we reviewed cost the Medicaid program an estimated $170 million between 2001 and 2003. Another area we reviewed is the extent to which states vary in their Medicaid reimbursements for the same drugs. We estimated that overall Medicaid could have saved $86 million in fiscal year 2001 if the 42 states that we reviewed had reimbursed at the same price as the lowest paying state for each of the selected drugs.

Overall we believe that states could reduce their spending on prescription drugs by adopting various strategies that other states have successfully used to contain costs. States also spend too much on prescription drugs because they do not adequately manage their Medicaid rebate billings and collections process. We've recently completed audits of rebate programs in 48 states and the District of Columbia. We found the rebate accounting systems were inadequate and information submitted to CMS was unreliable, thereby undermining CMS's ability to oversee the drug rebate process.

Our written statement also describes concerns we have about the negative effect of inconsistencies between the key values that are used for calculating rebates and reimbursements. We estimate that if rebates and

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reimbursements had been calculated using the same value, Medicaid would have achieved a substantial increase in added rebates. Our work in progress confirms that Medicaid continues to overspend because of this inconsistency in the rebate and the reimbursement processes.

Medicaid reimbursement should reliably reflect the actual costs of the drug to the pharmacy. We do not believe that occurs now, and states need to strengthen their ability to make reasonable payments for the drugs they do cover.

Mr. Chairman to conclude my testimony, we welcome and questions you may have.

CHAIRMAN JOE BARTON: Thank you, Mr. Reed. Mr. Vito, do you have any comments? No. Mr. O'Donnell. O'Connell, I'm sorry. Mr. Deland?

MR. DAVID DELAND: Good morning Mr. Chairman. Mr. O'Connell has agreed to allow me to go first as his statement will follow logically after mine. Good morning, Mr. Chairman. I thank you for having Texas attend this very important hearing. I'm David Deland, the Associate Commissioner for Medicaid and Children's Health Insurance Program for the State of Texas. I appreciate this opportunity to be with you today.

CHAIRMAN JOE BARTON: Thank you for being here.

MR. DAVID DELAND: Our main goal when setting reimbursement for the Texas Medicaid prescription drug

program, referred to as the Vendor Drug Program, is to make the reimbursement formula as fair as possible to all parties involved by reimbursing as closely as possible to the pharmacies' actual costs, and allowing the pharmacies an adequate fee to cover their costs to dispense that product. In working with the pharmacies we do this in a proactive and transparent manner. In Texas we spend approximately $2 billion a year on prescription drugs for Medicaid clients. Most states currently use private companies to access prescription drug pricing information by drug in order to set reimbursement levels for their pharmacies for prescription drugs dispensed in their Medicaid programs. These companies request pricing information from drug manufacturers by drug and then make this unregulated pricing information available to their clients for a fee. Unlike most other states, Texas does not solely rely on the pricing information provided by these private companies to set our reimbursement for prescription drug products. We take the proactive approach and do this due to the potential inaccuracy of the reported information and the actual cost of the product to the pharmacies. Texas Medicaid used similar pricing services as most states until the early 1980s when the Texas Vendor Drug Program studied ways to more accurately pay for drug products paid to pharmacy providers since we were having trouble obtaining accurate pricing information. Once we recognized

that the Average Wholesale Price was greater than the amount that Texas pharmacies actually paid the wholesaler for the drug product, we decided to do this: In other words Texas Medicaid was reimbursing our pharmacies at a higher amount than the pharmacies' actual price to purchase the drug product. Texas started requiring drug manufacturers to fill out an application and questionnaire in the early 1980s for their products to be considered for the Texas Medicaid list of prescription drugs. We required drug manufacturers to provide pricing information on a number of different kinds of prices for each prescription drug product in order to determine the appropriate reimbursement level for those products purchased from different sources, from Average Wholesale Price, the wholesale acquisition costs, the chain warehouse price, the direct price to the pharmacy, and similar pricing information. Our Vendor Drug Program took specific steps to further refine the reimbursement amount paid to our pharmacies including putting into place targeted prescription drug audits and pharmacy invoice audits and requesting additional pricing information directly from drug manufacturers. Based on information from some out of state pharmacies and our Texas Medicaid regional pharmacists, Texas Medicaid Vendor Drug Program initiated two targeted drug invoice audits, one in early 2000 and one in early 2001. We selected drug products with the greatest estimated

discrepancy in pricing from drug manufacturers to review during these audits, including over 300 brand name and generic prescription drug products. The audits found that significant discrepancies between Texas Medicaid reimbursement to our drug pharmacies and the amount the pharmacies were actually paying for most of the 300 products reviewed. As a result of these two targeted audits, we updated the base reimbursement amount for most of these specific drug products. The reimbursement updates to pharmacies for most of the products reviewed saves Texas Medicaid an annual $20 million in all funds.

Additionally, we completed an invoice audit of more than 674 pharmacies in 2001 through 2002. This audit also indicated that Texas was reimbursing the pharmacies at a significantly higher amount than the pharmacies' costs. We proposed to change the prescription drug reimbursement formula after this audit. Unfortunately the program was unable to proceed with the proposed changes due to legal challenges by the pharmacy association. This proposed rule was estimated to save Texas Medicaid millions of dollars annually do to studying more accurate levels for prescription drugs.

In addition to moving toward more accurate levels for reimbursement for product costs, we are moving to determine the most accurate dispensing fee that our program should pay

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the pharmacy. An August 2002 study completed by Myers and Stauffer indicated that the actual statewide median cost of dispensing a drug in Texas Medicaid is estimated at about 90 cents higher than the current dispensing expense.

Texas will continue to develop tools and request additional pricing information that will assist us in setting the most accurate reimbursement fee for our pharmacies. We will proceed with the following activities: One, continue developing aggressive state maximum allowable costs; two, require drug manufacturers to also report average manufacturer price; three, further define the accuracy of the price the wholesaler pays the manufacturer; and four, analyze the feasibility of implementing a more accurate dispensing fee. These additional price points will allow Texas to crosscheck all the reported pricing information to reach the most accurate product cost and dispensing fee for product.

In conclusion, Mr. Chairman, again, thank you, members, for giving Texas Medicaid an opportunity to be part of this important panel. Texas Medicaid works very closely with our partners, drug manufacturers and pharmacies in a transparent manner and a proactive way and is trying to establish a fair process that works for all parties involved.

CHAIRMAN JOE BARTON: Thank you, and I always try to do whatever I can to help Texas. My Chairman appreciates that, too. Mr. O'Connell, thanks for being here.

MR. PATRICK O'CONNELL: Thank you, Mr. Chairman. My name is Patrick O'Connell. I'm an Assistant Attorney General and Chief of the Civil Medicaid Fraud Section of the Texas Attorney General's Office. We thank you very much for giving us the opportunity to testify today.

In 1999, then-Texas Attorney General, now United States Senator John Cornyn, being concerned about fraud against the Texas Medicaid program created a civil Medicaid fraud section within our Attorney General's Office. Our section utilizes the Texas Medicaid Fraud Prevention Act to initiate civil litigation to recover funds wrongfully taken from Texas Medicaid. One of the first cases we received was filed by a small Florida pharmacy, Venacare of Florida you've heard from today. Venacare brought information to us showing that certain drug manufacturers—not all but certain drug manufacturers-violated Texas law by intentionally reporting prices to the Medicaid program that did not remotely equal prices they really charge for their products. As Mr. Deland has indicated, unlike most other states, which derive their pricing information from third parties, Texas requires the manufacturers who want their products to be eligible for Medicaid reimbursement in Texas to fill out this questionnaire for each drug they wish to be placed on the formulary. When Texas relies on an inflated price report in calculating a provider's estimated acquisition cost, the

resulting reimbursement to providers is well above the provider's actual acquisition cost, thus providing pharmacies with unintended windfall profits.

Based on the information that we received from Venacare, as well as information we discovered in our own preliminary investigations, General Cornyn authorized us to intervene against three defendants in September of 2000. This Texas lawsuit was the first-ever state intervention in a [inaudible] involving pharmaceutical manufacturer pricing fraud. The evidence we've discovered in our lawsuits and investigations shows that some manufacturers make conscious, deliberate business decisions to create enhanced spreads and to market the sale of the products based on those spreads. For example, we found that some manufacturers have engaged in the following activities: purposely reporting false and inflated wholesale prices to the Medicaid program in Texas; deliberately failing to report prices to certain classes of trade, in violation of Texas law; instructing their sales personnel to market spreads to their customers; creating spreadsheets showing pharmacies how much more profits they can make off of Medicaid when purchasing one manufacturer's product over another; and tying sales personnel compensation to success in marketing the spread. We also found that some manufacturers actually kept two sets of computer records for prices, one with the inflated prices that were reported to

the price reporting services and to Texas Medicaid, and another with their real contract prices that are used in their everyday business transactions with the manufacturer's customers.

As of May of 2004 we have settled with two defendants in our lawsuit for a recovery for the state and the federal government of $45.5 million. In both cases, Texas recovered more than two times the actual damages to the Medicaid program, plus our costs, our attorneys' fees of the relator. It's important for the committee to remember that these are Texas state settlements only. Texas is only approximately eight percent of the national Medicaid budget, so if you multiply by ten or twelve, I think you can see the numbers involved.

Our office continues to provide assistance to those authorities in other jurisdictions to others who are pursuing these defendants and other companies. We have developed close and cooperative working relationships with the United States Department of Justice, and with the other state Attorneys General who have initiated similar litigation. So far, 13 other states have followed Texas's and have sued various drug companies for false price reporting.

The litigation in Texas is still pending against one of the three defendants we sued in 2000 and we're scheduled to go to trial against that manufacturer in the fall of next

year. We've also intervened against three new additional defendants. The cases against those three defendants are in the discovery phase, and we anticipate trial in those cases to be reached in the Spring of 2006.

Despite our efforts, some unscrupulous manufacturers still continue to devise ways to defraud our Texas Medicaid program, and we are doing everything in our power to bring those companies to justice. Our current Texas Attorney General, Greg Abbott, has committed the resources of the agency to these efforts.

I would like to make clear that while Texas is pleased to have recovered these significant sums of money in the [inaudible] cases, litigation is clearly not the most efficient way to run this system. Our Texas Medicaid program has been required to spend thousands of man-hours responding to discovery requests and preparing for hearings, and preparing for impending depositions on litigation. The program could have used those hard-earned tax dollars to provide more and better services if the Vendor Drug Program personnel were not tied up in the litigation caused by the very manufacturers who've been gaining our system.

Thank you for your attention, and I'll be available for any questions.

CHAIRMAN JOE BARTON: Thank you very much, Mr. O'Connell. I want to thank all the panelists. Your testimony

has been very helpful in our process here. Mr. Reinhart, I want to start with you with a question, because I think I heard you say in your testimony that Michigan updates its list of prices on a daily basis?

MR. PAUL REINHART: For generics—

CHAIRMAN JOE BARTON: Is your mic turned on?

MR. PAUL REINHART: For generic drugs we do.

CHAIRMAN JOE BARTON: And how do you do that?

MR. PAUL REINHART: Well, our agency has significant staff constraints, so we have hired an outside entity that also is a pharmacist, and they monitor the market, each of the distributors, and will adjust prices accordingly. If the pharmacist—and we do this all over the Internet, so if the pharmacist indicates that they couldn't find the drug for that price, our consultant will send them back and tell them two places where they can get it.

CHAIRMAN JOE BARTON: And is this a nationwide service that you subscribe to or is this a Michigan-only creation?

MR. PAUL REINHART: This is a Michigan firm.

CHAIRMAN JOE BARTON: Do you know if they work in other states?

MR. PAUL REINHART: Not to my knowledge.

CHAIRMAN JOE BARTON: All right. But you're able to update your pricing, then, on a daily basis.

MR. PAUL REINHART: Well, we do that for generic drugs. We still have the more traditional for brand name drugs. We do use the Average Wholesale Price.

CHAIRMAN JOE BARTON: And do you know what cost that is to the state, to have that service, to utilize that service?

MR. PAUL REINHART: It's minor. I mentioned $130 million statewide. That component contributes about $40 million, and this service is less than half a million. It's very modest.

CHAIRMAN JOE BARTON: That's what I wanted to get to. Mr. Smith, why does it take CMS so long in some cases, as identified by Mr. Reed and his colleague Mr. Vito, to update these lists when these generics come out? And how many people do you have dedicated, and at what cost?

MR. DENNIS SMITH: The Federal Upper Limit right now, there are about 700 drugs on the Upper Limit. The last full update I believe was in 2001. We have updated on a specific basis when drugs come on, and it is not just one drug, but we have to assure that there are three. That is part of it. We have done 13 updates since 2001 to advise that these drugs would be put on the FUL.

I think part of the issue is the intensity of—part of the delay is waiting for three. Part of the intensity is that we go back and do a verification ourselves to make sure that

those prices indeed are available at that price.

CHAIRMAN JOE BARTON: Would you admit that the system that's in use today, or has been in use up until today simply isn't functioning as well as it should for the taxpayers?

MR. DENNIS SMITH: I would agree that we've done it in a historical basis and it's time to update what we are doing and how we are doing it, and as I said in my opening statement, a lot of our activity has been involved in providing other tools to the states. Obviously this is an operational one. We appreciate—

CHAIRMAN JOE BARTON: I know. I go back to—I read the IG's draft report and the testimony today, and it just seems like the problem remains despite repeated suggestions, and I'm not picking on you, but it's just something we all need to get involved in and figure out from our end what we need to fix and I think from CMS's end, specifically, fluoxetine. There are eight or nine generics in the market the day that the exclusivity period ended, and yet it took a considerable length of time to update the list, right?

MR. DENNIS SMITH: Again, that update was our verification that those prices—

CHAIRMAN JOE BARTON: But how long does it take to update?

MR. DENNIS SMITH: It took approximately a year for that verification.

CHAIRMAN JOE BARTON: And do you know how much loss to the taxpayer occurred during that period?

MR. DENNIS SMITH: I have not calculated that.

CHAIRMAN JOE BARTON: Compared to if an update had been done quicker?

MR. DENNIS SMITH: Again, I think this has shown us that we need to update our internal procedures.

CHAIRMAN JOE BARTON: One of the findings in the OIG's report or recommendations is that there's a new group of generics about to come onto the market that could have substantial costs associated with them, and so it seems clear to me as a business owner that it's going to be important from a business standpoint that your agency be ready to put those on the upgraded list. What assurance can you give our committee that that will happen short of a year or ten months?

MR. DENNIS SMITH: We are looking at that in itself, and understand when those will be coming into the market, and we will move quickly, but again, it is incumbent on us to do that verification that they are available as well. But we will do that update.

CHAIRMAN JOE BARTON: Do you need better notification from FDA when generics are going to come on the market?

MR. DENNIS SMITH: Yeah, I think we use the same resources that all purchasers have available to them. This

information is available. Again, the different compendium, that first what the FDA does, then the commercial that we use. We look at three different commercial products that are available, just as other purchasers and insurers do as well.

CHAIRMAN JOE BARTON: All right. I want to go to that. Mr. Reed, Mr. Vito, I'm told that some of the big purchasers in the private side and the insurance side move pretty rapidly when generics come to market in terms of adjusting their price structures. Are you familiar with that?

MR. ROBERT VITO: We are not, sir.

CHAIRMAN JOE BARTON: Do you agree with what Mr. Smith says in terms of the problems associated with trying to update or—I've read your recommendations. It seems like there's a real issue here in terms of being able to move swifter than we are. Is that correct?

MR. ROBERT VITO: We believe there is a problem. We believe it can be resolved by having a dedicated effort on CMS's part. We understand the amount of significant work that's involved in maintaining the list, adding the products to the list and deleting them, but it's certainly manageable if the FTEs are applied to it, the resources are applied to is that are necessary. It is our estimation that if you put these resources to that goal, the savings to the program, both the Medicaid and the federal government, will far exceed the cost that you would—

CHAIRMAN JOE BARTON: That's what seems obvious to me as well. You're talking really hundreds of millions, if not billions of dollars, and we've got a big whole in the bucket draining out all those savings quickly. How difficult would it be to update this on a more timely basis. How many people do you think it would take?

MR. ROBERT VITO: In our estimation, I think that would be better answered by CMS. However, we can say that if it's one, two three, FTE's, whatever those numbers are, the cost of the FTE's would be certainly outweighed by the savings achieved by the program.

CHAIRMAN JOE BARTON: Now I want to make sure that I'm not mixing the proverbial apples and oranges here. Is the price updating that Michigan is doing, using this outside service comparable to what we're talking about for updating these lists?

MR. ROBERT VITO: I'm not familiar with what Michigan is using. I can tell you, though, that it appears that they are doing more than just looking at the red book and the blue book and the Medispan or compendiums, is that correct? So it would be different.

CHAIRMAN JOE BARTON: It would be different. Different in terms of their resources to identify the prices?

MR. ROBERT VITO: Well, I believe that the Medicaid program, they are required to use the drug compendiums to

identify the lowest priced product and then add 150 percent to that. I believe that's what CMS does.

CHAIRMAN JOE BARTON: Is that correct, Mr. Smith?

MR. DENNIS SMITH: Yes, that's correct, and again, 1927, the rebate law itself, provision of Medicaid, those are the parameters that we work with.

CHAIRMAN JOE BARTON: So that's where we need to come into focus here to fix that if that's indeed the problem. Let me ask about the rebates, AWP versus AMP. Because it looks like we're paying at one schedule and reimbursing based on a different price. Is that correct, Mr. Reed, Mr. Vito?

MR. GEORGE REED: We issued a report a couple years ago exactly saying that. We estimated that about a billion dollars could have been saved over about a three-year period. Had the rebates been paid using AWP—we don't like AWP, but if you're going to reimburse under AWP, then it doesn't make sense to us to have a rebate process that uses Average Manufacturers' Price. You're using two different sets of numbers to basically try to bring a little bit more—

CHAIRMAN JOE BARTON: So how much are we losing as a result of this mismatched pricing?

MR. GEORGE REED: We had estimated a billion dollars for a three-year period ending around 1997 or so, but we're updating the data presently, and it's at least that much in

present day.

CHAIRMAN JOE BARTON: Yeah, would think in the growth in the percentage of Medicaid that's in prescription drugs that it would be at least that if not significantly more, when you look at the rapid escalation in costs in the last few years.

MR. GEORGE REED: And we believe that—again, we're not supporting AWP as necessarily being a good basis, but if you're going to—most states use that in some form in their reimbursement process, then in the rebate process you used it would at least bring another pressure point on the system, the industry, as to, if you're going to raise AWP, then you're going to run the risk of making the spread greater to the best price, which is how the rebate population uses those two sets of numbers.

CHAIRMAN JOE BARTON: And just quickly, in your report from a couple of years ago, you also looked at Oregon's Medicaid system and found that it wasn't operating appropriately and some $20 million in problems there. Do you know if they have responded in a positive way to you recommendations?

MR. GEORGE REED: I don't [inaudible].

CHAIRMAN JOE BARTON: Yeah, I'll get back to you on that. Mr. Stupak, I'd like to turn to you now for ten minutes.

REP. BART STUPAK: Thank you, Sir. Mr. Chairman, I'm sorry I missed most of this hearing. Sorry, I was in another hearing. But it's good to be here and welcome Mr. Reinhart from Michigan, and I did read your testimony. A couple of questions, Mr. Reinhart, if I may. How much do you estimate that Michigan saves each year under the preferred drug list that you've been using?

MR. PAUL REINHART: It's difficult to precisely partition. The preferred drug list and the multistate work hand in hand. I said earlier that our pricing strategies saved about $40 million so this other component would be about 90 million.

REP. BART STUPAK: Has anyone lost their prescription drug benefit as you've saved this money?

MR. PAUL REINHART: No, no, no one's lost.

REP. BART STUPAK: Michigan's been very aggressive in cutting their Medicaid prescription drug costs, particularly in the generic area. Do you think that your maximum allowable drug costs, or MAC, is more aggressive than most states?

MR. PAUL REINHART: I think it is. I think the daily component and the use of technology to convey those prices to pharmacists is a little more aggressive.

REP. BART STUPAK: With the daily component, you say MAC changes their prices every day?

MR. PAUL REINHART: They do, Mm-hmm.

REP. BART STUPAK: In your testimony you outlined how Michigan has benefited from prescription drug pooling purchase. The purchasing pool plan was approved in April, correct?

MR. PAUL REINHART: April 22nd.

REP. BART STUPAK: Okay. And I know you've explained the claw-back in your testimony, as part of your Medicare prescription drug bill. Can you please briefly explain it again, specifically what does it mean to Michigan, the claw-back provision in the Medicare bill?

MALE SPEAKER 1: Sure. Uh, states are required to help finance the Drug Benefit for dual eligibles. Our contribution will be calculated using our 2003 per person expenditures, per capita expenditures inflated through 2006 and the index that most people site are eleven or twelve percent annual increase. As I tried to argue earlier, our annual increases are below five percent currently because we have been so aggressive in managing the benefit. So even though in 2006 when the declining percentage will pay ninety percent of that per capita amount. It is still more than we could've managed the benefit to. Because of our lower growth rates.

MALE SPEAKER 3: Sure because your below that eleven percent and the assumption on eleven you are doing it a five therefore your gonna pickup that six if you will.

MALE SPEAKER 2: Um, uh.

MALE SPEAKER 1: How does this compare to other items in Michigan's Medicaid budget?

MALE SPEAKER 2: The, the pharmacy expenditure line grew much, at a much lower rate than the balance of the program. I included a chart in my written testimony that shows the caseload. The caseload has dramatically increased in Michigan, so everything is growing but this particular line grew at a rate somewhat below the balance of the program.

MALE SPEAKER 1: Is it fair to say that the Call Back Provision is going to cost Michigan about thirty million in 2007?

MALE SPEAKER 2: On a four year basis in 2007, thirty million.

MALE SPEAKER 2: Is that your statement?

MALE SPEAKER 1: Yes.

MALE SPEAKER 2: What about other states, do you have any idea what will happen there?

MALE SPEAKER 2: In talking to my colleagues, states that have been aggressive in, in, in constraining the growth in pharmacy spending that they started in 2002, 2003 and if, I think it is likely they will also increase. My colleague from Ohio was talking about an eighty million dollar figure.

MALE SPEAKER 1: So the states have been aggressive in trying to provide prescription drug coverage underneath the Medicaid Plan but still trying to save the taxpayers money.

Underneath the so-called Medicare Reform Bill passed they are actually going to be punished now with the Call-Back Provision?

MALE SPEAKER 2: At least initially. They, the, the state percentage decline to seventy-five percentages so at some point perhaps we will reach a break-even point. But certainly initially we feel cost will exceed what we would've spent.

CHAIRMAN JOE BARTON: Mr. Balin, you're a much bigger state than Michigan, do you agree with that? That the Call-Back Provision will cost states money and if so how much in your state?

MR. BALIN: Yes sir I do agree it will cost. The estimate in Texas I'm not certain what that is, what that figure is.

CHAIRMAN JOE BARTON: Mr. Leonard, Michigan's annual increases in Michigan's drug expenditures are below the National Average and in the other states. . . so when you get to this call back the only thing we can do to relieve you of that is to repeal that part of the bill.

Mr. Leonard: You could. I would have a variety of [laughter]. . .

MR. BALIN: Are there any other ways that you can think of. You could accelerate, immediately do the seventy five percent.

Mr. Leonard: Sure. That would be very helpful. Or a 100% would be [laughter].

MALE SPEAKER: 100% would be better I'm sure. Uh, let me ask you a little different area but Sunday there was an article in the New York Times about CMS has no plan for moving elderly Mercy Home patients on Medicaid to the new Medicare Benefit Drug Program and that is possible for these patients to select a drug card. How is Michigan going to do that? Because that is that dual eligible again.

Mr. Leonard: That is very important and we are very concerned about that. We are working hard. Michigan was one of the states that did receive a grant from CMS to, for education and outreach. Um, in, recently I know Mr. Smith has indicated that there will be an open enrollment period prior to December but in December states will be allowed for those who haven't selected, I think this is true. States will be allowed to automatically enroll beneficiaries into a card. So, at least should avoid a interval with no coverage but it will be a fair amount of work.

MALE SPEAKER: Mr. Balin, do you care to comment on that aspect of it? Most selecting the card there?

MR. BALIN: I'm sorry if you have to say that again sir.

MALE SPEAKER: Sure the article, I don't know if you saw it in the New York Times this past Sunday, it was about CMS has no plan for moving the elderly nursing home patients on Medicaid to the new Medicare Drug Benefit Program and that is

impossible for these patients to select drug cards. So how would Texas approach this?

MR. BALIN: Well.

MALE SPEAKER: You no longer have dual eligibles or anything .. . the Medicare Reform Bill has passed.

MR. BALIN: No we would have to analyze that further to see exactly what the impact would be on Texas.

MALE SPEAKER 1: Okay. Mr. Reed, if I can ask you a question. Uh, in a 2001 report on Medicaid's use on the average wholesale price, the OIG concluded that the reliance on reported average wholesale price as a basis of drug reimbursement was fundamentally flawed and CMS said it would look for solutions. This October 2003 report the OIG recommended that CMS and I am quoting now, "Review the current reimbursement methodology, work with states to find a method that more accurately estimates pharmacies acquisition cost and initiated a review of Federal Medicaid Rebates". Did CMS ever do this?

Mr. Reed: Uh, they, I don't think any action as such directly has taken but I believe CMS has brought the issue up to the states as a part of normal operations. Uh, I don't believe as such a fundamental change in the process has occurred yet. Perhaps Mr. Smith will. . .

MALE SPEAKER: Mr. Smith can you comment on that? Can you tell us why CMS has not worked to developed a more accurate

acquisition cost for the states to work with.

Mr. Smith: Well, again I think we have provided updates to the full list. We have also again I think much of our attention has been on helping states find other ways such as the purchasing pools and prior authorization, etc. So I think we've had a great deal of activity with the states in helping them to find ways to save money in the Medicaid Program.

MALE SPEAKER: But, but the report said it was fundamentally flawed really looked at CMS and the way the drug reimbursement was done and said it was fundamentally flawed and you said you would look for solutions. Other than working with states have you come up with solutions?

Mr. Smith: Well, again I, we have to work within a framework of making certain that there are at least three alternatives and to validate that they are available at those prices. That is an intensive process and as I stated earlier we're looking at internally on how we can improve the way we do update the full on a quicker basis.

MALE SPEAKER: Yeah, but the way you base it upon they said was fundamentally flawed so even if you are doing all this unless you take care of the fundamental, basis of it. . . I mean, I mean is there any logic to states reimbursing on the average wholesale price while the rebates are actually based on the average manufacturing purchase and well the average

manufacturing price and that is really not assured with the states. How, I mean, where is the logic here?

Mr. Smith: Mr. Stedpack, in terms of that basis, that comes from the Title 19 itself. That comes from the law that Congress established, however we do it under the law back in 1990. In terms of the having those two different standards.

MALE SPEAKER 1: So once CMS recommends to Congress and they change the law so you have a real basis not an average wholesale price but the average manufacturing price would save everyone a lot of money.

Mr. Smith: Uh, uh I believe we have twice have put it in the President's budget recommendations to address the pricing. On the pricing itself also I would like to. . .

MALE SPEAKER 1: Putting it in the President's budget that won't change it unless we change the laws.

Mr. Smith: That is correct.

MALE SPEAKER 1: Shouldn't you really come to Capital Hill and ask us to change the law on that so you use the average price?

Mr. Smith: You, certainly that, Congress has to take that action itself.

Male Speaker 1: Did CMS recommend that we the Medicare. . .

Mr. Smith: We did not submit legislation. No we did not.

[1] kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

MALE SPEAKER 1: Did you recommend they do it in the Medicare Reform Bill?

Mr. Smith: In Medicare, I believe it was to the average sales price instead. I don't know what uh, uh, in terms of the consideration of changing Medicaid at the same time. I don't what extent that.

MALE SPEAKER 1: Hey we should do it for Medicaid and Medicare, right? We have two different systems.

Mr. Smith: We do have two different systems. We do have two different systems on acquisition and in the rebate programs. And again I don't think Medicare has the rebate programs like Medicaid does. In acquisition cost also I know we focused a lot on the manufacturers side but I do want to at least bring to the sub-committees attention. When you do talk about AWP, uh, it is an impact on the pharmacy as well. Uh, the extent to which the pharmacy is being paid not only for its acquisition but also storage, counseling the Medicaid patient as well. You look not only at AW, because most states price their purchase on a AWP minus ten percent and AWP minus fifteen percent but they also add on a dispensing fee. That dispensing fee has large variation among the states so when you look at what the price that a states says in its state plan, This is what I want to reimburse our pharmacies for they are looking not just at the cost of the acquisition but also counseling that Medicaid patient which many argue that the Medicaid

recipient needs additional time at the pharmacy and your compensating the pharmacy for that as well. In addition, then how Medicaid differs, I'm sorry.

CHAIRMAN JOE BARTON: I understand the gentleman has one more question.

MALE SPEAKER 1: Let me ask one more while I have you here. On the Chips Program. As you know back on September 30, 2004 more than a billion dollars of funding on the CHIPS Program was reverted back to treasury. This money is money that states could have used for coverage. A number of states have insufficient funding this year and over the next three years more than seventeen states are projecting to have inadequate funds to cover their current children population. There is a Bi-partisan legislation in the house and senate to address this matter. The way I understand it, if the Administration objected publicly stating you wanted to spend the money to do more outreach instead. My question is, if the state doesn't have enough money to cover kids they currently cover what good does it do to do more outreach bringing more people into the program when there isn't enough money to cover the kids to start with.

Mr. Smith: First the money that expired, that money that expired Congress, when Congress created [inaudible] we created it on the basis that states would have three years to spend their allotments. The money that expired, the authority

to spend the money dated back to 1998, 1999 and 2000. That money was unspent because the states themselves didn't have enough kids covered to which they needed those resources. In terms of 2005 uh, the states including states that showed, are projecting shortfalls to us, we have sufficient funds that the Secretary, again that Congress gave the Secretary the authority to distribute unspent allotments. You take from one state that didn't use the money to give it to another state. That in itself will, we project and the states project will be sufficient funding through 2005. Thru the end of 2005, because you are adding that money plus three years of allotments including the new 2005 allotments. In terms of the legislation that was introduced that was based on a formula, that formula in itself would have left states with shortfalls in the long term. It did not solve all the problems.

MALE SPEAKER 2: We're not saying it is going to solve all the problems. We're saying states will have enough money to cover the kids. We wanted the money bi-partisan group and wanted the money to go back to the states to cover kids instead the Administration said no, we are going to use it for outreach. To bring more kids into the program when you don't have enough money to cover the kids in the program, why bring more kids in? A lot of us has sought as sort of a way of the Administration saying, we will give it to you next year only if we can block grant the Medicaid Program back to the states

which leave the states even further under funded.

Mr. Smith: Well again, I think what the President announced was that we should use money that the states themselves said we don't, we aren't going to use this money based on our coverage that the first the step to increasing the insurance is to actually enroll kids for programs they are already eligible for is the purpose. The second part of that was that Congress should come back and reauthorize the [inaudible] program. It has done great things. We are at record levels of coverage for kids and we want to do more.

CHAIRMAN JOE BARTON: Right, Thank you Mr. Smith. Thank you Mr. Stupak.

Mr. Smith: Thank you, Mr. Chairman.

CHAIRMAN JOE BARTON: Your welcome. I am going to turn now to the Chairman of the Pool Committee, Mr. Barton for questions.

MR. BARTON: Thank you Mr. Chairman. But before I go into questions, I have a point of personal privilege. I would like to introduce my wife, Jeri Barton, who is right behind me. My District Director, Ron Wright, from Arlington, Texas and his wife, Susan Wright. [Applause] Just a little bit of personal break. I'm going to direct most of my questions to our two friends from Texas who has testified and I am going to start by reading part of the statement that Mr. O'Connell has already put into the record. On Page 3 of his statement, he talks

about some of the things the State of Texas did in their investigation and I'm going to read a part of it and then ask Mr. O'Connell a question. The evidence that we discovered in our investigation shows that some manufacturers make conscious business decisions to create enhanced spreads and to market sale of their products based on these spreads. For example, we found that some manufacturers engaged in the following practices.

1. Purposely reported false and inflated prices to Texas Medicaid as well as the third party price reporting services in order to create enhanced spreads.

2. Deliberately failed to report prices to certain classes of trade in violation of Texas law.

3. Instructed their sales personnel to market spreads to customer.

4. Created spreadsheet showing pharmacies how much more profit they can make off Medicaid when purchasing one product over another.

5. Hide sales personnel compensation to success in marketing the spread.

We also found some manufacturers actually kept two set of computer records with prices. One with inflated prices that are reported to the price reporting services like First Data Bank or like in Texas case directly to the Medicaid program and another with real contract price that is used in everyday

business transactions with the manufacturers customers. Mr. O'Connell because of these results of the investigations that, that, that Texas Attorney General's Office found, what was the result of the lawsuits that was brought by the Texas Attorney General?

MR. O'CONNELL: As I indicated earlier Mr. Chairman, so far we have collected forty-five and half million dollars. That is more than twice the amount in what we believe were the damages incurred by the Texas Medicaid Program. Uh, and in addition we recovered the Attorney's fee and cost of the Attorney General.

MR. BARTON: Are there any lawsuits that are still pending?

MR. O'CONNELL: Yes, we have one still pending against Roxanne Pharmaceuticals which will be taking place in the fall of 2005 and we have also sued three other manufactures, Abbott Laboratories, McGall Pharmaceuticals as well as Baxter.

MR. BARTON: So the only, the only law suits that have been concluded in the State of Texas has won and you've got four other pending law suits.

MR. O'CONNELL: No we have settled two.

MR. BARTON: Settled two.

MR. O'CONNELL: One with Day Laboratories and one with Warick Division of Sherling and we have four others and then Senator Corning when he was Attorney General made clear that

there were other investigations going on and we are proceeding as quickly as we can with the staffing we have.

MR. BARTON: Is it reasonable to expect that the lawsuits that haven't been settled, that are still pending, that the outcome will be similar with what has already occurred.

MR. O'CONNELL: We certainly expect so.

MR. BARTON: I know, that would be obvious, this what I would think. What has Texas done to change its' Medicaid System as a result of these same investigations? Have there been any changes in the way Texas Administers its' part of Medicaid that deals with prescription drug reimbursement?

MR. O'CONNELL: Absolutely. Mr. Balin maybe can speak to you more than I but I do know that the cause of the prices that we found in our investigations they've conducted audits. Spent significant sums of money to conduct these audits, which I don't believe they should have had to do in order to get the real pricing that the pharmacies and the wholesalers are paying for these products. They then lowered the reimbursement rates in Texas for those particular prices. In addition and more importantly the maximum allowable cost that was referred to earlier that Texas maintains and those max was lowered significantly as well. In most cases my understanding is the Texas max is significantly lower than the Federal upper limit that is currently in place.

CHAIRMAN JOE BARTON: Mr. Balin do you want to elaborate on the changes that Texas has made to its system?

MR. BALIN: Yes sir. Thank you Mr. Chairman. That is correct. We seventy-five percent of the time Texas pays lower than the Federal Upper Limit. Also we have refined the pricing methodology in the state. Made it much more accurate. We also have three points that we feel makes the Vendor-Drug Program in Texas unique and that is

1. We have a pricing system that is proactive and transparent in determining the most accurate prices.

2. We have within our Vendor Drug Program a formulary unit, which is dedicated and focused in determining the most accurate prices.

3. We are the only state that has a questionnaire that we require the manufacturers to answer with specific pricing points that help us refine those true prices.

MR. BARTON: Is there any manufacturer or distributor that because of the changes that Texas has made or because of these law suits has chosen to not serve Texas? Has somebody backed out and said we don't want to play in that market anymore.

MR. BALIN: No. The numbers of pharmacies that are participating in the program have gone up for the last number of years instead of going down. There is one other thing that the Medicaid Program did that was particularly important I

think and that was, a rule was passed requiring manufacturers to report their AMP's directly to Texas. The rule required that the AMP's be maintained confidentially. As you know CMS gets those A& P's but that are not provided to the states. So far only sixteen percent of the manufacturers have complied with that rule. We have a problem when . . .

CHAIRMAN JOE BARTON: The AMP is Average Manufacturing Price?

MR. BALIN: The Actual Manufacturers price for the previous quarter, which would be kin to the average sale price that you instituted into Medicare. Only sixteen percent of the manufacturers have cooperated with us so far in that regard.

MR. BARTON: Now I just want to because I am about to run out of time. The Texas Attorney General who is now the United States Senator from Texas decided that there was reason to believe that corruption was occurring in the Medicaid Program in terms of prescription drug payments in Texas, so he instigated an investigation and so far resulted in several lawsuits successfully concluded and the State and Federal Government has recouped over forty-five million dollars. We have three or four lawsuits that are currently pending in addition the State of Texas had changed the way it has administered the Medicaid Program. Positive changes are significant cost savings. No provider has chosen not to provide so far it is a win-win for everybody in terms of

honesty and good government. My last question is, Is there any reason to believe that some system similar to what the State of Texas has instigated would not work at the Federal level if we did something similar?

MR. BALIN: In my opinion, no your honor. Obviously the concern that we have is that Texas has spent a tremendous amount of money to institute this system and I think most states, certainly the smaller states probably don't have the funds to do that, and the more money you spend trying to get the number right the less money you have to spend on your beneficiaries.

MR. BARTON: The two representatives from Texas think that what Texas is doing in a similar way obviously would have to be massaged to some extent, could be used in other states.

MR. BALIN: Absolutely.

MR. BARTON: Do you agree with that? Do you think what Texas is doing might could be useful in Michigan?

MR. BALIN: Yes I do.

MR. BARTON: Okay. Do you need any other, Mr. Smith, Mr. Reed, Mr. Veto, do ya'll see any reason to believe that something similar to what we are doing in Texas couldn't be used at the Federal level and in other state levels? Anybody?

MR. BALIN: Again, Mr. Chairman it goes back to part of the fundamentals of Medicaid. The Federal Government is working with Upper Limits and Frameworks, States and you have heard two

good examples today of how states themselves are involved in getting prices lower than that the Federal Upper Limits would've allowed. These states, that is the way Medicaid works.

MR. BARTON: But I mean is there, does anybody on this panel before we turn it back, because I have about a minute left. Fundamentally think we ought to maintain the status quo, is everybody in agreement that we ought to change the status quo and it is necessary to do that by Federal Statue that we ought to do that. We ought to actually change the Federal law and I'm not saying we go to what exactly what Texas is doing but to go to some system that really is based on actual sales prices with auditing and backup so that we have a transparency in the system so that anybody that has an interest can find out what is really going on. Is there anybody that disagrees with that?

CHAIRMAN JOE BARTON: Let the record show that all the heads [laughter].

MALE SPEAKER: I think everybody wants better than what we have.

MR. BARTON: With that Mr. Chairman I yield back the balance of my time.

CHAIRMAN JOE BARTON: The gentleman gives back his time. The Chair now recognizes the gentleman from Michigan, Mr. Rogers.

MR. ROGERS: Thank you Mr. Chairman and Chairman Barton for holding the hearing. One thing I have found thru this whole process and when you look at the monumental occasion that happened here not so long ago. The first time ever under Medicaid trying to provide a prescription drug benefit and hopefully applies some common sense. It was so big we have some problems. I know a good friend, Mr. Stupak, from Michigan was talking about the why don't we fix the Medicaid portion of it. We are still trying to figure out if we exactly got reimbursed or not for oncology. We are really talking about pharmacies in the Medicaid and trying to figure that out. We still have issues that we have to work out. It is a complicated, complicated, complicated, obviously I think we have all decided that. Better transparency, better availability for information. Shriner I want to congratulate you and the State of Michigan. You have been aggressive and you are certainly given credence to the old saying, No good deed goes unpunished. At least the first couple of years. I want to make sure that we are comparing apples to apples. Uh, I think you acknowledge that when it gets down to that seventy-five percent mark that is going to be a true savings for Michigan. Uh, that is in this Bill. As I understand you numbers you didn't add in that twenty-eight percent subsidy that is being paid to a statewide commission for its retiree health benefits. That is a big chunk of money that is able to

be applied to Medicaid or any other issue that states decides.

MALE SPEAKER: That is true. No I did not. I just focused on the Medicaid.

MR. ROGERS: Yeah, so it's not a true loss. What is really deceptive here is that we have the two best I think in the state. I think your number one and number two in keeping your cost down. I have to imagine if we put all the states in a hat and drew two out we would have a whole different story here about cost containment on Medicaid prescription drugs. This is kind of giving us a bit of a distorted view on where we are at. I think why that formula was there. I will offer you this commitment that I will work with Chairman Barton to make sure that we institute at least a little fairness and not punish the states that have been aggressive about keeping their cost down. I would caution next year is an estimate for you. You have done a great job. You've come down. The numbers in the last few years are very impressive. That's wonderful. We just want to make sure that number continues because it is a guess right now. You are making the best guess and we want to make sure we are accurate. We don't want to punish you for doing great things but we don't want to give you extra money for having a little bit of progress and then falling back either. As you can imagine with forty-eight states it makes it pretty complicated to get to the right conclusion. These hearings are incredible important for us to understand how we

tweak this thing and make it better and more service oriented. Especially in cases exactly like this. And just CMS I will throw you under the bus. We, I am hoping that you really enjoyed that today I can tell [laughter] by the expression and the sweat on your brow that you love that. The, I mean I hope we allow, my understanding in reading of this and thru self consultations is that there is a little wiggle room in this. It is not hard and fast and certain that CMS will have some ability to make some judgments when they look at their cost, how their charging back on that, that Call-Back Provision. Is that correct?

MALE SPEAKER: Uh, I will hand them that certain wet wiggle room that you might be referring to but I think overall the way the state contribution as we call it, is calculated again off the base of your. . . Congress enacted this a year ago. They had to establish something as a base. In 2003 was the calendar year that they used because that way the expenditures were what they were. It was set instead of basing it on estimates and then it was indexed by National Health Expenditures. That in itself historically is a benefit to states because of the growth and prescription drugs in the Medicaid Program is generally higher and historically higher than the National Health Expenditures. So right off the bat, Congress uh, provided a way for the states to save money in itself by doing a lower rate of growth. When you get states

like Michigan and Texas that have become more aggressive than what the National Health Expenditures have been, that is to the good on both sides. Then they are not only, yes it is an issue on the call-back but then they are saving that much money for the rest of the Medicaid Program as well. So I don't see. . .

MALE SPEAEKER: You mean projected growth savings is what you are saying over time.

MR. ROGERS: Correct because they are not saving that but they are saving it for the entire population not just. . .

MALE SPEAKER: Even states like Michigan and Texas and I heard Ohio mention, at the end of the day the ten-year thing, they are all reaping rewards.

MR. ROGERS: Yes sir they are. Compared to the baseline will be spending less than what they would be doing.

MALE SPEAKER: Which is a benefit... Again, I congratulate you on what you are doing. I know in November you went to this outside contractor. I think that is a great way to do it. As I looked at it and I'd just be interested in your cost on it. One of the immediate issues I guess that I looked at and raised my eyebrows at was your only dealing with distributors. So there maybe be even a better way to do it. I am not condemning what you have. I think it is a great thing but have you looked at other ways to try to do that. You are contracting with a firm who is taking distributor prices as you said through the net and other places. Can you tell me a cost

savings or can you tell me a better way to do it?

MALE SPEAKER: The savings on this firm estimate about forty million dollars in 2004. I have learned a lot today. We are dealing with the distributor and there is a step before that, that I think could be done. I don't know how Michigan couldn't do it by itself but could get better pricing information at that level. We still use the Average Wholesale Price for Brand Name Drugs and that's half of our spending, so. . . any attempts, efforts to improve that would be very helpful as well.

MR. ROGERS: Mr. [inaudible] I just want to go back on the New York Times article. I didn't get a chance to read the whole thing but my understanding is that they are not ineligible. They are just worried about their capacity in order to have access, is that correct?

MALE SPEAKER: That is correct. Most definitely, they are eligible. Most definitely they will be enrolled. The issue is really trying to take, again the overall arching concept of competition among plans and applying it to a kind of specialty market in long-term care. Uh, so again this is something that we believe that we are making great progress on and when the final rule is developed I think these people will see the concern has been alleviated. Uh, but most definitely we are going to be auto enrolling all of these individuals who are dual eligibles so they will become eligible and matching

them up with a plan that will do what they do today for low-income seniors. Uh, again, it is kind of a specialty market with the long-term care pharmacy providers themselves and helping them to work with the plan sponsors in developing the product that will meet the needs of our low-income citizens.

MR. ROGERS: And as I understand it, please correct me if I am wrong. There is a kind of loose framework under Medicaid that they hope will have a better management structure under Medicare. I am just getting an understanding of the cost. It doesn't mean it is going to diminish the services. It doesn't mean it's going to diminish what they are certainly eligible for. But it is forcing us to go through an understanding of exactly how we implement it which means we will have a better idea of cost and what it accurately cost us to take care of those patients. Is that correct?

MALE SPEAKER: Yeah.

MR. ROGERS: I'm not pulling a rabbit out of the hat. There is already a system under Medicaid, now we just have to transfer some mechanism to Medicare, is that correct?

MALE SPEAKER: That is correct.

MR. ROGERS: This isn't some insurmountable disguise falling.

MALE SPEAKER: We do not believe it is insurmountable at all and we believe we will come up with the models that guarantee access for to provide the quality of treatment that

people in nursing homes need at competitive price that is uh, uh, again it is a specialty market and how to link them together, we have made a great deal of progress and I think when final rule comes out people will be, will be very pleased with what we come up with.

MR. ROGERS: Okay thank you. I don't have too much further. I just want to thank you so much. We need assistance as we move forward on this. I like to see states like Texas and Michigan get rewarded. Being that you are from Michigan it is easy to say that all the other forty-eight ought to pay for the difference [laughter]. I'm trying to get a lot of help here from that. Uh, I do appreciate your efforts. I think we need to be cautious sometimes about some of what we heard from the State Administration. At the end of the day this will save Michigan money in a very large way. I think it is counter productive for this aspiring administration about the cost of this. There are things about this that we can fix to make it better. Absolutely no doubt. At the end of the day this is a good thing for the State of Michigan and they will save a significant amount of money. I look forward in working with you on that. Thank you.

CHAIRMAN JOE BARTON: This gentleman from Michigan.

MALE SPEAKER: In response to Mr. Rogers, questions I have a plan that they have ready to fix this nursing things up. Could you submit that to the Committee for the record so we

will have it, so we can look at it?

MALE SPEAKER: Uh, I. . .

CHAIRMAN JOE BARTON: I think we can ask him for that.

MALE SPEAKER: Is that the plan you have in response to Mr. Rogers questions?

MR. ROGERS: Again the final rule of how the long-term care pharmacies and the plan sponsors themselves will be working together to deliver the benefit.

MALE SPEAKER: Being that the plan is ready could you submit it to the committee before the final rule?

MR. ROGERS: Before the final rule?

MALE SPEAKER: Yeah.

MR. ROGERS: Again, my uh, uh, the proposed rates are already out. We are going through all the comments, etc. and expect to publish the final rates in early January.

MALE SPEAKER: Similar proposed rules, would you please?

MR. ROGERS: The proposed rules, absolutely.

CHAIRMAN JOE BARTON: Thank you. I am going to dismiss this panel now. Thank you very much for your testimony and your good work. It is most helpful in our committee's deliberations and we appreciate your sticking with us today. I know other committee members may have questions that they will want to submit to you for response along the way.

CHAIRMAN JOE BARTON: Okay, now I would like. . .

incorporated. David Marshall, PHD, Director of Category Management for Generics, CDS Corporation, John Zibell, PHD, Category Manager for Pharmacy Health and Wellness, Walgreen Company, and Frank Seagrave, PHD, Vice President of Pharmacy, Wal-Mart Stores, Inc. You are all aware that the committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath. Does any of you have an objection to providing your testimony under oath? Let's start with Mr. Seagrave, No do you have any objection to testify?

MR. SEAGRAVE: No.

CHAIRMAN JOE BARTON: Mr. Zibell?

MR. ZIBELL: No.

CHAIRMAN JOE BARTON: Mr. Marshall?

MR. MARSHALL: No.

CHAIRMAN JOE BARTON: Mr. Cavlet?

MR. CAVLET: If I can have a chair.

CHAIRMAN JOE BARTON: If we can get you a chair that would be helpful. We need one more chair at the witness table. This is Ms. Poletti, is it Poletti?

MS. POLETTI: Yes, I don't have an objection.

CHAIRMAN JOE BARTON: The chairman advises under the rules of the House and Rules of the Committee you are entitled to be advised by counsel. Does any of you desire to be advised by counsel? Mr. Seagrave? Counsel? Do you want to be advised

by counsel?

MR. SEAGRAVE: [inaudible]

CHAIRMAN JOE BARTON: You do? Could you identify your counsel please?

MR. SEAGRAVE: Mr. Fredrick Robinson.

CHAIRMAN JOE BARTON: Mr. Fredrick Robinson, right there. Okay. Mr. Marshall?

MR. MARSHALL: That's okay.

CHAIRMAN JOE BARTON: Mr. Cavlet.

MR. CAVLET: Mr. Mark Young.

CHAIRMAN JOE BARTON: Mr. Mark Young. Okay. Thank you. Ms. Poletti?

MS. POLETTI: Yes, Ed Miller.

CHAIRMAN JOE BARTON: Mr. Ed Miller is your counsel. Ms. Mars?

MS. MARS: Paul Doyle.

CHAIRMAN JOE BARTON: Paul Doyle. And Mr. Strimyer?

MR. STRIMYER: [inaudible]

CHAIRMAN JOE BARTON: Okay. Chairman is okay as opposed to Your Honor. Neither an attorney or judge [laughter] Yeah. In that case, now that you are all comfortably seated, will you all rise and raise your right hand. I want to make sure you are organized and if you swear the testimony that you are about to give is the truth the whole truth and nothing but the truth. Okay. Please be seated. You are now under oath

and you may give a five minute summary of your written statement. I am going to have Mr. Rogers take over the chair for just a moment and please proceed and Mr. Strimyer we will begin with you. Thank you again for being here.

MR. STRIMYER: Thank you Mr. Chairman. My name is. . .

CHAIRMAN JOE BARTON: Can you turn on you mike?

MR. STRIMYER: Until recently I was Senior Vice President of Aventis Pharmaceuticals. My responsibilities included legal matters, government relations and public policy in North America. Aventis is a global pharmaceutical company that has just been acquired by Sanofi to form Sanofi-aventis as a result of the merger I left the company. I am here today at the committee request as a private citizen. I understand that the purpose of today's hearing it to address issues relating to AWP Based Reimbursement of prescription drugs under Medicaid. I have been asked to discuss with the committee the policy positions developed by Aventis during my tenure with respect to AWP Reimbursement for Prescription Drugs. As much as I am no longer employed by Sanofi-aventis, I can not say whether the company still supports the policy positions taken during my tenure nor can I speak to what the company will do in the future with respect to these matters. I joined Marian Laboratories, one of the predecessor companies of Aventis in 1982. Over the past twenty years I have been actively engaged in prescription pharmaceutical industry as an attorney and

senior executive. It was in my capacity as head of Government Relations and Public Policy that I over saw the development of Aventis position on reimbursement for pharmaceuticals under Medicare and Medicaid. The pharmaceutical industry has seen many changes since I joined Marian. The complexity, potency, and value of the products that the industry develops have changed as has the entire distribution system of those products. One thing however has not changed. The reliance on AWP as a reimbursement benchmark of both government and private payors. To understand this reliance one has to look back nearly forty years. In the late 1960's about the only people who did not pay for prescription drugs out of their own pockets were employees of the pharmaceutical companies and people qualified for Medicaid. Therefore if felled to Medicaid to try to build systems to meet the task of paying for these drugs. I think it is important to remember that it was the 60's a computer with as much computing power as today's notebooks had not been built and would have filled an entire building. Medicaid needed simple manual systems. As a result, the concept of Average Wholesale Price or AWP was created by the Director of Medical, a California Medicaid Agency. The idea was rather than having a pharmacist report what he had paid to purchase a product and then going through some type of audit procedure to make sure that that was the case, it would be administrative simpler to always pay the same amount for a given drug. At the time it

was established AWP was not intended to be what was actually paid by the pharmacist to the wholesaler but it was a good surrogate for administrative efficiency. Beginning in 1969 Med-Cal reimbursed pharmacies for Medicaid patient prescriptions by paying AWP plus a dispensing fee. As third party coverage of the prescription drug cost became more wide spread by both government and private payors the reliance on AWP became more evasive. Let me fast forward through two of the major trends in the pharmaceutical industry that have made AWP a problematic reimbursement benchmark. These trends are consolidation in the wholesale drug industry and the rise in managed care including pharmacy benefit managers. For branded prescription drugs AWP typically reflects a 20 – 25% mark up over the wholesale acquisition cost. The manufacturers list price to wholesalers also known a whack. This markup roughly corresponded to the wholesalers markup in the early days of AWP. However, drug wholesalers have seen technologic change that has dramatically increased the efficiency of scale in that industry. The change fostered incredible competition and lead to consolidation of the industry. Three companies now account for over 90% of the wholesale drug business and they do it on gross margins of less than 5%. That means that an AWP that remains static at 20-25% markup over whack began overstate the price paid by the retail pharmacist. The 1980’s saw the rise of managed care and PBM’s. Whatever else they may have done,

they forced big pharmaceutical companies to aggressively compete on price. They did this by limiting the number of drugs a drug plan would pay for and then negotiating with the manufacturers for rebates beyond the preferred list known as a formulary. They also forced pharmacies to compete on price by requiring pharmacist to sign contracts if they wanted to server the population covered by the plan. I should point out that all these agreements used AWP as a benchmark price. While these trends were occurring there was tremendous pressure to AWP at a fixed markup from whack. AWP had been codified as the benchmark price by statue or regulations of the public sector and by contract in the private sector. As the difference between an AWP and real prices paid by pharmacist and providers began to increase that difference was used to compensate for lack of payment of services. A change in the current well known relationship of AWP to Whack would have had far reaching affects on the provision of health care services. In 1990 Congress recognized the private sector payors were able to negotiate substantial discounts from pharmaceutical manufacturers. To take advantage of these negotiations for Medicaid Congress included provisions in the Budget Reconciliation Act requiring pharmaceutical manufacturers to pay a rebate on Medicaid purchases that was based on the best price negotiated by private sector payors. The 2002 policy document that was provided by Aventis to the Committee reflects

the results of an effort to point out the problems associated with relying on AWP benchmarking in government reimbursement of prescription drugs. Given the reality of the change in environments in which those products are used if was Aventis's view that appropriate reimbursement methodology needed to reimburse providers for the drugs they expensed at or near their cost to acquire those drugs while also fully and appropriately paying them for their professional services they provided in connection with dispensing those drugs. I appreciate the opportunity to appear before the Committee today and would be happy to answer your questions regarding the use of AWP as a base for reimbursement.

CHAIRMAN JOE BARTON: Ms. Mars.

MS. MARS: Good morning, Mr. Chairman and distinguished member of this committee. Thank you for the opportunity to appear before you today. For the past fifteen years I have been the Chief Financial Officer of DLP, founded in 1978 and located in Napa, California, it is a specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drugs for the treatment of respiratory disease and respiratory related allergies. In addition to our facility in Napa we also have a distribution center in Allen, Texas. Last year Congress and the Administration took important steps to reform and improve Medicare Reimbursement Policy when it past the Medicare Modernization Act. As you know the system of

reimbursement using a percentage of AWP badly needed to be reformed and many in the pharmaceutical industry including DAY supported reform. Medicaid reimbursement has typically had a spread between the cost of the drug paid by the provider and the reimbursement amount. That spread goes to the provider not to the manufacturer. Until the mid 1990's my understanding is that it was not unusual for sales people when speaking to customers to compare their spreads with those of their competitors. Beginning in the late 1990's as a result of litigation, government investigation and the OIG Compliance Program Guidance my understanding is the industry has become sensitive to this practice and has largely stopped. At DAY we have implemented a major compliance program over the last few years designed to insure that our sales force is compliant with the OIG Guidance. Is the spread is still meaningful to providers? Yes because they often depend on the spread to cover their cost of dispensing which often exceeds the dispensing fees they receive from Medicaid. How does DAY set AWP for generics? At DAY our historical practice for generic drugs is to accept the generic AWP as a percentage off of the brands AWP when the product is launched. Usually that percentage has been around ten percent. After that, our practice has been not to change AWP on generics. Why doesn't DAY lower its AWP on generic drugs? The simple answer is that given the system that now exist our customers won't buy from us

if we lower our AWP. This was confirmed about a year and a half ago when a reporting service lowered their published AWP for our drugs without our consulting us. Our customers told us that they would stop buying from us with the lower AWP. This could have put many of our employees out of work overnight. So we went to court and the court issued a temporary restraining order. Why do we need AWP at all? At this point the current system is based on AWP and customer rely on it and won't buy a product without it. As evidence of this about two years ago, because of litigation we tried to market a new drug with no AWP. Our customers said they would not buy it, so we set an AWP, which happened to be lower than those of our competitors. As a direct result of this lower AWP we sold almost nothing of a drug for which we had projected to have sale of six million dollars. Inexperience taught us that reimbursement reform has to come from the government and be applied to the whole industry. If a generic company especially a small one like ours try to buck the AWP system on its own, it can be forced our of the whole business line. Through our profits on generic drugs increases the spread increases and in DAYS case the answer is no. First it is important to keep in mind that the drug manufacturers don't get the money from the spread. The money realized from the spread goes to the providers. Second, in the case of generic drugs a larger spread actually means a lower profit to the manufacturer. Because generic drugs are a

commodity price competition is fierce. If the spread for a particular generic drug is getting larger it is almost always because the AWP is remaining the same while the actual selling price is getting lower. At the same time our cost is increasing and our margin is declining. The situation has shown dramatically in the case of Albuterol. Which has been repeatedly sited on CMS reports as having some of the largest spreads of any drug. In the last ten years, the spread on Albuterol, which is one of DAYS biggest generic products in terms of volume has been getting larger and larger as the price drops because of competition. Have our profits increased as the spread has grown? No. At the current time we are actually close to break even on Albuterol due to the continuing erosion of the market price. As I said at the outset I am the Chief Financial Officer at DAY. I have held that position since 1989. Most of the documents that I was asked about in my staff interview or they came to me afterwards came out of our Sales and Marketing Department and with some exceptions where I was copied or was the addressee I saw them for the first time during this litigation. Having said that I need to add that I have learned a lot about AWP in these documents and the litigation and I will try to be as helpful as I can when answering questions. Thank for you time and I'd be pleased to answer any questions.

CHAIRMAN JOE BARTON: Thank you Ms. Mars, we appreciate

you being here. Ms. Poletti. Thank you.

MS. POLETTI: Mr. Chairman and members of the sub-committee, my name is Leslie Poletti. I am appearing today on behalf of Roxanne Laboratories where I am Senior Product Manager. I am here today at your request to assist you in your efforts to examine Medicaid Reimbursement. Roxanne is a leader in the development, manufacturing and marketing of generic pharmaceutical products. We are proud to produce medicines that extend and improve patient's lives while reducing reliance on more expensive alternative treatment options including hospital stays and evasive medical procedures and more prescription products. We are committed to continuing to provide lower cost pharmaceuticals to meet the health care needs of Americans. As you know Roxanne is one of 26 manufacturers from whom the sub-committee requested documents in connection with this investigation and to reimbursements under Medicaid. Roxanne voluntarily produced several thousand pages of documents and provided witnesses for informal interviews on two separate occasions. Roxanne understands the importance of the Congressional Oversight Process and determining the need for and establishing basis for legislation improving the Medicaid system. We therefore agree to the sub-committee's request that we appear today to answer any questions on which the members believe we can provide you with useful information. We have been advised the Energy and

Commerce Committee may develop legislative recommendations to reform Medicaid Reimbursement Policies, which we understand currently are establish on a case by case basis under a variety of complex formulas. As you know as a manufacturer of multi-source products our revenues come exclusively from purchases from our customers who in turn sells to parties or patients. We do not sell prescription pharmaceutical products directly to patients nor to we receive any payments from Medicaid. However, we will support any effort by Congress to bring greater efficiency and simplicity to the system including much needed guidance from the government. We believe any reform should maintain an incentive for using generic drugs and insure that an appropriate and viable economic framework remains in place for healthcare providers to serve patients. I would be pleased to answer any questions on issues that you have identified and own materials we have previously provided to you. Roxanne looks forward to working with you as you address these issues.

CHAIRMAN JOE BARTON: Thank you for being here today. Mr. Cavlet. Thank you for being here.

MR. CAVLET: Thank you Mr. Chairman and members of the sub-committee. I am Tim Cavlet, Senior Vice President of Sales and Marketing of Barr Laboratories. We are a leading manufacturer of generic pharmaceuticals. Mr. Chairman I know that you and others want to reduce the cost of prescription

drugs for Medicaid patients. You goal and Barr's Business Objectives are well align. Barr's generic drug business is designed to offer the same medicines as branded companies but at a lower cost. The products we manufacture and sell are mostly in tablet and capsule form. They are dispensed to patients by others not by Barr. Barr does not receive reimbursements under Medicaid. Like other generic manufacturers Barr does offer a vehicle for reducing Medicaid cost. When a pharmacy dispenses a generic drug to a Medicaid patient, the reimbursement to Medicaid is usually lower and often substantially lower than it would be for a branded product. In that way promoting the use of generic products helps to reduce Medicaid cost. Branded drug reimbursement system providing incentives to pharmacies to dispense generic drugs is vital to achieve cost reductions. Generic drugs by definition are second to market not first. Pharmacies must be convinced to stock and dispense our products as an alternative to a branded product that has been on their shelves for years. The drug reimbursement systems including Medicaid do not create incentives to dispense generic drugs. Substantial cost savings will be lost. I know the sub-committee has questions about AWP or Average Wholesale Price. As AHS found years ago AWP does not represent and actual wholesale price or an average of actual prices. Instead I sent out my written testimony. AWP is simply a publicly reference price. Many drug reimbursement

systems including some state Medicaid agencies use AWP in certain instances as a reference point to calculate reimbursement levels for those who dispense drugs to patients. Because they recognize it, AWP is not an actual acquisitions price. These agencies reimburse at a percentage off of AWP. If a generic manufacturer lowered its AWP unilaterally in a multi-source generic environment pharmacist might choose to dispense a competitors generic product. I would be pleased to answer any questions to answer any questions the sub-committee may have and thank you for your consideration.

CHAIRMAN JOE BARTON: Thank you Mr. Cavlet. Mr. Marshall.

MR. MARSHALL: Mr. Chairman and distinguished representatives. On behalf or CVS Corporation I would like to thank the committee for inviting CVS to appear today. To participate in this important hearing. CVS shares the committee's goal in reducing the cost of prescription drugs for all of our customers. The single most effective action that can be taken to achieve that goal is to promote the use of generic drugs wherever possible. It is my responsibility at CVS to purchase generic drugs at the lowest possible cost. I am pleased to have the opportunity to answer your questions to the best of my ability today. Thank you.

CHAIRMAN JOE BARTON: Okay Mr. Marshall. Mr. Z. . . is it Zibell?

MR. ZIBELL: Zibell.

CHAIRMAN JOE BARTON: Your comments?

MR. ZIBELL: I have no comment but I am ready to answer any questions.

CHAIRMAN JOE BARTON: Thank you for being here. Mr. Seagrave.

MR. SEAGRAVE: Thank you Mr. Chairman. My name is Frank Seagrave. I am a registered pharmacist in Louisiana, Colorado, and Mississippi. I'm currently the Vice President of Pharmacy for Wal-Mart Stores, Inc. I'm familiar with the struggle that many states are currently having with their Medicare expenditures. Medicaid business at Wal-Mart represents about eleven percent of our prescription business. I believe that Wal-Mart and our 11,500 pharmacists are part of the solution. Currently retail pharmacy Medicaid reimbursement is based on a formula consisting of two parts. Estimated acquisition cost plus a dispensing fee. Everyday low price or EDLP as we call it is a core belief of our company. It greatly benefits the Medicaid program in many states because our EDLP is often below the Medicaid allowable price. When this happens they get charged the lower price. Wal-Marts EDLP therefore is a value to the Medicaid Program. I believe that generic drugs are the best opportunity for savings in the Medicaid Program. The average price of a Medicaid Program that was filled with a brand name drug at Wal-Mart in 2002 was $88.53. When a

Medicaid prescription was filled with a generic drug the average price was $20.25, a savings of $68.28. Therefore the average Medicaid price of a prescription filled with a brand name drug was 439% higher. Generics are deemed to be bio-equivalent and therapeutically equivalent and should be mandatory when they are available. At Wal-Mart we dispense generic drugs over 94% of the time when one is available. Wal-Mart is effectively negotiating good cost on generic drugs because generics are available from multiple manufacturers and therefore commodities. This is not the case with brand name drugs. Wal-Mart has no greater leverage for branded drug products than any other class of trade pharmacy provider. There is great disparity between what brand name drug manufacturers charge retail pharmacies and the lower prices they charge other classes of trades such as hospitals, mail order pharmacies and HMO’s. Thus, an average sales price or ASP Model for drugs suspense to Medicaid recipients would be inequitable for retail pharmacies. Wal-Mart currently accepts all endorsed Medicare Discount Cards. We’ve been aggressive in providing educational literature regarding the Discount Cards to our customers. The program has been a success at Wal-Mart. We look forward to the opportunity to serve the needs of our Medicare customers when the Medicare Drug Benefits starts. Wal-Mart pharmacists and all retail pharmacists are a valuable part of the Healthcare System in the communities that we serve.

Pharmacist routinely consult with customers and answer questions about prescription and over the counter drugs as well as general healthcare issues. Pharmacists are consistently regarded as one of the nations most trusted professionals. In summary, Wal-Mart is committed to continue to provide the best service to our Medicaid customers in any reimbursement system as long as it provides fair payment for the service and product delivered, protects the customer safety and allows the nations retail pharmacies to participate. Thank you.

CHAIRMAN JOE BARTON: Thank you, I appreciate your comments Mr. Seagrave. I just want to say at the outset that, that we don't want to do anything here that would create a disincentive to generic use. I think we all agree that that is an important component of holding down cost and giving consumers choice but we do need to make sure that the tax payer benefits from the savings. I think so we can take care of those who need help that today are frankly robbed at help because of some cases lack of funds. So I want to start beginning with issue of the AWP with this panel. Do each of you believe that the AWP reflects the actual selling price that you charge for your products? Will you just give a kind of yes or no answer, Mr. Stradamyer?

MR. STRADAMYER: No it does not.

CHAIRMAN JOE BARTON: Your answer is no. Ms. Mars?

MS. MARS: No it does not. Ms. Poletti?

MS. POLETTI: No it does not.

CHAIRMAN JOE BARTON: Cavlet?

MR. CAVLET: No.

CHAIRMAN JOE BARTON: Mr. Marshall? Zibell? Seagrave? So all of you agrees that it's not a legitimate selling price reflection. Reflection of your selling price. Do you adjust the AWP of your products after you have set them and if so under what circumstances, Mr. Stradamyer?

MR. STRADAMYER: Well. . .

CHAIRMAN JOE BARTON: Can you bring that really close? Make sure the button is on.

MR. STRADAMYER: Okay, the, in the brand industry AWP generally reflects a 20 –25% markup over Wholesale Acquisition Cost, WHACK. So WHACK is increased AWP goes up accordingly.

CHAIRMAN JOE BARTON: So you do adjust your AWP then, on a regular basis?

MR. STRADAMYER: Well, I can't say companies adjust the AWP. The reported AWP by the reporting services put out the AWP. Most companies including Aventis do not set a. . . most brand companies do not set an AWP.

CHAIRMAN JOE BARTON: Oh, okay. Ms. Mars.

MS. MARS: In our case and in the case of generics we historically have not had a practice of raising our AWP. For the brand products we have increased AWP as the WHACK has increased.

CHAIRMAN JOE BARTON: Okay. Ms. Poletti.

MS. POLETTI: Generally we do not change our AWPs.

CHAIRMAN JOE BARTON: Your Micon?

MS. POLETTI: Generally we don't change our AWPs once they are established. We have changed some AWPs for one reason or another.

CHAIRMAN JOE BARTON: Why wouldn't you adjust them to reflect the market?

MS. POLETTI: Why wouldn't we?

CHAIRMAN JOE BARTON: Yeah.

MS. POLETTI: It's generally a standard in the generic industry that you set your price for AWP and you don't adjust it.

CHAIRMAN JOE BARTON: Mr. Cavlet.

MR. CAVLET: An instance where I can think AWPs are.

CHAIRMAN JOE BARTON: Is that mike on?

MR. CAVLET: Can you hear me sir?

CHAIRMAN JOE BARTON: Yeah.

MR. CAVLET: Okay. An instance where I can think AWPs are increased in our business would be in a sole source inert situation. We are the only generic on the market. If there was a brand price increase and we felt there might be an opportunity and we would make a decision to raise our generic price, we would raise both our AWP and our price to maintain. I think I heard earlier today that the generally there is a 90%,

you know, difference between the brands and the generic price. That is the instance where I can think the AWP my increase sir.

CHAIRMAN JOE BARTON: Let me go to your testimony and I am going to quote it here Mr. Cavlet. You said and I quote it, "It is generally known in the pharmaceutical industry and related government agencies that average wholesale price (AWP) is a referenced price only and does not represent the actual selling price charged by the manufacturer for its products". I would like you to, do you have or you don't have the notebook, do you to turn to Tab One. Do we have, we don't have, they can't turn to Tab One. There we go. Uh, in our exhibit binder there you will see OIG compliance program guidelines for pharmaceutical manufacturers. On the bottom of Page 23733 an I quote, "The government sets reimbursement with the expectations provided are complete and accurate and where appropriate manufacturers reported prices should accurately take into account price reductions, cash discounts and free goods, etc". In light of these OIG Guidelines if you report an AWP aren't you required to make sure it is up to date and accurate?

MR. CAVLET: Who are you directing the question?

CHAIRMAN JOE BARTON: To each of you, yeah. To you and Ms. Poletti and Ms. Mars.

MR. CAVLET: I will take the question first. The, the, it, it, in the industry is to report the AWP as a reference price. I do believe what is reported is up dated as we do

provide our AMP. The average manufacturers price which does take into account all of those.

CHAIRMAN JOE BARTON: Give that AWP is also used, as a reimbursement mechanism shouldn't it be accurate to the market? I mean shouldn't it represent something?

MR. CAVLET: It has been industry practice and the practice bar that it is strictly a referenced price and it is set in relation to the branded price.

CHAIRMAN JOE BARTON: Ms. Poletti.

MS. POLETTI: I would agree with that. Um, and there is really no core guidance for us to follow that tells us how to calculate that number.

CHAIRMAN JOE BARTON: Ms. Mars.

MS. MARS: I would agree with my colleagues and I think we have heard many times today that the system is broken. There is no statutory definition of AWP to the extent of there is clear guidance as the gentleman from BARR said, we have been reporting AMP but the industry practice as it is and the lack of statutory guidance industry practices prevail.

CHAIRMAN JOE BARTON: All right. Uh, I'm gonna go. Turn to Tab 37 if you would, Ms. Poletti. Mr. Cavlet you can turn it for her if you want [laughter]. Whatever. I should have said that at the outset. Uh, this is Document Number 0199-02002, the second page of the document 0200 states that Roxanne's bids for Furosemide business was rejected, not

because the sales price was too high but solely because the AWP was too low. Are AWP and/or reimbursement factors in negotiations with retail customers? Wanna talk about that? That document?

FEMALE SPEAKER: Uh, Furosemide was a very unique situation for us in that there were some changes in the market that allowed opportunities for us to potentially to gain new business. When we tried to gain the new business we were repeatedly told that our AWP was out of line with our competitors and upon looking at that discovered that they were significantly below our competitors such that regardless of how low our contract price was no one would buy the product.

CHAIRMAN JOE BARTON: So AWP, I mean, I guess what I see here is that AWP is how you get market share and the higher it is the better chance you have to get market share because somebody is making money on the spread. The people making the money are the purchasers, right?

FEMALE SPEAKER: I would disagree with that. I think it is, or in our experience its been a rare occasion that customers have discussed any of that with us and this occasion it is my impression that the only reason it was discussed was because we were out of line. They weren't asking us to increase the spread over what the current market was. They were just asking us to be on a level playing field.

CHAIRMAN JOE BARTON: Okay. Uh, I'll try and tell you

what Tab this one is. There is a Tab 39. If you will go to that. This is the right. . . yeah. It says here uh, this is to Judy Waterier from Anthony Tivolareo. It says Judy as you know Caremark had shown interest with our Furosemide back in April. After a review of our AWPs on the products the opportunity was dead. Our AWPs are 78% below the rest of the industry. I am not aware of any competitor with AWPs below a hundred dollars for bottles of 40mg thousands. Milan and Zenith are approximately 120, ours is 29. Caremark's committed that they could not possibly award the product to us unless we increased our AWPs. Janet Miller also added that Roxanne has a history of having AWPs out of sync with the rest of the industry. I don't know why we have to wait until our customers complain before we adjust an AWP. Major customers, Walgreen's, Wal-Mart, CVS, Medico, Caremark expect there leading suppliers to retain there AWPs. Not executing this Court Competency reflects negatively on Roxanne and promotes a perception of Roxanne not understanding industry dynamics. I hope this helps. The would appear to me to reference more than just Furosemide. Does it appear that way to you?

FEMALE SPEAKER: No he does say that we have a history. I'm not sure what he is basing that on. Typically, we set our pricing and we don't monitor our AWPs once they are set.

CHAIRMAN JOE BARTON: And why would he say, I don't know why we have to wait until our customers complain before we

adjust it, an AWP. In this case he is referencing Furosemide and weren't able to get business. Actually we were on the verge of discontinuing the product because we couldn't gain customers and it was based on the fact that our AWP was so far out of line with the rest of the market was.

CHAIRMAN JOE BARTON: Okay if you would turn to Tab 38 in the binder. This document also notes that when AWP is out of line with the rest of the market it is a bigger issue than a straight price. This email goes on to mention concerns associated with a decision to raise AWP including scrutiny and consumer backlash. Can you discuss those concerns?

FEMALE SPEAKER: Anytime pharmaceutical companies do a price increase, it's scrutinized. The AWP in particular because that is one of the prices that is publicly available for everyone to see.

CHAIRMAN JOE BARTON: But it appears in this case at least to, in order to get market share. . . am I missing it? In order to get market share you're having to increase your AWP.

FEMALE SPEAKER: We were having to bring it in line with our competitors, yes. They weren't asking us to raise it above our competitors. That was not my impression.

CHAIRMAN JOE BARTON: What effect does raising the AWP have on the price that they pay for the product?

FEMALE SPEAKER: The customer? It would not have an

impact on the price that they paid.

CHAIRMAN JOE BARTON: So what is the benefit to them for a higher AWP set by you which I assume is an arbitrarily set AWP.

FEMALE SPEAKER: Well in this case they weren't buying our product. They were buying the competitors products whose was much higher. So in that case there would have not been an impact on what they were currently buying verses what.

CHAIRMAN JOE BARTON: No my point is, your incentive to raise the AWP is to get market share, is it not?

FEMALE SPEAKER: In this case it was to bring ourselves inline so we could actually compete on a contract price.

CHAIRMAN JOE BARTON: Right. So you get more market share?

FEMALE SPEAKER: Sure.

CHAIRMAN JOE BARTON: And it doesn't cost the purchaser any more and it doesn't cost you anything to have a higher AWP.

FEMALE SPEAKER: True.

CHAIRMAN JOE BARTON: So the loser in this is the government, right? The taxpayers?

FEMALE SPEAKER: I wouldn't agree with that because. . .

CHAIRMAN JOE BARTON: Why?

FEMALE SPEAKER: At the time they were already buying one of our competitor's products that was already at level. My

changing that price didn't advantage.

CHAIRMAN JOE BARTON: Okay but you're company would benefit by changing it if it allowed you to get market share. I guess the point is not to pick on you or Roxanne specifically. I don't mean to do that necessarily other than as an example of the pressures within the market place that drive a higher AWP in order to get more market share. The actual price paid by the purchaser is no more. You have indicated that. Uh, the AWP you are all just competing up here to see who's got the highest because that creates the biggest spread and . . .

FEMALE SPEAKER: I, I'm not sure that's the way it's really done. I know in our case we set the AWP and we don't monitor AWPs of our competitors. We typically don't change our AWPs.

CHAIRMAN JOE BARTON: Well in this case you were monitoring and had all the data. It is in the email.

FEMALE SPEAKER: Well in this case we were monitoring it. It was so far out of line that our competitors would bring it to our attention that hey even if you have the best supply and the lowest contract price I can't buy your product because you are not in line on this other reference price.

CHAIRMAN JOE BARTON: And the other reference price does what for them?

FEMALE SPEAKER: Uh, it would've put us in line with

everyone else?

CHAIRMAN JOE BARTON: No it creates the spread right? The AWP creates the spread with the actual purchase price, right?

FEMALE SPEAKER: It would be one of the factors that their reimbursement is based on, yes.

CHAIRMAN JOE BARTON: All right. Our time has expired. Thanks for the patience of the Committed, Mr. Stupak.

MR. STUPAK: Thanks Mr. Chairman. Although along that line say that 37, 38, 39. Mr. Cavlet on page 8 says, if a generic manufacturer unilaterally reduces its AWP for a given product relative to the AWPs of other generic manufacturers for the same product, pharmacies would have an incentive to purchase another manufacturers drug that did not reduce its AWP. So basically what is going on here, if you keep the AWP high then the pharmacies make more money off of it. Right?

MR. CAVLET: I believe what I tried to say in my written testimony is that the AWPs is set up as a reference price.

MR. STUPAK: Right.

MR. CAVLET: If in an age, multi-source situation, if there were multiple competitors I believe that if a company such as BARR was to unilaterally reduce its AWP and if we're still on the situation where its not an FUL or not Mack we're dealing with AWP reimbursement formulas, why I have no example

or any experience to give you an example of it, my fear might be that it would put a situation in place where we may have that type of decision.

MR. STUPAK: Ms. Mars you testified that you had a product where you lowered you AWP and you couldn't get customers to buy it. Right?

MS. MARS: Yeah, we've had a couple of situations like, we tried to launch a product without AWP.

MR. STUPAK: Right. You established an AWP and it was lower than the rest and customers wouldn't buy it.

MS. MARS: That is correct and the other situation we did not lower our AWP but one of the reporting services chose to do so without our knowledge. As a result of that, we got that many calls from pharmacist basically saying that they wouldn't be able to buy our product in the future if that situation was not changed.

MR. STUPAK: So if we lowered the AWP why won't the pharmacies buy the drugs? If it is a lower AWP your paying a lower price you could pass that savings on to your customers as you claim you like to do. So why wouldn't you buy a drug with a lower AWP? Mr. Marshall, Mr. Zibell, Mr. Seagrave.

MALE SPEAKER: As I stated earlier uh, my responsibility to CVS is to purchase the lowest possible cost generic product. I do not focus on the AWP value in negotiations. The market is very fluid and dynamic and very

highly competitive marketplace.

MR. STUPAK: That is not what these people are saying. They are all saying if you keep you AWP at the market standard. It's not fluctuating. If you bring it lower you don't get any customers. You're the customers. You're the pharmacist. You're the customers. Isn't it true why you don't want a lower AWP, if you have a lower AWP your reimbursement from the government and from the insurance company is discounted off of that AWP. So therefore, if the AWP is lower your profit is lower on that drug. Is that true?

MALE SPEAKER: Again, I don't focus on the AWP. My initiative or my.

MR. STUPAK: Whoa. How about just a yes or no? I don't care if you focus on it or not. Doesn't it stand the logic, if you have a lower AWP and you are reimbursed and that AWP is discounted by Medicaid and by the big insurance companies the lower the AWP the lower the profit for the pharmacy. Yes or No?

MALE SPEAKER: Yes. If the reimbursement was based on AWP yes that is correct.

MR. STUPAK: You tell me it's not?

MALE SPEAKER: No I'm agreeing with you but that would be it.

MR. STUPAK: Sure. How about Mr. Zibell, would you agree with that? Lower AWP means lower profit, who do you

represent, CVS or Walgreen's?

MR. ZIBELL: It, it would depend on whether or not the product is reimbursed based on AWP. If it were then the profit would. . .

MR. STUPAK: Medicaid is reimbursed based on AWP.

MR. ZIBELL: In some situations, yes. There are Federal Upper Limit and Max situations put on by the Federal Government and the individual states but if it was based strictly on AWP, if you lower AWP the reimbursement would be lowered.

MR. STUPAK: Well, we're looking at the list right here. Medicaid prescription reimbursement information by state is all based upon AWP plus a little bit more. So the lower the AWP, lower the profit too. So if you are really concerned about what the customers pays wouldn't you want to buy your drugs from these manufacturers who has a lower AWP to pass that savings onto your customers.

MALE SPEAKER: I haven't had a situation presented to me where the AWP has been lower.

MR. STUPAK: Well not you personally but to your company.

MALE SPEAKER: Well I am the purchaser of generic pharmaceuticals and that is the case.

MR. STUPAK: And you represent what company?

MALE SPEAKER: Walgreen's.

MR. STUPAK: So this email then that they referred to I believe it is exhibit number 38, I don't know why our customers complain before we adjust an AWP. Major customers (Walgreen's, Wal-Mart, CVS, Medico, Caremark)expect they are leaving suppliers to maintain they're AWPS. I guess you are mentioned in this one.

MALE SPEAKER: Well, from the manufacturers standpoint I have never indicated that direction today, any manufacturer.

MR. STUPAK: Mr. Seagrave do you care to comment? If you lower your AWP you could lower the price for the customer, right?

MR. SEAGRAVE: I would agree with the other two gentleman if reimbursement is based upon the AWP only then our reimbursement would be less if it was based on AWP. I would comment though that we heard testimony from the previous panel from some gentleman from Michigan and in Texas where they indicated that they do have maximum allowable cost in place and they base their reimbursement off of that and not off of AWP.

MR. STUPAK: Well, how can this side of the table, Mr. Stradamyer, Ms. Mars, Ms. Poletti, Mr. Clevit be saying that they can't sell anything unless it is based on its AWP, which is higher price in user normal. That is not the only reason. I mean the side of table is right here. Left or right. There's no one in the middle.

FEMALE SPEAKER: I think the issue is that it needs to

be a level playing field and I don't think the manufacturer is as concerned with exactly what the reimbursement rate is. The issue is it has to be the same for all manufacturers competing with that specific product.

MR. STUPAK: Well, manufacturer wouldn't be concerned because you are trying to get part of market share. Makes sense you would lower your AWP to get a bigger market share but if the customer, the pharmacies won't buy it unless you maintain a higher AWP because that is what their profit is based upon. So the system really is broken.

FEMALE SPEAKER: Yeah the system is broken and it really needs to be a reimbursement rate set by somebody outside of the manufacturing so it is a level playing field for all the manufacturers.

MR. STUPAK: Let me ask you this question and let's go right down the line. We've known for years and we have heard again today that the average wholesale price or AWP and the WHACK or Wholesale Acquisition Cost, how much most states base their Medicaid Reimbursement formulas on fictitious numbers. You know it, Congress knows it, CMS knows it and the states know it. As the two billion dollars in fines and settlement indicate the manufacturers have benefited from an AWP system but so have the providers. The big losers have been the taxpayers and the poor who are most vulnerable to losing their healthcare when there are budget crunches. Sicker, uninsured

and untreated people don't benefit any of us. The systems need to be changed. But any changes, any changes need to be fair, transparent, efficient and effective. CMS expert panel recommends that reimbursement be based on actual acquisition cost to the pharmacies. Aventis made this recommendation in 2002. I would like to hear from each of you how would you change the system?

MR. STRADAMYER: Well as we said in our policy statement that we think the actual acquisition cost is the best way to start your structure on your reimbursement system.

MR. STUPAK: You mean you would still put in a dispensing fee and a co-pay?

MR. STRADAMYER: Whatever, for, for pharmacist that dispense drugs there would a dispensing fee and for physician office drugs there would be a physicians service fee. That needs to be adequately dealt within its own right but the right is the actual acquisition cost.

MR. STUPAK: The key is for the pharmaceuticals to use the actual acquisition cost. MS. MARS:

MS. MARS: Uh, I agree it should be cost based and reasonable service fee amount to be provided. In the case of getting the cost for the manufacturer, you know, I would just caution the committee in our case most of our sales are to wholesalers and distributors. Um, so when we report and average selling price that may not be reflective of what the

pharmacy is actually paying and that needs to be considered in developing the methodology.

MR. STUPAK: Ms. Poletti.

MS. POLETTI: I would agree that any system that is put into place needs to encourage the use of generic, lower cost generic and it needs to take into account all of the issues that impact all of the parties, manufacturers, the pharmacies, the patients, and the government. I'm not sure that we can sit here today and put forth a proposal.

MR. STUPAK: Mr. Cavlet.

MR. CAVLET: I think the important issue here and what you're getting at is in a situation where we have many competitors entering the market and we are seeing dramatic decrease in acquisition price, I or our customers that an AWP based reimbursement system may not be the best solution. I think that is the key issue here. There needs to be reliance on.

MR. STUPAK: Mr. Marshall.

MR. MARSHALL: Yeah, we at CVS be open to dialogue to discuss a program that would provide coverage for Medicaid patients. It would offer a program that cover the cost and adequately . . . cover dispensing fees associated with filling a prescription. Again just to reiterate that would promote the use of lower cost generics.

MR. STUPAK: Mr. Zibell.

MR. ZIBELL: I think that is the most important part is that you don't want to take away the incentive to dispense the generic over the brand. The focus here has really been on the, the markup of generic pharmaceuticals but not much attention has been paid to the small markup that results from the calculation based on brand name pharmaceuticals. So I think you have to keep that in mind also.

MR. STUPAK: Mr. Seagrave.

MR. SEAGRAVE: I think there is a lot of possibilities and a lot of things we could talk about and ways to fix the system. I think primarily what we would want to do is focus on the increase use of generic drugs. Then I think we need to come up with a fair and equitable formula where we address the adequate dispensing fee, the adequate cost of goods and services and we'll offer our support into finding that solution.

MR. STUPAK: Thank you Mr. Seagrave.

CHAIRMAN JOE BARTON: Gentleman time has expired. Thank you. The Chair recognizes the gentleman from Michigan, Mr. Rogers.

MR. ROGERS: Thank you Mr. Chairman. Wow was it a great day when I got the Healthcare Committee and Energy and Commerce. I went to a reference point to make sure that we were talking about the same rule of law and I went to page 23733. I don't know how ya'll do it. And when I look at the

fact that there is no real guidance in this AWP, if we have found an enemy in this whole thing I think it is us. The United States Congress. To create a system that has a perverse incentive in it for the customers of these manufacturers to try to establish a price point that says, look I know they are not going to cover my proper dispensing cost so I have to build that in and I'm going to make sure obviously that we make a little bit on the drug itself and dispensing cost so I gotta try to figure out how to pump up this AWP to make sure of which they are not given me credit for, I get credit for when I am building in my profit margin on running a pharmacy. Wholly mackerel! I don't know how we got here. This thing has growed. I appreciate ya'll being here. I have to tell you where there is profit there is normally confusion or where there is confusion there is profit. I would venture to guess that most of you have been subject to lawsuits on pricing. Has any of you experienced the lawsuit on pricing?

FEMALE SPEAKER: Yes.

MALE SPEAKER: Yes sir.

MR. ROGERS: Let the record reflect that I think everybody on that panel is shaking their head. The only people smiling are your counselors on the other side of you [laughter]. I mean this thing is absolutely amazing. Can you explain to me, when this lawsuit happens to your company, based on the confusion in which I think the Federal government has

been a big part of this problem. What does it do, what does the cost structure do to the cost of your product? Your time and talents dedicated to trying to run a business and getting low cost drugs to the market.

FEMALE SPEAKER: It takes a tremendous amount of our resources. Both time and money that frankly would be much better spent reducing our prices and our cost.

MR. STUPAK: Is there, do you have any idea, it's probably not a fair question. Do you have any idea what percentage of cost, is there anyway I could get anywhere close to a figure of what this lawsuit problem of your cost structure. I mean you build it in every year I imagine.

FEMALE SPEAKER: I'm sure we can find that out for you.

MR. STUPAK: That would be helpful to do that. Anyone else? Obviously you have, even the bigger pharmacies have you been subject to these suits as well?

MALE SPEAKER: I'm not personally aware of that. I'm in the purchasing department and then I try to keep the cost as low as possible. I'm not aware of a pricing war.

MR. STUPAK: I think we all know the question. I mean this is a significant cost and it's a confusion that we have created for you to try to have to deal with. Uh, I agree. I appreciate ya'll being here. We are going to have to do something about this. This is absolutely not. . . let me ask you this, could you go to a Medicare Pricing System, ASP plus

six, fill in the blank? Is this something, I mean this is the structure that seems to be a little bit closer to taking in account your cost of distribution and the cost of the drug and the ability for you to keep your door and lights on and to pay people. Any thoughts? Nobody wants to commit to a pricing structure. They are pretty smart. I see your lawyers tugging on the back of you if you do. Don't do that. That means no bonus this year. Uh, quite obviously this pricing structure thing is a problem. Let me ask you this other question. You do sense my frustration and I certainly sense yours in trying to go through this and understand it. And by the way that first 22,000 pages was riveting. I loved it [laughter]. Would it be, what problem would it cause for you and I will address this to Ms. Poletti, to provide your pricing structure to the states? Is that a problem? Could it happen?

MS. POLETTI: We could provide whatever information was required by the state as we currently do.

MR. STUPAK: And is that per day as well would that be...

FEMALE SPEAKER: We would be fine with providing pricing information to the states. We would hope that it be kept confidential from our customers.

MR. STUPAK: Obviously. I'm not sure that is the right answer but or nothing today we have a transparency problem, availability of information problem and this God awful system

that we have created. That's a build in these perverse incentives for people to start dealing against each other, not for lowering prices in the free market competition but to try to jack them up a little bit to cover cost that we haven't recognized at the Federal Government is a real issue for you and your operation. That is an issue that I hope, if nothing else that we walk away from this hearing today and try to deal with that very, very serious issue and again I appreciate you all being here in your fourth rightness and trying to get us to this answer. And again I, I found this out in this oncology issue that we have created this really bad system and then we blamed people for trying to participate in applying any business sense that they could possibly muster in this God awful system that we created and then we come back a few years later and said, how could you have done that? That is awful and it's the system that we created. Thanks for having the patience to hang in there and try to offer a local cost drugs to your customers. Hopefully we will have some relief on this lawsuit side of it as well and I know that is an absolute waste of money in our healthcare system. We gotta fix it and hopefully Mr. Chairman we can work to eliminate what is obviously a very confusing large ugly system and try to implement rules and regulations and with that I give it back to the Chairman.

CHAIRMAN JOE BARTON: The Chair now recognizes the

gentleman from New Jersey, Mr. Ferguson for questions.

MR. FERGUSON: Thank you Mr. Chairman. I appreciate you holding this hearing. I don't have any questions at this time but I share many of my colleagues concerns about AWP. Clearly this is an issue that is going to continue to draw a lot of attention from folks on this panel and folks on our committee and I really look forward in engaging in that debate because it is clearly many problems which need to be addressed and I thank the Chairman and the Committee for holding this hearing.

CHAIRMAN JOE BARTON: I appreciate your participation. Uh, Mr. Marshall, I want to come back on some questions. I would like to turn your attention to Tab 37, maybe Miss, oh you got one there, good. In the exhibit binder, Pages 2001 and 2002, purportedly quote a voice mail left by a CVS buyer, Matt Leonard. Do you know who Mr. Leonard is, Mr. Marshall?

MR. MARSHALL: Yes. I replaced Matt Leonard. He was the person in my position prior to me taking the current role.

CHAIRMAN JOE BARTON: And is he still with the company?

MR. MARSHALL: Yes he is.

CHAIRMAN JOE BARTON: In what role does he have now?

MR. MARSHALL: He is a Vice President of Pharmacy Merchandising.

CHAIRMAN JOE BARTON: So where is he in the hierarchy with you?

MR. MARSHALL: I report to Matt.

CHAIRMAN JOE BARTON: Okay so you report to Mr. Leonard. This is a voice supposedly left by him in June or July of 2000 concerning Furosemide. It says and I quote. "CVS would award Roxanne the product if we (Roxanne) would adjust our AWPs to reflect where the other generic companies are, otherwise CVS would award the Zenith Gold Line. Does CVS emphasize AWP or reimbursement when negotiating with these folks?

MR. MARSHALL: I have not seen this document prior to this time and it was my understanding that counsel had spoken with counsel for the committee that documents that had not been reviewed previously would not be reviewed today. I would like to verify that.

CHAIRMAN JOE BARTON: Who did your counsel speak to on the Committee about that?

MR. MARSHALL: I believe it was Mr. Stone.

CHAIRMAN JOE BARTON: Yeah, my understanding is that there was not an agreement like that. They tried to show you all the documents we got.

MR. MARSHALL: I would be more than willing to review this document and come back to you with a response.

CHAIRMAN JOE BARTON: Well, why don't you take your time right now to take a look at it if you don't mind. Because it says, says CVS is looking for Furosemide vendor, apparently

the HICFA max are changing shortly and they are not happy with the margins and their current supplier did not have the new max available to share with me but being public record I'm certain we should have them somewhere. In fact, I think Bob has them on his desk. In the past CVS has ask for AWP less 55% to be competitive on generics. I'm not sure how the MACK impacts this. I would like to discuss this with Bob or Anthony before we bid. For now I have listed the request bid price AWP less 50 and then it says ML, CVS would award Roxanne the product if we would adjust our AWPs to reflect whether other generic companies are otherwise it would award it to CF Goldline. If you look at Tab 38, you will see that the document there which I am told you have been made aware of prior to this hearing is almost identical in its language or reference points to this issue. Have you seen that document before, Tab 38? It is a set of emails or yeah, Tab 38. My counsel indicates that you were made aware of this document.

MR. MARSHALL: I've seen the lower portion, yes. The lower portion of that page.

CHAIRMAN JOE BARTON: And for the record, this is an email from Steve Snyder to Judy Waterier at Roxanne, right? It says gang, CVS is looking for a Furosemide vendor, apparently the HICFA max are changing shortly and I just read most of this. It goes on to say that I request that we discuss this Thursday or Friday, etc. It is similar to the document that on

Tab 36. The issue is do you know Mr. Leonard or do you ever look at AWPs?

MR. MARSHALL: As I mentioned earlier regarding negotiations of lowest cost. The manufacturer provides me with a published AWP or their AWP and references that AWP in a conversation or a proposal, very often I will use that AWP value as a point of negotiations not to instruct or ask that value be changed in anyway shape or form but to the extent that I am offered a discount off of AWP for example that a manufacturer indicate that they would sell it to CVS for AWP less 40%. I may come back and say I would like to have it at AWP minus 60% as a good negotiating tool. All within the context of that value having been provided to me. For no other purpose other than to derive at a lower cost.

CHAIRMAN JOE BARTON: I thought earlier you testified that you didn't look at AWPs as a negotiating point. I believe I testified that I do not consider AWP as far as requesting any changes to that value but to the extent that it is presented to me by a manufacturer I will use it as a point of leverage to try to get him lower.

CHAIRMAN JOE BARTON: Do you ever inquire about AWP, what it is and how much off you are being offered?

MR. MARSHALL: As a standard AWP is provided when a proposal is provided to me for new product or for a existing product.

CHAIRMAN JOE BARTON: So it is something you look at then?

MR. MARSHALL: I am aware of it, yeah.

CHAIRMAN JOE BARTON: Do you require it to be provided to you when you are purchasing a product?

MR. MARSHALL: We require it to put it into our systems.

CHAIRMAN JOE BARTON: So you are asking for AWP. The pricing on AWP.

MR. MARSHALL: Yes I am asking for the value.

CHAIRMAN JOE BARTON: Why do you ask for that?

MR. MARSHALL: We need it to set up an item in our systems at CVS.

CHAIRMAN JOE BARTON: What purpose does it serve in your current system then? Is it to determine the spread?

MR. MARSHALL: No I am not certain but it may have some role in third party processing down stream but I am not sure as to the purpose that we need it.

CHAIRMAN JOE BARTON: You don’t know what use it has in your company.

MR. MARSHALL: I need to have that value to set up a new item that is correct.

CHAIRMAN JOE BARTON: I guess I am. You don’t know why you need it. You just know you need it.

MR. MARSHALL: It is a value that I need to populate in

our purchasing system.

CHAIRMAN JOE BARTON: But you don't know what role it plays in the Purchasing System.

MR. MARSHALL: I believe that down stream it may be used in our third party processing systems.

CHAIRMAN JOE BARTON: And that third party processing system does what? Is that the billing system of the government?

MR. MARSHALL: The Third Party System would be responsible for managing our third party claims.

CHAIRMAN JOE BARTON: And who are those? Who are third party claims?

MR. MARSHALL: Private as well as Medicaid.

CHAIRMAN JOE BARTON: So this does play a relationship in the billing to Medicaid.

MR. MARSHALL: Yes as far as me populating that value and ultimately downstream it maybe used for that purpose.

CHAIRMAN JOE BARTON: You are telling me that you don't negotiate that AWP value when you are making a purchase.

MR. MARSHALL: That is correct. I may negotiate a discounted purchase price.

CHAIRMAN JOE BARTON: Okay let me be clear. I realize you don't necessarily set the AWP but you negotiate a percentage off of the AWP, is that right?

MR. MARSHALL: In some instances when I am presented

with a price by a manufacturer and it is referenced as a discount off of a AWP. For example, the price we are willing to sell this to CVS is 40% off of our established AWP as the negotiator I may ask for 50% off of the AWP.

CHAIRMAN JOE BARTON: But you have never asked them to raise an AWP or said it is hard to buy your product because your AWP is so low.

MR. MARSHALL: That is correct.

CHAIRMAN JOE BARTON: Ms. Poletti, I am curious then, hold on just a minute. I'm sorry Mr. Marshall can you go to Tab 42? You should have seen this I am told by counsel. This is an email. Is that correct?

MR. MARSHALL: Yes I have seen this.

CHAIRMAN JOE BARTON: You have seen this. This is an email to Matthew J. Leonard, Subject: Roxanne Cyclofosfamide. Thank you. It says Matt I thought an email might be a little quicker and easier than trying to exchange voice mails on this. We spoke about this about a week or so ago. You indicated that our spread was not significant enough to peak your interest. I would like to approach my company as what it might to take to get CVS onboard. Can you provide me with CVS's annual volume of the twenty-five and fifty milligram product. Also pass me the volume that you believe CVS would sway to the generic. If I can bring you a fifty to sixty percent spread via a contract price. Thanks, Steve Snyder National Account Manager Eastern

Midwest Is this not also reference the spread being important. The AWP verses what you pay.

MR. MARSHALL: Yes in this case. Just to clarify my interpretation of the spread here is the established AWP of the manufacturer and a requested price to CVS. Again I can't comment on something that was written by another individual but my interpretation would be similar to what I described earlier as far as the lever in negotiating a lower purchase price when you are presented with an AWP value.

CHAIRMAN JOE BARTON: Ms. Poletti, if you can turn to Tab 36. This is an email to Judy Waterier from Robert Socorro I believe. Uh, it is a list the AWPs for I assume your competitors. Is that correct?

MS. POLETTI: Yes.

CHAIRMAN JOE BARTON: They are like 151.90, 141, 151, 140 and then Roxanne is at 45.

MS. POLETTI: Correct.

CHAIRMAN JOE BARTON: How did you AWP get so out of line from these others?

MS. POLETTI: Again we set our pricing when we launch, typically when we launch the product and then we don't revisit the AWP, It is typically set as a standard off of the brand in the generic industry and we wouldn't typically readdress it. In this case, I can't say why the other competitors were higher.

CHAIRMAN JOE BARTON: Did you readdress it in this case for Furosemide.

MS. POLETTI: We had to.

CHAIRMAN JOE BARTON: And why?

MS. POLETTI: Because our AWP was so far out of line as you can see with our competitors that they wouldn't buy the product.

CHAIRMAN JOE BARTON: I am confused between you and Mr. Marshall here because he says the AWP doesn't necessarily, he hasn't said it but he is going to negotiate off of the purchase price, right? And you are saying it is not high enough and we are talking about CVS here in the middle.

MS. POLETTI: I think we are talking about a very rare occasion. We might talk. . .

CHAIRMAN JOE BARTON: But I think it is indicative to practice in the industry.

MS. POLETTI: Well I am not sure that it is. I think this is a situation that it was so far out of line with our competitors that. . .

CHAIRMAN JOE BARTON: Well what would the purpose be for your raising it?

MS. POLETTI: Our purpose?

CHAIRMAN JOE BARTON: Yeah.

MS. POLETTI: It was to just put us on a level playing field.

CHAIRMAN JOE BARTON: And for what purpose did you need to be on the level playing field?

MS. POLETTI: Because

CHAIRMAN JOE BARTON: To get market share?

MS. POLETTI: Absolutely.

CHAIRMAN JOE BARTON: Market share you need to raise your AWP which you said you don't normally do once it is set.

MS. POLETTI: That is true. This is again is a very unique situation. We were faced with discontinuing the product because nobody would buy it no matter even if our contract price was on a level playing field with our competitors and our service level and we were rated the AWP which is one additional factor was so far out of line.

CHAIRMAN JOE BARTON: It was out of line because the spread matters to those buying the product.

MS. POLETTI: In some cases I would assume that was true.

CHAIRMAN JOE BARTON: I would assume in every case although it might not be as dramatic as this. This spread plays into to it here, tell why it wouldn't play into it everywhere else.

MS. POLETTI: I think as long as you are in a relatively the same ballpark it hasn't been our experience that it is something that's dwelled on. AWP is generally a referenced price that is sometimes primarily in new launched

products used as just as a reference point in contract negotiation.

CHAIRMAN JOE BARTON: But it is a reference point that is used.

MS. POLETTI: Yes.

CHAIRMAN JOE BARTON: I mean, I am having trouble believing that it is not an important part of this discussion.

MS. POLETTI: I am sure that it is an important factor in some decisions. I don't know that it is something that dwelled on in every case.

CHAIRMAN JOE BARTON: So you don't think it is a big deal, AWP?

MS. POLETTI: No absolutely I think AWP and the issues need to be addressed. Is reimbursement something that we discuss in normal discussions with our customers, No.

CHAIRMAN JOE BARTON: Uh, this will be a question to the representatives of various pharmacies. Medicaid dispensing fees vary fairly widely from state to state. However the National Average for Medicaid dispensing fees appears to be somewhere in the neighborhood of four dollars per prescription. By way of comparison the committee obtained data showing what the pharmacies receive in the way of dispensing fees from some of their larger third party payors. One pharmacy chain also submitted data showing the average dispensing fees for all of its retail customers. This data showed an average of

approximately $2.25 per prescription on the private side. Why should Medicaid be paying more in the way of dispensing fees than private payors? Mr. Marshall should be start with you?

MR. MARSHALL: I understand the data that you presented to me. My understanding that there are two components to reimbursement. There is a negotiated formula that may involve the AWP or Federal Upper Limit or the MACK price and also there is the dispensing fee. So I think you information is face value but I really couldn't come to a conclusion as to whether we would be paying more for Medicaid verses the private plans other than the absolute value to dispensing fees.

CHAIRMAN JOE BARTON: Are the numbers correct from your perspective on the dispensing fees?

MR. MARSHALL: I'm not as closely tied to this in my current role. I knew that the Medicaid was a little higher than $3.00 and in the private a little higher than $2.00.

CHAIRMAN JOE BARTON: So we are in the ballpark here from your historical factor. Okay but you can't comment as to why Medicaid should be paying more of a dispensing fee than other third party payors.

MR. MARSHALL: Again I think you need to consider the entire equation of the overall reimbursement.

CHAIRMAN JOE BARTON: Mr. Zibell.

MR. ZIBELL: I am not really familiar with the figures presented or how they apply to Walgreen's but I would agree

that you can't look at just the dispensing fee you have to figure the cost component and how that figures into the calculation also.

CHAIRMAN JOE BARTON: All right Mr. Seagrave.

MR. SEAGRAVE: I think your numbers are fairly accurate. But I will tell you when we look at reimbursement we don't look at one segment of the formula we look at the ingredient as well as the dispensing fee. We look at the total reimbursement. We don't look at one component or the other. I will mention with respect to our Medicaid and Medicare business it is not a business that we would negotiate as we do with the commercial payors such as the PBM and the HMOs so when we are looking at the business we are looking at total reimbursement.

CHAIRMAN JOE BARTON: I appreciate that. In fact, based upon the data provided by the pharmacies Medicaid actually pays slightly more for ingredient cost I am told. I guess what I want to sure of is that we move forward on the policy side is that we do the best we can to get it right. That we don't have a situation where we are paying more for drugs than we should and more than private payors are paying. We ought to pay what is fair and I don't believe AWP is fair. We are just guessing off of a percentage off of AWP and there is all these systems. I also want to make sure that pharmacist are properly compensated so that if we change how your are being paid or how the system functions that we don't short

change it and pharmacist suddenly write to all our contingents and we are not going to dispense anymore or because those turkeys in congress changed the formula. But I don't think it is right either to have a formula that ends up over compensating on the drug side and under compensating on the dispensing side or over compensating on both. We need to try to figure out how to get it right because the cost are exploding around us and I would like to see a marketplace work and work honestly. Work ethically and I think Aventis got to this issue a bit when they realized AWP was gonna become a tar baby for the industry. And I commend you for noticing that and for taking action because I am amazed that AWP prior to this hasn't been blown out of the water and after seeing what we went through on Medicare and that something changes for Medicaid prior to this. I turn to the gentleman from Michigan, Mr. Stupak.

MR. STUPAK: Thank you Mr. Chairman. Mr. Cavlet, the statement you made in your testimony states that again that if a generic manufacturer after unilaterally reduce its AWP for a given product relative to the AWPs of other generic manufacturers of the same product pharmacies would have the incentive to purchase another manufacturers drug that did not reduce its AWP. Why did you say that in your testimony?

MR. CAVLET: I believe that it could eventually could happen. I mean I could not think of an instance where it has

happened. I think I mentioned that earlier. My fear was a great disparity that between AWPs of generous products that potentially the company that had the lowest AWP may not be in a position to sell their product in a system where there is AWP based reimbursement in terms of that type of system.

MR. STUPAK: Has your company ever had the lowest AWP and had it purchased by the pharmacies? Have you lowered your AWP to be the lowest and have that happen where they purchased your AWP?

MR. CAVLET: No.

MR. STUPAK: Ms. Mars if the pharmacies would purchase the lower AWP could you lower your AWPs on your products and stay in business?

MS. MARS: As I mentioned before the key to this and similar to what Ms. Poletti said there has to be a level playing field. The manufacturer has no incentive to keep their AWPs high. We are just trying to compete in a fair market. So whatever the government chooses for the reimbursement system we want there to be a level playing field for all manufacturers of the same product.

MR. STUPAK: Sure. Point is, you could lower all your AWPs and still stay in business couldn’t you?

MS. MARS: Probably not. As I have testified we had a similar experience . . .

MR. STUPAK: And the reason why you couldn’t was

because they wouldn’t purchase it right?

MS. MARS: I don’t believe they would. In fact, the product I mentioned we had a lower AWP we did not raise our AWP. We no longer sell the product because we could not compete.

MR. STUPAK: Only because no one would purchase it.

MS. MARS: Correct.

MR. STUPAK: But if they would purchase it at a lower AWP you probably could lower all your AWPs on the products you sell and probably still stay in business as long as someone would purchase your product. Correct?

MS. MARS: Correct.

MR. STUPAK: And in your testimony and why wouldn’t they purchase your product?

MS. MARS: Well because they are being reimbursed at a much lower rate for our product than someone else’s in this particular case.

MR. STUPAK: Correct. So if the company wouldn’t make as much money and give the taxpayer customers the one that pays, right?

MS. MARS: Correct.

MR. STUPAK: Thank you I have nothing further, Mr. Chairman.

CHAIRMAN JOE BARTON: Thank you Mr. Stupak. Uh, we don’t have anything else at this time for the committee. I

greatly appreciate your insights and your patience and we look forward in staying in communication with all of you. This is the third panel dismissed. The record will remain open for ample opportunity for members to submit other questions or testimony and with that the sub-committee is adjourned.

[END RECORDING]