MEDICARE PAYMENTS FOR CURRENTLY COVERED PRESCRIPTION DRUGS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

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MEDICARE PAYMENTS FOR CURRENTLY COVERED PRESCRIPTION DRUGS

THURSDAY, OCTOBER 3, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:38 a.m., in room 1100 Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
September 26, 2002
No. HL–18

CONTACT: (202) 225–3943

Johnson Announces Hearing on Medicare Payments for Currently Covered Prescription Drugs

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on pricing mechanisms for drugs covered under the Medicare program. In addition, the hearing will examine physician reimbursement for administration of these prescription drugs. **The hearing will take place on Thursday, October 3, 2002, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include the Administrator of the Centers for Medicare and Medicaid Services (CMS), academics, and providers. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Medicare does not cover most outpatient prescription drugs. However, it does cover certain categories of outpatient prescription drugs, including drugs used in dialysis, organ transplantation, cancer treatment, and certain drugs used with durable medical equipment, such as infusion pumps and nebulizers. According to the U.S. General Accounting Office, about 450 outpatient drugs are covered under these categories. Medicare payments for covered drugs have skyrocketed, increasing beneficiary and taxpayer costs, and driving potentially inappropriate clinical decisions.

In 1992, Medicare paid about $700 million for prescription drugs; eight years later, it paid $5 billion. (Between 1999 and 2000, payments increased by $1 billion.) In addition, just 35 drugs account for 82 percent of Medicare spending and 95 percent of the claims volume.

The Balanced Budget Act of 1997 (P.L. 105–33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of the average wholesale price (AWP) for the drug. AWPs, however, are not defined by law or regulation. The AWPs are reported by drug manufacturers to organizations that publish the data in compendia. Medicare carriers use the published data in calculating payment for Medicare covered drugs, but AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. The AWP for a product is often far greater than the acquisition cost paid by suppliers and physicians. In addition, AWPs do not reflect the discounts, rebates or "charge backs" that manufacturers and wholesalers customarily offer to providers. Therefore, AWPs represent neither average prices nor prices charged by wholesalers.

Medicare pays an excessive amount for covered drugs. The U.S. Department of Health and Human Services Inspector General found that Medicare beneficiaries and taxpayers could save more than $200 million on one drug alone—albuterol, an inhalation therapy drug—if the drug were reimbursed at prices available to commercial purchasers. Moreover, a higher AWP creates a higher beneficiary copayment and premium, because beneficiaries are responsible for a copayment equal to 20 percent of Medicare's payment for the drug. In some cases, the beneficiary's copayment is greater than the physician's or supplier's actual total cost for the drug.

Some manufacturers reportedly use inflated AWPs as a strategy to increase market share. Physicians and suppliers are reimbursed based on the inflated AWP, but actually pay much less to acquire the drug. The larger the "spread" between the actual price and 95 percent of the AWP, the greater the incentive to use the product. This inappropriately influences clinical decisions and may harm patient care, while driving over-utilization of services.

Some physicians have expressed concerns about lowering Medicare reimbursements for prescription drugs. They assert that they are under-reimbursed by Medicare for their costs in administering the drugs, and claim that the overpayments for drugs to cover their practice expenses. Oncologists, for example, argue that Medicare does not adequately reimburse them for the practice expenses associated with providing treatment to cancer patients in outpatient settings.

There is little rationale for using Medicare overpayment for drugs as a mechanism to reimburse physicians for practice expenses. Medicare has a well-defined procedure for examining the adequacy of physician payments under the physician fee schedule. As provided for under the Benefits Improvement and Protection Act, oncologists recently submitted results from a new survey on practice expenses to CMS as part of this review. Because any increase in practice expense reimbursements to one specialty, such as oncology, must be budget neutral under current law, other specialties would experience decreases in their practice expenses, unless Congress were to provide new money to recognize these practice costs.

In announcing the hearing, Chairman Johnson stated, "The AWP process is seriously flawed. It's costing Medicare beneficiaries and taxpayers too much because Medicare is paying inflated prices. We must inject competition into the program to bring market forces to bear on reimbursement for drugs. The Administration says that they will fix the problem if Congress does not act, but it will take congressional action to ensure that our seniors continue to have access to high-quality cancer care."

FOCUS OF THE HEARING:

Thursday's hearing will highlight problems with the AWP system for determining Medicare reimbursements for currently covered prescription drugs, and examine alternative mechanisms for determining Medicare payments.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Due to the change in House mail policy, any person or organization wishing to submit a written statement for the printed record of the hearing should send it electronically to *hearingclerks.waysandmeans@mail.house.gov*, along with a fax copy to (202) 225–2610, by the close of business, Thursday, October 17, 2002. Those filing written statements who wish to have their statements distributed to the press and interested public at the hearing should deliver their 200 copies to the Subcommittee on Health in room 1136 Longworth House Office Building, in an open and searchable package 48 hours before the hearing. The U.S. Capitol Police will refuse sealed-packaged deliveries to all House Office Buildings.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. Due to the change in House mail policy, all statements and any accompanying exhibits for printing must be submitted electronically to *hearingclerks.waysandmeans@mail.house.gov*, along with a fax copy to (202) 225–2610, in Word Perfect or MS Word format and MUST NOT exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. Any statements must include a list of all clients, persons, or organizations on whose behalf the witness appears. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at http://waysandmeans.house.gov.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call (202) 225–1721 or (202) 226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman JOHNSON. Good morning. This morning's hearing is very important in our effort to strengthen our Medicare Program. The evidence is overwhelming that Medicare is paying way too much for some items of durable medical equipment (DME) and prescription drugs. It is imperative that we adopt a system that more accurately aligns costs and payments.

While this would not normally be a difficult task, it is a very difficult problem at this time because most cancer care is paid for through drug reimbursements. This means that as we change the way we pay for drugs, we must also realistically and accurately reimburse for the practice expenses associated with the delivery of, for example, chemotherapy. These practice expenses are significant—personnel, special equipment, costly drug inventories and insurance to cover them, and so forth.

So assuring reimbursement for practice expense is no easy task, yet it has been only a minor part of the average wholesale price (AWP) discussion. The U.S. General Accounting Office (GAO) tried identifying practice expenses, but neglected to focus its work appropriately on oncologists who deliver such care in an office setting. The oncology community was slow, as well, to rise to this quite daunting task.

However, now we are developing the needed information. Today we are unified in our quest to change the way we pay for Medicare-covered drugs and the way we pay for the costs of administering those drugs.

While I am keenly disappointed in the GAO study, I am pleased that the oncologists have taken advantage of a provision I wrote in the Benefit Improvement and Protection Act. The provision permits groups to submit practice expense data and requires the Centers for Medicare & Medicaid Services (CMS) to evaluate that data and use it if it meets certain standards. The most recent data is very important and particularly significant because of our earlier failure to collect appropriate information.

Overpaying for drugs burdens seniors with copayments that in some instances exceed the cost paid for the drug by the physician, pharmacist, or provider of durable medical equipment. On the other hand, underpayment will, without question, deny seniors access to life-saving care.

Medicare spending on part B drugs is very concentrated. Just 35 drugs account for 82 percent of Medicare spending, and 95 percent of the claims volume. Furthermore, Medicare payments for covered drugs have skyrocketed, increasing beneficiary and taxpayer costs. In 1992, Medicaid paid about $700 million for prescription drugs. In 2000, it paid $5 billion, a 700-percent increase over 8 years.

Medicare's payment for these drugs is prescribed in law. The Balanced Budget Act 1997 specifies that Medicare pay 95 percent of the AWP, for the drug. The AWPs, however, are not defined by law or regulation. They are reported by drug manufacturers to or-

ganizations that publish the data in compendia, like the Red Book. Medicare carriers use the published data to calculate payment.

The problem is that AWPs do not reflect the actual price paid by purchasers. Nor do they accurately account for the costs associated with administering the drugs, for which no other Medicare payment is made. The AWPs are often far greater because they do not reflect the discounts, rebates, or so-called charge backs that manufacturers and wholesalers customarily offer to providers. On the other hand, for cancer drugs, they have the costs of inventory, insurance, special equipment, nursing, and other personnel that are not captured in any other payment.

Examples of overpayment abound, forcing seniors to bear higher copayments and premiums. Beneficiaries pay a copayment equal to 20 percent of Medicare's payment for the drug. For some drugs, beneficiaries are, indeed, paying more in copayments than physicians or suppliers are paying to purchase the drug.

Consider Vancomycin, with an AWP of $382. The beneficiary would pay 20 percent, or $73. The provider would pay $5, on average. That is a $73 payment by the beneficiary for a drug that cost the provider $5.

Here are just a few examples comparing one company's 2001 AWP, as reported in the Red Book, and the actual wholesale prices determined by the U.S. Department of Justice. Vancomycin, the Red Book reported AWP was $382 compared to the U.S. Department of Justice actual price of $5, an injectable drug. The other two are also injectable. In the interests of time, I am going to skip over the details.

A second and equally serious problem are reports that some manufacturers use inflated AWPs as a strategy to increase market share. If Medicare reimburses physicians and suppliers based on the inflated AWP, providers have a greater incentive to use the products with the larger spread. Providers may base prescribing decisions on economic incentives rather than clinical appropriateness. This practice may harm patient care and drive over-utilization of services.

Of all countries, America has the greatest access to cancer care. In recent years, there has been a revolution in cancer care, enabling physicians to deliver the latest in quality care in many small centers across America. Medicare does not reimburse oncologists for the practice expenses associated with providing treatment to cancer patients in outpatient settings. Consequently, they have come to rely on the overpayment for drugs to cover these costs.

Before we eliminate overpayments, we must assure appropriate reimbursement for practice expenses. While all agree on this, I am determined it be done accurately and fairly. I am disappointed with the relatively small amount of attention that has been focused on this issue and will pursue it in questioning.

We are very pleased to welcome the Honorable Thomas A. Scully from the Centers for Medicare & Medicaid Services again before us, and on our second panel, George Reeb, Michael J. O'Grady, Ph.D., Paul A. Bunn, Jr., M.D., John D. Jones, and Kim Glaun, whom I will introduce a little bit more at a later time. Mr. Stark?

[The opening statement of Chairman Johnson follows:]

Opening Statement of the Hon. Nancy L. Johnson, a Representative in Congress from the State of Connecticut, and Chairwoman, Subcommittee on Health

Good morning. This morning's hearing is a very important one in our effort to strengthen our Medicare program. The evidence is overwhelming that Medicare is paying way too much for some items of durable medical equipment and prescription drugs. It is imperative that we adopt a system that more accurately aligns costs and payments.

While this would not normally be a difficult task, it is a very difficult problem at this time because most cancer care is paid for through drug reimbursements. That means that as we change the way we pay for drugs, we must also realistically and accurately reimburse for the practice expenses associated with the delivery of, for example, chemotherapy, and these practice expenses are significant, personnel, special equipment, costly drug inventories, and the insurance to cover them and so forth.

So assuring reimbursement for practice expense is no easy task, yet it has been only a minor part of the AWP discussion.

The GAO tried identifying practice expenses but neglected to focus its work appropriately on oncologists who deliver such care in an office setting. The oncology community was slow as well to rise to this quite daunting task. Now, however, we are developing the needed information and today, are unified in our quest to change the way we pay for Medicare-covered drugs . . . and the way we pay for the costs of administering those drugs.

While I am keenly disappointed in the GAO study, I am pleased that oncologists have taken advantage of a provision that I wrote in the Benefit Improvement and Protection Act that permits groups to submit practice expense data and requires the Centers for Medicare and Medicaid Services to evaluate that data and use it, if it meets certain standards. Their most recent data is very important and particularly significant because GAO failed to collect appropriate data in the study we sought for that purpose, though unintentionally.

Overpaying for drugs burdens seniors with co-payments that in some instances exceed the cost paid for the drug by the physician, pharmacist, or provider of durable medical equipment. On the other hand, underpayment will without question deny seniors access to life-saving care.

Medicare spending on Part B drugs is very concentrated: just 35 drugs account for 82 percent of Medicare spending and 95 percent of the claims volume.

Furthermore, Medicare payments for covered drugs have skyrocketed, increasing beneficiary and taxpayer costs. In 1992, Medicare paid about $700 million for prescription drugs; in 2000, it paid $5 billion, a 700 percent increase over 8 years, though the number of drugs used has soared as well.

Medicare's payment for these drugs is prescribed in law. The Balanced Budget Act of 1997 specifies that Medicare pay 95 percent of the average wholesale price, or AWP, for the drug. AWPs, however, are not defined by law or regulation. They are reported by drug manufacturers to organizations that publish the data in compendia, like the Red Book. Medicare carriers use the published data to calculate payment.

The problem is that AWPs do not reflect the actual price paid by purchasers, nor do they accurately account for the costs associated with administering the drugs, for which no other Medicare payment is made. The AWPs are often far greater because they do not reflect the discounts, rebates or so-called "charge backs" that manufacturers and wholesalers customarily offer to providers. On the other hand, for cancer drugs, the heavy costs of inventory, insurance, special equipment, nursing and other personnel are not captured by any other payment.

Examples of overpayment abound, forcing seniors to bear higher copayments and premiums. Beneficiaries pay a copayment equal to 20 percent of Medicare's payment for the drug. For some drugs, beneficiaries are paying more in copayments than physicians or suppliers are paying to purchase the drug.

Consider vancomycin, with an AWP of $382. The beneficiary would pay 20 percent of the Medicare reimbursement of $363, or $73. The provider would pay about $5, on average. That's a $73 payment by the beneficiary for a drug that costs the provider $5.

A second and equally serious problem are reports that some manufacturers use inflated AWPs as a strategy to increase market share. If Medicare reimburses physicians and suppliers based on the inflated AWP, providers have a greater incentive to use products with a larger "spread" between the actual price they pay and Medicare's reimbursement. Providers may base prescribing decisions on economic incen-

tives rather than clinical appropriateness. This practice may harm patient care, and drive over-utilization of services.

Of all countries, America has the greatest access to cancer care. In recent years there has been a revolution in cancer care, enabling physicians to deliver the latest in quality care in many small centers across America. Medicare does not reimburse oncologists for the practice expenses associated with providing treatment to cancer patients in outpatient settings. Consequently, they rely on the overpayments for the drugs to cover these costs. Before we eliminate these overpayments, we must assure appropriate reimbursement of practice expense. While all agree on this, I am determined it be done accurately and fairly and am disappointed with how little real attention seems to be focused on it in today's testimony and will pursue this matter in questioning.

We are pleased to welcome Tom Scully from the Centers for Medicare and Medicaid Services who will give us his views on AWP reform.

Our second panel will include:

- George Reeb, from the Office of the Inspector General in the Department of Health and Human Services will update us on his findings comparing AWP to actual acquisition costs;
- Michael O'Grady from Project Hope will discuss a competitive bidding approach to establishing Medicare reimbursements for outpatient drugs;
- Dr. Paul Bunn from the American Society of Clinical Oncology will tell us about the new information on practice expenses that the Society has collected and submitted for consideration; and
- Kim Glaun from the Medicare Rights Center will present concerns from beneficiaries perspective.

I look forward to your testimony.

Mr. STARK. Thank you, Chairman Johnson, for holding this hearing today. I could not agree with you more. It is clear that the pharmaceutical industry, and its partners are bilking Medicare beneficiaries and the program, perhaps out of billions of dollars.

I will not repeat many of your observations because they hold. This illegal behavior, I think, harms each and every one of us. Medicare pays more for the services it covers, and the taxpayers pay more, in many cases, or beneficiaries pay more.

The drug companies will argue in their defense that they are operating within the letter of the law. They will not change their behavior unless and until the law changes. Well, I disagree with their interpretation of the law. I certainly will agree with them that they are right. We should change the law, and that will take care of that.

I have introduced a bill which would end the outrage. It is a market-based solution which would require Medicare to pay the true average market price for the drugs currently covered. That means we pay for what the doctors or the hospitals actually pay. It is consistent with the GAO recommendations. It is achievable in a short timeframe. It is enforceable, very stiff penalties, and it also recognizes that we must address the inadequacies of the current reimbursement to the doctors.

One of the reasons this is so prevalent is that the doctors feel they are underpaid for the administration. They make it up through marking up the drugs. I do not think that is the way to do it. I think if they are underpaid, we should address that, as well. Then we will have a solution.

I would like to put some human terms on this. There is an enterprising person in Florida. I know this sounds like a little advertising, but that is okay. He looked up on the web—he was mad about this problem and found my bill. He wrote to one of our staff

Members on the Committee on Ways and Means. He says, "Terry, I would like to thank you for your time and effort in helping track down the price of cancer drug Leucovorin, $14.88. The fascinating 20 percent that I have to pay is $51.08. It does not take a rocket scientist to figure out that the numbers are questionable, not only the price of Leucovorin, but every item on the page would raise eyebrows."

"My problem is, of course, that our HMO, health maintenance organization, dropped out of our county and now we only have Medicare. The facts will show that what I have to pay for my wife's chemo are out of line. Paying a 20-percent copay is okay as long as the doctor's numbers were fair. The page I will fax to you will show that there is a problem. Please thank Congressman Stark for his effort in trying to right the wrong. Please give my regards to Congresswoman Karen Thurman, as she helped me with the U.S. Department of Veterans Affairs (VA) health program, parentheses, this is only a personal opinion, but she is the jewel of Citrus County."

[Laughter.]

Mr. STARK. "Thank Terry and you. If you would send me your fax number, I will send you the document I have from the doctor."

I would like to ask that the Harper's personal address be redacted but that the letter be made part of the record, Madam Chair, and I submit it.

Chairman JOHNSON. So ordered.

[The letter from Mr. and Mrs. Harper follows:]

Terri Shaw
Washington, DC

Terry,

I would like to thank you for your time & effort that you gave in helping track down the price of the cancer drug (leucovorin). ($14.88), & the fascinating 20% that I have to pay, is $51.08. It does not take a rocket scientist to figure out that the numbers are questionable????.

Not only the price of leucovorin, but every item on the page would raise eyebrows. I will fax the document from the doctor as I am having trouble with my scanner. My problem is of course is that our HMO dropped out of our county & now we only have Medicare.

The fax will show that what I have to pay for my wife's chemo are out of line. Paying a 20% co-pay is o-k as long as the doctor's **numbers** were fair!!!!!!!. The page that I will fax to you will certainly show that there is a problem.

Please thank Congressman Stark for his effort in trying to right a large wrong in our Medicare Program.

Please give my regards to Congresswoman Karen Thurman, as she helped me with the VA health program. (This is only a personal opinion but, she is the jewel of Citrus County).

Thank you Terry & if you would send me your fax number I will send the document I have from the doctor. Once again, we thank you.

Bob & Florence Harper

Mr. STARK. I look forward to hearing what our witnesses have to say.

[The opening statement of Mr. Ramstad follows:]

Opening Statement of the Hon. Jim Ramstad, a Representative in Congress from the State of Minnesota

Thank you, Madam Chairwoman, for holding this important hearing today.

The Medicare program is broken. Physicians are declining to see Medicare patients because of low reimbursement rates, reimbursement for new technologies used in outpatient settings is scheduled to be severely cut, and seniors in Minnesota pay higher premiums and receive fewer benefits than seniors in many other states under the Medicare+Choice program.

The biggest factor driving all of these issues is the arbitrary formulas used in the Medicare program to determine reimbursement rates. Medicare reimbursement must be reformed to reflect real world market transactions.

At the same time, we must make sure that new approaches to reimburse based on actual costs are accurate and truly encompass all costs associated with the medical procedure. Reimbursement for medical devices used in outpatient care is a perfect example of the inability of our system to accurately capture and report actual costs associated with medical services.

For example, the proposed 2003 rule for the outpatient prospective payment system is based on nearly 60 million hospital claims. One would assume these claims provide an accurate view of the costs associated with performing a medical procedure. Unfortunately, further review of the hospital claims shows significant flaws in the hospital coding process. For example, these claims, which served as the basis for 2003 payment rates, included submissions showing cardioverter-defibrillators used in colonoscopies and carpal tunnel surgeries and pacemakers used in cataract surgeries. In fact, of the 3,322 single-procedure claims for pacemaker insertions reviewed, 50 percent of those claims were coded incorrectly.

Madam Chairwoman, Medicare's reimbursement policies must be reformed to reflect costs, and these costs must be accurate. Medicare's ability to accurately reimburse for Medicare services may be the biggest determinant of what medical services are available to our seniors. These aren't just reimbursement formulas or proposed rules—these may be life or death decisions for millions of elderly Americans.

Thank you, Madam Chairwoman, for holding this hearing, and I look forward to working with you to ensuring that seniors have access to the health care they need and deserve.

Chairman JOHNSON. Mr. Scully?

STATEMENT OF THE HON. THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

Mr. SCULLY. Madam Chairwoman, Congressman Stark, and Members of the Subcommittee, thank you for having me here today. I am always happy to be here on an issue I think we have so much agreement on.

Obviously, as I think we all know, we all wanted to be talking about larger Medicare prescription drug issues this year. We still hope to get a Medicare drug benefit out of Congress this year. That seems increasingly unlikely. From the Administration's point of view, we would like to congratulate you for getting a Medicare prescription drug bill out of the Committee and out of the House. We certainly are committed to getting that legislation passed as soon as we can.

Back to AWP, this is a longstanding problem. Medicare pays about $5 billion a year for about 450 outpatient drugs. We pay far more than any of the purchasers of these drugs, and the agency has been determined for many years to try to find a way to fix it.

This is the third time I have testified on AWP this year. Having testified on a lot of issues, I can tell you that rarely have I seen the kind of bipartisan support for fixing a problem that this issue has. Senator Baucus and Senator Grassley in the Senate Committee on Finance were both very supportive of fixing this problem. Chairman Tauzin and Congressman Dingell were literally jumping up and down in their hearing to fix this problem. The Administration is very anxious to work with all of Congress, including this Committee, to fix this problem.

I think this is clearly one place where Congress has a very huge problem that needs to be fixed. There are a number of ways to fix AWP. We support a lot of what the Committee has been talking about in your proposal on competitive bidding. We think that is one approach that could easily work. Mr. Stark's approach is another. The House Committee on Commerce, as you probably know, proposed using the average sales price (ASP), which is similar to Mr. Stark's bill. I think we have been saying all year long, we may have opinions. We would work with any one of them. The one thing that is clear is we are overpaying for all these drugs.

Just to give you one example on the competitive bidding front, which we think in the long range—in the short range, an ASP approach or picking a new and better AWP may be the short-term fix. We believe, however, that even those numbers potentially could be gamed in the long run, as AWP has been. In the longer term, we think a more market-oriented approach may work.

Just to point out one example, in San Antonio last year in our DME competitive bidding proposal, we put out a bid for Albuterol, a widely used drug for asthmatics, and we received 30 bids. Eleven companies out of the 30 were accepted. We saw a 25-percent reduction in the price that we paid. It worked out to about average wholesale price minus 30, not average wholesale price minus 5. Not every drug is that easy to compete with. San Antonio is a big town. We understand competitive bidding may have other issues in smaller markets. It is very clear that we are overpaying and not paying market prices for drugs.

We are also very concerned, as you are. We have said to the oncologists and others, that there are a number of areas—particularly, oncology, hematology, and dialysis facilities—where providers rely on the cross-subsidy from high average wholesale prices for drugs to make up for what they perceive, in some cases probably correctly, to be an underpayment for their basic services. We think on any proposal to fix AWP needs to address that.

The GAO report, that came out earlier said that they believe that the oncology practice expense payments were underpaid by about $49 million. An earlier CMS report suggested that number was $52 million. We have been spending a lot of time with the oncologists, and it is part of our ongoing rulemaking. I cannot get into the details they submitted, but it is significantly higher, which probably is not surprising given the number. We do think that we need to find the right amount for practice expenses. As we reduce the overpayments for AWP, that we need to make adjustments probably, at the very least, for oncologists, hematologists, and for dialysis facilities.

There are problems here. This fits into a broader payment concern. We believe the easiest way to fix this is for Congress to fix it, because if you fix it and we get the savings through average wholesale price, you can redistribute the appropriate money back into the base to pay oncology fees. It is very unclear at this point whether the agency has the ability to do that administratively.

Our concern is we could save, we could discuss any number, say $100 million a year to $1 billion a year on overpayment for AWP. We have looked at legally whether we could actually save the money administratively and put it back in the payment rates. It is

not clear. It is not clear that we cannot, but it is also not clear that we can. It would clearly be much cleaner to take the savings and for Congress to put the money back in the program.

If we cannot put it back in administratively, you can see the potential problem we have. If we were to add, let us say hypothetically, $100 million a year back for the oncologists, we are in a context, at least right now, which we also hope to fix, where we are looking at a physician update of negative 4.4 percent on the base conversion factor next year—an outcome I think all of us are hoping to avoid in the next few weeks for which the Administration strongly supports technical fixes.

In the context of fixing payments to oncologists, if in the current setting we had to put $100 million back into the base for oncology fees as we fix the AWP, that update would not be negative 4.4 percent, it would be negative 4.6 percent. So, the idea in a budget neutral sense of fixing the oncology practice expenses as you save money in AWP is probably not particularly appetizing for anyone, including the oncologists. So it may be an option, but it is not clear that we can do that legally. That is one of the major reasons all year long we supported the idea of Congress making this fix and telling us, at least directing us, even if it is in somewhat vague terms, to make the market-base fix and to put some of the money back into the appropriate practice areas.

There are a number of impacts of AWP that I do not think a lot of people understand. We clearly way overpay for drugs, but I want to go through one example because I think while we overpay for drugs. It is obviously a huge problem for taxpayers if we are overpaying $1 billion a year on drugs, which some folks claimed, but it also has an impact all through the rest of the health care system. So, I brought some charts today to illustrate that.

About 80 percent of these drugs are paid for in physicians' offices, but about 20 percent are paid for in hospital outpatient settings. As you know, right now we are going through a rewrite of our hospital outpatient rule, which is incredibly complicated. I am spending a great amount of time on. Last year, we paid most of what are called pass-through drugs at 95 percent of AWP, and when we pay that, we significantly overpaid for a lot of drugs.

This year, in our draft rule, we used about 60 million claims to figure out the real rate that hospitals paid for drugs. Those rates came down significantly, and they will come down. In the final rule, they came down a lot, and I used the draft rule data. In the final rule, we are actually using even better data and better claims. I think some of the drug prices will go down and others will go up, so there will be some significant changes.

Last year, the reason I put this chart up is this does not just cost the taxpayers $1 billion. If you look at what we paid on that chart—and you probably cannot read it too well from that distance and I apologize—what you will see is that for some drugs, we will overpay a lot. I will just give you an example: Retuxin last year. When we paid at 95 percent of AWP, we paid $372. This year, when we are using actual hospital claims to pay it, the price is dropping by 20 percent.

Each of the first four drugs on the chart are cancer drugs. As you go down the line, you will find that when you switch from 95 per-

cent of AWP, which we paid in the outpatient setting, to real prices that hospitals pay, you frequently end up with 75 or 80 percent of the AWP. So obviously for taxpayers, paying that lower rate is the right thing to do.

What a lot of people do not realize is the hospital outpatient pot is a finite, roughly $17-billion pot. If you switch to the next chart, I think what you will find is that in addition to paying too much, when we have to put more money into overpaying for drugs, and it is somewhat similar but different for devices, you also have to take money out of basic services. So last year, for instance, the payment in an outpatient setting for colorectal colonoscopies dropped 16.3 percent. For mammographies, it went down 13.2 percent. For emergency room (ER) level visits, the mid-level ER visits, it went down 3.7 percent. When you take out overpayments for drugs you free up money to go back into the base services because it is a finite pot. If we are paying too much for drugs, we are not necessarily just paying too much from taxpayers. We are also taking resources out of other areas for critical services, like colonoscopies, mammographies, and ER visits.

So this year, we found that we took a lot of money out of the payments, and we had overpaid for AWP. We now have 60 million claims, in the final outpatient rule. We are going to take down a lot of payments for a lot of drugs to what we think are far more market oriented, far more appropriate levels. What you find is, and these will change in the final rule, but you will find double-digit increases over last year for payments of colonoscopy, double-digit increases for mammographies, and probably close to double-digit increases for the basic emergency room visit. There is also a direct tradeoff between overpaying for drugs and underpaying for basic hospital services that a lot of people do not understand.

So it is not just bad policy for taxpayers to overpay for outpatient drugs, and it does not just have the impact of spending too much taxpayer money. It also has the impact of negatively affecting hospitals on their basic services for critical preventive services and critical things like emergency room visits. I do not think the connection is often made in that regard.

So we are determined for a variety of reasons, mainly so that we do not overpay for drugs, but also to make sure that we have the accurate payment for base physician and hospital services, to fix this policy. I think it is clear on a bipartisan basis that this is bad payment policy. We have an enormous level of bipartisan support to fix it. It is very clear.

We would very, very much like to have Congress fix AWP this year if you can do it before you go. If you cannot, the Administration is committed to fixing it on our own. I will tell you that, just in brief, if Congress does not fix it this year, our plan is to pick one of our 23 contractors—right now, we have 23 contractors that pay—they, each one of them measures AWP on their own, and they decide what AWP is locally. When you do a poll of those contractors, which we have done, you will find that the payments vary massively and their interpretation of the AWP varies massively.

So administratively, our plan immediately would be later this year to pick one contractor—we have a couple that we believe are better than others. We will pick our best of the 23 carriers and tell

them that they are going to be essentially the common price determiner for what is real AWP. We think that would immediately save $100 million a year.

Then our plan would be to go out and do a much more detailed market survey. Most of our carriers are Blue Cross plans. They know what they are paying for people for the same drugs who are under 65. We believe that if we did nothing but identify appropriate market prices, we could probably save as much as $500 million a year.

We think Congress can probably do more if you direct us to do any one of the hybrid approaches that you have, but our view is the number one thing that we should not do is let this go on any longer. It needs to be fixed as soon as it possibly can.

We would be very anxious to work with the Committee and Congress to try to fix this in the next 2 weeks by any one of the approaches that have been suggested. If not, I think the Administration is committed to fixing it on our own administratively during the course of the next 6 months. Thank you, Madam Chair.

[The prepared statement of Mr. Scully follows:]

Statement of the Hon. Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services

Chairman Johnson, Congressman Stark, distinguished Subcommittee Members, thank you for inviting me to discuss Medicare Part B reimbursement for prescription drugs. As you know, prescription drugs have become an increasingly important component of modern health care, particularly for Medicare beneficiaries. The President has taken a number of steps to provide immediate relief to America's seniors and people with disabilities who have high drug spending, and we are continuing to work closely with Congress to strengthen Medicare by including a comprehensive prescription drug benefit. I would like to thank you for your hard work on creating prescription drug legislation. Although we are disappointed that Medicare beneficiaries still do not have comprehensive drug coverage, we remain hopeful that we can continue to work together to enact this crucial benefit as soon as possible.

It is also critically important that we improve the payment system for the small number of outpatient drugs currently covered by Medicare. It is clear that Medicare's payment system for those covered drugs, based on average wholesale price, or "AWP," is seriously flawed. The Medicare program relies on the prices reported by drug manufacturers to set payment rates. We all agree that Medicare should pay appropriately for all the services and treatments covered by Medicare, including the limited drugs that we currently cover. At the same time, we need to be certain that Medicare pays physicians and other providers appropriately for their services when they furnish drugs to beneficiaries. We support fair, competitive payments for Medicare prescription drugs. We understand that the Committee is working on such a proposal and we look forward to working with you.

By law, Medicare does not pay for most outpatient prescription drugs. However, there are some specific exceptions where Medicare covers pharmaceuticals, such as those drugs that are not self-administered and are furnished incident to a physician's covered services. In these cases, the law requires that Medicare pay physicians and other providers based on the lower of the billed charge or 95 percent of the drugs' AWP. Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare bases its drug payments, are vastly higher than the prices drug manufacturers and wholesalers actually charge physicians and providers. That means Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers are spending far more than the "average" price that we believe the law intended them to pay for these drugs. Some affected physicians and providers have suggested that these Medicare "drug profits" are necessary to cross subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the administration of chemotherapy for cancer. We believe that finding a way to pay appropriately for both the drugs and the services related to furnishing those drugs is a better approach.

Clearly, Medicare drug pricing is complex. Over the years, numerous legislative efforts have made progress toward developing an effective alternative to AWP.

These efforts have aimed at ensuring that Medicare and its beneficiaries do not pay more than they should for the prescription drugs that Medicare covers, and that physicians and providers are compensated appropriately for their services. We continue to believe that a legislative remedy to this problem would be preferable, and we will work with Congress to implement effective legislation. However, if necessary, we are prepared to build on the strong evidence and best ideas for reform developed in Congress by taking action under the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which provided some authority for the Secretary to act after reviewing the General Accounting Office (GAO) report to Congress. Under BIPA, we could move to a market-based system for drugs and adjust payments for services related to furnishing drugs such as practice expenses for oncology administration. As we look to the future, particularly as we add broader prescription drug coverage to Medicare, it is vital that we develop market-based, competitive pricing systems for drugs so that we do not repeat the past mistakes of overpayment. We are committed to working with Congress to amend the current system to make sure that Medicare pays a fair, competitive price for all benefits, including the limited drugs the program now covers.

MEDICARE'S LIMITED DRUG BENEFIT

The Centers for Medicare & Medicaid Services (CMS) pays most of the health care expenses of almost 40 million Medicare beneficiaries. If Congress were creating the Medicare program today, we believe it would certainly include a prescription drug benefit. When the Medicare program was enacted in 1965, however, prescription drugs played a less prominent role in health care than they do today. Although by law Medicare does not generally cover over-the-counter or outpatient prescription drugs, Medicare does cover some drugs, including:

- Drugs that are not self-administered and furnished "incident to" a physician's service, such as prostate cancer drugs;
- Certain self-administered oral cancer and anti-nausea drugs;
- Certain drugs used in conjunction with certain durable medical equipment or infusion devices, (e.g., the albuterol that is put into nebulizers, which are devices used by asthma patients);
- Immunosuppressive drugs, which are used subsequent to organ transplants;
- Clotting factors for beneficiaries with hemophilia;
- Erythropoietin, the drug that constitutes Medicare's largest drug expenditure, is used primarily to treat anemia in end stage renal disease patients and in cancer patients; and
- Osteoporosis drugs furnished to certain beneficiaries by home health agencies.

These drugs are typically provided in hospital outpatient settings, dialysis centers, or doctors' offices, and are purchased directly by the physician or physicians and providers. Generally, Medicare does not cover preventive drugs such as vaccines. However, Medicare law provides coverage specifically for certain vaccines, namely influenza, pneumonia, and hepatitis.

By law, Medicare carriers generally pay for these drugs based on either the actual charge or 95 percent of the AWP, whichever is lower. This adds up to more than $5 billion a year for currently covered drugs, approximately 80 percent of which is paid by the Medicare Trust Funds. In general, Medicare beneficiaries must also share in the cost of purchasing these drugs, except for the flu and pneumonia vaccines, through their Part B premiums, the $100 Part B annual deductible, and a 20 percent coinsurance.

MEDICARE PAYMENT FOR CURRENTLY COVERED DRUGS

The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. Traditionally, AWP has been based on prices that are reported by drug manufacturers and printed in compendia such as the *Red Book*, published by Medical Economics Company, Inc. However, manufacturers and wholesalers are routinely offering physicians and providers competitive discounts that reduce the actual amount the physician or physicians and providers pays for the drugs. These discounts are not reflected in the published price and reduce the amount many physicians and providers actually pay to levels far below those prices published in the *Red Book*. However, Medicare's regulated payment system is tied to the published price of the drugs, precluding the program from obtaining competitive discounts for the drugs it covers. In addition, use of the AWP, as reported by manufacturers to companies that compile such prices, creates a situation where a manufacturer can, for certain drugs, arbitrarily increase the reported AWP and, in turn, offer physicians a deeper "discount." Furthermore, the deep competitive discounts, compared to the reported AWP, offered by drug

manufacturers could give physicians and physicians and providers incentive to use a particular manufacturer's products for Medicare beneficiaries.

To give an example, a recent General Accounting Office report found that Medicare payments in 2001 for Part B-covered outpatient drugs were often much higher than the prices paid by physicians and pharmacy providers. The GAO reported that discounts of 13 to 34 percent off AWP were widely available for many physician-administered drugs. GAO also noted that two other physician-administered drugs had discounts of 65–86 percent.

This Committee, CMS, the Department's Office of the Inspector General (IG), and others have long recognized the shortcomings of using AWP as the basis for Medicare drug reimbursement. The IG has published numerous reports showing that true competitive market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the *Red Book* and other similar publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP (less 5 percent). It is simply unacceptable for Medicare to continue paying for drugs in an outdated, non-competitive way that costs beneficiaries and the program far more than it should.

In the past, the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid by physicians and providers. However, these efforts have been unsuccessful. For example, the Agency's proposed June 1991 physician fee schedule included payments based on 85 percent of AWP. The Agency also proposed that certain high volume drugs be reimbursed at levels equal to either the lesser of 85 percent of AWP or the physicians' and providers' estimated acquisition cost. The Agency received many comments, primarily from oncologists, indicating that an 85 percent standard was inappropriate. Most comments indicated that while many drugs could be purchased for less than 85 percent of AWP, other drugs were not discounted. Other comments suggested that while pharmacies and perhaps large practices could receive substantial discounts on their drug prices, individual physicians could not. As an alternative, beginning with 1992, the Agency established a policy for Medicare to pay either the AWP or the estimated acquisition cost, whichever was less.

Since the estimated acquisition cost approach proved to be unworkable, subsequent legislation was proposed that would have required Medicare to pay physicians their actual acquisition cost for drugs. Under this proposal, physicians would tell Medicare what they paid for the drugs and be reimbursed that amount, rather than the Agency developing an estimate of acquisition costs and paying physicians based on that estimate. After considering this proposal, Congress adopted an alternative approach in the Balanced Budget Act of 1997 (BBA), setting Medicare's payment for drugs at the lesser of the billed charge or 95 percent of AWP. While this brought Medicare payments closer to the prices that physicians and providers pay for drugs, Medicare payments for many drugs were still significantly greater than the competitive discounts obtained by physicians. The system still tied Medicare payments to the artificially inflated industry-reported list prices. In fact, in a December 1997 report, the IG found payments based on AWP to be substantially greater than the prices available to the physician community. As an alternative to actual acquisition costs, Congress considered proposals to pay all Medicare drugs at 83 percent of AWP, a compromise between 95 percent of the AWP and the average discount found by the IG.

In May 2000, the Department of Justice (DOJ) and the National Association of Medicaid Fraud Control Units made advertised market wholesale prices for 49 drugs covered by Medicaid available to State Medicaid programs and to First Data Bank, a drug price compendium owned by the Hearst Corporation. These wholesale prices, culled from wholesale catalogs circulated among the physician and provider community, while not reflecting certain other discounts such as rebates, were closer to the actual average wholesale prices for these drugs than the drug manufacturers' reported AWP. In 2000, the Agency sent this new information to Medicare carriers and instructed them to consider these alternative wholesale prices as another source of AWP data in determining their January 1, 2001, quarterly update for many of these drugs. Due to concerns about Medicare reimbursement for the administration of the chemotherapy and clotting factor drugs, the Administration instructed our carriers not to use the data for those drugs at that time. Anticipating Congressional action that was soon enacted in BIPA, establishing a moratorium on decreases in Medicare drug reimbursement rates, the Agency in December 2000 postponed Medicare carriers' use of the DOJ data while the GAO conducted a study of Medicare drug pricing and related payment issues. BIPA also provided some authority for the Secretary to address AWP after reviewing the GAO's findings.

FLAWS IN AWP THAT AFFECT THE OUTPATIENT RULE

The shortcomings that I've discussed today regarding AWP also affect payment in the outpatient prospective payment system (OPPS). More specifically, it has affected perceptions about the updated payments for OPPS for 2003. In 2000, CMS adopted a prospective payment system for outpatient services delivered by hospitals, which includes the drugs and devices used in a procedure. By law, payments must be based on the relative cost of treatment. The law further requires that CMS must make additional payments, called "pass-through payments," for new drugs and devices. These payments are allowed for two to three years and, for drugs, are calculated to be the difference between the amount in the rate for existing products and the average wholesale price for the new product. The total dollars set aside for these new drugs and devices currently is limited to 2.5 percent of total spending for services under the outpatient prospective payment system. By law, CMS must use AWPs as reported by the manufacturer for these drugs to set payment rates for these drugs and to calculate the amount funded out of the pass-through pool. Using AWPs that overstate the costs of some drugs results in higher "pass-through payments" and makes less money available for other items eligible for pass-through payments.

In 2003, as a result of collection and analysis of nearly 60 million actual hospital claims, we have been able to set payment rates more accurately. As the payments for some procedures go up, payments for other ones go down and vice versa. However, a recent *New York Times* article misrepresented the impact on payments to hospital outpatient departments. Although payments for many items will be lower in 2003, overall Medicare payments to outpatient departments are projected to increase by almost 8 percent, reflecting hospitals' estimated acquisition costs rather than manufacturers' reported wholesale prices for prescription drugs. While proposed rates for many drugs are lower than 2002 rates, 2002 rates were likely greatly overstated in many cases because they were based on overinflated manufacturers' AWPs.

The story is similar with respect to our payments for procedures using pass-through devices. For 2002 rates we used prices reported by manufacturers to set payment rates for these types of procedures. The other hospital costs for the procedure, such as the operating room, supplies, and nursing time, were calculated using the latest available charges from approximately 50 million hospital claims and the latest available cost reports. I'd like to discuss a couple of examples of how payment rates have changed over the past several years for procedures that use pass-through devices. In my first example, payment for the insertion of a cardioverter-defibrillator, a hospital in 2001 received $7,411 for the procedure plus an additional amount for pass-through devices used during the procedure. The additional payment amount for pass-through devices was equal to the hospital's charges for the device(s) reduced to costs using the latest available hospital's cost-to-charge ratio (CCR). For 2002, the estimated cost of the procedure was about $1,500. Using claims and cost report information from hospitals, we would have added another $6,800 for device costs and the total payment would have been about $8,300. However, because we folded in an additional amount based on prices submitted to us by manufacturers, we added another $11,100 to the payment—bringing the total device-related costs to $17,900. Thus, in 2002, a hospital receives about $19,400 plus an additional amount in pass-through payments. For 2003, we have determined that the total payment for the procedure should be about $9,400. This payment reflects the cost of the procedure ($1,550) plus the estimated cost of devices used with the procedure ($7,850). Because pass-through eligibility for the devices that are being used with this procedure will expire January 1, 2003, we have fully incorporated their estimated costs, using hospital claims and the latest available cost reports, into the costs of the procedure. Similarly in my second example, the implantation of a drug infusion device, a hospital in 2001 received $561 plus an additional amount for pass-through devices used during the procedure. The additional payment amount for pass-through devices was equal to the hospital's charges for the device(s) reduced to costs using the latest available hospital's cost-to-charge ratios (CCR).

For 2002, the estimated cost of the procedure was about $940. Using claims information from hospitals we would have added another $3,800 for device costs and the total payment would have been about $4,750. However, because of the fold-in based manufacturers' reported prices, we added another $2,400 to the payment—bringing the total device-related costs to $6,200. Thus in 2002 a hospital receives about $7,150 plus an additional amount in pass-through payments.

As noted in the proposed rule, we estimate that the total payment for the procedure for 2003 should be about $6,660. This payment reflects the estimated cost of the procedure ($1,640) plus the estimated cost of devices used with the procedure ($5,020). Because pass-through eligibility for the devices that are being used with

this procedure will expire January 1, 2003, we have fully incorporated their estimated costs into the procedure.

To the extent that CMS has to overpay for devices, payments for and access to other services for all beneficiaries are reduced. For example, between 2001 and 2002, payment for diagnostic mammography fell 13 percent. Under the proposed 2003 rates, the rationalization of payment for many devices has helped to allow for an 18% increase in diagnostic mammography payments. In the end, from 2000 to 2003, payment rates for most procedures using pass-through devices will have increased steadily and significantly. We shouldn't be allowing artificial prices nor artificial AWPs to undercut access to basic, preventive, and other services for beneficiaries.

CONCLUSION

Medicare beneficiaries rely on prescription drugs to treat a wide variety of chronic and acute conditions. For many seniors, in the traditional fee-for-service plan, the coinsurance that they pay is tied to Medicare's payment rate. We must find a fair way to make sure that Medicare beneficiaries and taxpayers do not pay excessive prices for prescription drugs that are far above the competitive discounts that are widely available today to other Americans. We need to pay appropriately for all Medicare benefits, including the prescription drugs we do cover and the services required to furnish those drugs. We look forward to working with you Mrs. Chairman, this Committee, and the Congress to implement improvements in Medicare's payment policy for currently covered drugs. Thank you for the opportunity to discuss this important topic with you today, and I am happy to answer your questions.

APCs for Basic and Preventive Services						
APC	**Description**	**2001 Rate**	**2002 Rate**	**Difference in 2001 vs. 2002 NPRM Rate**	**Proposed 2003 Rate**	**Difference in 2002 vs. 2003 NPRM Rate**
0158	Colorectal Colonoscopy	$400.93	$335.46	−16.3%	$393.19	+17.2%
0271	Mammography	$35.17	$30.54	−13.2%	$35.89	+17.5%
0601	Mid-level clinic visit	$50.24	$48.36	−3.7%	$54.09	+11.9%
0611	Mid-level ER visit	$106.01	$109.95	3.7%	$138.34	+25.8%

Drug APCs for Select Cancer and Other Drugs with Pass-Through Status Set to Expire January 1, 2003								
APC	**Descriptor**	**Brand Name**	**2001 Total Units**	**2001 Median Hospital Cost Per Unit**	**2002 Payment Rate (Net of Pro-rata Reduction)**	**2003 Proposed Payment Per Unit**	**Percent Difference Between 2002 Payment (net of pro-rata and 2001 median cost)**	**Percent Change in 2003 Proposed to 2002 Payment Rate (Net of Pro-rata Reduction)**
0849	Rituximab cancer treatment	Rituxan	207,331	$310.85	372.38	$296.97	+20%	−20.3%
7046	Doxorubicin hcl liposome inj	Doxil	36,834	$247.41	294.08	$236.12	+19%	−19.7%
0844	Pentostatin injection	Nipent	258	$1,161.78	1355.13	$1,108.83	+17%	−17.0%
0858	Inj cladribine per 1 MG	Leustatin	10,482	$46.18	34.79	$43.69	−25%	25.6%
7042	Capecitabine, oral, 150 mg	Xeloda	204,556	$1.93	2.00	$1.56	+3%	−22.0%
0733	Non esrd Epoetin alpha Inj	Procrit	12,272,503	$10.32	$9.46	$9.88	−8%	+4.5%
0734	Darbepoetin alfa, 1 mcg	Aranesp				$4.74		

Chairman JOHNSON. Thank you for your testimony, Mr. Scully.

Unfortunately, last night, I only had your Senate Committee on Finance statement of March. While I reviewed that, that was the most we had and my morning did not allow me to look at the statement that we just received. I am delighted to hear of the more detailed information that you have. It is absolutely true that you need to be able to respond to drops in drug prices as volume rises, as well as other changes in the market. So, I hope that we will be able to work together to get this job done.

The new Gallup survey results developed by the American Society of Clinical Oncology (ASCO), as they will testify later, do give us some very concrete information. Will you be willing to work with them on that data and its implications for reimbursement of practice expenses? The Gallup survey does use the same methodology that the American Medical Association and CMS uses for other payment costs.

Mr. SCULLY. Absolutely. I believe we have been working with them a lot on their data, and we will probably end up incorporating it in whatever policy we use, to the extent we can.

Chairman JOHNSON. The biggest and most dramatic difference is the issue of payment for non-physician work, that so many other types of personnel are necessary to deliver this care, that it does not come out in the way we generally calculate payments. So, we do have to look differently at practice expenses in the delivery of cancer care than we do in some other areas. Would you agree on that?

Mr. SCULLY. Absolutely, and I think we have acknowledged that we need to make some changes in the practice expense payment for oncologists. As you probably remember, we went through one of your oncology clinics in your district earlier this year. I think it is clear that in a number of these settings, the base practice payments are underpaid, but they also are relying on a transfer subsidy, basically, of excessive margins on AWP. We believe we should pay people correctly in both situations.

Chairman JOHNSON. Thank you. In preparing for this hearing, I looked at the list of the 32 drugs that are 82 percent of the cost for the government. While Albuterol was on that list, none of the other couple of pages of examples of gross spreads were on that list. I want to know whether or not your agency is going to be able to, of the 450 drugs, give us a better understanding of which of those drugs are oral, which are injectable, and which we have a practice expense component, because you cannot treat them sort of all the same.

If some are just an injection in an office that is in addition to a whole other office procedure or visit for which a physician is reimbursed, that is different than if it is part of a day-long process of treatment. So, it is interesting to me that some of the largest abuses, some of the biggest spreads are in oral and injectable drugs, with which there is not, to my knowledge, a significant practice expense issue.

So, it would be very helpful if you could provide for the Committee a list of those that you think there is a practice expense issue associated with. Then, the other critical piece of information

to doing this right, is which of those drugs are sole-source, which are dual-source, and which are multi-sourced. You can compete where there is multi-source. You cannot compete where there is sole source, and in some of the cancer areas, that is a very big issue. So, do you think you will be able to provide us with that kind of information in the near term as we move forward trying to resolve this?

Mr. SCULLY. Absolutely. We would be happy to.

[The information follows:]

Centers for Medicare & Medicaid Services
Washington, DC 20201
1/6/03

Hon. Nancy L. Johnson
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
2113 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Johnson:

The attached table shows information for the top 35 drugs that account for 86.5 percent of Medicare spending for currently covered drugs paid for by part B carriers. Drugs paid by intermediaries (e.g., to ESRD facilities for epoetin, vitamin D and iron preparations, and to hospital outpatient departments for separate drug APCs or for pass-through drugs) are not shown on this table. The table shows both the technical and common names for the drug as well as the clinical indications for which the drug is used.

Medicare Spending: In 2001, allowed charges were $6.4 billion for all carrier paid drugs. The 35 drugs shown on the table account for $5.6 billion. Seven drugs account for 50.5 percent of spending for carrier-paid drugs ($3.2 billion). The top drug, Procrit, accounts for 12.1 percent of spending. Two interchangeable prostate cancer drugs, Lupron and Zoladex, combined account for 17.2 percent of carrier paid drugs. Two drugs furnished via a covered item of durable medical equipment, Albuterol and Ipratropium Bromide, account for 12.8 percent of carrier drug spending.

Competition: The table also shows the type of competition for the drug, i.e., whether the drug is sole source, multi-source or generic. This information is primarily from the hospital outpatient department prospective payment system classification for the 30 of these drugs covered under that system and from the FDA Orange Book for four drugs. Other than unclassified injections:

- Twenty of the 35 drugs, representing 44.0 percent of Medicare carrier drug spending are sole-source.
- Nine of the 35 drugs, representing 25.2 percent of Medicare carrier drug spending are multi-source.
- Five of the 35 drugs, representing 16.4 percent of Medicare carrier drug spending are generic.

Form of Administration: The table also shows the form of administration for the drug. Other than unclassified injections, which account for 1.0 percent of drug spending and have multiple forms of administration:

- Twenty-two of the 35 drugs, accounting for 38.0 percent of carrier spending, are administered by intravenous infusion.
- Two of the 35 drugs, accounting for 12.8 percent of carrier spending, are administered through an inhaled solution, i.e., through an item of Medicare-covered durable medical equipment. Specifically, albuterol and ipratropium bromide are inhaled as an aerosolized solution through a nebulizer.
- Two of the 35 drugs are oral immunosuppressive drugs taken to prevent rejection of an organ transplant. They account for 1.5 percent of carrier spending.
- Eight of the 35 drugs, accounting for 33.3 percent of carrier spending, are administered through injections. Of these, two are subcutaneous injections, two are injected into a joint, three are administered through intramuscular injections and one can be administered by subcutaneous or intramuscular injection. Medicare pays a separate fee for administration of these injections.

Payment for Drug Administration/Dispensing: Medicare pays a separate fee for injections. Each of the subcutaneous and intramuscular injections and injections into a joint would receive such separate payment.

Medicare pays a separate fee for administration of chemotherapy drugs (and other drugs administered through intravenous infusion such as Remicade for rheumatoid arthritis).

Oncologists and rheumatologists have raised issues regarding the adequacy of payment for the administration of drugs. These concerns generally involve the administration of intravenous infusion drugs and other drugs that are not taken orally. Oncologists argue that Medicare payment for chemotherapy administration is too low and drug overpayments are necessary to subsidize a practice expense underpayment. Rheumatologists make a similar argument with respect to infusing Remicade.

Medicare does not make a separate payment for administration of clotting factor to treat hemophilia. A draft GAO report recommends that Medicare lower payment for clotting factor and establish a separate payment for clotting factor administration.

It has been suggested that ESRD facilities use their Medicare drug mark-ups to compensate for what they believe to be inadequate composite rates. It has also been suggested that there may be issues about administration or dispensing of infusion drugs (other than chemotherapy drugs) furnished via an item of Medicare-covered durable medical equipment. Suppliers of durable medical equipment have argued that there is an administration or dispensing issue regarding inhalation drugs furnished through durable medical equipment, such as nebulizers.

CMS clinical staff have reviewed the remaining carrier paid drugs that Medicare currently covers. For drugs not on the list of top 35 drugs, the same types of issues would arise for chemotherapy, clotting factor, ESRD facility separately billable drugs and infusion and inhalation drugs furnished via durable medical equipment. Our clinical staff review does not suggest different types of administration issues for the remaining drugs.

There are two types of issues regarding using some of the savings from a revised method of paying for drugs currently covered in Medicare to pay for administration or dispensing of these drugs. First, for drugs where the administration is paid under the physician fee schedule, increases in administration payments would need to be done in a manner that is not budget-neutral under the physician fee schedule. Second, for drugs where the administration is not paid under the physician fee schedule, there an administration or dispensing fee would need to be established. We would be glad to work with the Committee staff to provide technical assistance to address both of these issues.

Sincerely,

Hon. Thomas A. Scully
Administrator

ALLOWED CHANGES FOR TOP 25 DRUGS PAID BY CARRIERS
CY 2001 Through November 2002

HCPCS Code	Description	Clinical Indication(s)	Type of Competition**	Allowed Charges*** (in millions)	Percent of total Medicare drug spending	Cumulative percent of total Medicare drug spending	Form of Administration
Q0136	Non-ESRD epoetin alfa inj (Procrit)	Treatment of Anemia: in cancer patients on chemotherapy, related to AZT treatment of HIV–AIDS, from chronic kidney failure; reduction of allogenic blood transfusion	Multi-source	$779.9	12.1%	12.1%	Subcutaneous, Intravenous bolus
J9217	Leuprolide acetate (Lupron)	Advanced prostatic cancer; central precocious puberty; endometriosis; Uterine leiomyomata (fibroids)	Sole-source	$665.5	10.4%	22.5%	Intramuscular
J7644, J7645	Ipratropium Bromide (Atrovent)	Bronchospasm (Asthma and chronic obstructive lung disease) Rhinorrhea: perennial rhinitis, common cold	Generic	$469.5	7.3%	29.8%	Inhaled solution]
J9202	Goserelin acetate implant (Zoladex)	Advanced prostatic cancer; central precocious puberty; endometriosis; Uterine leiomyomata (fibroids)	Sole-source	$437.2	6.8%	36.6%	Subcutaneous
J7619, J7618, J7620, J7625	Albuterol	Asthma, chronic obstructive lung disease	Generic	$354.4	5.5%	42.1%	Inhaled solution
J9265	Paclitaxel injection (Taxol)	Cancer: ovarian, breast, lung; AIDS-related Kaposi's sarcoma	Multi-source	$269.2	4.2%	46.3%	Intravenous infusion
J9310	Rituximab cancer treatment (RituXan)	Non-Hodgkin's lymphoma	Sole-source	$269.2	4.2%	50.5%	Intravenous infusion

J2430	Pamidronate disodium (Aredia)	Reduce high calcium levels caused by cancer; bone metastases from cancers and multiple myeloma; Paget's disease	Sole-source	$193.4	3.0%	53.5%	Intravenous infusion
J1745	Infliximab injection (Remicade)	Rheumatoid arthritis; Crohn's disease	Sole-source	$196.1	3.1%	56.5%	Intravenous infusion
J9170	Docetaxel (Taxotere)	Cancer: breast, lung	Sole-source	$167.9	2.6%	59.1%	Intravenous infusion
J9045	Carboplatin injection (Paraplatin)	Ovarian carcinoma	Sole-source	$165.2	2.6%	61.7%	Intravenous infusion
J1441 (480 mcg) J1440 (300 mcg)	Filgrastim injection (Neupogen)	Myelosuppresive chemotherapy; Bone marrow transplant; Peripheral Blood Progenitor Cell collection, severe chronic neutropenia	Multi-source	$163.1	2.5%	64.2%	Intravenous infusion, Subcutaneous
J9206	Irinotecan injection (Camptosar)	Metastatic carcinoma of the colon or rectum	Sole-source	$161.4	2.5%	66.7%	Intravenous bolus and infusion
J9201	Gemcitabine HCl (Gemzar)	Cancer: pancreatic, lung	Sole-source	$136.9	2.1%	68.8%	Intravenous
J1561,3	IV immune globulin (IveeGam, Biogam BayGam, Panglobulin)	Immunodeficiency; low platelets (ITP); bone marrow transplants; HIV infection; severe blistering skin diseases	Generic	$118.0	1.8%	70.6%	Intravenous Infusion
J1260	Dolasetron mesylate (Anzemet)	Antiemitic (for vomiting after chemotherapy); Prevent of treat post-operative nausea	Multi-source	$112.6	1.8%	72.4%	Intravenous infusion

ALLOWED CHANGES FOR TOP 25 DRUGS PAID BY CARRIERS—Continued
CY 2001 Through November 2002

HCPCS Code	Description	Clinical Indication(s)	Type of Competition**	Allowed Charges*** (in millions)	Percent of total Medicare drug spending	Cumulative percent of total Medicare drug spending	Form of Administration
J7320	Hylan G–F 20 injection (Synvisc)	Pain from knee osteoarthritis	Multi-source	$84.7	1.3%	73.7%	Injected into joint
J3490	Drugs unclassified injection	Multiple	Not applicable	$66.0	1.0%	74.7%	Multiple
J0640	Leucovorin calcium injection (Wellcovorin)	Cancer (after methotrexate)	Generic	$63.0	1.0%	75.7%	Intravenous
90658 (3 yrs) 90659 (whole)	Flu Vaccine	Influenza prevention	Multi-source	$74.1	1.2%	76.9%	Intramuscular
J2405	Ondansetron HCl injection (Zofran)	Antiemitic (for vomiting after chemotherapy)	Multi-source	$60.3	1.0%	77.9%	Intravenous infusion
J9355	Trastuzumab (Herceptin)	Breast cancer	Sole-source	$54.8	0.9%	78.8%	Intravenous infusion
J7517	Mycophenolate mofetil oral CellCept	Allogenic transplants prevent organ rejection	Sole-source	$55.0	0.9%	79.7%	Oral
J7190	Factor viii (Monarc-M)	Hemophilia	Generic	$50.7	0.8%	80.5%	Intravenous infusion
J2820	Sargramostim injection (Leukine)	Bone marrow transplant; recovery of neutrophils after chemotherapy	Sole-source	$41.7	0.7%	81.2%	Intravenous infusion
J0151	Adenosine injection (Adenoscan)	For use in cardiac stress testing when patient cannot exercise	Sole-source	$40.3	0.6%	81.8%	Intravenous infusion

J7192	Factor viii recombinant	Hemophilia	Multi-source	$40.7	0.6%	82.4%	Intravenous infusion
J1526	Granisetron HCl injection (Kytril)	Antiemetic (nausea and vomiting after chemotherapy)	Sole-source	$34.7	0.5%	82.9%	Intravenous
J7507	Tacrolimus oral (Prograf)	Prevention of transplant rejection	Sole-source	$39.5	0.6%	83.5%	Oral
J9390	Vinorelbine tartrate (Navelbine)	Cancer: Lung, breast, ovarian	Sole-source	$34.2	0.5%	84.0%	Intravenous injection
J7315, J7316, Q3030, J7317	Sodium hyaluronate (Hyalgan; supartz)	Knee pain from osteoarthritis	Sole-source	$34.4	0.5%	84.5%	Injection into joint
J9350	Topotecan (Hycamtin)	Cancer: ovarian, small cell lung	Sole-source	$33.0	0.5%	85.0%	Intravenous infusion
J9000	Doxorubicin injection (Adriamycin)	Cancer: leukemia, kidney, sarcoma, breast, ovarian, bladder, thyroid, lung, lymphomas, stomach	Multi-source	$31.9	0.5%	85.5%	Intravenous injection
J2352	Octreotide acetate injection (Sandostatin)	Acromegaly, carcinoid tumors, VIPomas, severe diarrhea	Sole-source	$30.6	0.5%	86.0%	Intramuscular or subcutaneous
J0585	Botulinum toxin injection (Botox)	Dystonia, strabismus and blepharospasm, spasticity	Sole-source	$28.6	0.5%	86.5%	Intramuscular
			TOTAL	$5,558.4	86.5%	86.5%	N/A

*Does not include Epoetin for ESRD or any other drugs paid for by intermediaries.
**Type of competition based on the 202 OPPS pass-through drug classification.
***Allowed Charges are what Medicare allows before application of deductible and coinsurance.

Source:
Facts and Comparisons, 2001
USPDI, 2002
FDA *Orange Book*

Chairman JOHNSON. There are two other issues I wanted to bring up. One is that I do not believe you have the authority, and you indicated that it is not at all clear to you whether you have the authority. I think you have the authority to compete prices. I think at least that may be less difficult. I would worry about your competing prices and changing prices without the authority to take the money saved and use whatever portion the data indicates to reimburse for practice expenses without putting that money into the big pool of practice expense dollars where it would be averaged across every other physician and increase practice expenses for every physician in every discipline and not adequately increase oncologists.

So as you approach this problem, are you looking at defining in the law clearly that the practice expense money used to reimburse for the drugs whose price we are going to cut will stay with the physicians who have those practice expenses, and not allow that money to sink into the general pool from which practice expenses for every other practicing physician affected by Medicare are reimbursed? Do you think that you have the authority, and are you committed to achieving that goal?

Mr. SCULLY. Well, we are certainly committed to achieving the goal. We would certainly like to make the fix in a context where we do not have a negative 4.4-percent pot, first of all. I think it is clearly appropriate to put the practice expense funds back where they are needed, and there may be other categories, but as I said, oncology is probably number one. Other areas we have identified that rely on AWP for margins are hematologists and dialysis facilities. We clearly think that you should put the money back in where there is a problem. I think we are committed to doing that.

It is unclear, and I have spent a lot of time on it, legally whether we—how we can do that. It would be a lot cleaner and a lot better if Congress directed us to do it that way.

Chairman JOHNSON. We will need to direct you to do it that way, but we will also need help on the clarity of the law. We have spent hours and hours on this. It is hard to define those dollars, keep them in the pool that will reimburse the people appropriately, then have our clean savings, and then maintain that after year one.

So this is an issue that if we do not address correctly, it will, without question, close cancer treatment centers across the country. Our hospital-based cancer treatment facilities are not capable of absorbing the number of patients that need attention, nor would they provide access to elderly people who often are not able to drive themselves. So, the access issue is critical. We are blessed to have developed this system that provides greater access to cancer care than any other Nation provides its elderly, or its citizens. So, we want to be sure to do this right. It does need to be done, but it must be done correctly.

Last, in your experience with bidding drug prices, what standards are you finding you will need to include to prevent things like the following? This is an example that comes to me from California, where they have had some experience in this.

The health plan changes the drug that it is going to offer for a patient, a cancer patient, monthly depending on where they get the lowest price. Now, that can be very difficult for the continuity of care. That is one problem. The second problem is that sometimes they take the powder form, because it is the cheapest, but that takes 20 minutes in a shaker machine in order to dissolve the powder form into an injectable component. It does come in a liquid form. So, if you just look at price, you are going to shift some very significant personnel costs on providers. That is not fair. We have to be able to deal with that.

Secondly, mail order alone does not work. Mail order can be delivered to your doorstep and sit in the sun and have no effect afterward or be badly affected. Some of these are very toxic agents, and how they are delivered, when they are delivered, and the physician having ample lead time so that if a drug needs to be complemented by another drug to address white cell problems, that drug is also there, is important.

So, these problems are real. They have been experienced by physicians who are dealing with plans that competitively bid cancer drugs. We cannot go nationwide with a program that does not set some standards in regard to what kinds of costs could be forced on a physician, what kinds of disruption in continuity of care can be tolerated, and what the standards must be for certain kinds of drugs in terms of mail order delivery and handling, because if some of these drugs are not managed by the wholesaler in an appropriate fashion, they will not do the job. They will be compromised in their effectiveness. Some oncologists actually go and check the wholesaler. They make unannounced visits to see that the drugs are well managed.

So far, we do not have an example of a competitive bidding system in which there are such quality controls. Has your agency gotten into this? Will you be able to work with us on this issue of quality controls?

Mr. SCULLY. Sure. I think whether it is the DME competitive bidding where you are doing it or whether it is drug competitive bidding, it is going to take a number of years to phase it in rationally. I do think there are some benefits to it.

Clearly, we are not trying to just get low prices. The drug that I mentioned, Albuterol, we had 30 bidders, and we took 11. I think in the past, we had very little oversight of who was selling it, and in the competitive bidding process, we have a site inspection and probably more oversight of the people who won the bids. So, in some ways, we are more involved in the process of overseeing the people that are actually selling the drugs. Clearly, by having a third of the bidders win, quality is every bit as big a factor as price, which I think we need to be clearly focused on.

In the case, I believe, of the San Antonio demo, we actually hired an ombudsman, a third-party ombudsman, to accept complaints and do independent review of what is going on. So there are clearly ways—I think there are ways that, potentially, you could have better oversight and better quality, and at the same time create at least some pressure to get better prices.

Chairman JOHNSON. Thank you. I look forward to working with you. It certainly is disturbing that things like Leucovorin, and

the calcium have a spread of 6,581 percent. So, I do not differ with you that this is a problem that we need to address, both out of fairness to the taxpayers——

Mr. SCULLY. If I can just give you one more example, and I do not want to pick on them, because I actually had good results, but I had, I think, a fairly important cancer drug that came in with an AWP a couple months ago of $28,000, because I am sure that is what they thought was a neat price. I found out that the VA was paying about, depending on how you calculate it, $12,000 to $14,000. This happened to be the in outpatient setting. We came to a very good resolution which will not be final until the rule comes out, but I think we actually ended up determining pretty close to a reasonable price.

The bottom line is, in most cases, had this drug not been $28,000, and the vast bulk of them are not, they are usually $300, and I had not happened to notice it because it was so huge, which is almost by accident, people make up AWPs. Whatever they just happen to think is a great price goes in the Red Book as an AWP, and we pay it. That is a crazy process.

In this case, because it was such a high-priced drug and it happens to be, I think, a pretty good cancer drug, I think we talked to the company and came up with a very rational result that will pay an appropriate price and give great access to patients. What scares me is how many of the other ones that are not that big that we do not notice that just come through and get paid for automatically. It is a crazy process.

Chairman JOHNSON. I absolutely agree with you. We are very careful in what we pay for every other purchase in Medicare, and we should be careful about what we pay for drugs.

The VA example that you give is very important, though, for people to remember. We appropriate dollars to the VA to deliver the drug to the patient, and that is the practice expense issue that we also have to give equal time to.

Mr. SCULLY. I had the VA's budget for 4 years in the last Administration. I do not mean to compare the VA price. It is one of many indicators. It was a flag for me that——

Chairman JOHNSON. Absolutely.

Mr. SCULLY. The VA has a totally different delivery mechanism.

Chairman JOHNSON. Mr. Stark?

Mr. STARK. Thank you, Madam Chair.

I gather that you have outlined what you could do if we do not act, but you do not think it would be as effective because of reserving the savings to adjust the payments to the providers. I also gathered in your testimony, I think you said or indicated that you thought it would be best to go currently with actual cost and build the payment constraints on that, looking forward to moving to a competitive bidding system, is that a summary of——

Mr. SCULLY. I think I tried to say, Congressman Stark, all year to the three Committees involved is that we just want to get something done, and we are interested——

Mr. STARK. I think I heard you say that you could get into using the actual price more quickly and then move on, perhaps, it would take some time to work on a bidding——

Mr. SCULLY. I think in the short term, you could clearly make an argument that going to an average manufacturer's price (AMP) or ASP-type price clearly delivers the quickest change and probably the quickest savings. My only concern there is if, and obviously there are a lot of interested parties in this, if they get locked into a new price, like an ASP or AMP, for years, they will come back and say, we do not need to do it anymore. You have got whatever your number is. I believe in the long run, a more competitive market-based approach is probably going to work better.

Mr. STARK. They are both market based, I mean. It is a question—I am curious. The GAO is going to tell us that the Albuterol, you said you could save 25 percent in your experiment, and GAO tells us that 85 percent discounts are generally available. What is wrong with using the generally available discounts? Is there something wrong with the people who are buying it that way and saving 85 percent instead of 25 percent?

Mr. SCULLY. My view is we should find the best price we can pay and try to save as much money as we can.

Mr. STARK. Consistent with getting quality drugs.

Mr. SCULLY. Yes.

Mr. STARK. Let me confess, and this is a very difficult confession to make, but I am unaware, probably because I do not pay enough attention, but I am unaware of the proposal that our Committee is now considering for competitive bidding, mostly because they have not shared it with the minority. I am aware of the bills that would take various average pricing. Could you summarize for us what you see as the current difference in these programs, and what are the problems we would have to solve if we go to bidding? As I say, this is something we have never discussed, and I would be interested in getting your read on it.

Mr. SCULLY. I am not sure the competitive bidding approach has been sketched out in detail with the Administration, either. We have talked about it because we have been asked by various committees, because I have a lot of staff who have spent years on this, to think about different approaches. I do not think it has gotten much more than conceptual, certainly nothing written I have seen.

I think the basic concept is similar to the DME-type thing: in major metropolitan areas in particular, over the next few years, that we would—essentially, we did an Albuterol for large-volume drugs, go out and have competitive pricing opportunities. I think the problems you have there are similar to what we have in other competitive bidding. In rural areas and smaller towns, it is going to be more difficult, and you probably have to have some kind of—what I believe our alternative would be is kind of have a market-based pricing mechanism.

Mr. STARK. That is what I was going to ask you. Where Kaiser, say, in my district has got half the people, they can get probably a lower bid than the pharmacist in Susanville, where they have got a 10-bed hospital. Whereas we could average the price that Kaiser gets, with the Susanville price, we would get somewhat lower. Whether it would be lower for more or fewer people, I do not know. That is a problem, I gather, unless you have a winner-take-all, which I gather the industry would object to.

Mr. SCULLY. I am not sure that is—our approach, I think, is generally to—in a place like San Antonio, you can have 30 bidders and pick 11, I think you are probably going to get a result. In a rural area, I am not sure it is—we are going to be concerned about having one bidder.

I do think, however, that most of our carriers are Blue Cross plans. If you talk to Palmeto or River Bend, which is South Carolina or Tennessee, they have millions of people who buy the same drugs under 65 years old. It is not that difficult to figure out what the market for under-65-year-olds are. In many cases, our contractors are not allowed to do that.

I think it is certainly possible to measure what the prices are for people in commercial plans, and frequently these are the same contractors we use, and pay what the commercial rates are instead of a made-up rate.

Mr. STARK. Do you envision picking one contractor in an area?

Mr. SCULLY. No. The only thing we envision, as an administrative situation in the short run, if Congress did not act, is we would probably pick—we have 23 Part B carriers that do this now. They do it independently. We have been trying to get all 23 of them, for a variety of reasons, to communicate better. What we would probably do is pick whoever we thought was the best one, had the best staff and the best information, and say for the other 23—AWP is different in all 23 right now. We could at least pick one and say, "This is the reference price. If you want to pay differently, explain to us why."

Mr. STARK. Thank you. Thank you, Madam Chair.

Chairman JOHNSON. Mr. McCrery?

Mr. MCCRERY. Thank you, Mr. Scully, for joining us this morning. Frankly, between your testimony, which was excellent, and your responses to the questions from Mrs. Johnson and Mr. Stark, I do not have a whole lot of questions left to ask. However, let me explore a couple of things.

First of all, Mrs. Johnson was adamant that CMS research the extent to which the practice expenses should be bolstered to make up for the drop in the AWP or in the price for the drugs, and I am wondering how much research CMS has done or how much research you have access to that would allow you to accurately make up that difference?

Mr. SCULLY. I think the whole system—arguably, the physician fee schedule, relative value units (RVU), which I have been involved in, as have many on the Committee, for 15 years, is never perfect. As I said, the GAO report, I think, said $49 million. We said $52 million earlier in the year. We spent a lot of time with the oncologists since. We have a lot more data. The number is probably a little higher than that. I am sure it will never be perfect, but I am pretty confident we have a lot of different reference points to figure out the right amount, and——

Mr. MCCRERY. For every specialty?

Mr. SCULLY. Probably—certainly for oncology, we spent a lot of time on it. I think we have a fairly good idea for hematology, which is smaller, and probably not as good for dialysis facilities, but I think we have a pretty good idea. There may be others that I have

not mentioned, but those are the three that I have had flagged by the staff as the biggest problem areas.

Mr. MCCRERY. Does CMS plan to do a continual review of the practice expenses, the changes in technology, the changes in office set-up and all the things that one has to look at?

Mr. SCULLY. It is pretty controversial every year with the physician community as it is, so I think we are constantly reviewing, especially in the practice expense guidelines, which the Secretary withdrew earlier this year. We work with all the specialty groups through the Relative Value Update Committee (RUC), which is done on the guidance that we convene all—the Resource Utilization Committee, which makes all the recommendations for all the RVUs and practice expenses every year. I think we continually discuss this all year long in Committees with all the specialty groups. So, we are very focused on it.

I think because of the cross-subsidy in oncology for AWP, even the RUC has acknowledged that over the years—I think everybody acknowledges it—there has been an underpayment for practice expenses and for AWP.

Mr. MCCRERY. Speaking of subsidies, you mentioned that you could easily look at the under-65 population and get an accurate reflection of the price of a drug. Is it not true that that drug, that under-65 population could be subsidized by the reimbursement from Medicare, which is vastly overblown?

Mr. SCULLY. Yes, but I think, and we had this discussion on the prescription drug issue—it may sound unrelated, but I am not sure it is—on our drug card. Seniors pay the highest cost for drugs right now, and I think if they were organized, they would pay—we think they would pay 15 percent less. Do we expect prices to go up as a result for people under 65? Yes. Right now, seniors are cross-subsidizing non-seniors, and I think, arguably, if we squeeze the price of AWP down, do we expect there might be some increases in the commercial market? There probably would be. Clearly, we are vastly overpaying right now.

Mr. MCCRERY. Yes, we clearly are, but my point is that the under-65 price does not necessarily reflect the true market price because it is being subsidized by the artificially high price that they get from Medicare.

Mr. SCULLY. Yes.

Mr. MCCRERY. What I am really getting at here is that this whole thing is a mess.

[Laughter.]

Mr. MCCRERY. I was down in Shreveport visiting the pathologists, and they are concerned about the technical component of their reimbursement being considered to be in the Diagnosis Related Group (DRG). There are scores of examples of that type of judgment that CMS has to make, that we have to make, and in my view, the market should be making. Would it not help a lot if we were to adopt the recommendations of the National Bipartisan Commission on Medicare and go to a premium support system that the market then would make these decisions rather than a bunch of people sitting up here that have not a whole lot of knowledge of all the intricacies of those market decisions?

Mr. SCULLY. Well, Congressman, as I think you probably know, philosophically, I completely agree with you, and I think that, as I mentioned, Blue Cross of South Carolina, Blue Cross of Tennessee, all these companies make these judgments every day in the under-65 market. In the over-65 market, CMS fixes prices. I think that will probably continue for a while. With the system we have, I will be the best price fixer I can be.

We clearly think that, obviously, in the long run, that the under-65 market, the Blue Cross plans and other insurers make these judgments, and we think they probably make them more accurately than we do. We are stuck with a not particularly good system, and we are trying to make the best of it. I totally agree with you.

Mr. MCCRERY. [Presiding.] You have my sympathy. Mrs. Thurman?

Mrs. THURMAN. Thank you. Thank you for being here. Until the last question, it sounded like everything was going along just pretty good here.

[Laughter.]

Mrs. THURMAN. I would say it is heartening to hear that we are all kind of on the same page here. I happen to have had an opportunity just a couple of weeks ago to visit a cancer center, and many of the issues that we are talking about here certainly were a part of our discussion and their concerns. Certainly, the nursing staff at the center was, I mean, by far the best, along with the doctors, but they are just saying they cannot continue to do what they are doing because of the cost of the practice and doing the service.

So, I do think we need to get to the bottom of this and figure out, and I think we should be honest about it. I think we should say, you do this work and this is what you get paid for. This is what the drugs cost, and we cannot hide this stuff anymore. So I would say that.

I am curious within some of the staff that you have talked about, if they have looked at all, if we were to fix this, because of the 25 percent of Medicare beneficiaries that have Medigap? Would there be a reduction in cost for them, as well, or could our premiums go down in that area? Has anybody looked at that?

Mr. SCULLY. I am not sure we have calculated the details of that, but clearly in the physician office, it is usually at least 20-percent co-insurance.

Mrs. THURMAN. Right.

Mr. SCULLY. So if we had a significant reduction in prices, let us say it is just 15 percent, then seniors save 20 percent of that. In the outpatient setting, as you know, the copayments are all over the board, but we have a long-term policy to fix it, which Congress passed. I think we are still looking at probably 45-percent average copayments. So, in the outpatient setting, seniors are paying frequently 45 percent of the drug prices. Clearly, there would be some savings to seniors.

Mrs. THURMAN. So, we could suggest in the Medigap that they need to be looking at some cost reduction if this were fixed in that way.

Mr. SCULLY. Yes.

Mrs. THURMAN. Second, I want to thank you for meeting with some of our constituents, I guess, with the University of Florida

and others on the protein bead issue. Can we fix this at all? This also is an issue of payments on cancer therapy.

Mr. SCULLY. This has to do with our extremely popular pending outpatient rule. My tongue is in my cheek.

Mrs. THURMAN. I believe it does have something to do with your extremely popular——

[Laughter.]

Mr. SCULLY. The outpatient rule, as I think a lot of the Committee know, I was involved in, when I was not in the government, is incredibly complicated. It has got a lot of problems. We are getting better at the pricing every year.

When we did our draft rule that came out on August 8, essentially, we took 60 million claims and we pushed the button, and the computer spit out the right rates. There were many price changes, and I think many of them legitimate, for drugs and devices that went down. As I mentioned, the benefit is colonoscopies, emergency room visits went up.

For the final rule, we have culled through the data, met with, I think, lots and lots of people from the industry, including a number of people from Florida and a number of other medical centers about proton beam devices. I have tried to be very open to everybody in the world that wanted to come and meet with us. We are using a lot narrower chunk of the data that we think is more accurate, about 45 to 50 million claims. I think you will see a lot of device-related and drug-related ambulatory payment classifications (APC) go up in the final rule, and I think the calculations will be far more accurate. I probably spent 2 or 3 hours a day on this every day.

I do not think everybody in the world will be happy. I think the final results of that rule will be probably more accurate. On a relative basis, people will be happier with the final rule than they were with the draft rule. My guess would be that particular payment is probably one of them.

Mrs. THURMAN. Then just last, as you can imagine, we are starting to hear from our nursing homes. I know this not the subject of this hearing, but we need to give some idea back to folks at home on the nursing home issue, because I believe they took their 10-percent cut in payments. I just wondered if we are supportive of efforts in Congress to eliminate or postpone these 10 percent cuts.

Mr. SCULLY. Well, in fairness, I do not think it is fair to portray it as a cut. I have a lot of friends in the nursing home industry, and I have had this friendly debate with them. In fact, I would note that I have hired—this is a little bit off-track, but I hired a number of Wall Street analysts who work for CMS who look at the relative health of the industries from public information. We put out a very detailed 45-page report on the health of the nursing home industry and these add-ons—and what would happen if they went—and they are on our website. I think it is very accurate, and I will be happy to send it up.

We have done the reports on hospitals. We are putting out one tomorrow or Monday on devices. We have done them on nursing homes, on home health, and my view is that we have responsibilities regularly just to figure out how people are actually doing—if they are making a reasonable margin or if they are losing money.

We are trying to figure out accurately from publicly available information how they are doing, if it is the right thing.

In the nursing home field, largely based on that report that we did earlier this year, Congress spent $12 billion a year on Medicare nursing homes, and we added $3 billion in temporarily. The Administration had the discretion to continue $1 billion, and we did that earlier this year. Congress is talking about adding back what are add-ons and the House bill added on about another $1 billion. The Senate did about the same. I think that we are up in the air about that, whether that should be done or not.

Chairman JOHNSON. [Presiding.] Mr. English of Pennsylvania.

Mr. ENGLISH. Thank you, Mr. Scully. At the risk of missing a procedural vote, I do have a question that I wanted to pose to you.

A lot of the discussion about AWP reform is focused on cancer treatments and oncologists, which is one of my areas of interest. Is it not true that there are also some other types of non-cancer therapies that should be included in discussions to ensure that all patients continue to have access to medically necessary therapies? Can you tell me the other types of health care providers, disease states, and drug therapies we should be keeping in mind as we design policies to ensure patient access, and what other types should we be taking into account?

Mr. SCULLY. I think there are a lot of different provider areas that may have small impacts from AWP, and we are certainly willing to work with the Committee to identify those. I think the big dollars are largely in oncology, probably the second biggest is in dialysis facilities who also rely on margins from AWP, and hematologists, the third. I think almost every physician, to some degree, that administers drugs probably has some beneficial cost-shifting benefit from AWP. I think those are the three big areas.

Mr. ENGLISH. My impression is that there are some others that would also be impacted by AWP, including osteoarthritis, rheumatoid arthritis, multiple sclerosis (MS), acquired immune deficiency syndrome (AIDS), and anemia. Have you solicited input from any non-cancer physician provider groups about these issues?

Mr. SCULLY. We have, and I think some of the ones you mentioned, clotting factors is one very large one. I mean, we are more than happy to meet with any of them and discuss any appropriate data they have.

Mr. ENGLISH. Very good. Thank you, and I appreciate your participation today. I also want to thank you again for coming to Northwestern Pennsylvania to help us with some of the reimbursement reform issues and hope to be able to host you there again.

Mr. SCULLY. I am happy to do it. Thanks.

Chairman JOHNSON. Thank you, Mr. Scully. I would hope that as you look at some of these other areas, that you also give some attention to the issue of respiratory therapists. The role that respiratory therapists play in home care is something we need to better understand in making these reimbursement decisions.

Also, I would like to comment for the record that I am concerned about your references to the GAO study and their $49 million. Having spoken with them at great length about their study, they also would acknowledge that their sample of oncologists was very small and that it under-represented the office practice delivery of chemo-

therapy. Eighty percent of all patients receive their care there. They included in their study not only surgeons, who just do cancer surgery, but also hospital-based cancer treatment facilities whose reimbursement structure is different.

So I think, in spite of the fact that I put the provisions in that asked for the study, not only are these results we can't use, but they acknowledge themselves that they did not do what you did in my district. You went into an office practice and see what the expense of the temperature-controlled containers are, what you have to keep on hand, the Occupational Safety and Health Administration, OSHA, prescribed hoods under which you have to manage the dosages, the waste, because once you open something, you have to throw the rest away.

So, there are a lot of costs associated with delivery that they explicitly did not look at. Whereas, the Gallup survey results that the oncologists have finally completed and have gone to Lewin, who I think is your contractor, do go to those issues.

So, I hope that since it is the same methodology as is normally used and so on and so forth, that we take that data extremely seriously so that we do not make a mistake, because this is an area in which we really cannot afford to do it wrong. As important as it is for the government to start paying for drugs properly, it is every bit as important for us to try to pay accurately in an area where we have never paid. So, this is new territory, and because it is new territory, it must be an add-on to the practice expense pool and not a part of that practice expense pool.

So, I hope you will have your legal staff begin helping us define the legal structure that we need to keep that money available for the purposes for which we need it. If we free it from the drug payment structure, we will be able then to both pay fairly for drugs and pay fairly for delivery.

Congresswoman Dunn, I am glad you got back.

Ms. DUNN. Thanks.

Chairman JOHNSON. We expect to have an hour after this vote, so we wanted to keep going.

Ms. DUNN. Thank you very much, Madam Chairman. Thank you, Mr. Scully, for coming today.

I want to take an opportunity today to ask you a couple of questions that have to do with reimbursements. In the State of Washington, we continue to be concerned about the inequitable payments for managed care plans and physicians, and find that we increased funding for both of these groups in the Medicare prescription drug bill that the House did pass earlier this year, but we are particularly concerned in my State about the inequities that are due to geography.

I am hopeful that as we look at this issue—this is a continuing long-term issue—that we will be able to work together and find legislative and administrative answers to solving our problem dealing with the parity in payments. I would like today to get your commitment to work with me and other Members of the Congress who are eager to get this situation squared away in order to address these inequities.

Mr. SCULLY. Absolutely. As I said when I was in Seattle earlier in the year, when we spent a day hearing from a lot of people

about this, I think the Medicare+Choice rates, which were significantly improved in the House bill. The Administration has a strong interest in getting those rates more effectively targeted this year, I think there is a fairly significant increase in the House bill. I think we had continued erosion in Medicare+Choice nationally, but I know in Seattle, you have got a major problem for the plans in the State, and I have tried to keep them in. They have been raising premiums, and it is all due to the rate repayment. We are very concerned about that.

We are also concerned about how the area rates are set and why they are significantly higher in some regions and lower in the others. We are committed to working with you. Equally on the hospital wage index and the physician geographic practice cost indexes or GPCIs, it is called, that are regionally varied, there are a lot of different components that go into that and most of them are legislative. We are very happy to work with you to make them more accurate.

Ms. DUNN. That is good. That is really important. As we see plans raising their premiums, which is my great worry in our State, where we have lost too many plans already, the willingness of the Administration to work with us on remedies is very much appreciated. I will look forward to that.

Also, when you were in Seattle, we worked on another issue, which is the reimbursement for certain drugs. Of course, that is what we are talking about today. Right now, the Medicare Program is paying 95 percent for certain drugs that are biologics. Some of these drugs that are biologics are very expensive. Self-injected versions already exist in the market that may be cheaper and allow more choice to patients. For example, we have self-injected biologics that can treat multiple sclerosis or rheumatoid arthritis, but these are not currently covered by Medicare.

I have introduced legislation to allow Medicare coverage of self-injected biologics as a substitute for covered drugs or biologics. One way to reduce costs of drugs, of course, is to encourage competition by allowing replacements of a self-injected biologic in the place of a covered drug. Even with a comprehensive prescription drug bill, we still need to address AWP as we try to find a solution for that much larger problem.

I hope that we can do something to reduce costs by encouraging competition. I would like to just probe your thoughts today on allowing coverage for self-injected biologics, which do cut costs in the long run because they take the burden off the clinics, off the hospitals, off the physicians, yet are not currently covered.

Mr. SCULLY. Well, this is another complicated problem. As you know, we went through a very detailed program guidance earlier this year on self-injectables. The current law says that we pay for outpatient drugs that are not usually self-injected, which after great mounds of legal advice, we determined meant they had to be done in an office more than 50 percent of the time. That brings up some very strange results.

For example, with MS, we determined—the good news is, for a drug like Avonex, which is only covered in about half the country, it is now covered everywhere, which is a very prevalent MS drug.

That was because we determined in a national survey that more than half the time, it was done in a physician's office.

A number of other very successful MS drugs, some of which are taken by friends of mine, were not covered because they are generally not self-injected, so they were not covered. Similarly with rheumatoid arthritis. Remicade and Enbrel are two great drugs. After our survey, we covered Remicade, I believe, and did not cover Enbrel for the same reasons.

You can certainly make a good argument that that, policy-wise, does not make a lot of sense, and we are more than happy to talk about it. We made the determination that we think we followed the law as clearly as we possibly could and clarified coverage as much as we could to, I think, the benefit of a lot of patients. Clearly, we do not believe under current law we can pay for drugs that are not usually—that are usually self-injected.

Ms. DUNN. Thank you very much, Mr. Scully. I do want to just give you one example of where we could be saving some money by covering both those drugs for rheumatoid arthritis. The covered drug is $17,000. The self-injected version is $15,000. It would be a savings of about $2,700. So, we will continue to make our case, and I appreciate your willingness to listen to us and possibly at the proper time act to include these drugs as choices for others that are currently included.

Mr. SCULLY. I try to be sensitive to all these things, but as you know, I have rheumatoid arthritis, so that one I know a lot about. There is a very good policy argument for that.

Ms. DUNN. Thank you. Thank you, Madam Chairman.

Chairman JOHNSON. Mr. Ramstad?

Mr. RAMSTAD. Thank you, Madam Chair, and thank you, Tom, for being here today and for spending as much time discussing with me the outpatient rule, particularly as it relates to procedures using technology. You know my concerns. I am very concerned that the proposed outpatient rule will cut reimbursements for medical devices, which means that these reductions will negatively impact Medicare beneficiaries' access to new medical procedures. I believe seniors should have the same access to medical devices, to procedures using medical technologies that other health care patients enjoy.

I guess my concerns can be boiled down to two principal concerns. First of all—and they both relate to the methodology used to determine 2003 rates. As we have discussed, the inaccuracy of hospital data, I think, is obvious, the problems there. Second, the underlying methodology using the cost-to-charge ratio.

Now, I know we have talked about the third-party data that CMS has been presented. Are you willing to use third-party data where appropriate? That is my first major question.

Mr. SCULLY. I think this is—as I said, I am spending probably 2 or 3 hours a day on this and have for the last month. I am confident that the final rule will have accurate payment. We really cannot use third-party data except to figure out where we are just wrong and need to go back and scrub our own data more. We have 60 million claims, as I mentioned. We are only using a little under 50 million claims. We used 60 in the draft rule.

The reason we use third-party data, and we have used a lot from the drug companies and device companies, is to figure out where our calculations from our data are just way off, and in many cases, they have been. In addition, I also called up the three very large buyer groups, and we cannot use their data, either, but I called them up and I identified personally about 35 drugs and devices that seemed to be way off. I called up independent buying groups and confidentially they gave me the prices they pay in the market. We have used that to further target places where our data might have been off.

The bottom line is that we are using lots of independent data, more than anything else, to figure out outliers where we may have made a mistake. It is clear to me we have way overpaid for a lot of things last year. I am confident when the final rule comes out that we will have appropriate prices for virtually every procedure that includes a device.

Mr. RAMSTAD. When I look at the 2001 data, which shows the pass-through pool is about half the size that CMS projected for 2002, even assuming the billings would increase by 50 percent from 2001 to 2002, the pro rata reduction was at least a third larger than it needed to be. As far as the underpayments are concerned, would you use the authority that we gave you to compensate underpayments in a previous year to increase this year's conversion factor? Is that——

Mr. SCULLY. This system is so complicated. I have been working on Medicare for over 20 years, and there has never been any law passed more complicated than this one. I am not sure—we still do not know for 2001, because I went through this—this morning with the staff. We are not certain exactly how much we spent in 2001, much less 2002. So, I am not sure we could make an accurate calculation.

The good news is, I do not believe at this point, and the regulation comment period does not close until October 8, and we do not want the rule out until November 1, but my guess is right now that for this year, we will not have to have any pro rata reduction and that we will be able to live with it in the pass-through pool. I think as every year goes on and we get a little better at calculating both the rates and what we are likely to spend, we will be more accurate. At this point, I am not sure we could, even if we wanted to, say we actually did not spend as much as we should have in previous years. We do not actually know exactly right now.

Mr. RAMSTAD. In the regulations, CMS acknowledges that the deep cuts from 2002 to 2003 that I initially broached would likely impact access to new technology in the outpatient setting, as I said before, and that is my concern. How many of these APCs do you think you will be able to fix by the final rule, Tom? Are you willing to use your authority to keep some APCs within about 10 to 15 percent of their current year rates until more accurate data can be secured?

Mr. SCULLY. I think we will have some mechanisms in the final rule to make sure that if there were any things that were real outliers, that they do not take too big a decrease. I literally have gone through personally every one of these devices of any signifi-

cance in great detail, looked at the rates from past years, looked at commercial rates, and I am pretty confident.

What we did last year, just to clarify, is—because we did not have any other data—we frequently called up companies and got their manufacturers' list price and put them in the rule. I think in some cases, I understand people in some places looked like they got a big cut. I also think that we clearly way overpaid for some devices in past years.

The initial rule that came out this summer, which caused a lot of panic, probably, in many cases, came out with rates that were a lot lower than the final rule will be. As I said, that came purely out of essentially pushing the button and coming up with the computer data on 60 million claims that may not have been as accurate as we would like. We spent enormous amounts of time going through this device by device, drug by drug, and I am confident that when I sit down with you on November 2 when the rule comes out, that I can go through device by device and discuss every one, where we went with which price and that they will be fair.

Mr. RAMSTAD. Let me just conclude, Madam Chairman, by saying I am very, very hopeful that you are willing to use your authority to keep some APCs within about 10 to 15 percent of their current year rates until the data are accurate. I think that, for the integrity of the system and the spirit of fairness, is very, very important, and I hope you will so agree.

Mr. SCULLY. I would be happy to—I think when you—I am very confident—I spent a lot of time on this rule. I do not expect everybody in the country to be happy with it, but I do think trying to keep the balance, as I mentioned, because we clearly overpaid for a lot of things in previous years that hurt base hospital services like colonoscopies and emergency room visits. I try to keep that balance in mind, that we need to find the right amount to pay for it. We do not actually pay for devices. We pay hospitals a capitated rate for the services that include devices.

I expect many of the ones that, you know, some of the bigger outliers, like defibrilators and others, I spent an enormous amount of time looking at various other sources, including our own data. I am confident we will come out with a fair payment.

Mr. RAMSTAD. Thank you.

Chairman JOHNSON. Thank you very much, Mr. Scully. I would appreciate it if you would get back to the Committee as soon as you can in terms of the lists of drugs that you think are going to be most impacted and the ones that are going to be least impacted, and also with language that you would suggest as to how to keep the practice expense money that we save from better competing the prices of drugs separate from other practice expense money so that we can allocate it to the purposes for which we need it.

Thank you very much. I appreciate your being here today on this important subject.

Mr. SCULLY. Thank you very much.

Chairman JOHNSON. On our second panel, George Reeb from the Office of Inspector General (OIG), in the U.S. Department of Health and Human Services, will update us on his findings comparing AWP to actual acquisition costs.

Dr. Michael J. O'Grady from Project HOPE, Health Opportunities for People Everywhere, will discuss a competitive bidding approach to establish Medicare reimbursements for outpatient drugs.

John D. Jones from Prescription Solutions will discuss how drug reimbursements are handled in the private market.

Dr. Paul A. Bunn, Jr., from the American Society of Clinical Oncology will tell us about the new information on practice expenses that the Society has collected and submitted for consideration.

Kim Glaun from the Medicare Rights Center will present concerns from the beneficiaries' perspective.

Thank you all for being here. I regret that we got a little late start, but we will try to keep going through any votes that might be called in respect for your individual schedules. Mr. Reeb?

STATEMENT OF GEORGE REEB, ASSISTANT INSPECTOR GENERAL, CENTERS FOR MEDICARE AND MEDICAID AUDITS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY ROBERT VITO, REGIONAL INSPECTOR GENERAL, EVALUATION AND INSPECTIONS, PHILADELPHIA, PENNSYLVANIA

Mr. REEB. Thank you and good morning, Madam Chairman. I am George Reeb, Assistant Inspector General for the Centers for Medicare and Medicaid Audits within the U.S. Department of Health and Human Services. I am accompanied today by Robert Vito, who is our Regional Inspector General for Evaluations and Inspections. We appreciate the opportunity to be here before you today regarding the important issue of Medicare payments for prescription drugs.

My written testimony describes several Office of Inspector General reports that found Medicare and Medicaid paid too much for prescription drugs. I would like to briefly summarize that information for you.

Medicare's current payment methodology adversely affects both the Medicare trust fund and Medicare's beneficiaries, who are responsible for a 20-percent coinsurance payment. This occurs largely because Medicare and Medicaid base reimbursement to physicians and suppliers on inflated average wholesale prices.

Our work has consistently shown that published AWPs bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers. In general, Medicare reimburses physicians and suppliers at 95 percent of AWP. Similarly, most State Medicaid agencies reimburse pharmacies at AWP minus an average of about 10.3 percent.

Medicare's total payments for prescription drugs have risen steadily over the past decade. In 2001, Medicare paid $6.5 billion for drugs, an increase of $1.5 billion from the previous year. Unlike Medicare, which currently covers a narrow range of drugs, Medicaid, as you know, covers most outpatient prescription drugs and total Medicaid payments were almost $24 billion in fiscal year 2001.

Over the past 5 years, the Office of Inspector General has issued a number of reports on Medicare reimbursement for prescription drugs. Medicare's coverage of outpatient drugs is limited primarily to drugs used in dialysis or in transplantation and cancer treat-

ment. Physicians and suppliers purchase these drugs, administer or provide them to Medicare beneficiaries, and then submit the bill to Medicare for reimbursement.

In our reports, we have compared Medicare reimbursement for drugs to prices available to the VA, to Medicaid, and to wholesale prices available to physicians and suppliers. For just 24 drugs that we studied, we found Medicare could have saved between $425 million to $1.9 billion a year by basing reimbursement on prices available to other sources.

Although this hearing pertains to Medicare, I would also like to mention our work on Medicaid primarily because it confirms that AWP is not a realistic basis for drug reimbursement. Both our Medicaid and Medicare work serve as a red flag that if the Medicare prescription drug benefit is expanded, the current payment methodology could lead to billions of dollars in excess payments.

In Medicaid, we found that there was a significant difference between the pharmacy acquisition costs for drugs and their published AWPs. In our latest report, we found that pharmacy acquisition costs ranged from 17 to 72 percent below published AWPs. These percentages are not considered discounts available to most pharmacies, such as volume discounts. We believe that if States would reimburse pharmacies for Medicaid patient prescriptions more in line with the actual acquisition costs of the drugs, substantial savings could be realized by the Medicaid program.

Publishing artificially high AWPs can be used as a marketing device to increase the drug companies' market share. For instance, because physicians and suppliers get to keep the difference between their actual acquisition cost and the inflated reimbursement amount, this spread can serve as an inducement for suppliers or physicians to use one brand of drug over another. While inflating the AWP does not increase the amount the manufacturer receives for each unit of the drug, it can increase their market share by creating an incentive for physicians to prescribe the manufacturer's drug instead of a competitors. This occurs, obviously, at the expense of the Medicare Program and its beneficiaries.

We have had some recent legal cases which illustrate some of the problems associated with Medicare's current reimbursement. Because the price spread is so large and Medicare reimbursement is so lucrative for the drug Albuterol, some mail-order pharmacies have made illegal kick-back payments to durable medical equipment suppliers for patient referrals and a $10 million civil settlement was had from one pharmacy group.

In another legal case, Bayer Corp. agreed to pay $14 million last year to resolve its liability in the Medicaid program. Although Bayer did not admit liability, the United States alleged that Bayer had knowingly set and reported the AWPs for these drugs at levels far higher than the actual acquisition costs for the majority of its customers and caused these customers to receive excess Medicaid reimbursement. They made misrepresentations to the Medicaid program for certain information that is used in the rebate programs and knowingly reported and underpaid the Medicaid rebates.

In October of last year, the United States announced an $875 million settlement with TAP Pharmaceutical Products, Incor-

porated. The TAP allegedly reported AWPs for Lupron at levels that were far higher than the actual cost. They encouraged customers to bill for free samples they provided, and they paid kickbacks to physicians and were underpaying rebates to the Medicaid program.

A drug reimbursement system should be based on real prices available in the marketplaces. Physicians and suppliers, including pharmacies, should be fairly reimbursed at levels that ensure beneficiaries have access to the drugs they need. We recognize that some physician groups say that overpayments for prescription drugs simply make up for inadequate payments for their practice costs. We agree that the physicians need to be properly reimbursed for the patient care. However, we do not believe that the payment for artificially inflated AWP prices is the appropriate mechanism because it just exacerbates the problem.

We would be happy to answer any questions you may have.

[The prepared statement of Mr. Reeb follows:]

Statement of George Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Madam Chairman. I am George Reeb, Assistant Inspector General for the Centers for Medicare and Medicaid Audits within the Department of Health and Human Services. I am accompanied by Robert Vito, Regional Inspector General for Evaluation and Inspections, Philadelphia. We appreciate the opportunity to appear before you today regarding the important issue of Medicare payments for currently covered prescription drugs. I am here to describe the findings of several Office of Inspector General (OIG) reports showing that Medicare and Medicaid pay too much for prescription drugs. This occurs largely because of the use of the average wholesale price (AWP) as the basis for calculating reimbursements to physicians and suppliers, including pharmacies. We have consistently found that the AWPs which Medicare and Medicaid use are not really wholesale prices. I will also describe settlements of two cases which included the issue of manufacturers' use of the AWP as a marketing tool, at unnecessarily high costs to taxpayers and beneficiaries.

Background

For the most part, AWPs (which are not clearly defined by law or regulation) are compiled in drug compendia such as Medical Economics' *Red Book*. As our reports have indicated, the published AWPs that Medicare and Medicaid use to establish drug reimbursement bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers.

In general, Medicare reimburses physicians and suppliers at the published AWP less a discount of 5 percent (i.e., 95 percent of the AWP). Of this amount, Medicare beneficiaries are responsible for a 20 percent coinsurance payment. Similarly, most state Medicaid agencies reimburse pharmacies based on the AWP of a drug less a discount which averages about 10.3 percent nationally. Federal regulations require that each State's reimbursement for a brand name or certain other drugs not exceed, in the aggregate, the lower of estimated acquisition costs or the providers' usual and customary charge to the public for the drug. Some states require a small copayment for each prescription filled by a pharmacy.

The current cost to Medicare and Medicaid for currently covered drugs is in the billions. Medicare's total payments for prescription drugs have risen steadily over the past decade. In 1992, Medicare paid about $700 million for prescription drugs; by 2001, it paid $6.5 billion. Between 2000 and 2001 alone, payments increased by $1.5 billion. Unlike Medicare which currently covers a narrow range of drugs, Medicaid covers most outpatient prescription drugs. Medicaid payments for prescription drugs totaled almost $24 billion in FY 2001. Our reports, which I am summarizing in this testimony, have shown time after time that Medicare and Medicaid pay too much for drugs.

Medicare Pays Too Much—OIG Reports

Medicare's coverage of outpatient drugs is limited primarily to drugs used in dialysis, organ transplantation, and cancer treatment. Medicare also covers certain vaccines and drugs used with durable medical equipment such as infusion pumps and nebulizers. Physicians and suppliers purchase these drugs, administer or provide them to Medicare beneficiaries, and then submit a bill to Medicare for reimbursement. Medicare's current payment methodology for prescription drugs adversely affects the Medicare trust fund and Medicare's beneficiaries, who are responsible for 20 percent of the allowed amounts.

Over the past 5 years, the OIG has issued a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. For example, we studied the prices for 24 Medicare covered drugs ($3.1 billion of the $3.9 billion in Medicare drug expenditures in 1999) comparing Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and Medicaid. We found that Medicare and its beneficiaries would have saved $1.6 billion for these 24 drugs by paying the VA's Federal Supply Schedule price. For half of the drugs, Medicare paid more than double the VA price. The savings would have been $761 million a year by paying the actual wholesale prices available to physicians and suppliers. For every drug in our review, Medicare paid more than the wholesale price available to physicians and suppliers and the VA Federal Supply Schedule price. We also found that Medicare would have saved over $425 million or almost 15 percent a year for the 24 drugs by obtaining rebates similar to the Medicaid program.

Subsequently, we updated the findings of this report with more current drug pricing information and estimated that, of the $3.7 billion Medicare spent for 24 drugs in 2000, the program would have saved $1.9 billion if the drugs had been reimbursed at prices available to the VA. Over $380 million of this savings would have directly impacted Medicare beneficiaries in the form of reduced coinsurance payments. In some cases, the VA price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. Further, we estimated that, if Medicare paid the actual wholesale prices available to physicians and suppliers for these 24 drugs, the program and its beneficiaries would save $887 million a year. If Medicare paid for these drugs based on catalog prices, beneficiaries would pay over $175 million less in coinsurance. The potential total savings available to both Medicare and its beneficiaries is probably higher than our estimates, assuming data for all Medicare drugs is similar to that for the 24 we analyzed.

In other reviews, we reported that Medicare pays nearly double the Medicaid price and almost seven times more than the VA for one milligram of albuterol, a drug used with a nebulizer to treat asthma, emphysema, and other respiratory problems. Nearly every chain pharmacy we contacted sold generic albuterol at prices less than Medicare paid for it. According to our survey results, any consumer could buy a monthly supply of albuterol from Internet pharmacies for around $63. For the same monthly supply, Medicare and its beneficiaries would pay $120, $96 from Medicare and $24 from the beneficiary. The VA's entire monthly payment of $17.50 for albuterol is less than just the beneficiary's $24 coinsurance payment under Medicare. The VA price for albuterol has fallen by more than 50 percent over the last 3 years, from $0.11 per mg in 1998 to $0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at $0.47 per mg.

We also found that Medicare and its beneficiaries would save $279 million a year if ipratropium bromide were reimbursed at the median price paid by the VA. The VA's purchase price has decreased considerably over the last 3 years, from $1.29 per mg in 1998 to $0.66 per mg in 2001. In contrast, the Medicare reimbursement amount has remained constant at $3.34 per mg. We also found that Medicare would save between $223 million and $262 million a year if ipratropium bromide were reimbursed at prices available to wholesalers and suppliers. The median catalog price available to suppliers was $0.82 per mg, the median supplier invoice price was $1.18 per mg, and the median wholesale acquisition cost reported by manufacturers was $1.20 per mg.

Aside from the obvious problem that AWPs can be arbitrarily inflated, resulting in inappropriate Medicare payments, the use of AWP as a basis for reimbursement in Medicare has other potential adverse side-effects. For instance, because physicians and suppliers get to keep the difference between the actual price they pay for the drug and 95 percent of its AWP, this "spread" can serve as an inducement for suppliers or physicians to use one brand of the drug over another. Thus, publishing an artificially high AWP can be used as a marketing device to increase a drug company's market share. Such a tactic increases the profit of the suppliers or physicians who purchase the drug because, while not paying the artificially inflated AWP

amount, they are reimbursed based on that inflated amount. While inflating the published AWP does not increase the amount the manufacturer receives for each unit of the drug product, the higher profits available to physicians and suppliers may lead them to purchase one brand of drug over another, thereby increasing a manufacturer's market share. This in turn increases the profits of the drug company. All of this occurs at the expense of the Medicare program and its beneficiaries.

Medicaid Pays Too Much—OIG Reports

Although this hearing pertains to Medicare, I would like to mention our work in the Medicaid program because it confirms that the average wholesale price (AWP) is not a realistic basis for drug reimbursements. Our Medicaid work also serves as a red flag that, if Medicare is expanded to cover more prescription drugs, particularly those that beneficiaries can obtain from pharmacies, it would be unwise for Medicare to reimburse pharmacies at Medicare's current rate of AWP minus 5 percent (i.e., 95 percent of AWP).

In Medicaid, we found there is a significant difference between pharmacy acquisition costs for both brand and generic drugs and the basis for most states reimbursement for drugs—the average wholesale price (AWP). We believe if states would reimburse pharmacies for Medicaid patient prescriptions more in line with the actual acquisition costs of the drugs, substantial savings could be realized by the Medicaid program.

As a follow-up to our previous work, we conducted nationwide reviews of pharmacy acquisition costs for both brand name and generic drugs reimbursed under the Medicaid prescription drug program during Calendar Year (CY) 1999. Since most states use AWP minus a percentage discount, which varies by state, as a basis for reimbursing pharmacies for drug prescriptions, the objective of these reviews were to develop an estimate of the discount below AWP at which pharmacies purchase brand and generic drugs.

We obtained pricing information from 217 pharmacies in 8 states, which resulted in an analysis of thousands of invoice prices that included both brand and generic drug products. We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. Our estimates were that pharmacy acquisition costs for brand name drugs in 1999 was an average of 21.84 percent below AWP and for generic drugs an average of 65.93 percent below AWP. These estimates were both higher than our previous 1994 studies of 18.30 for brands and 42.45 for generics.

In each of these reports, we recommended that the Centers for Medicare & Medicaid Services (CMS) require the states to bring pharmacy reimbursement more in line with the actual acquisition cost of both brand and generic drug products.

In response to comments made by both state Medicaid officials and industry representatives, we further analyzed the results of our studies of CY 1999 expenditures. This additional information was a breakdown of discount percentages for various brand and generic drug categories from single source innovator through drugs with and without Federal upper limits. Based on the results of our additional analyses, if states continue to reimburse for drugs based on AWP, we recommended that CMS encourage the states to consider using a multi-tiered reimbursement methodology. These tiers should be oriented to the significant differences in pharmacy acquisition costs depending on the drug's category of brand, generic, subject to Federal upper limits, etc. The current method used by most states for reimbursing for brand name drugs and non-Federal upper limit multiple source drugs using a single percentage discount does not consider these large differentials found during our additional analysis.

The discount percentages in this report ranged from 17.2 to 72.1 percent below AWP. These percentages do not consider discounts available to most pharmacies such as volume discounts, prompt pay discounts, and related rebates. The Medicaid program, unlike the Medicare program, includes a rebate component that is based, in part, on the average manufacturers' price (AMP). However, our report does not address the disconnect caused by basing Medicaid reimbursements on AWP while basing rebates on the AMP. That practice could result in higher cost and lower rebates for the States under Medicaid. In an earlier report we recommended tying the rebate to the AWP rather than the AMP.

Recent Settlements

Recent settlements further illustrate some of the problems associated with Medicare's current reimbursement methodology. Because of the price spread is so large and Medicare reimbursement so lucrative for the drug albuterol, some mail-order pharmacies have been tempted to capitalize on the difference by making illegal kick-

back payments to durable medical equipment suppliers for patient referrals. A civil settlement totaling $10 million was reached with one pharmacy that engaged in this conduct. Issues of inflated AWPs were also associated with recent settlements involving Bayer Corporation and TAP Pharmaceutical Products Inc.

Bayer Corporation. In January 2001, the United States settled a qui tam False Claims Act case with the Bayer Corporation, a major pharmaceutical manufacturer. Under the terms of a settlement negotiated by a team of Federal and state law enforcement officials, Bayer agreed to pay $14 million in order to resolve its liability to the Medicaid program. This case was investigated and handled by a team of Federal and state representatives—including the OIG, representatives of the Medicaid Fraud Control Units of four states and the Texas Attorney General's Office, the United States Attorney's Office for the Southern District of Florida, and the Department of Justice.

Through this settlement, Bayer resolved its liability under the False Claims Act and the Medicaid Rebate Statute for its conduct in connection with six of its drugs between January 1993 and August 1999. Although Bayer did not admit liability, the United States alleged that Bayer: 1) knowingly set and reported AWPs for these drugs at levels far higher than the actual acquisition cost of the majority of its customers and caused those customers to receive excess Medicaid reimbursement, 2) made misrepresentations to the Medicaid programs of certain states, and 3) knowingly misreported and underpaid its Medicaid rebates for the drugs.

TAP Pharmaceutical Products, Inc. In October of last year, the United States announced a major global health care fraud settlement with TAP Pharmaceutical Products Inc. ("TAP"). TAP agreed to pay a total of $875 million to resolve its liability, the largest health care fraud settlement ever. TAP also agreed to plead guilty to violating Federal law governing the use of drug samples. The investigation centered on TAP's sales and marketing efforts to physicians who used TAP's prostate cancer drug, Lupron. The company routinely provided free samples of Lupron to physicians, expecting that those physicians would bill the free samples to the patients and Medicare. TAP also allegedly paid kickbacks to physicians, HMOs, and others in the form of grants, debt forgiveness, travel, and entertainment, and other items to induce them to purchase Lupron. In addition, TAP allegedly set and reported AWPs for Lupron at levels far higher than the actual acquisition cost of the majority of its customers and caused those customers to receive excess reimbursement from Medicare and Medicaid. TAP also allegedly underpaid rebate amounts due to the states under the Medicaid Rebate Statute.

Conclusion

A drug reimbursement system should be based on real prices available in the marketplace. Physicians and suppliers, including pharmacies, should be fairly reimbursed and at levels that ensure that the drugs are accessible. If reimbursement is set too low, some beneficiaries may not be able to obtain needed prescription drugs. We recognize that some physician groups have raised concerns about Medicare's attempts to lower reimbursement for prescription drugs. Specifically, these physician groups say that overpayments for prescription drugs simply make up for inadequate payments for their practice costs. We agree that physicians need to be properly reimbursed for patient care. However, we do not believe that the payment of artificially inflated drug prices is an appropriate mechanism to compensate them.

This concludes my testimony. I appreciate the opportunity to address this important issue with you today. I welcome your questions.

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Chairman JOHNSON. Thank you very much. Dr. Bunn?

STATEMENT OF PAUL BUNN, M.D., DIRECTOR, CANCER CENTER, UNIVERSITY OF COLORADO, DENVER, COLORADO, AND PRESIDENT, AMERICAN SOCIETY OF CLINICAL ONCOLOGY, ALEXANDRIA, VIRGINIA

Dr. BUNN. Chairman Johnson and distinguished Members of the Subcommittee, thank you for the chance to discuss with you the views of the American Society of Clinical Oncology, or ASCO, concerning payment for chemotherapy in physicians' offices. We also appreciate Mr. Stark's efforts to move the debate forward and that he has recognized the need to reform both the drug payments and the practice expense at the same time.

With more than 19,000 Members, ASCO is the world's leading organization representing cancer physicians and researchers. I am the elected President of ASCO and serve as Director of the University of Colorado Cancer Center in Denver. My specialty as a medical oncologist is the care of patients with lung cancer.

I would like to begin by summarizing several facts regarding cancer care in the United States. First, scientific evidence indicates that cancer mortality rates are declining in the United States. This decline can be attributed to advances in screening, early detection, prevention, and therapy. These advances have been realized largely through the Nation's investment in cancer research and Congressional support for the national cancer program.

Second, the U.S. cancer care system is the best in the world. In this system, care is provided primarily in the outpatient office setting because it is preferred by patients who benefit from its convenience, its efficiency, and its quality. Academic cancer centers play a major role in scientific discovery and education, but are not equipped to provide chemotherapy services to the majority of cancer patients.

Third, most cancer chemotherapies and supportive care agents are delivered most effectively in the office setting. This is possible because of improvements in chemotherapeutic drugs with fewer side effects, improved chemotherapy delivery systems, better medications for system management, and highly qualified support staff, including specially trained nurses, pharmacists, and other health professionals.

Fourth, the reduction in cancer mortality and improved quality of care come with associated increases in cost. Most of these cost increases are due to increases in non-physician services, such as chemotherapy administration and other essential patient services.

Fifth, Medicare more than adequately reimburses for the costs of drugs but under-reimburses for practice expenses. The ASCO has long believed that the current system of reimbursement is fundamentally flawed, but can only be fixed by reform in all parts of the system. The net result of such simultaneous changes would be to preserve the quality and integrity of cancer care in the country today.

The ASCO is concerned that sudden changes in drug reimbursement without correction in practice expense payments could have a ripple effect that would adversely impact the quality of care for our patients. Academic centers such as my own could not absorb a significant influx of new patients from physician offices that might be unable to continue to provide chemotherapy services.

With that background, I want to make it clear that both I personally and ASCO favor reform of the current system. Let me briefly set forth what is necessary.

On the practice expense side, ASCO has advocated making direct estimates of the cost involved in furnishing cancer therapy. If Congress wants to use a system based on surveys of practice expenses per hour, we believe the following are required.

First, CMS should take into account the new data derived from the recently completed Gallup survey to determine practice expenses per hour of physician work. The data indicate significant underpayment for these expenses.

Second, CMS must eliminate from its payment methodology bias against services that do not involve physician work, these services being critical to oncology care.

Third, Medicare must commit to pay in full for all actual costs incurred.

On the issue of payment for drugs themselves, we have no strong preference among the methodologies under consideration. Competitive bidding sounds promising, but we have no idea of how it might play out in a practical manner, given the necessity to maintain inventories of drugs for both Medicare and non-Medicare patients. The overarching point with respect to payment for drugs, it is necessary to cover all the costs of making the drugs available to Medicare beneficiaries with cancer. This means we must account for the variability in the capacity of individual physicians to acquire drugs at the lowest possible price. Moreover, we have to accept, regardless of the underlying payment mechanism, that maintenance of an inventory of expensive, toxic, and sometimes unstable drugs bears its own costs and these should be reimbursed by Medicare.

The ASCO is very eager to work with Congress and with CMS to reach a solution that will assure Medicare beneficiaries continue to receive the best possible cancer care.

Thank you again for inviting me here today, and I am happy to answer your questions.

[The prepared statement of Dr. Bunn follows:]

Statement of Paul Bunn, M.D., Director, Cancer Center, University of Colorado, Denver, Colorado, and President, American Society of Clinical Oncology, Alexandria, Virginia

Chairman Johnson and Members of the Subcommittee, thank you for the opportunity to appear before you to discuss a topic of great importance, not just to the physicians whom I represent, but also, more importantly, to the patients with can-

cer whom we treat. That issue is the means by which the Medicare program pays for cancer treatment services for our senior citizens. This has been a technically complex and difficult issue, but ASCO is committed to working with you towards an appropriate solution. What is at stake is the quality and accessibility of essential services for cancer patients.

My name is Paul Bunn. I am a medical oncologist who specializes in the treatment of patients with lung cancer. I am Director of the Cancer Center at the University of Colorado and currently serve as President of the American Society of Clinical Oncology (ASCO).

I want to thank you, Chairman Johnson, for your leadership not only on this issue but in quality cancer care generally. We recall your early and consistent support for Medicare coverage of patient care costs in clinical trials, leading up to the eventual National Coverage Decision in which Medicare agreed to extend such coverage in late 2000. And we are very grateful that you championed legislation to require the General Accounting Office (GAO) to conduct studies that would give critical answers to questions about the cost of providing cancer care in physician offices. As you indicated in your Advisory for this hearing, "it will take congressional action to ensure that our seniors continue to have access to high-quality cancer care." We agree completely with that goal.

Let me make clear at the outset that neither my income, nor the revenues of the Cancer Center that I head are influenced by the controversy involving reimbursement for office-based treatment that I understand to be the focus of the Subcommittee today. I am based at a Cancer Center that provides cancer treatment mostly in its outpatient department, therefore I do not anticipate that changes in the payment mechanism for drugs in physician offices will have any direct impact on me or on my institution. Moreover, my entire oncology career has been spent either at the National Cancer Institute or at an academic medical center, neither of which is directly affected by this reimbursement matter.

Necessity for Comprehensive Reform

Nevertheless, I am quite concerned that sudden or sharp changes in reimbursement levels in any part of the comprehensive cancer care system in our country might have a ripple effect that could influence all other parts of the system and, in turn, all cancer patients. For example, in my own position at the Cancer Center, I know that we could not readily absorb a significant influx of new patients from physician office practices, nor could we continue to provide quality cancer care if our own drug reimbursement were reduced. Any reform must ensure that quality care remains accessible to the approximately 80% of cancer patients who receive chemotherapy in physician offices.

With that background, I first want to make clear that both I personally and my organization ASCO favor reform of the current system. We do not relish being targets for those who correctly point out that some drugs are reimbursed by Medicare at a rate that exceeds the acquisition cost. It is particularly troublesome when one focuses on the fact that the drugs where such excess payments occur are not usually the new sole-source drugs that are the cornerstones of modern chemotherapy, but instead they are older multisource or generic drugs that are less important to cancer care but still useful and necessary in patient care. While physicians are targeted for harsh criticism when such drugs are overpaid by Medicare (and by beneficiaries through their copayments), we should recognize that it is the payment system itself, not wrongdoing by physicians, that perpetuates any overpayments.

What can be done to fix that payment system? We believe, as we have previously testified before congressional committees, that reform must be comprehensive, encompassing both overpayments for drugs and underpayments for the costs of administering the drugs. In that regard, Chairman Johnson, we assume that you have signaled your agreement by crafting legislation in both the Balanced Budget Refinement Act of 1999 and the Benefits Improvement and Protection Act of 2000 specifically requiring GAO to study shortcomings in Medicare practice expense payments.

Unfortunately, the GAO consideration of these issues failed to get to the core issue of the cost of administering chemotherapy in the office setting and the chronic Medicare underpayment of those costs because GAO, contrary to the statutory instruction, conducted no "nationwide study" and collected no new data regarding "resources necessary to provide safe outpatient cancer therapy services and the appropriate payment rates for such services."

Practice Expense Reimbursement

Although the GAO failed to produce the most useful type of data, ASCO recently contracted with the Gallup Organization to conduct a survey of oncology practices

in order to determine their practice expenses per hour of physician work. This survey employed the methodology of the American Medical Association SMS survey used by Medicare to set payment rates. Practice expenses per hour does not directly indicate the cost of furnishing any specific service, but it is a component of Medicare's methodology for setting payment rates.

ASCO has long asserted that past survey results were inadequate to capture true costs of oncology practices because they included only a small, unrepresentative group of oncologists. Therefore, in order to address the paucity of data, ASCO engaged Gallup to conduct a new survey of oncology practices that would provide more reliable answers. Gallup has now completed its survey, and the resulting data were forwarded to the contractor of the Centers for Medicare & Medicaid Services (CMS) for evaluation. The CMS contractor, the Lewin Group, has completed its analysis of the data and forwarded its conclusions to CMS.

As analyzed by Lewin, the survey data show that CMS dramatically underestimated oncologists' practice expenses per hour; the survey, adjusted for inflation, reflects that oncologists' actual practice expense is roughly 90% higher than CMS' current assumptions. Additional analysis, still underway, may increase the gap between actual expenses and what Medicare assumes to be the case.

In view of the complexity of the CMS methodology for converting practice expenses per hour into actual payment amounts, we are uncertain how Medicare reimbursement will be affected by these new data. We are, however, hopeful that we will be able to work with CMS to determine whether the current methodology, after taking into account this important new information, will result in adequate payment amounts.

Aside from consideration of the new data, we believe it is also necessary for CMS to revise its current methodology to eliminate its bias against services that do not involve physician work—a very substantial part of oncology services. Both GAO and the Lewin Group have independently concluded that the current CMS methodology is biased against zero physician work value services and thus leads inevitably to lower payment amounts for those services. In addition, once the methodology is revised to result in an accurate determination of the costs involved, Medicare must actually pay these costs in full.

With the availability of new data to support the longstanding assertion of oncologists that their practice expenses are under-reimbursed, and hopefully with the willingness of CMS to eliminate its bias against certain categories of services, the time may be ripe for comprehensive revision of Medicare payment for cancer care in physician offices. ASCO looks forward to working with CMS and the Congress to find the right resolution of an enduring debate over appropriate payment levels for these services.

Drug Reimbursement

Assuming meaningful practice expense reforms can be implemented, it is essential also to change the way in which drugs are reimbursed by Medicare. Our preferred approach would be to conduct market surveys in an effort to identify true market costs. Through such a mechanism, the system could eliminate the large disparities between Medicare payments and acquisition costs that occur when generic or other competition drives the price down over time while the Medicare payment remains fixed.

I am aware that the Ways & Means Committee has developed a general concept of competitive bidding for purchase of drugs. Personally, I am in favor of a competition-based approach to just about any business endeavor, but I must admit I have questions about the practical applications of competitive bidding in this context.

Those questions largely revolve around the fact that physicians, or clinics, or hospitals or anyone purchasing cancer drugs, will most likely be purchasing for both Medicare and non-Medicare patients. It would be extremely difficult, if not impossible, for providers to segregate Medicare drugs from those purchased outside the system, presumably through the normal market mechanisms.

The implications of an overarching drug purchasing authority that might eventually exert influence on private as well as public purchases have to be resolved by high-level policymakers. Because we have serious reservations about the underlying concept, we would like to focus on the elements that we think should be incorporated into a reimbursement system for drug purchases that would be an alternative to the current average wholesale price (AWP) approach.

Perhaps most importantly, we must recognize the tremendous variation in ability of different purchasers to obtain volume- or other-discounts. Any fixed payment, whether derived through competitive bidding or otherwise, should allow for the fact that small market purchasers may be unable to obtain the designated price.

It is also important to recognize that maintenance of an inventory of expensive and toxic chemotherapy drugs has its own attendant costs. These costs include spillage, wastage, the opportunity cost of investment in an expensive drug inventory, and unpaid patient coinsurance, or bad debt. In some states, sales or other locally imposed taxes must be covered.

The general principle that should be applied with respect to drug reimbursement is that Medicare payment should cover the full and actual costs of acquiring and maintaining the drugs in preparation for treatment of cancer patients. Drugs should not be a profit center for physicians, but neither should they suffer loss as a result of maintaining a drug inventory for the benefit of cancer patients. With your help, I am certain that we will be able to develop a system that satisfies these simple requirements.

Maintenance of Quality Cancer Care

The preeminent concern for all of us should be maintenance of quality care for beneficiaries with cancer. Over the course of the past several decades, there has been a revolution in the ability to deliver life-saving cancer care to patients. Once life-threatening toxicities of chemotherapy can now be managed, and newer therapies are more targeted and feature fewer and less serious side-effects. These advances, however, do not come without their costs.

Many of the practical advances in cancer care are now realized in the physician office setting, often far from urban or academic medical centers. Science has made this technology transfer possible, but it is not impervious to being undermined if financial support is withdrawn. Patient advocates in the cancer community feel strongly that any solution to this problem should maintain the current quality care for cancer patients.

Cancer patients now fare much better than just a few years ago. Tremendous progress in cancer treatment has made it possible for cancer patients to experience the same quality of care whether it is in a community doctor's office or a hospital department. Quality care, however, can be placed in jeopardy if payment for services is precipitately reduced, regardless of the treatment setting.

I urge you and your Subcommittee Members to consider carefully the potential impact of any changes in payment for cancer chemotherapy drugs or services, and take those considerations into account before pursuing any legislative action.

Chairman JOHNSON. Thank you very much, Dr. Bunn. Dr. O'Grady?

STATEMENT OF MICHAEL J. O'GRADY, PH.D., SENIOR RESEARCH DIRECTOR, PROJECT HOPE, BETHESDA, MARYLAND

Dr. O'GRADY. Madam Chairwoman, Members of the Subcommittee, my name is Michael O'Grady, and I am a Senior Research Director at Project HOPE. I appreciate the opportunity to comment today on how Medicare's payments for currently covered drugs might be improved.

I would like to start with three key points. One has been pointed out before. The current system is overpaying for the drugs Medicare covers.

Two, the evidence is in from the CMS competitive bidding demonstrations and other public and private insurers that competitive purchasing of drugs can yield significant savings without hurting quality or beneficiary access.

Third, a reformed payment system based on competition between drug manufacturers for access to the Medicare market and competition between pharmaceutical benefits managers (PBM) or other group purchasers to have the opportunity to be Medicare's purchasing agent has the opportunity to provide the highest quality drugs at the most competitive price.

Some background on the problem. Certainly, basing payments on average wholesale price has long been a problem and it is well

demonstrated by both the OIG reports and the GAO reports on this issue. As a general rule, any payment formula that relies on data that cannot be effectively verified, either through audits or other means, always will leave itself vulnerable to that sort of manipulation.

The AWP-based formula is a prime example of how hard it is to get an administered price done correctly. Every year, CMS tries to accurately estimate thousands of different prices across thousands of different counties across America using, at best, 2-year-old data. This almost Herculean task is almost impossible to do accurately.

Now, how to correct the problem. Unlike most problems in Medicare payment policy, there is an example of how this might be solved. The evidence from the CMS competitive bidding demonstrations is quite encouraging. In the example brought up before by Mr. Scully, in San Antonio competitive bidding saved Medicare 25 percent over what it would have paid for the drug Albuterol. There were no discernable effects on beneficiary access found by the evaluation team that came in afterward. Outside of Medicare, both public and private insurers have made heavy use of pharmaceutical benefit managers, PBMs, to help negotiate discounts and managed benefits.

Some considerations in thinking about how to design a new system. An essential design consideration is getting the incentives right. Use the competitive natures of the industries involved to maximize Medicare's goals, design a payment system so drug manufacturers, suppliers, and providers will be most successful in the new system by providing the highest quality products at the most competitive prices.

There are two areas where competition can be used to encourage more prudent purchasing. First would be competition among drug manufacturers for access to the Medicare market. The second would be competition among group purchasers, for example, PBMs, to supply drugs to Medicare's providers.

Now, this type of competition for access to the market. The largest example that is currently out there is used by the State of California for CalPERS, the California Public Employees Health Plan. The CalPERS takes bids from a number of different health plans every year with the understanding that not all health plans will necessarily be allowed to offer coverage to the approximately 1 million State and municipal employees and retirees. The result has been an active competition between California health plans to offer the most coverage at the lowest price.

Medicare could apply the same method by designing a payment system that has drug manufacturers compete for access to the Medicare market. Medicare could use PBMs or other group purchasing organizations the same way employers do, to negotiate with the drug manufacturers for group discounts.

Now, the other type of competition that might work has to do with competition to supply Medicare's providers. A familiar example of this type of competition is found with the Federal Employees' Health Benefits Plan, or FEHBP, where insurers compete with one another to enroll workers and retirees in their particular plan. The government sets its contribution based on an average premium bid

by the insurers. Then the workers and retirees shop between plans for the best plan at the most affordable price.

A similar design could be used where PBMs and other group purchasers compete to offer Medicare-covered drugs to Medicare's providers. This could be done by having PBMs bid to participate in a program based on discounts they already have or believe they can get from the manufacturers. The government payment to providers could be set at an average price for a particular drug. Providers would have the ability to shop between different suppliers and choose one they were happiest with in terms of price and service.

Now, to conclude, the best chance of maximizing quality and access while minimizing Medicare's expenditures lies in designing a purchasing system that builds on competition between both manufacturers and PBMs. By structuring the competition at two levels and having group purchasers act as the intermediaries, the link between the drug manufacturers and the providers that has caused so much trouble in the past has been effectively broken.

How the competition is structured is key to the success of a new program. The incentives of all actors, manufacturers, PBMs, and providers, have to be structured in the same direction. They only gain by providing quality products and service at the best possible price. Thank you very much.

[The prepared statement of Dr. O'Grady follows:]

Statement of Michael J. O'Grady, Ph.D., Senior Research Director, Project HOPE, Bethesda, Maryland

Madam Chairwoman and Members of the Subcommittee, my name is Michael J. O'Grady and I am a Senior Research Director at Project HOPE. Previously I have served on the professional staff of the Senate Finance Committee, The Bipartisan Commission for the Future of Medicare, The Medicare Payment Advisory Commission and The Congressional Research Service. In those various roles I have had a chance to extensively study the Medicare program and a number of different health insurance programs, including the Federal Employees Health Benefits Program (FEHBP), the California Public Employees Retirement System (CalPERS) and private sector employer-provided health insurance programs. I appreciate the opportunity to comment today on the how Medicare's payments for currently covered drugs might be improved.

Three Key points:

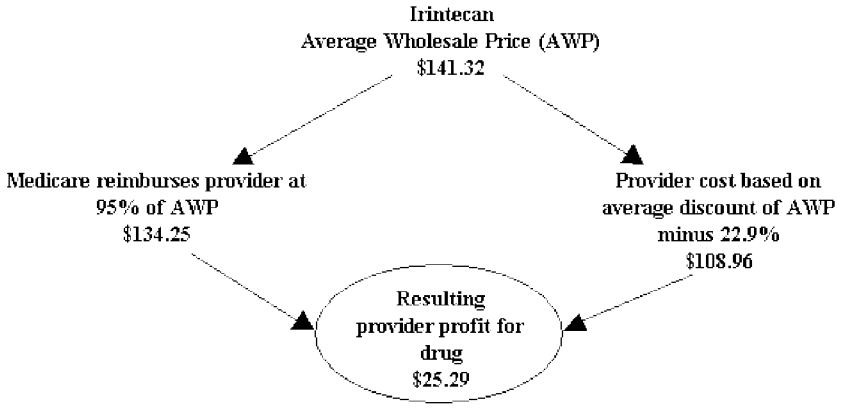
1) The current payment system is overpaying for the drugs Medicare covers.
2) The evidence is in from the CMS competitive bidding demonstrations and other insurers that a competitive purchasing of drugs can yield significant savings, without hurting quality or beneficiary access.
3) A reformed payment system based on competition between drug manufacturers for access to the Medicare market and competition between PBMs to be Medicare's purchasing agent has the opportunity to provide the highest quality drugs at the most competitive price.

Background:

The Problem: A basing payment on the average wholesale price (AWP) has long been a problem. The overpayments associated with the formula are well documented by the Office of the Inspector General (OIG) and the General Accounting Office (GAO).[1] The vulnerability of the current AWP-based payment formula to gaming by manufacturers has resulted in significant overpayments by Medicare. Figure 1 provides an example of the problem with the AWP-based formula. As a general rule, any payment formula that relies on data that cannot be effectively verified, through audits or other means, leaves itself vulnerable to manipulation.

[1] **Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost.** Report to Congressional Committees United States General Accounting Office, GAO–01–1118, September 2001.

Figure 1
Medicare Payment vs. Provider Cost for Part B Outpatient Prescription Drugs: An Example



Source: *"Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?"* Dawn M. Gencarelli, National Health Policy Forum, NHPF Issue Brief No. 775/ June 7, 2002, based on information from U.S. General Accounting Office, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, September 2001 (GAO–01–1118), Washington, D.C.

The AWP-based formula is a prime example of how hard it is to get administered prices right. Every year CMS tries to accurately estimate thousands of different prices in thousands of different counties. This almost Herculean task is very hard to do accurately.

How to Correct the Problem: Unlike most problems with Medicare payment policy, this problem has a relatively straightforward solution. The evidence from the CMS competitive bidding demonstrations is in and the results are encouraging. CMS conducted successful durable medical equipment demonstrations projects in Florida and Texas. In the San Antonio competitive bidding demonstration, pharmacy suppliers were asked to bid for Albuterol, a drug used for respiratory illnesses with a nebulizer. Medicare saved an estimated 25 percent over what it would have paid without competitive bidding and there were no discernable effects on beneficiary access (see Table 1).[2]

Table 1: Average Price Reduction and Estimated Percent Savings, Polk County, Florida, and San Antonio, Texas: Final Period in Each Site [3]

DMEPOS Category	Polk County, Florida		San Antonio, Texas	
	Average Price reduction (%)	Estimated Percent Savings, Oct. 01—Sept. 02**	Average Price reduction (%)	Estimated Percent Savings, Feb. 02—Dec. 02* **
Oxygen Equipment and Supplies	19.4	19.4	21.8	17.7
Hospital Beds & Accessories	34.1	33.2	25.7	27.6
Urological Supplies	7.4	6.8	N/A	N/A
Surgical Dressings	3.8	3.6	N/A	N/A
Wheelchairs & Accessories	N/A	N/A	20.1	23.8
General Orthotics	N/A	N/A	9.5	20.3

[2] *"Second Annual Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies."* U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Baltimore, Maryland, September 2002. http://www.cms.gov/healthplans/research/dmebid.asp

Table 1: Average Price Reduction and Estimated Percent Savings, Polk County, Florida, and San Antonio, Texas: Final Period in Each Site [3]—Continued

DMEPOS Category	Polk County, Florida		San Antonio, Texas	
	Average Price reduction (%)	Estimated Percent Savings, Oct. 01—Sept. 02**	Average Price reduction (%)	Estimated Percent Savings, Feb. 02—Dec. 02* **
Nebulizer Drugs (Albuterol)	N/A	N/A	**21.4**	**25.3**

*Final period of the San Antonio demonstration is less than 1 year.

**Estimate of percent savings assumes 1999 volume for Polk and 1998 volume for San Antonio.

Notes: (1) The average price reduction indicates the average price decline when comparing the demonstration prices to the prices on the statewide fee schedule for 2001. The percent differs between the average price reduction and the savings because the two calculations use slightly different volume weights. (2) Detailed data comparing round one and round two prices in Polk County can be found in the Appendix, Chapter 2, Section 2.2.2.

Outside of Medicare, public and private insurers have made heavy use of pharmaceutical benefit managers (PBMs) to help negotiate discounts and manage benefits. A recent study found that that PBMs managed 71 percent of insured purchases at retail drug stores in 1999.[4] The success of PBMs in the Medicare program will depend on the structure and incentives the program provides. A study by the Kaiser Family Foundation found the potential for PBM's to provide a cost-effective Medicare drug benefit were significant, if structured properly.[5]

For Medicare to ignore the effective tools used by all other major insurers, both private and public, is inefficient at best and irresponsible at worst.

As the deliberations on a possible outpatient drug benefit continue. A smarter, more efficient and more flexible CMS is a necessary starting point. CMS has to move up the learning curve on the smartest, most efficient ways to purchase pharmaceuticals.

What are the essential goals in redesiging Medicare's drug reimbursement?

1) Ensure beneficiary quality and access, while being as prudent a purchaser as possible.

The Medicare program has a responsibility to the beneficiaries to provide high quality health care. The Medicare program also has a responsibility to the taxpayers' to be as careful as possible with their tax money. Indirectly the Medicare program has a responsibility to providers. Like any other insurer, if Medicare treats providers unfairly and pays them less than the cost of providing care, underpayments will eventually result in reduced quality and access for beneficiaries. Paying providers fairly does not mean overpaying providers. Given the dangers to Medicare's financial viability associated with the approaching retirement of the baby boom generation, Medicare must negotiate for the most competitive prices possible and take full advantage of the government's considerable buying power.

2) Ensure flexibility and adaptability to change:

If there is any certainty in this policy area, it that things will be in almost constant change. Any payment policy that is not flexible enough to adapt to those changes runs the risk of overpaying for some drugs, underpaying for others and possibly denying Medicare beneficiaries access to the latest breakthroughs.

Technological change affects payment policy in two key ways: 1) New products are constantly becoming available and 2) The price of established products may change significantly over time.

Whether to cover a particular drug is a decision made separately within CMS. However, setting the payment is part of the payment methodology and critical in determining how available the drug will be to beneficiaries. In the case of new, breakthrough drugs still under patent, no insurer is in a very strong negotiating position. But even patented drugs find themselves in competition with other patented drugs developed by other manufacturers. Given the serious competition between drug manufacturers there are opportunities for negotiation. The alternative method of setting a fixed government rate is in effect a "take

[3] Op. cit., footnote #3, page 4.

[4] *"The Role Of PBMs In Managing Drug Costs: Implications For A Medicare Drug Benefit,"* Prepared by: Anna Cook, Ph.D., Thomas Kornfield, M.P.P., Marsha Gold, Sc.D., Mathematica Policy Research, Inc.

Prepared for: The Henry J. Kaiser Family Foundation, January 2000, page 7.

[5] Ibid. page xi.

or leave it" situation, without the flexibility to adapt quickly to an evolving situation.

Over time the price for a particular drug may change significantly and a well-designed payment methodology will take these changes into account. The clearest example is when a drug comes off patent and generic alternatives become available. But, even while still patented, the price can change significantly and usually in a downward direction. There are economies of scale and competition for other patented drugs that reduce the price of a drug.

The opposite can be true as well. One of the more interesting results of the CMS competitive bidding demonstrations was that while most prices came down well below the traditional CMS rate schedule, this was not universally true. There were some products were prices had risen and the CMS administered price was well below the negotiated price. Perhaps the suppliers were not the effective negotiators they had been on the other products, or perhaps the administered price was too low. To repeat an earlier point, trying to set an appropriate price without negotiation is extremely difficult. In the case of Part B covered drugs the evidence points to significant overpayment, but the opposite is also true. It is just very hard to accurately set thousands of prices in thousands of different counties. The potential for both overpayment and underpayment is high.

How to achieve these goals?

How can Medicare develop a payment method that will achieve these goals? An essential design consideration is getting the incentives right. Use the competitive nature of the industries involved to maximize Medicare's goals. Design the payment system, so drug manufacturers, suppliers and providers will be the most successful by providing the high quality products at the most competitive prices.

There are two areas where competition can be used to encourage more prudent purchasing:

1) Competition among drug manufacturers for access to the Medicare market.
2) Competition among group purchasers, e.g., PBMs, to supply the drugs to providers.

Competition for access to the market—The California Public Employees Retirement System (CalPERS) is an example of an insurer using competition for access to help control spending. Due to effective union contract negotiations by the California state employees unions, the state contribution towards an employee's health insurance was generous, sometimes more than 100 percent of premium costs. Without some effective method to negotiate, the health plans would have no incentive to ever bid below the state contribution. Offsetting this disincentive, CalPERS has taken bids from a number of different health care plans, with the understanding that not all plans would necessarily be allowed to offer coverage to the approximately one million state and municipal employees. The result has been active competition between California health plans to offer the most coverage at the lowest price and premiums below the level of the state contribution.

Medicare could apply the same method by designing a payment system that has drug manufacturers compete for access to the Medicare market. This could be done using PBMs or other group purchasing organizations. PBMs currently negotiate savings with manufacturers based on their ability to purchase in volume. The PBMs represent a collection of groups, typically employers, who allow the PBMs to negotiate for them. Failure to reach a successful negotiation with the PBM results in the manufacturers drug not being covered or covered at a higher beneficiary copay. Medicare can use PBMs or other group purchasing organizations the same way employers do, to negotiate with the drug manufacturers for group discounts.

Competition to supply providers—A familiar example of this style of competition is the Federal Employees Health Benefits Program (FEHBP). Insurers compete with one another to enroll workers and retirees in their plans. The government contribution is fixed as a percentage of the weighted average premiums bid by the insurers, which means insurers with higher bids are more expensive to the workers and retirees. Premium cost growth is slowed as workers and retirees shop between the plans for the best plan at the most affordable price.

A similar design could be used where PBMs and other group purchasers compete to offer Medicare covered drugs to Medicare providers. This could be done by having the PBMs bid to participate in the program based on the discounts they already have, or believe the can get, from drug manufacturers. If there were a number of PBMs or group purchasers negotiating to supply Medicare covered drugs; providers would have the ability to shop between the different suppliers for the best price and service.

The government payment to providers could be set to the average price of the drug. The providers would have the ability to choose among the multiple PBMs for the most competitive price and the best service. By setting the payment to the average price of the drug, the provider is assured that there are PBMs offering the drug at that price, but the provider incentives are to shop for lower cost PBMs within the system.

Concluding remarks:

The best chance of maximizing quality and access, while minimizing Medicare expenditures lies in designing a purchasing system that builds on competition between both manufacturers and PBMs.

By structuring the competition at two levels and having PBMs and other group purchasers act as intermediaries, the link between drug manufacturer and the providers is effectively broken.

How the competition is structured is key to the success of the program. The incentives of all actors, manufacturers, PBMs and providers, have to structured in the same direction—they only gain by providing quality products and service at the best possible price.

Chairman JOHNSON. Thank you, Dr. O'Grady. Mr. Jones?

STATEMENT OF JOHN D. JONES, VICE PRESIDENT, LEGAL AND REGULATORY AFFAIRS, PRESCRIPTION SOLUTIONS, COSTA MESA, CALIFORNIA, ON BEHALF OF PACIFICARE HEALTH SYSTEMS, INC.

Mr. JONES. Chairman Johnson, Representative Stark, and Members of the Subcommittee, I want to thank you very much for this opportunity to testify. I am John Jones, Vice President of Legal and Regulatory Affairs for Prescription Solutions, which is a subsidiary of PacifiCare Health Systems. I am a pharmacist by training.

Prescription Solutions is a pharmacy benefit management company which manages $2 billion of prescription drugs annually. We handle about 200,000 claims every day. Nearly 15,000 of those claims are filled through our mail service facility.

We support efforts that promote competition in the market for Medicare-covered drugs. We applaud the Subcommittee's work on the House-passed Medicare prescription drug bill which seeks to accomplish this. My goal today is to describe how PacifiCare, as a private payer, uses competition-based tools to provide beneficiaries with prescription drugs in a cost-effective manner. I then will illustrate how using these purchasing and quality management techniques can result in better clinical outcomes. Finally, I will highlight how price setting mechanisms can disrupt this model and create barriers to cost-effective drug pricing.

For years, the drug delivery system was fragmented and lacked a cohesive infrastructure that could effectively monitor utilization, ensure appropriate use, and maximize efficiencies. Spurred by recent increases in utilization and cost of part B covered drugs, Prescription Solutions developed a better model that uses a series of management tools. These include the following: a highly automated mail service pharmacy, specialty pharmacies dealing with AIDS and transplant, home infusion management, close coordination with infusion centers, and obtaining drugs through wholesalers and manufacturers at discounted prices.

The mix of tools we use can be influenced by the reimbursement model for a particular provider group. Three basic models are used. First, the provider group assumes the risk for outpatient drugs.

Second, the health plan assumes the risk and pays the pharmacy claims to the provider. Third, the PBM supplies the drugs and bills the health plan or insurer.

Using these techniques, we are able to achieve efficiencies that have allowed us to pass many of those savings on to our Members in the form of more comprehensive benefits. However, this is becoming more challenging in the Medicare+Choice program.

One important component of Prescription Solutions' model is that we integrate the need to manage the purchasing and cost of part B covered drugs with the need to produce the best overall health outcomes. For example, a use of formularies actually serves to improve the quality of care. Contrary to the conventional belief that formularies exist simply to control the cost of drug therapy, there are many aspects as to the proper administration of a formulary that have more to do with quality and clinical effectiveness.

In one instance, we received a request for a non-formulary antibiotic medication, which is Vancomycin oral. The treating physician had prescribed this drug for a serious knee infection. Due to the way this medication works, by being taken orally, it cannot get into the blood stream in a high enough concentration to effectively treat the infection. We contacted the physician to change the medication to an intravenous form, notwithstanding the fact that the intravenous drug was significantly more costly than the oral medication. The oral form would have had no benefit and potentially would have led to a more serious problem, including a need for surgery.

Prescription Solutions agrees that the current AWP system for determining payment for covered drugs is flawed in that it does not reflect the prices paid by suppliers and physicians. To us, AWP is simply a benchmark price that is independently established and maintained. It is useful as a tool. Increasingly, contracts with pharmaceutical manufacturers and pharmacy providers are based upon negotiated discounts from AWP.

The AWP concerns are not the whole story. We would encourage the Subcommittee to understand the impact of another drug pricing rule which has brought impact in the pharmaceutical market as a whole, and that is the Medicaid best price rule. In simplest terms, the best price rule requires a drug company to give the State Medicaid programs the deepest discounts that it gives to the other purchasers. Manufacturers use the requirement as a shield against aggressive negotiations by private sector companies such as ours. The net effect is to artificially increase the price to all purchasers. Thus, the rule limits the effect that competition can have on price. It results in the States paying a higher price for drugs. In effect, while the best price rule was intended to reduce costs, it has become a good example of price controls failing to achieve the original purpose and raising drug prices for all consumers.

In closing, we would commend the Committee for seeking solutions to the payment issues created under the AWP reimbursement system. We believe that Prescription Solutions' model, a closely integrated component of a health plan delivery system, is a template for how drug coverage and quality management can provide value to beneficiaries and decrease the overall cost of health care. Thank you very much.

[The prepared statement of Mr. Jones follows:]

Statement of John D. Jones, Vice President, Legal and Regulatory Affairs, Prescription Solutions, Costa Mesa, California, on behalf of PacifiCare Health Systems, Inc.

INTRODUCTION

Madam Chairman, Representative Stark, and Members of the Subcommittee, thank you very much for the opportunity to testify at the hearing on the payment of prescription drugs currently covered by Medicare. I am John Jones, Vice President of Legal and Regulatory Affairs for Prescription Solutions, which is based in Costa Mesa, California.

BACKGROUND

Prescription Solutions, a pharmacy benefits management (PBM) company, was founded in 1993 as a subsidiary of PacifiCare Health Systems, Inc. (PHS). Prescription Solutions serves approximately six million individuals, including members of managed care organizations, and union trusts, retirees, third-party administrators, and employer groups. Our goal is to provide the highest quality drug coverage in a cost-effective manner. Access and affordability are the cornerstones of everything we do. Our company manages approximately $2 billion of prescription drugs annually. We handle approximately 200,000 prescription claims per day of which nearly 15,000 are filled through our mail-service facility in Carlsbad, California.

Our parent company, PHS, is one of the nation's largest health care services companies. Primary operations include managed care and indemnity products for employer groups and Medicare beneficiaries in eight states and Guam serving 4 million members. Approximately 800,000 of these members are in our Medicare+Choice health plan, Secure Horizons. PHS and Prescription Solutions strive to provide a high quality, cost-effective pharmacy benefit for both our commercial members and Medicare beneficiaries.

Our testimony today focuses on three points: We support efforts that promote competition in the market for Medicare-covered pharmaceuticals and to describe for the Subcommittee how PacifiCare, as a private payer, uses several processes to cover prescription drugs that are currently covered by Medicare in a cost-effective manner. Second, we believe that bringing appropriate purchasing and quality management techniques into the program can result in better clinical outcomes. And third, how price-setting mechanisms create barriers to cost effective drug pricing and contracting for care.

Competition and Prescription Solutions Processes

The key to Prescription Solutions' ability to operate efficiently is that it is a PBM, which was founded to support the drug coverage provided to the enrollees of health plan products provided by PHS. As such the ability to integrate managed care concepts with effective purchasing is worth review as Congress considers improving payment for Medicare-covered services. Since we believe that competition is key to our success, our testimony will describe some of the techniques we employ.

As outlined in greater detail below, we utilize a variety of dynamic methods to manage our business in order to achieve efficiencies that permit us to provide a broader overall prescription benefit than the company might otherwise offer in the absence of those efforts. Nonetheless, over the past two or three years, these efficiencies have been more challenging to achieve for drugs that Medicare does not cover. In response to these market pressures, Prescription Solutions continues to strive to improve quality, safety, and cost management techniques. As referenced in various studies by the GAO and other public policy experts, the effect of various price setting mechanisms (i.e. Medicaid Best Price) on the market have not achieved the expected goal of reducing overall program costs.

Recent cost increases and breakthrough biotechnology therapies have spurred new efforts to develop and implement coordinated processes to manage costs and improve health outcomes. Until recently, PHS risk or financial responsibility for these products had been delegated to medical groups and hospitals through capitated arrangements. Those entities in turn shifted accountability to home health, durable medical equipment, infusion centers and other providers. The result was a lack of a cohesive infrastructure that can effectively monitor utilization, ensure appropriate use and maximize efficiencies, thereby minimizing costs and encouraging providers to accept risk for the provision of those services.

Recently, the utilization of Part B covered drugs has soared due to both technological advances in oncology and biotechnology. At the same time, the costs of these agents also have soared; supplying providers and patients in a convenient and cost effective manner has become difficult. More seriously, the delivery system for medi-

cations has become fragmented. Since many firms focus on providing a specific category of agents or a limited range of products and services, providers have had to work with many different entities creating further inefficiencies and less focus on quality of care.

In response to this situation, Prescription Solutions strives for comprehensive solutions that create preferred product choices and clinical management. Prescription Solutions does not rely on any one technique to purchase and provide Medicare-covered drugs, but rather on a combination of tools. Dependent on the type of pharmaceutical or treatment, our programs can integrate some or all of the following processes:

- Mail Service Pharmacy. Prescription Solutions operates a highly automated pharmacy that ships prescriptions and over-the-counter drugs by mail. Mail service is most routinely used to supply maintenance medication to patients on long-term therapies. For complex treatment protocols, our PBM will coordinate with the clinician, product and DME vendor, and medical management to mail overnight the drugs and equipment necessary to provide the drug. This eliminates the need for the physician to coordinate with several vendors.
- Specialty Pharmacies. The PBM will coordinate with pharmacies that provide niche therapy products by mail. Examples of such therapies would be drugs for the treatment of AIDS, transplants or infertility.
- Home Infusion. The PBM will assure that companies which provide injectable medication that will be administered in the patient's home is delivered with the proper equipment by mail or a local delivery service.
- Infusion Centers. Prescription Solutions will work with the organizations that provide injectable medications in a clinical setting. Typically, patients go to such centers for cancer treatments.
- Wholesaler/GPO. In this instance, the PBM obtains the drug through large purchasing groups at discounted rates. This purchasing price helps determine the reimbursement rates.
- Reimbursement Methods. There are three basic models. In the first, provider groups assume the risk for all in-office furnished pharmaceuticals. Dependent on the market, this model applies to less than 50 percent of the providers. In a second model, the health plan assumes the risk and the physicians send claims for covered pharmacy services to the health plan; claims are paid on a schedule of billed charges or on a discount off AWP. Finally, the PBM may supply the drugs on order or supplements inventory, and Prescription Solutions bills the health plan or insurer. In this instance, the provider does not have to negotiate pricing with multiple vendors. Between 30 to 40 percent of our PBM business falls into this model.

Because Prescription Solutions is able to compete by leveraging the numbers of subscribers, contracted networks, and pharmacy arrangements, we can achieve efficiencies that, when integrated with the rest of the PHS health care and disease management services, have allowed us to pass many of those savings on to our members in the form of more comprehensive benefits. However, as is well known, this is becoming more challenging in the Medicare+Choice program.

Improved Clinical Outcomes

One important outcome of Prescription Solutions ability to compete efficiently for cost-effective drugs is that we integrate the need to manage the purchasing and cost of Part B covered drugs with the need to produce the best overall health outcomes while managing total health costs. For this reason, many physicians from our contracted groups have stated that they can deliver better quality of care in a managed environment than in fee-for-service.

I would like to illustrate the point with a couple of examples. We offer an integrated approach to management of specific diseases that involve physicians, pharmacists, and patients. We improve quality of care and quality of life. These programs often encourage the use of medication and can sometimes increase the cost of pharmaceutical care, but these costs often are offset by a decrease in the cost of overall health care. For example, the use of beta-blockers after a first heart attack is strongly supported by the research and national guidelines to help avoid future adverse cardiovascular events. The national average for the use of beta-blockers is only about 70 percent; our program has demonstrated 85 to 95 percent compliance with the guidelines. Prescription Solutions actively supports other disease management programs, such as those for diabetes and congestive heart failure. We work closely with patients and their physicians on the use of the most efficacious drugs.

A second example illustrates our use of formularies as quality enhancement tools. By our definition, a drug formulary or preferred drug list is a compilation of drugs that have been reviewed for safety and efficacy. Contrary to the conventional belief that formularies exist to simply control the costs of drug therapy, there are many aspects to the proper administration of a formulary that have more to do with quality and clinical effectiveness. In one of our cases, a request for a non-formulary antibiotic medication, Vancomycin oral, was received in the prior authorization department. The treating physician had prescribed this drug for a serious knee infection. Due to the way this oral medication works, it could not get into the blood stream in a high enough concentration to effectively treat the infection. We contacted the physician to change the medication to an intravenous form. Notwithstanding the fact that the intravenous drug was significantly more costly than the oral medication, the latter would have had no benefit and potentially could have led to a more serious problem, including the need for surgery.

Concerns With Current Pricing Mechanisms

Finally, Prescription Solutions agrees with Members of Congress that the current AWP system for determining payment for covered drugs is flawed in that average prices and prices charged by wholesalers do not reflect the prices paid by suppliers and physicians. In fact, the tension that the AWP system has created led to changes in how health plans, like PHS, contract with certain specialists for Medicare-covered drugs, as we described earlier. To us, the AWP is simply a benchmark price that is independently established and maintained. We use it as a value used to negotiate purchasing, discounts and rebates of drugs. Increasingly, contracts with pharmaceutical manufacturers, pharmacy providers, and clients using our services are based upon negotiated discounts from AWP for the prescriptions being dispensed.

But AWP concerns are not the whole story, and we would encourage the Subcommittee to understand the impact of a rule on drug costs to the Medicaid program, and which has broad impact in the pharmaceutical market as a whole, i.e., the Medicaid "best price" rule. In the simplest terms, the best price rule requires that whenever a drug company gives a deeper discount to an insurance plan, PBM, or other purchasing entity than the current discount offered to the states' Medicaid programs, the deeper discount must be offered to the states as well.

While on the surface this may seem to be a logical requirement, in practice, the rule has created a floor price for many branded drugs, thus inhibiting competition on price among the pharmaceutical manufacturers with similar products. Because the Medicaid best price and Federal Supply Schedule (FSS) pricing structures require the most favorable pricing available to any entity, manufacturers use the requirement as a shield against aggressive negotiations by private sector companies such as ours. The net effect is to artificially buoy-up the price to all purchasers since a pricing concession that would discount a product below the Medicaid or FSS price would result in substantial losses for the public book of the manufacturer's business.

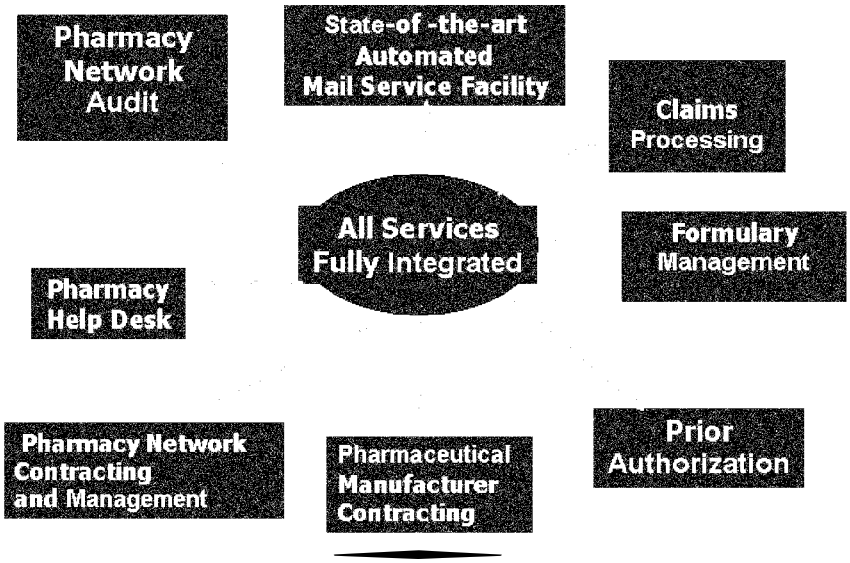
The reason is simple. The rule limits the effect that competition from multiple private purchasers—health plan PBMs, insurers, hospitals, clinics and pharmacies—can have on price because the drug companies would be required to give that same price to all 50 state Medicaid programs as well. It is not a bargain for the manufacturers and results in the states paying a higher price or floor for the drugs provided under the program.

A further complication is that PBMs do not know the "Best Prices" for drugs and have no realistic way of learning this information. Thus, if a pharmaceutical company states in negotiations that it can not give a bigger discount because of "Best Price" considerations, the PBM has no way to verify or rebut this claim. In effect, while the best price rule was intended to reduce costs, it has become a good example of price controls failing to achieve the original purpose and raising drug prices for all consumers.

Conclusion

In closing, we would commend the Subcommittee for seeking solutions to the payment issues created under the AWP reimbursement system. We would like to emphasize two key points: first, we support a system that allows for competition; and second, we believe it is critical that the ability of Prescription Solutions and similar entities to continue to achieve their quality management goals through integrated purchasing and management systems is not compromised. We believe that Prescription Solutions' PBM model—a closely integrated component of a health plan delivery system—is a template for how drug coverage and quality management can provide value to beneficiaries and decrease the overall cost of healthcare. Thank you for the opportunity to testify.

Prescription Solutions PBM Structure



Chairman JOHNSON. Thank you, Mr. Jones. Ms. Glaun?

STATEMENT OF KIM GLAUN, WASHINGTON COUNSEL, MEDICARE RIGHTS CENTER, NEW YORK, NEW YORK

Ms. GLAUN. Good morning, Madam Chairman. My name is Kim Glaun, and I am the Washington Counsel at the Medicare Rights Center. The Medicare Rights Center is a national consumer service organization with offices in New York, Washington, and Baltimore, working to ensure that older and disabled Americans get good, affordable health care.

Every year, the Medicare Rights Center hears from more than 60,000 Americans with Medicare who have questions about their Medicare benefits, rights, and options. Thank you for inviting me to share with the Subcommittee the consumer perspective on Medicare's payment scheme for covered drugs.

Every day, the Medicare Rights Center hotline hears from scores of older and disabled Americans who cannot afford their prescriptions. Medicare's current policy of covering only a limited number of drugs and paying for them based on the average wholesale price often forces elderly and disabled persons with cancer and other serious medical conditions to spend more out of pocket than their small fixed incomes allow. This policy should be changed.

Take, for example, Mrs. Thomas. While she is fictional, we have spoken to countless men and women like her who face the same difficulties she does in getting critical care. Mrs. Thomas is 75 years old and lives in Texas, which, like most States, does not have a State pharmaceutical assistance program. Like the majority of people with Medicare, Mrs. Thomas suffers from two chronic conditions, congestive heart failure and cancer. Like the typical person with Medicare, her annual income is about $16,000, too high for

her to qualify for Medicaid or other low-income assistance programs.

For someone like Mrs. Thomas, out-of-pocket costs for medications and treatment for her heart condition alone could easily cost $5,000 annually. A Medicare supplemental policy to fill voids in Medicare could cost her $1,500 annually. If Mrs. Thomas cannot afford supplemental insurance, she will need to pay all Medicare gaps herself and is likely to forego critical treatment.

Like most older and disabled Americans, Mrs. Thomas needs Medicare to offer a good, affordable prescription drug benefit. Instead, Medicare only offers her limited coverage for some of her cancer drugs. The current policy of basing Medicare reimbursements on the AWP directly harms Mrs. Thomas and millions of other vulnerable and older disabled men and women.

First, as the U.S. General Accounting Office has documented and my fellow witnesses and Administrator Scully have testified today, the AWP bears little relation to the amount doctors and suppliers actually pay for drugs and is grossly inflated. Because Medicare patients pay 20 percent of the amount Medicare reimburses for drugs and Medicare premises payment rates on the inflated AWP, older adults and persons with disabilities are overpaying for their medications.

Second, Medicare's inflated payments for medications drive up the costs of Medicare supplemental policies. Insurers pass on to policy holders the cost of inflated coinsurance payments through premium increases. Premium hikes have made supplemental policies unaffordable for a growing number of older and disabled Americans with Medicare.

Third, the AWP creates perverse financial incentives that could result in inappropriate prescribing at the expense of people with Medicare's health and quality of care. The difference or spread between the AWP-based price and the price a physician actually pays for the drugs is essentially profit. The greater the difference between the Medicare price and the actual price, the more profit a physician keeps. The government should not be perpetuating a system that induces doctors to prescribe drugs based on their own financial gain rather than clinical efficacy.

In sum, Medicare's current policy of pegging drug reimbursement under part B to the arbitrary AWP subsidizes physicians, suppliers, and manufacturers at the expense of older and disabled Americans and America's taxpayers. It is due time that Medicare use its market leverage to lower prescription drug prices for people with Medicare rather than accept the pharmaceutical industry's pricing structure as a given. A Medicare policy of paying prices that the pharmaceutical industry charges its most favorite customers comports with Medicare's pricing practices for doctors, hospitals, providers, and suppliers. A more rational payment system will protect people with Medicare, the common good, and the public purse.

Congress must respect the need to pay doctors and hospitals rates that encourage them to continue to serve people with Medicare, but moving toward a system based on acquisition costs would institute much needed, reasonable reforms and success in lowering

both people with Medicare's cost sharing and taxpayer expenditures for currently covered drugs.

In conclusion, we urge you to save the Medicare Program from wasteful expenditures and to conserve those dollars to help more people with Medicare get good, affordable prescription drugs. Thank you.

[The prepared statement of Ms. Glaun follows:]

Statement of Kim Glaun, Washington Counsel, Medicare Rights Center, New York, New York

Good morning, Madam Chairman. My name is Kim Glaun, and I am the Washington Counsel at the Medicare Rights Center.

The Medicare Rights Center is a national consumer service organization, with offices in New York and Washington, working to ensure that older and disabled Americans get good, affordable health care. Under a contract with the New York State Office for the Aging, with funding from the Centers for Medicare and Medicaid Services, we operate New York State's Health Insurance Assistance Program hotline. We also operate a National Medicare HMO Hotline that assists elderly and disabled Americans who are struggling to get needed care and coverage from their HMOs.

Every year the Medicare Rights Center hears from more than 60,000 Americans with Medicare, who have questions about their Medicare benefits, rights and options and problems accessing critical care. Their greatest problem by far is securing affordable prescription drugs. We thank you for inviting MRC to share with the Ways and Means Committee Subcommittee on Health the consumer perspective on the issue of prescription drug costs for people with Medicare.

Ensuring Older and Disabled Americans Get the Prescriptions They Need

Every day, MRC hears from scores of older and disabled Americans who cannot afford their prescriptions. Even those fortunate enough to have coverage for some of their medications under Part B or through a Medicare HMO struggle to afford premiums and copays for this coverage. Medicare's current policy of covering only a limited number of drugs—and paying 95% of the Average Wholesale Price for these drugs—often forces elderly and disabled individuals with cancer and other serious medical conditions to spend more out of pocket than their small fixed incomes allow and they should be expected to pay. This policy should be changed.

Take for example, Mrs. Thomas, an amalgam of Medicare Rights Center's clients. She is 75 years old and lives in Texas, which, like most states, does not have a state pharmaceutical assistance program. Like the majority of people with Medicare, Mrs. Thomas suffers from two chronic conditions, congestive heart failure and cancer. Like the typical person with Medicare, her annual income is about $16,000, too high for her to qualify for Medicaid or other low-income assistance programs. Like most people with cancer and congestive heart failure, she is on multiple medications.

The Centers for Medicare and Medicaid Services estimates that out-of-pocket costs for medications and other health care needs relating to congestive heart failure alone can easily cost someone like Mrs. Thomas close to $5,000 a year. On top of that she would pay about $1,500 a year for Medicare supplemental coverage to fill other gaps in Medicare. If she cannot afford to pay for this coverage and opts to pay the coinsurance costs herself, she will have to spend even more and is likely to go without critical treatment. Like many people the Medicare Rights Center hears from, Mrs. Thomas is thinking about buying her drugs from Canada on the Web, a practice that is illegal but that more and more older and disabled Americans are following as a way to get affordable medications.

Like most older and disabled Americans, Mrs. Thomas needs Medicare to offer a good, affordable prescription drug benefit. Instead, Medicare only offers her limited coverage for some of her cancer drugs. The current policy of paying 95% of the Average Wholesale Price for these drugs directly harms Mrs. Thomas and millions of other vulnerable older and disabled men and women. It also needlessly saps money from the Medicare program and taxpayers to the clear benefit of the pharmaceutical industry and certain providers.

First, the AWP is a price that manufacturers derive using their own criteria and is not defined by any Federal law or regulation.[i] The fact is, as recognized by the U.S. General Accounting Office, the Average Wholesale Price is neither "average" nor "wholesale."[ii] It is much higher than what most other American purchasers are paying for these drugs. So long as Medicare pays for drugs based on the average wholesale price—and not on the much lower prices paid by other large purchasers—people with Medicare will often end up paying much higher coinsurance for their covered drugs than they would otherwise be paying.

Second, these inflated prices for Part B medications drive up the cost of Medicare supplemental insurance, which millions of people with Medicare purchase to fill Medicare's coverage gaps. Medigap insurers must pay more in coinsurance for Part B covered prescription drugs than they would be paying if the Federal Government paid a lower price for these drugs. Of course, Medigap insurers simply pass these costs on to their policyholders by raising their premiums. As a result, the data shows that an increasing number of older and disabled Americans with Medicare, people like Mrs. Thomas, can no longer afford these policies.[iii]

Third, the AWP creates perverse financial incentives that could result in inappropriate prescribing at the expense of people with Medicare's health and quality of care.[iv] The difference, or "spread", between the AWP-based price and the price a physician actually pays for the drugs is essentially profit. The greater the difference between the Medicare price and actual price, the more profit a physician keeps.[v] The government should not be perpetuating a system that motivates doctors to prescribe drugs based on their own financial gain rather than the best treatment for the thousands of people with Medicare like Mrs. Thomas.[vi]

Finally, when the Federal Government overpays for prescription drugs, it drains the Medicare Trust Fund and harms all U.S. taxpayers.[vii] The Federal Government negotiates discounted drug prices on behalf of veterans, Department of Defense employees and retirees, and other Federal employees and retirees.[viii] The Federal Government should assure real discounted prices for Medicare-covered drugs.

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[i] Gencarelli. Dawn M., *Average Wholesale Price for Prescription Drugs; Is There a More Appropriate Pricing Mechanism?* Issue Brief No. 775, National Health Policy Forum, June 7, 2002, 2, list visited on October 1, 2002 from http://www.nhpf.org/pdfs/8–775+(web).pdf.

[ii] Laura A. Dummit, *Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices,* testimony before the Senate Finance Subcommittee on Health, March 14, 2002 (GAO–02–53IT). William J. Scanlon, *Medicare Part B Drugs: Program Payments Should Reflect Market Price,* testimony before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, US House Committee on Energy and Commerce, September 21, 2001, (GAO–01–1142T), US General Accounting Office, Washington, DC, 2, accessed October 1, 2002 at http://www.gao.gov/new.items/d011142t.pdf.

[iii] Pourat, N., T. Rice, G. Kominski, and R.E. Snyder, 200. "Socioeconomic Differences in Medicare Supplemental Coverage." Health Affairs 19 (5): 186–96. The Detroit News, Business, B, August 14, 2002.

[iv] At root, the AWP is a marketing tool, utilized and manipulated by the physicians, suppliers and manufacturers to gain profit. See Rep. Sherrod Brown, *Congressional Hearing: Medicare Drug Reimbursement: A Broken System For Patients and Taxpayers,* September 21, 2001 Washington, DC, Energy and Commerce Committee—Subcommittee on Oversight and Investigations, last visited on October 1, 2002 at http://www.kaisernetwork.org/health_cast/uploaded_files/ACF121.pdf

[v] Janet Rehnquist, testimony before the Senate Committee on Finance, March 14, 2002 Washington, DC, last visited on October 1, 2002, 3, at http://oig.hhs.gov/testimony/docs/2002/020314fin.pdf.

[vi] Companies and individuals have taken advantage of these perverse incentives. Recent litigation has highlighted how pharmaceutical companies can manipulate the AWP to increase profits. Most recently, in October, 2001, TAP Pharmaceuticals agreed to pay almost $900 million to settle a civil and criminal lawsuit brought by the United States and other private and governmental entities. TAP paid substantial criminal and civil fines for allegedly developing and implementing a fraudulent pricing scheme, as well as for marketing misconduct, in connection with their drug Lupron. See U.S. v. Tap Pharmaceuticals Prod., Crim. No. 01–CR-1–354–WGY (D. Mass. December 4, 2001), sentencing memorandum available at http://www.prescriptionaccesslitigation.org/documents.htm (last visited October 1, 2002). Similarly, Bayer agreed to pay $14 million to settle a lawsuit alleging that they had improperly inflated the AWPs for a number of Bayer drugs, including AIDS and hemophilia drugs. Associated Press, Report: Bayer to Pay $14 Million in Probe of Drug Prices, at http://fyi.cnn.com/2000/health/09/18/bayer.drugs.ap (last visited Oct. 1, 2002).

[vii] Chairman Bilirakis, *Congressional Hearing: Medicare Drug Reimbursement: A Broken System For Patients and Taxpayers,* September 21, 2001 Washington, DC, Energy and Commerce Committee—Subcommittee on Oversight and Investigations, last visited on October 1, 2002 at http://www.kaisernetwork.org/health_cast/uploaded_files/ACF121.pdf

[viii] Supra note 2, at 2 ("We found that Medicare would have saved $1.9 billion of the $3.7 billion it spent for 24 drugs in 2000 if the drugs were reimbursed at prices available to the VA. Over $380 million of this savings would directly impact Medicare beneficiaries in the form of reduced coinsurance payments.")

In sum, Medicare's current policy of pegging drug reimbursement under Part B to 95% of an arbitrary AWP subsidizes physicians, suppliers and manufacturers, at the expense of older and disabled Americans and America's taxpayers.

Helping People with Medicare While Preserving the Medicare Trust Fund

It is due time that Mrs. Thomas and the millions of people in similar financial and health situations be able to afford the medications they need. It is long past time for Medicare to use its market leverage to lower prescription drug prices for people with Medicare rather than accept the pharmaceutical industries' pricing structure as a given. A Medicare policy of paying prices that the pharmaceutical industry charges its most favored customers is both consistent with Medicare's pricing practices with doctors, hospitals and other providers and suppliers and in the interest of people with Medicare, the common good and the public purse.

Congress must respect the need to pay doctors and hospitals rates that encourage them to continue to serve people with Medicare. But moving toward a system based on acquisition costs would institute much needed, reasonable reforms and success in lowering both people with Medicare's cost-sharing and taxpayer expenditures for currently covered drugs.

Conclusion

In conclusion, we urge you to save the Medicare program from wasteful expenditures and help more people with Medicare to get good affordable prescription drugs. Every dollar the Federal Government saves through lower prescription drug prices under Medicare Part B is money that can go to covering additional prescription drugs that millions of people with Medicare desperately need.

I thank the Ways and Means Committee Subcommittee on Health for this opportunity to testify on behalf of older and disabled Americans.

Chairman JOHNSON. Thank you very much. I thank the panel for their testimony. Ms. Glaun, I thank you for your eloquent description of the burden that high-priced drugs place on our elderly. I am hopeful that we will pass some prescription drug legislation this year. I am very proud that this Committee did get a bill through the House, that particularly for the low-income seniors would take essentially all the costs off them, so I certainly share with you that concern.

I also am very conscious of the copayment burden that high-cost drugs place on our seniors and the danger of the spread driving a physician's decision as to what to use. In light of the testimony that indicates that 80 percent of our seniors get chemotherapy in practice-based cancer treatment centers, do you have any concern about access to those centers if we concentrate only on price and not on practice?

Ms. GLAUN. I completely agree with the parties that have testified and you, Madam Chairman, as well, when you have said that at the same time we fix the prices that Medicare is paying, that we need to adequately reimburse providers and physicians for their practice expenses. Our goal is to assure access to quality care for our beneficiaries.

Chairman JOHNSON. Thank you very much.

Dr. O'Grady, and Mr. Jones, you can enter in on responding to this question if you care. Dr. O'Grady, you mentioned that the evidence is in on competitive bidding, and yet CMS has done one competitive bidding in one county in Florida and one competitive bidding in one city in Texas. They competitively bid hospital beds, urological supplies, surgical dressings, wheelchairs and accessories, and general orthotics. The only drugs they competed were nebulizers and oxygen.

Now, to take that evidence and assume that you can crosswalk it over to chemotherapy drugs is, in my mind, risky. I believe com-

petitive bidding has a place here, there is no question about that. The examples that you give of competitive bidding are amongst plans, and you also Mr. Jones, when a plan bids competitively or uses the competitive approach in purchasing, they have underneath them an integrated delivery system and that is our problem. We do not have underneath drug pricing and Medicare an integrated delivery system, and if we do not pay properly for that, as Mr. McCrery said in his questioning, which I had to miss some of, we should not have to be doing this. If we had integrated delivery systems in Medicare, we would not have to be doing this.

We do have to do this. So, in a sense, the Federal Employee Health Benefit Plan analogy and Mr. Jones' Prescription Solutions analogy, while useful and demonstrating the power of competitive bidding, particularly in the setting of integrated care delivery systems, in a sense, it circumvents the hardest part of the nut that we have to crack.

So, I would like your comments on how do we get at the practice expense. Then I just want to go on to Dr. Bunn. I want him to be thinking about it. I mean, we need to understand, what are these drugs we are talking about? When I read about their toxicity, what is it? I go through a clinic, and they show me a drug that if it gets misplaced and does not go through the needle and it gets in the skin, it can cause a chain of erosion.

So, I want us to understand a little more clearly, not only what competitive bidding might do for us, but the terrific challenge we face in managing the delivery of highly toxic drugs that are highly sensitive to temperature and other things. I do not think, Mr. Reeb, that the OIG has done any investigations of these particular kind of drugs. The examples we are getting are from Albuterol and others that are more simple, either orally or nebulizer or injectably taken.

So, this issue of systems of delivery is the hard nut to crack here. We cannot dodge it or seniors will not have access to care. It is that simple. Dr. O'Grady and Mr. Jones, if you would like to comment, and then, Dr. Bunn, if you would like to comment, and finally, Mr. Reeb, if you would like to comment, you are welcome to do so.

Dr. O'GRADY. Sure. To start off in terms of thinking about the competitive bidding demo and also where this sort of negotiation and bidding has been done in the past, and is there enough of a track record to have some confidence to move forward? Certainly, CMS has done a good job on this particular demo. They have also followed up to find out whether there was any problem with access, any problem with the quality of care that the beneficiaries received, and they had outside people come in from the University of Wisconsin, and kind of verify what was going on and do the evaluation. That all came back fairly positively.

Broader than that, you are absolutely right that the experiment was on Albuterol. We know that from other public purchasers, as well as private, including FEHBP, that this notion of negotiating prices has certainly gone on for quite a long time. It certainly works well within an integrated setting where you can have this balance, that Mr. Jones talked about. It is also, as Mr. Scully said, with the pre-65 population, the Blue Cross-Blue Shield plans are doing this sort of stuff all the time.

My point would not be that this is only one part of the things to do. Certainly, you have to look at the other part of the issue and make sure that the overall payment makes sense. If it does not make sense, at some point, you will hit some access problems.

So, it is certainly within Medicare's prime set of responsibilities to make sure that they pay fairly, but mostly that is to be because of their responsibility to beneficiaries to protect them, and if they do not get the price right, that will hurt beneficiaries. It is also balancing that protection that they have to provide to taxpayers.

Chairman JOHNSON. It does not bother you that none of the things that they have had experience in competitive bidding with are complicated to deliver, that their experience, in fact, is extremely limited?

Dr. O'GRADY. I think it would be a better experimental design to use some of those drugs that you are talking about and then find out, how much does the price come down?

The one thing I would also like to be quite clear on this is if you look carefully at that report, there are other things that go on there where, after competitive bidding, the price was higher. Now, part of that is back to the point I made about it is very hard in an administered price system to get the price right, different locations, different things. Things change.

Chairman JOHNSON. I appreciate that.

Dr. O'GRADY. So you are trying to pay kind of an accurate price, and this sort of one-size-fits-all approach sometimes overpays, other times underpays. A better situation in a public policy sense would be something that could adapt to change, adapt to different parts of the country, different markets, and take that into account. That is one of the real positive aspects of competitive bidding.

Chairman JOHNSON. Mr. Jones?

Mr. JONES. Prescription Solutions has a number of clients that it serves as a PBM. PacifiCare is the largest of them. We have other clients that are not integrated, and they look for savings when it comes down to injectable drugs, as well.

Because we purchase large amounts of injectable drugs from the manufacturers, we get good prices for all of our clients. The delivery systems in delivering it to a clinic or to physician offices is no different than the drug company would use. We use the same protections in trying to make sure they are shielded from temperature and humidity and all of those things. So, the physician would get the drug product in the clinic similarly as if they ordered it directly, but they would be able to take advantage of our purchasing power.

So, it is really not much different than that. It is just that we get better pricing because we are——

Chairman JOHNSON. Excuse me. I guess I did not quite understand. So you only deal with the drug component? You do not deal with the reimbursement to the physician and the system?

Mr. JONES. In a non-integrated system, you are exactly right. It is the drug alone.

Chairman JOHNSON. Furthermore, because we do also have reports from users in California about problems, would you be happy to work with us on any problems that you have seen develop?

Mr. JONES. Surely.

Chairman JOHNSON. Dr. Bunn?

Dr. BUNN. Thank you for the opportunity. I agree with you entirely. There are issues of quality as well as cost, and, of course, as a physician, we are concerned with quality.

I guess the example that was incited this morning and, I think, your examples were outstanding, of course, was the pharmacist in St. Louis who decided he could make money by diluting the drugs, and certainly the physicians would not feel that a system that allowed that to happen is one that either the Congress or the physicians should support. So, we are certainly not opposed to some competitive system that would ensure quality and that the physician has some control over the quality.

You are also quite right that these agents are mixed and they are toxic, and the way they are mixed and the way they are stored is extremely important. Many of these will become inactive at improper temperatures, with improper shipping or storage. If they show up in a doctor's office overnight express and sit there outside and they need to be refrigerated, obviously, that is not going to work.

So, basically, I think what you said we would reiterate, and I think you said it very well.

Chairman JOHNSON. Dr. Bunn, if we were motivated, could we be using some of the dosages that are left? For instance, if you open something and you use half of it, could we be using the other half for a patient that is also there at the same time if we were allowed by law? Should we be looking at the sheer waste we impose on the system because something was opened?

Dr. BUNN. That example would not be a great thing to be doing, but things could be packaged potentially differently by pharmaceutical manufacturers to optimize the flexibility so as not to have waste. Using the same vial with multiple needle sticks would not probably be the best way to get at that.

Chairman JOHNSON. What about the personnel that are required? The practice expense formula looks at physician work hours, but we have a hard time taking into account non-physician contributions. You mentioned in your statement the highly qualified support staff that clinics depend on. Could you describe that in a little more detail and also some of the equipment and insurance costs that are also part of the practice expense bundle, that if not taken into account, will not enable people to stay in the practice of delivering cancer care?

Dr. BUNN. Right. We believe there have been two fundamental problems with the practice expense side. First of all, there was inadequate data and an inadequate database for which to estimate the true costs. You brought up today, we agree entirely with you that the GAO data is totally flawed and totally inadequate. We agree that the CMS is has also not developed adequate data. We do believe that the Gallup survey now does provide that data.

We also believe, as you alluded to, that there is a flawed methodology for making the calculations that is biased against non-physician work, and it does happen that oncology practices have the largest amount of that. So, we believe that in addition to using the new data provided, both ASCO and the Congress need to work with CMS to develop an adequate methodology to account for those true

expenses, which are the non-physician-related expenses that are largely attributable, like anything, to personnel, largely trained nurses, pharmacists, and other health professionals. Each oncology office has a large number of those.

Chairman JOHNSON. Thank you very much.

Mr. Reeb, would you just clarify for the record, if you know—I am not sure whether you know or not, but has the OIG looked at drugs used in chemotherapy or have the drugs that they have focused on studying been more like Albuterol?

Mr. REEB. We have looked at both oncology drugs and other drugs, but our work has come from the pricing side. We are a problematic looking kind of an agency. The spread that is created with the AWP difference to the acquisition costs, whether it be at a physician's office or whether it be from a Medicaid agency in their program. So, we have not looked—I mean, we have focused on that because the amount of money at stake allows for these kind of situations to develop.

Chairman JOHNSON. You have not done any work on what the cost of the delivery system is and whether it is more or less than the spread?

Mr. REEB. No, ma'am.

Chairman JOHNSON. I mean, it is also conceivable that in some instances, it could be more than the spread, it could be equal to the spread, it could be less than the spread, or it could be a lot less than the spread.

Mr. REEB. Yes, exactly.

Chairman JOHNSON. Okay. Thank you.

Mr. REEB. We have not done work in that area.

Chairman JOHNSON. Mr. Stark?

Mr. STARK. Thank you, Madam Chair. I would like to thank all of our witnesses, in particular Mr. Reeb and Mr. Vito from the OIG, whose work in this area has called our attention to a serious problem that we hopefully can correct and save the government some money. Unfortunately, you do not get a raise. You guys ought to work on commission. You would be better off. We do appreciate and the public will appreciate the work that you do.

Ms. Glaun, the work that you do for beneficiaries also should not go unnoticed, and I am sure that my colleagues in Maryland send their constituents to you frequently and that you are a great deal of assistance. Unfortunately, California is a little long distance for us to refer our constituent service cases to you, but we also appreciate the work that you do in this.

I guess I just have a couple of questions. It seems to me, Dr. Bunn, if you will not mind my putting aside the question of reimbursement for practice expense, I am really not sure that is what this hearing is about. I recognize it as a problem, but aside from yourself, the people here, I think we are dealing more with the cost of the unit of a prescription that your colleagues administer. We do recognize that some of that problem has been exacerbated because of problems with the reimbursement for the professional services that your group renders.

I hope that we can separate that. I hope that we can find an adequate reimbursement, an adequate, fair reimbursement system for the physicians. I hope that we can find an efficient way to get the

best price to which we ought to be entitled from the pharmaceutical industry for our beneficiaries.

I am not even sure it is a dispute or a disagreement, but there seems to be at issue whether or not we should bid for a pharmaceutical, the price of a drug, and then in what form. I do not hear any enthusiastic support for a winner-take-all. Somebody mentioned in the testimony, Dr. O'Grady, that you could underpay. Now, I am missing something. If you are talking about underpaying Dr. Bunn's gang, I am with you. How would you underpay AMGEN for Epoetin alfa (EPO) once you set a price for it? It is the same EPO in Wapakoneta, Ohio, as it is in Oakland, California, is it not?

Dr. O'GRADY. One of the things that can happen here, and I guess the best example I can think of right now is—one of the things involved when CMS tries to do this, that is just a very tough nut for them to crack, is that there is always this lag having to do with the data that they collect. So they are always working from about 2 years behind.

Mr. STARK. Okay——

Dr. O'GRADY. No, but——

Mr. STARK. I am with you, but once you set a price for a pharmaceutical that is in a specially compounded potion, and if you are buying basically branded, ethical prescription drugs, you cannot underpay for it. I mean, you are paying the same price across the country. There is nothing wrong with that, is there?

Dr. O'GRADY. No.

Mr. STARK. Okay.

Dr. O'GRADY. It is not so much that. It is more the idea that the price changes, and you have not taken it into account.

Mr. STARK. All right. I just wanted to—because the question comes up, and Mr. Scully was talking about it, that if you have got a lot of clout, a big purchasing base, you can get a better price than some small clinic in a small State that does not have the market clout to demand a lower price based on volume.

To that end, I would ask Mr. Jones to deal with the issue that was brought up where you find that we can get, what, a 25 percent savings in these, as Mr. Scully pointed out, but we can get almost a 65 or 80 percent savings, a lot more, where we took the actual price. So, why should we not do it with the actual price as long as that dichotomy holds?

Mr. JONES. Our company would try to assess on a regular basis what that actual price is. Because we also buy drugs, we have a pretty good indication of——

Mr. STARK. So we pay based on what you pay, right?

Mr. JONES. They take advantage of that, yes.

Mr. STARK. I mean, that is what I would think. Do you know whether PacifiCare uses more than one PBM to service its beneficiaries?

Mr. JONES. No. It is one PBM. It is ours. We are a subsidiary company of PacifiCare.

Mr. STARK. Even if you were not, would it not be to their advantage to use one? Would they not get better prices by concentrating their buying power in one provider?

Mr. JONES. In this case, almost every year, the question is are we giving PacifiCare the very best deal, and they will actually make us compete against competitors. They will invite people in to check, yes.

Mr. STARK. How many of your other clients—you serve other managed care plans.

Mr. JONES. Yes.

Mr. STARK. How many of them have multiple PBMs?

Mr. JONES. There are a few, not many. Most of them will choose one after a competitive process.

Mr. STARK. Although that is a concern that we have heard here if the government went to bidding, and there are some impracticalities, some people may not be able to serve the entire country, but I am just trying to find out, my sense is that if we do go to bidding, which I am less comfortable with, we do not have a system, that the extreme, the most competitive would be winner-takes-all, would it not? That really would be the toughest competition.

Mr. JONES. If that winner can provide all services——

Mr. STARK. Yes. You hit it right on the head. If they could provide the quality and the coverage for the market.

Mr. JONES. Then there is the issue of ongoing competition. A winner with a long contract may not be that——

Mr. STARK. Then the price goes up and you have knocked the other competitors out of the box, so there is nobody to come up and bid the next time.

Mr. JONES. Yes.

Mr. STARK. That is a good observation, and it further is a problem. I think this is between us and the Committees here and—I still want to say Health Care Financing Administration, I can never remember what their name is now—between CMS, we are going to have to figure out what is a system. It seems that we could go to the actual price now and phase into something else if that worked.

Dr. Bunn, did you want to add something to the discussion?

Dr. BUNN. I think there are a couple of other facts in the drug cost besides what you just mentioned, which is what you pay for. First of all, these drugs have to be given on a very set schedule and they have to be available when the patient is due. If you delay, it is going to decrease the effectiveness.

So, there are several things here that will adversely affect a rural practitioner. Again, you have to have an inventory and you have to have it available at the time. If, for example, the patient progressed or had some toxicity, then you would be stuck with that drug and that drug might go out of date before it could be used in another patient in a rural area. Also, sometimes the pharmacist or the nurse make a mistake and spill the drug. Obviously, this is not often, but that is an added cost. You cannot bill that to somebody else. So, that is sort of a cost of the drug that has to be taken into consideration, as well.

So, I think there are some issues with inventory and wastage and so on that have to be considered in the cost, as well.

Mr. STARK. Keep going. How does that—so I will stipulate to that. Now, what is better, to use an average price across the Na-

tion so that the Marshfield Clinic pays the same amount as Kaiser in Oakland, or do you suggest a different system that would resolve that problem? Finish that up.

Dr. BUNN. Well, I think we all have the same goal, which is come the closest to the actual cost as possible. I am not sure that having an average cost for the entire United States of America would be best, because, obviously, the cost in a physician practice is going to be different, and then you are going to create some huge winners and some huge losers.

Mr. STARK. Can you generalize, and my time is up, but Dr. Bunn, can you generalize for us, in the non-Medicare payers, Blue Cross, whomever, when they reimburse oncologists, do they pay for spillage, wastage, how do you bill there? Is it different from what we have been discussing here? Is there a general standard procedure that the Blues across the country, say, would reimburse your members for non-Medicare payers that is different from what we are talking about today?

Dr. BUNN. Largely not. As you know, government to a certain extent sets standards. I would say in non-Medicare patients, we have some of the same cross-subsidization going on where actually the insurance companies will a bit overpay for the drugs, knowing that practice expenses and spillage and so on are going to be covered by the overage. Again, we do not think that is probably the best way for either the insurance company or the government to be reimbursing.

Mr. STARK. Do they pay you as a percentage of average wholesale or do they negotiate a rate with you, a price for the drug? How is that done?

Dr. BUNN. It is actually variable, but in many instances, it is the same as the government.

Mr. STARK. Thank you. Thank you, Madam Chair.

Chairman JOHNSON. Thank you very much. Congresswoman Thurman?

Mrs. THURMAN. Madam Chairman, a lot of the questions have been asked today. We have kind of exhausted some of this, but maybe you can just help me reemphasize a little bit of this, because one of these competitive bidding areas is now in a new part of the district, so obviously I am going to be more actively involved in the competitive bidding issue.

I would say to Dr. O'Grady, when you talk in your testimony—and if this has already been answered, it is okay, I am just trying to clarify it—recent findings from Medicare's competitive bidding demonstrations for durable medical equipment in which Medicare saved 25 percent over what it would have otherwise paid for one particular drug, Albuterol, based on these findings, you argue that Medicare should undertake competitive bidding. When GAO reported in September 2001 that the average widely available discount from AWP in 1999 for the unit dose form of Albuterol was 85 percent, why should Medicare just accept the savings of only 25 percent when discounts of 85 percent are widely available to us?

Dr. O'GRADY. I think that the difference between the 85 and the 25 percent figure are a big question mark. This was not done in Polk County. This was done over in San Antonio. So, what they did is have a number of bidders who went out and negotiated.

Now, back to Mr. Stark's point, it was not a winner-take-all. It was so that the providers could, or in this case the beneficiaries were choosing this for their nebulizers, could pick between a number of different suppliers, and so it might be price that they pick on or it might be service or availability, things like that.

Now, when they negotiated this, they got 25 percent off the Medicare rate and the GAO guys found 80. I made a note to call GAO and ask them what was going on there, what they thought. Perhaps the folks from the Inspector General have a feel for what might explain that kind of a gap.

Mrs. THURMAN. Mr. Jones, you wanted to respond?

Mr. JONES. Albuterol is a good example of a drug that changes dramatically. If you bid, the product can fall in price fairly dramatically. So you can bid here and it falls down here, and your bid is still in effect.

These drugs change often, dropping by 80 percent over a 6-month time period once the patent expires and various competitors come onto the scene and produce it generically, and it is not uncommon for drugs to drop that rapidly. It makes us quickly take notice and try to adjust, and it is one of the issues of how you establish your contracts, can you take advantage of those pricing drops.

I empathize in doing a pilot in trying to get a window in time on the costs of things. It is difficult to do.

Mrs. THURMAN. Mr. Reeb, do you have anything to add to that?

Mr. VITO. Yes, ma'am. I believe that the price of Albuterol that we were able to track over time has dropped significantly, yet the AWP has remained the same. That is why the Medicare Program has continued to pay that amount of money, because they base their reimbursement on AWPs, not on the acquisition costs that people were able to get the product for.

Mrs. THURMAN. Dr. Bunn, I also am concerned with what happens to some—we have a lot of larger areas, and then, quite frankly, what I am seeing out there is that there actually are larger cancer centers now than there have been in the past. I am curious of how smaller groups or sole practitioners actually purchase their medicines, and how do we give them the opportunity to participate in any of this? It is a real concern when you have a lot of rural areas around. How do they do it? What happens to them? Do we end up losing some folks and not giving them the care because of this?

Mr. JONES. I have experienced both in rural and urban areas. I have lived most of my life in rural areas, and I have lived the last 30 years in urban areas. We have buying groups that are available to small pharmacies and mom-and-pop stores as well as the mega-chains that have their own buying structure. It is not impossible for smaller pharmacies to aggregate and get better pricing.

Mrs. THURMAN. Ms. Glaun, did you want to add to that? You looked like you were——

Ms. GLAUN. No.

Mrs. THURMAN. Okay. My time is up, but we thank you all and, hopefully, we can all sit down and work some of this out together. Always remember, it is about the patient and us on this end who have to worry about the taxpayers.

Chairman JOHNSON. I thank the panel very much. That was very interesting, Mr. Jones, the varied sizes of buying groups within the same structure. Perhaps we will follow up on that later.

Thank you all very much for your testimony. I appreciate it. I do believe that this is a problem that needs to be addressed, that with adequate data and with a good methodology and with a legal structure that guarantees that we will be able to use the savings to reimburse practice costs, we should be able to save the taxpayers really a dramatic number of dollars and make Medicare more efficient and also a better program to serve our seniors. Thank you.

Finally, I would like to include in the record a statement submitted by Laura Thevenot, Executive Director of the American Society for Therapeutic Radiology and Oncology, Incorporated.

[The statement of Ms. Thevenot follows:]

Statement of Laura Thevenot, Executive Director, American Society for Therapeutic Radiology and Oncology, Inc.

Introduction and Summary

The American Society for Therapeutic Radiology and Oncology, Inc. ("ASTRO") is a professional organization of more than 7,000 members, including physicians (radiation oncologists), radiation scientists (radiobiologists, radiological physicists), radiation therapy technologists and radiation oncology nurses. These specialists comprise the expert medical team that uses radiation to treat patients with cancer. Radiation therapy is recognized as one of the most effective methods of treating cancer and other diseases. Between 50 and 60 percent of cancer patients are treated with radiation at some time during the course of their disease. ASTRO's Membership represents community cancer centers and hospitals as well as major education and research centers from the U.S. and around the world. ASTRO publishes the leading scientific journal in radiation oncology in the world.

ASTRO commends the Subcommittee on Health for examining issues related to Medicare payments for those prescription drugs that are currently covered by Medicare. However, ASTRO is concerned that proposals to revise Medicare's payment methodology for drugs, and to more properly reimburse medical oncologists for the practice expenses [1] involved in the administration of cancer drugs, may have an unintended and adverse impact on continued patient access to high-quality radiation oncology services. While we agree that there are weaknesses in Medicare's system for reimbursing medical oncology services, we are concerned about the potential unintended consequences of correcting these problems. We request that Congress include appropriate statutory language to ensure that payment for radiation oncology services and other similarly impacted services are not reduced as a result of efforts to ensure appropriate payment for medical oncology services.

Background

Medicare's method for determining payments for practice expenses for physicians' services is extremely complex. In addition to the specialty-specific payment "pools" that exist under the Medicare payment system, there is a pool reserved for a group of technical component-only services (i.e. services for which there is no physician work component) provided by a number of different specialties. Many of the medical oncologists' procedures reside in this so-called "zero work pool" ("ZWP"), along with other capital-intensive procedures for specialties such as radiation oncology, diagnostic radiology, cardiology and others. In 2002, services in the ZWP experienced a 4–6% cut in practice expense payments due to relatively minor shifts in the mix of services shown in the utilization data. These cuts, combined with the 5.4% cut in the conversion factor for 2002, equaled a 10% or greater loss in reimbursement for those services. Since publication of the 2002 Physician Fee Schedule, we have worked with other specialties and with the Centers for Medicare & Medicaid Services ("CMS") to determine why these losses occurred, and to ensure that similar cuts do not occur again in the future.

It is our understanding that Congress may consider changing the way that drugs, including chemotherapy drugs, are reimbursed. In addition, we understand that the

[1] Practice expenses include the provision of facilities, equipment, supplies and non-physician personnel. For radiation oncology, these services include radiation therapy delivery, and services with substantial amounts of resource-intensive physicist time.

practice expense payment methodology for chemotherapy administration is being examined. Related to this review is a proposal for modifying the practice expense payment methodology for chemotherapy administration. This proposal, if adopted, would effectively remove chemotherapy administration from the ZWP. As previously stated, the mix of services in the pool, which changes based on each year's utilization data, significantly affects the amount of money allocated to the entire pool. Since chemotherapy administration is among the most frequently performed services in the ZWP, the removal of these services would have a significant, negative impact on the remaining specialties in the pool.

Request for Congressional Assistance

For radiation oncology, technical component services are the foundation of our work. In addition to physician planning and management, the care we provide to cancer patients is heavily dependent on the skilled services of medical physicists, dosimetrists and radiation therapists, whose codes in the ZWP have been hit especially hard. The decreased Medicare payments—compounded by decreases from many insurers that base their payments on the Medicare Fee Schedule—will adversely affect our ability to maintain critical staff and to provide therapy using the advanced technology that is now available. In the long term, without sufficient practice expense reimbursement, future research and development will slow as device manufacturers see that their customers are unable to afford their products. The net effect of all these cutbacks will be reduced access to quality care by cancer patients. These problems must not be exacerbated by inadvertent reductions that could result from revisions in payment methodology for medical oncology services.

ASTRO requests that if Congress decides to enact legislation that addresses the practice expense payments for chemotherapy administration, that it do so in a manner that protects the practice expense payments for all medical services remaining in the ZWP, including radiation oncology, from further inappropriate reductions.

Chairman JOHNSON. The hearing is adjourned.

[Whereupon, at 12:49 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

STATEMENT OF THE AMERICAN ASSOCIATION FOR HOMECARE

The American Association for Homecare (AAHomecare) submits the following testimony on the Pricing Mechanisms for Drugs Covered Under the Medicare Program to the Subcommittee on Health of the Committee of Ways and Means. AAHomecare represents home health agencies and suppliers of durable medical equipment (DME), supplies and services. AAHomecare members represent every segment of the homecare community, including suppliers that furnish infusion and inhalation therapies to Medicare beneficiaries in their homes.

Under the Balanced Budget Act (BBA) of 1997, Congress established payment for Medicare covered drugs at 95% percent of the average wholesale price (AWP) for the drug. A drug's AWP is set by the manufacturer and published in compendia of drug prices produced by a number of companies. Medicare carriers use the prices published in the compendia to calculate drug payments. This payment methodology has been criticized recently because there can be a wide spread between the drug's AWP and the price a physician or supplier pays to acquire the drug. While AWP may not be an ideal methodology for Medicare Part B drug payments, AWP payments for the drugs used in home infusion and home inhalation therapies cover the cost of services necessary to furnish these therapies safely and effectively in the home. Because Medicare does not otherwise reimburse suppliers for the costs of these services, this payment system has permitted beneficiaries to receive quality infusion and inhalation therapies in their homes.

Current Medicare policy limits payment for infusion and inhalation therapies to what is covered and paid for under the DME benefit. This means that the Medicare program does not explicitly reimburse homecare pharmacies for the array of services necessary to furnish these therapies safely and effectively to patients in their homes. This is in contrast to the way private sector health plans typically define and pay for these therapies. Typically, private sector plans make separate payments for the drug and non-drug components of the therapy. The private sector has embraced home infusion and inhalation therapies, recognizing the patient care benefits and significant savings that accrue from moving care to non-acute settings and preventing otherwise predictable hospitalizations.

A change in the way Medicare pays for covered drugs will require a corresponding change in how these medically necessary services and functions are paid for. Trim-

ming drug payments back without providing for separate payment for those activities that, until now, have been subsidized by the drug payment would be an unwise policy that may have potentially grave consequences for Medicare beneficiaries.

A Revision To AWP Drug Payments Must Include Payment For The Service Costs Of Furnishing Inhalation And Infusion Therapies To Beneficiaries In Their Homes

There is no question that there can be a large spread between the AWP and acquisition costs of drugs used in homecare. However, the acquisition cost of the drug is only a small part of the costs that homecare pharmacies incur in furnishing inhalation and home infusion therapies to Medicare beneficiaries in their homes. Medicare policy limits coverage and payment for these therapies to only the drugs, equipment, and supplies that are used in the therapy. In actuality, however, inhalation and infusion therapies furnished to patients at home involve far more than simply the delivery of drugs, supplies, and equipment to a patient. Provided safely and properly, these therapies require an array of services and ancillary functions provided by trained health professionals. While not separately paid for by the Medicare program, these services and functions are reimbursed in large part through the payments for the drugs, supplies, and equipment. The drug payment in particular subsidizes these services and functions.

In 2001, the American Association for Homecare commissioned a study by the Lewin Group, "Product and Service Cost of Providing Respiratory and Infusion Therapies to Medicare Patients in the Home." The study included statistically valid data from 19 homecare pharmacies of varying sizes and geographic locations. The Lewin study found that the acquisition cost of drugs used in inhalation and infusion therapies represented only 26 percent of the total costs of caring for Medicare beneficiaries. The remaining 74 percent of the total costs were comprised of clinical and administrative labor, billing and collection costs, indirect or overhead costs, inventory/warehouse/delivery expenses and bad debt. These functions and costs clearly are subsidized by the drug payment.

Importantly, these staff and administrative expenses are legitimate clinical and operating costs that are generally recognized by Medicare for providers in other care settings. Direct patient services for home infusion and inhalation therapies include patient evaluation and monitoring and compounding and dispensing drugs and solutions. These therapies require specialized pharmacy services, and pharmacies must have staff available to respond to emergencies and questions regarding therapy. Pharmacies also provide training and education to the patient (and often the patient's family). Inhalation and infusion therapies also require the services of a nurse or respiratory therapist to perform a variety of functions, including patient screening and assessment, patient training regarding the administration of the pharmaceuticals, and general monitoring of the patient's health status. The pharmaceuticals, equipment, and supplies are delivered to the patient's home. Finally, staff, including licensed pharmacists, pharmacy technicians, respiratory therapists, and registered nurses are on call 24 hours a day. We describe these patient care services and administrative expenses more fully below.

Direct Patient Services For Home Infusion And Inhalation Therapies

Patient Evaluation

Initial patient intake is an important component for both inhalation and infusion therapies. The pharmacy must collect information on the clinical status of the patient and assess the potential for drug interactions. For home infusion and inhalation therapies, the patient evaluation is usually based on clinical information obtained from the nurse's assessments, communications with the physician and patient, the physician's orders, analysis of laboratory test results and other pertinent clinical information. Sometimes, the pharmacist will visit an infusion therapy patient, particularly if he or she has the appropriate clinical training and experience.

As therapy proceeds, the pharmacist's findings and recommendations are communicated at intervals to the physician, nurse, and other professionals involved in the care of the patient. Interdisciplinary communication occurs at team conferences and as needed throughout the course of home treatment. Detailed information about the patient's compliance with and response to the prescribed treatment regimen is documented in the database the pharmacist maintains for each patient. Therapy goals are updated periodically and modifications are communicated to other caregivers. The pharmacist also obtains laboratory and other data on the patient from the physician or other sources and adds these data to the clinical monitoring file on the patient.

Compounding and Dispensing Drugs and Solutions

Before filling an order for an infusion or inhalation patient, the pharmacist gathers information about the patient's medical history, reviews and updates the patient's medication profile, examines the attending physician's orders for new or continuing prescriptions, prepares computations needed for processing orders for drugs or equipment, and, if necessary, telephones the patient to answer questions and schedule deliveries.

Home infusion drugs and solutions must be prepared under environmentally controlled conditions, as mandated by various regulatory and accreditation agencies. Sterile admixtures are prepared in a Class 100 clean air environment, using aseptic techniques. Final documents are subject to routine quality control procedures designed to insure the accuracy of the preparations, product integrity, and sterility. Depending on the pharmacy's volume of business and applicable legal restrictions, trained pharmacy technicians may prepare drugs under a pharmacist's supervision.

Each patient's prescription is filled in quantities and at intervals sufficient for continuous service. Frequency of drug preparation depends on several factors, including expected duration of treatment, frequency of dose administration, home delivery schedules, drug stability or shelf-life, and patient stability. The average time required to compound, dispense, assemble, and package a patient's order depends, in part, on the number of doses in an order, the quantity of each dose, the number of compounded doses per delivery, the volume and number of ingredients and the complexity of compounding.

An order for a medication may be filled in single or multiple doses. Where the patient base is large, a pharmacy technician may perform related tasks under a pharmacist's supervision, if state law permits. If a pharmacy's volume is small, the pharmacist typically performs all tasks needed to compound and dispense drugs.

Patient Monitoring

Appropriate clinical monitoring is essential to ensure the safe administration of home infusion and inhalation drugs. With respect to inhalation therapies in particular, monitoring patient compliance is essential to achieve therapeutic effectiveness. Homecare pharmacies maintain ongoing programs to oversee patients' compliance and to ensure that patients receive appropriate refills of their prescriptions.

As with any other type of medical care, complications may result from infusion therapy. If these complications are not recognized and addressed in a timely manner, serious injury and even death may occur. Ongoing clinical monitoring is therefore essential to minimize or prevent complications associated with infusion therapy and to optimize desirable outcomes. Nurses and pharmacists must be adept in identifying the signs and symptoms of the infectious, metabolic, physiological, and psychosocial complications that can occur, and in managing them.

Throughout the course of therapy, and particularly after a nursing visit, the pharmacist reviews an infusion patient's clinical information collected by the nurse, discusses the findings with the attending physician, assesses the continuing appropriateness of the current medication schedule, participates in multidisciplinary patient care conferences to examine the patient's progress and to establish future goals, and communicates with the patient's other caregivers regarding the patient's compliance and progress. Clinical monitoring activities also include establishing testing and monitoring schedules, reviewing laboratory findings, evaluating any identified problems that may have occurred, and developing corrective action plans.

Administrative And Support Services For Home Infusion And Inhalation Therapies

There are significant direct and indirect administrative and support services that impact the quality of patient care. Home infusion and inhalation therapies cannot be coordinated and delivered effectively without adequate administrative and support personnel. Many of these requirements are established by licensing boards, accrediting bodies, private insurance plans, and Federal and state health programs. Other activities are simply part of managing and operating any health care entity. Examples of administrative and support services include quality improvement programs, utilization review, medical records management, coordination of insurance benefits, claims processing, medical waste management, personnel management, inventory control, orientation programs for new employees, and clinical development and education programs for management and staff.

Accreditation, for example, is an indirect cost that affects the quality of care delivered by homecare suppliers and providers. Accredited companies must meet quality standards for patient care and business functions in order to maintain accreditation. Accreditation offers the public the assurance that an accredited company meets or exceeds an objectively verifiable standard of care. It will be a setback for Medicare

beneficiaries if Medicare reimbursement does not adequately reimburse providers and suppliers for the cost of meeting quality standards. If accreditation costs are ignored by Medicare, Medicare beneficiaries will receive a lower standard of care than individuals enrolled in private sector health plans. In addition to accreditation, there are costs associated with complying with state licensure and professional board requirements.

Homecare pharmacies also incur significant costs in complying with Medicare program rules, especially those pertaining to billing and documentation. These include, among others, the following:

- Accumulating documentation to support claims for services
- Preparation of claims
- Communication with physicians regarding completion of certificates of medical necessity and other documents required by the program of physicians.
- Communication with carriers regarding claims and documentation
- Participating in medical review process with carriers on particular claims
- Delays in payment from the program

It is worthwhile to note that both the General Accounting Office (GAO) and the Office of Inspector General (OIG) for the Department of Health and Human Services have acknowledged that the costs of complying with Medicare program rules are higher than the costs of compliance for other government and private payers [1] In a comparison of payments for home oxygen therapy by Medicare and the Veterans Administration (VA), the GAO concluded that Medicare's documentation and other administrative requirements warranted a 30% higher payment for oxygen. The GAO also acknowledged that CMS must account for the costs of the services necessary to furnish Medicare covered items when performing inherent reasonableness reductions. Similarly, the OIG concluded that the higher costs of complying with Medicare program rules could justify charging Medicare more than other private or government payers.

Utilization For Drugs Used In Inhalation Therapies Is Directly Related To The Increase In The Number Of Patients With Chronic Obstructive Pulmonary Disease (COPD)

It has been suggested that the increase in the utilization of drugs used in inhalation therapies is related to the difference between the drugs' acquisition costs and the AWP for the drugs. It is important to remember that physicians—not homecare pharmacies—prescribe these medications. It is likewise crucial to consider the broad demographics of the patient population that receives these drugs.

Patients who require inhalation therapy suffer from chronic obstructive pulmonary disease (COPD). According to a report recently released by the National Institutes of Health [2], COPD is the fourth leading cause of death in the United States, and, of all leading causes of death in the United States, the incidence of COPD continues to rise. Death rates from COPD increased 22% in the last ten years. The number of patients with COPD doubled in the last 25 years, along with expenses related to the disease. Between 1985 and 1995, for example, the number of physician visits for COPD increased from 9.3 million to 16 million. The number of hospitalizations for COPD in 1995 was estimated to be 500,000. Medical expenditures for COPD in 1995 amounted to $14.7 billion.

Inhalation drug therapy plays a critical role in the management and stabilization of COPD. COPD patients are diagnosed earlier and placed on these medications sooner to stabilize their symptoms and, as a result, reduce other medical expenses, such as repeat hospitalizations and physician visits, that are associated with the disease. The use of two respiratory medications, Ipatropium Bromide and Albuterol Sulfate, individually and in combination are widely supported in the clinical literature. The costs of treating these patients with inhalation therapy are modest, especially in light of the potential for a reduction of other health care expenses for this population.

Finally, respiratory drugs are for a chronic, ultimately fatal illness that requires daily drug therapy to help people with COPD avoid exacerbations. Many of these individuals remain on these medications for the remainder of their lives. As COPD

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[1] Letter dated May 15, 1997, Re: Comparison of Medicare and VA Payment Rates for Home Oxygen, from William Scanlon, Director, Health Financing and Systems Issues, GAO to William Roth, Chairman Committee on Finance, United State Senate; Medicare Payments Use of Revised "Inherent Reasonableness" Process Generally Appropriate, GAO/HEHS–00–79, July 2000; OIG Advisory Opinion 98–8.

[2] GOLD Initiative For Chronic Obstructive Pulmonary Disease, April 2001.

progresses, the number of treatments per patient increases, accounting for the higher volume for these drugs.

Conclusion

A comprehensive analysis of the services necessary to safely furnish inhalation and infusion therapies to beneficiaries in their homes must be part of any proposal to revise drug payments. Medicare payment for covered drugs should not be changed without providing a mechanism for Medicare to cover and pay for those services. For any reduction in payment for covered drugs, there must be a corresponding payment for the services required to furnish inhalation and infusion therapies in the home. We remain willing to work with Congress and the Centers for Medicare and Medicaid Services to develop an appropriate mechanism to accomplish this important objective. For additional information, contact Asela M. Cuervo, 703–836–6263.

Statement of the American College of Rheumatology

Introduction

The American College of Rheumatology (ACR) is an organization of physicians, health professionals, and scientists that serves its members through programs of education, research, and advocacy that foster excellence in the care of people with arthritis, rheumatic and musculoskeletal diseases. Arthritis means swelling, pain and loss of motion in the joints of the body. There are more than 100 rheumatic diseases that cause this condition that can sometimes be fatal—in both children and adults of all ages. These chronic diseases cause life long pain and disability.

Arthritis is the leading cause of disability in the United States, affecting approximately forty-three million Americans. Arthritis has been found to rank first among the ten leading health problems of individuals age 50 and older. By the year 2020, the prevalence of arthritis will increase to an estimated 60 million Americans. The provision of care to people who are disabled contributes significantly to the financial costs paid by the government, private insurers, and to society as a whole. More than $65 billion are spent yearly due to medical costs and lost productivity associated with arthritis and related diseases each year.

ACR appreciates the opportunity to provide written testimony to the Ways and Means Health Subcommittee, and our organization is available as resource to the Subcommittee as it continues its review of the issues surrounding the current pricing methodology for Medicare Part B covered drugs and the possible downstream effects of reform in this area. The College's testimony will discuss the potential impact of pricing revisions that are implemented without corresponding adjustments accounting for the costs of administering these services. Within that framework, the focus of our testimony will be the profoundly life-improving infusion therapy services provided by rheumatologists to many Medicare beneficiaries with arthritis and related diseases.

Discussion

The College emphatically believes that physicians should be adequately reimbursed by Medicare and private payers to a degree that covers all costs associated with care and allows for reasonable payment to physicians, in keeping with the underlying philosophy of the resource-based relative value system that is the basis for reimbursement in the Medicare program. However, current reimbursement levels for infusion therapy services are based on pre-1998 data. Therefore, reimbursements for newer therapies often do not reflect the complexity, risks, and true practice expenses associated with their administration. The lack of adequate compensation will only increase as additional biologics complete clinical trials and are approved for use.

In the current payment methodology, the College recognizes that payments to physicians for the purchase and administration of drugs subsidize physician practices in many cases where adequate practice expenses are not being reimbursed. Much of the current debate relates specifically to infusion therapies.

A change to the drug reimbursement policy that does not reflect the needs of practitioners to meet their costs and receive reasonable compensation for their services will force some physicians to stop offering infusion services to Medicare patients, which will limit patients' access to valuable, life-affecting therapies. If physicians cannot offer these therapies, patients may be referred to hospitals and academic medical centers—institutions that may not be equipped to handle the increased demand and to whom significantly higher reimbursements will be provided through Medicare.

Further, the College is concerned that proposed methodological adjustments intended to address shortfalls in practice expense reimbursement subsequent to the implementation of pricing revisions may be directed toward specific specialties or categories of services. We therefore urge Congress to examine the entire universe of disease groups and specialties that might be affected by such methodological revisions to ensure that broad categories of patient populations and provider groups, such as those with arthritis and related diseases and the rheumatologists who treat them, are not adversely affected by such a change.

Recommendations

In recognition of these facts, and for the overall purpose of assuring that patients will continue to have access to the best available therapies, the College believes that policymakers in Congress within the Ways and Means Health Subcommittee and beyond should:

- Aggressively support those payment methodologies that allow physicians to be paid at a reasonable level for their services;
- Oppose payment methodologies that rely on outdated or incomplete data to calculate reasonable payment levels;
- Advocate for coverage of all competitive treatment methodologies, regardless of their route or frequency of administration;
- Ensure that any methodological revisions apply to all affected disease groups and specialties.

Conclusion

The ACR commends the Ways and Means Health Subcommittee for addressing issues surrounding the quality of care delivered to Medicare beneficiaries, with particular emphasis on patients with arthritis and related diseases. We appreciate the opportunity to provide input to your efforts, and look forward to working collaboratively with the Congress to advance the goal of comprehensive health care delivery within the Medicare program and appropriate and fair payment for Medicare providers.

Statement of Timothy M. Bateman, M.D., Chairman, Government Relations Committee, American Society of Nuclear Cardiology, Kansas City, Missouri

The American Society of Nuclear Cardiology (ASNC), a 4,500 member professional society dedicated to education and quality clinical excellence in the delivery of nuclear cardiology services, is pleased to submit its views on proposals to revise Medicare's payment methodology for drugs being considered by the Ways and Means Health Subcommittee.

ASNC believes that solutions proposed for reforming practice expense reimbursement in administering cancer drugs may have an unintended, extremely severe adverse impact on continued patient access to many important services. The Society is particularly concerned that many patients who need diagnostic tests for cardiovascular disease may not receive those tests resulting in the unnecessary expenditure of millions of dollars at a later date. Heart disease remains the leading killer of both men and women. Testing by nuclear cardiologists to ascertain the existence of cardiovascular artery disease has led to reduced incidences of death from heart disease. This progress could be reversed by unwise legislative decisions. The Society is particularly concerned that while the subcommittee corrects one problem, it could create unintended burdens for many specialties including nuclear cardiology. ASNC requests that the Ways and Means Health Subcommittee include statutory language in any legislation it approves related to a readjustment of practice expense payments to physicians that would ensure that payments for services with no physician work component ("Zero Work Pool" services) are not reduced as a result of the subcommittee's action related to the adjustment of practice expense payments for medical oncology services.

Medicare's method for determining payments for practice expenses for physicians' services is extremely complex. In addition to the specialty-specific payment "pools" that exist under the Medicare payment system, there is a pool reserved for a group of technical component-only services (i.e. services for which there is no physician work component) provided by a number of different specialties. Many of the medical oncologists' procedures reside in this so-called "Zero Work Pool" (ZWP), along with other capital-intensive procedures for specialties such as diagnostic radiology, radiation oncology, nuclear cardiology, nuclear medicine, echocardiography, and others. In 2002, services in the ZWP experienced a 4–6 percent cut in practice expense payments due to relatively minor shifts in the mix of services shown in the utilization data. These cuts, combined with the 5.4 percent reduction in the conversion factor

for 2002, equaled a 10 percent or greater loss in reimbursement for those services. Since publication of the 2002 Physician Fee Schedule, specialties affected by these cuts have worked together, and with the Centers for Medicare & Medicaid Services (CMS), to determine why the losses occurred, and to ensure that similar cuts do not occur again in the future.

Today's hearing examines proposals for changing methodologies of reimbursing chemotherapy drugs and practice expense payment methodology for chemotherapy administration. Should the subcommittee modify the practice expense payment methodology for chemotherapy administration, clinical oncology services could be removed from the ZWP. This modification potentially could have a devastating impact on those specialties that remain in the ZWP. The mix of services in the pool which changes based on each year's utilization data, significantly affects the amount of money allocated to the entire pool. ***Since chemotherapy administration is among the most frequently performed services in the ZWP, the removal of these services would have a significant negative impact on the remaining specialties in the pool.***

Technical component services are the foundation of many of the specialties in the ZWP. The decreased Medicare payments—compounded by decreases from many insurers that base their payments on the Medicare Fee Schedule—will adversely affect the ability to provide care using the newest and most advanced technology to detect CAD that is now available. In the long term, without sufficient practice expense reimbursement, future research and development will slow as pharmaceutical and device manufacturers see that their customers are unable to afford their products. The net effect of all these cutbacks will be reduced patient access to quality care. These problems must not be exacerbated by inadvertent reductions that could result from revisions in payment methodology for medical oncology services.

The American Society of Nuclear Cardiology requests that should the Ways and Means Health Subcommittee address practice expense payments for chemotherapy administration legislatively, that it do so in a manner that protects the practice expense payments for all medical services remaining in the ZWP from further inappropriate reductions.

Statement of Peter Blitzer, M.D., President, Association of Freestanding Radiation Oncology Centers

My name is Dr. Peter Blitzer, and I am the President of the Association of Freestanding Radiation Oncology Centers (AFROC). We are a national association representing over 150 freestanding radiation oncology centers throughout the country, dedicated to the conduct of high quality radiation oncology services in non-hospital settings. On behalf of our members, I would like to thank Chairman Nancy Johnson, Ranking Member Pete Stark, and the entire Ways & Means Health Subcommittee for allowing AFROC to submit this testimony concerning the issue of the Medicare program's use of average wholesale price (AWP) in determining reimbursement rates for prescription drugs, particularly as it relates to the field of medical oncology.

AFROC is concerned that certain proposals in Congress aimed at revising Medicare reimbursement rates for practice expenses associated with the administration of oncology drugs by medical oncologists may have an unintended and disproportionate impact on radiation oncology services provided in freestanding centers to cancer patients. We request that, in implementing and enacting legislation aimed at changing current reimbursement policies in this area, Congress include appropriate statutory language to ensure that radiation oncology and other highly capital intensive services are not subjected to unintended consequences that may arise from the effort to ensure appropriate payment for medical oncology services.

Medicare payments for practice expenses associated with the provision of radiation oncology, medical oncology, and other highly resource intensive services ("technical component services" [1]) are reimbursed under the Physician Fee Schedule and are subject to a special payment methodology—the "zero work pool" (ZWP) methodology. The ZWP methodology essentially groups all technical component and certain other services into the same "pool" for Medicare payment purposes. Due to the structure of the overall "pool" of services, should Congress seek to modify the reimbursement methodologies for some of the services in the "pool" (e.g., chemotherapy

[1] "Technical component services" are comprised of the provision of facilities, equipment, supplies, and non-physician personnel. These services differ from "professional component services," which are primarily comprised of physician work.

administration), such a modification could potentially have an unintended impact on other ZWP services (e.g., radiation oncology technical component services).

A case in point is this year's Medicare payment levels for ZWP services, which were reduced by approximately 4% as a result of relatively minor adjustments in the "mix" of services in the pool. Because of this reduction, budget neutrality adjustments, and the 5.4% reduction in the Medicare conversion factor, Medicare payment for radiation oncology technical component services was reduced by a devastating 9%–12% this year. AFROC has been working with the Centers for Medicare & Medicaid Services to ensure that any future adjustments to the utilization "mix" in the ZWP do not result in further unintended payment reductions for technical component services.

It is our understanding that Congress is currently considering modifying the Medicare payment methodology for reimbursing medical oncologists and others for drugs furnished "incident to" physician services. In conjunction with its consideration of this issue, it is also our understanding that Congress is considering whether medical oncologists who administer oncology drugs in their offices are appropriately reimbursed for their practice expenses. Indeed, proposals already have been made to significantly modify the methodology used to determine payment for medical oncologist's practice expenses.

AFROC is not in a position to comment on Medicare payment for oncology drugs or the cost of administering these drugs. However, AFROC is concerned that if chemotherapy administration services are removed from the ZWP methodology or if other steps are taken to establish a special payment methodology for these services, there may be a significant, unintended and disproportionate impact on radiation oncology and other services that remain in the ZWP.

As freestanding radiation oncology centers have already discovered this year, even relatively minor adjustments in the "mix" of ZWP services can dramatically affect Medicare payment levels for all services in the pool. Since chemotherapy administration services are among the most frequently performed services in the pool, any adjustment to the payment methodology applicable to these services may have an extraordinary impact on radiation oncology and other ZWP services, unless CMS is directed to implement any modifications in the payment methodology applicable to chemotherapy administration in a manner that does not have a disproportionate impact on ZWP services.

To that end, AFROC requests that if Congress pursues legislation aimed at addressing the practice expenses of medical oncologists for the administration of oncology drugs, it do so in a manner that does not disproportionately affect radiation oncology or other ZWP services. In the event that such legislation is pursued, AFROC would welcome the opportunity to work with you to craft appropriate statutory language that meets the goals of your policy objectives while guarding against any unintended consequences that may arise.

Statement of the National Alliance for Infusion Therapy, and the National Home Infusion Association, Alexandria, Virginia

The National Alliance for Infusion Therapy (NAIT) and the National Home Infusion Association (NHIA)—representing providers and manufacturers of home infusion drug therapy supplies, equipment and services—submits this statement for the hearing record for consideration by the Subcommittee of Health.

Home Infusion Drug Therapy

Home infusion drug therapy involves the administration of a drug through a needle or catheter. Typically, infusion drug therapy involves the full clinical management of patient care for those who require a drug therapy that is administered intravenously. It may also involve situations where drugs are provided through other parenteral (non-oral) routes. Infusion drug therapies are used only when less invasive means of drug administration are clinically unacceptable or less effective. Medications are administered by infusion only upon the prescription of a treating physician.

A team of clinical pharmacists, high-tech infusion nurses, patient service representatives and delivery and reimbursement professionals support patients and their caregivers throughout the treatment process. The services provided by the team are inextricably linked to the therapies and are often mandated by accrediting bodies whose standards ensure quality of care outside of the hospital setting, as well as by the professional standards of practice of the American Society of Health-System Pharmacists and the Intravenous Nurses Society. Due to the extremely sen-

sitive and invasive nature of infusion therapies, the standards of practice are some of the most rigorous in the practice of pharmacy and nursing.

This high level of practice standards is also echoed in the facility requirements for the provision of home infusion drug therapies. Home infusion drug therapies must be prepared in high-tech, stringently controlled environments. Due to the nature of these therapies, in many cases the quality assurance standards even exceed hospital inpatient facility standards for preparation of intravenous medications.

In short, the professional pharmacy services, supportive staff infrastructure and practice expenses required to ensure the safe and effective administration of infusion therapies are extensive. Despite this extensive clinical infrastructure, home infusion drug therapy provides a safe, patient-preferred and extremely cost-effective alternative to inpatient treatment.

Medicare Coverage and Payment for Home Infusion Drug Therapy

Providers and suppliers of infusion drug therapies in the home setting are not paid separately by Medicare for the critical services and practice expenses described above. Medicare does not have a separate benefit for infusion therapy, but instead, infusion drugs provided in the home setting are covered exclusively under Medicare's benefit for durable medical equipment. The only items that are explicitly covered and reimbursed under this limited benefit are the drugs, equipment and supplies. Unlike other health care professionals who administer infusion and injectable drugs currently covered under Medicare Part B, providers and suppliers of home infusion drug therapies do not have a mechanism under Medicare that provides them with reimbursement for the services and facilities necessary to provide these therapies.

This is an extremely important point for policymakers to consider as they seek to reform outpatient drug reimbursement. Since the Medicare program does not explicitly reimburse pharmacists for their practice expenses and professional services (including such home infusion services as compounding), pharmacists currently are "paid" for these costs and functions primarily through reimbursement for the drugs. Similarly, Medicare does not explicitly pay for nursing services provided by infusion therapy providers. A nurse performs many functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals and general monitoring of the patient's health status. To the extent that Medicare reimburses for such services, it is largely through the drug payment. As explained in greater detail below, reductions in drug payments must be accompanied by a contemporaneous re-allocation of payment for these necessary professional services. If drug payments are reduced drastically without such a re-allocation, Medicare beneficiaries will not be able to receive home infusion drug therapy because the costs of therapy will exceed by a large margin the available reimbursement for the therapy.

It is important to emphasize that none of the specialized pharmacy services are covered under any other Medicare benefit. In a minority of cases, Medicare home infusion patients may meet the "homebound" requirement and qualify for the home health benefit. In such instances, the nursing services described above might be covered under that benefit. For all other Medicare home infusion patients, the nursing services are not covered by the home health benefit. Likewise, the home health benefit does not cover the provision of drugs.

In contrast to Medicare, private sector insurance plans and private managed care plans have embraced home infusion drug therapy over the course of the last two decades, and commercially insured patients represent 70 to 80 percent of home infusion drug therapy patients. The private managed care community has recognized that infusion therapy administered in the home is a tremendous source of cost-savings, and the private sector provides coverage for a growing list of infusion therapies.

Private sector health plans and payers typically recognize the professional services and practice expenses necessary to provide infusion drug therapy in the outpatient setting through a separate "per diem" reimbursement that is paid for each day the patient is receiving therapy. This per diem payment is made in addition to the cost of the drug and nursing visit.

As home infusion drug therapy has become a staple of major medical coverage in the private sector, Medicare's refusal to see these therapies as anything other than the delivery of supplies and equipment is crossing a line from poor policy to surreal. Despite the uncontradicted and overwhelming evidence of the clinical need for these services, the Medicare program persists in defining these multifaceted drug therapies as requiring no greater effort than is involved in the delivery of a walker or wheelchair. Unless Medicare's coverage of these therapies is brought into line with the private sector, Medicare beneficiaries ultimately will suffer in two important

ways. If the provision of therapy becomes limited to what Medicare actually covers, then the beneficiaries will suffer from seriously reduced levels of care. Or, more likely, suppliers will simply cease providing care to Medicare beneficiaries to avoid the consequences of providing substandard care.

Reliance on AWP to Calculate Reimbursement

NAIT and NHIA understand the criticism expressed by Members of this Subcommittee, as well as other Members of Congress, regarding the current practice of relying on average wholesale price (AWP) as a basis for calculating Medicare and Medicaid outpatient drug reimbursement. The imperfections of the AWP methodology are well-known and extensively documented.

It should be noted that the September 2001 General Accounting Office study highlighted that home infusion therapies represent only a small percentage of current Medicare Part B drug expenditures. As a result, the GAO "did not analyze the costs of infusion therapy drug provided in the home setting because they do not account for a substantial share of Medicare drug spending or volume."

For the reasons stated above, at the present time the drug payments for infusion therapy subsidize other functions that the Medicare payment methodologies do not reflect appropriately. The costs of these services and functions far outweigh the costs of the drug product, but these costs are clearly lower than the charges that would be incurred if the patient received treatment in an alternate setting. For home infusion drug therapy, the drug payment is the only available payment mechanism for the services that are essential to providing good quality care. The longstanding use of AWP to determine reimbursement has masked the failure of Medicare and Medicaid payment policies to define and account for the service component.

If changes to the methodology used to calculate drug reimbursement result in substantially reduced drug payments, without corresponding changes to ensure adequate reimbursement for the service component of providing infusion therapies, the end result will virtually guarantee an inability of providers to continue to provide these services. Without the availability of home infusion services, Medicare beneficiaries will be treated in more costly settings.

Recommendations

We urge Congress to recognize the need for a meaningful analysis of all of the drugs, items, professional services, and facility requirements necessary to provide various types of drug therapies to beneficiaries in a manner that is consistent with the standard of care in this country and private accreditation standards. To restrict the analysis to the difference between drug acquisition cost and Medicare reimbursement is to examine only one small piece of the equation. Such a narrow analysis would fail to meet the overarching goal of using Medicare resources as judiciously as possible.

Before instituting drug payment reform, Medicare must accurately define infusion therapy and create quality standards based on the standards currently and widely used in the private sector. Medicare should then establish a fee schedule that reflects all the covered components of the therapies to accompany the AWP-based drug payment changes.

We look forward to working cooperatively with the Subcommittee to explore solutions that are in the best interests of the financial integrity of the Medicare program, as well as the best interests of the health care needs of the Medicare beneficiaries that rely on home infusion drug therapies.

Oncology Nursing Society
Pittsburgh, Pennsylvania 15275–1214
October 13, 2002

The Honorable Nancy Johnson
Chair
Health Subcommittee
House Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

Dear Chairwoman Johnson:

On behalf of the Oncology Nursing Society (ONS)—the largest professional oncology group in the United States composed of more than 30,000 nurses and other health professionals dedicated to ensuring access to quality care for people with cancer—we are writing to submit this letter as written testimony to be included in the record of your recent hearing on "Medicare Payments for Currently Covered Pre-

scription Drugs." We very much appreciate this opportunity to provide our input and stand ready to work with you, your colleagues, the Centers for Medicare and Medicaid Services (CMS), and others to address Medicare oncology and nursing payment related issues to ensure that Medicare beneficiaries with cancer receive quality care.

ONS shares the concerns of Congress and CMS regarding the ongoing viability of the Medicare program and recognizes the need to take steps now to preserve access to care for all beneficiaries with cancer. In the attached "principles" document, you will see that ONS—along with seventeen of our partner organizations in the cancer community—has endorsed Representative Jim Greenwood's principles for Medicare "reform" of the current Average Wholesale Price (AWP) system of payment for Medicare reimbursable prescription drugs. ONS feels strongly that the Medicare program should neither overpay nor underpay for benefits and services. Moreover, ONS maintains that the current AWP payment policy unfairly results in larger copayments for Medicare beneficiaries and distorts the entire cancer care payment system.

To that end, we join you and your colleagues in calling for reform and advocate that Congress develop—and CMS implement—new policies that ensure that the full range of services provided in the provision of cancer care is reimbursed adequately and appropriately. The attached principles document—along with a joint letter (attached) sent by ONS with the National Patient Advocate Foundation (NPAF) to Senate Finance Committee Chairman Max Baucus—make clear that ONS fully supports reform but maintains that changes to the "AWP system" cannot occur at the expense of patient access to community-based, quality care. We feel strongly that reductions in drug payments should occur only simultaneously with commensurate increases in reimbursement for chemotherapy administration and associated supportive care services.

As you know, cancer is a complex, multifaceted, and chronic disease, and people with cancer require specialty-nursing and clinical interventions at every step of the cancer experience. To that end, people with cancer are best served by multi-disciplinary teams of health care professionals specialized in oncology care, including nurses certified in that specialty. Approximately 4 out of 5 cancer care encounters occur in community settings, where oncology nurses play a central role in the provision of quality cancer care as they are principally involved in the administration and monitoring of chemotherapy and the associated side-effects patients may experience. The shift in the provision of cancer care from inpatient to outpatient, community-based settings has resulted in significant benefits for patients and savings for the health care system as a whole.

However, despite this important change in the provision of cancer care, ONS believes that the current Medicare payment system fails to adequately recognize the reality of the current contributions made by oncology nursing and other clinical staff in this "new" outpatient system of care. As anyone ever treated for cancer will attest, oncology nurses are intelligent, well-educated, highly skilled, compassionate professionals who provide quality clinical, psychosocial, and supportive care to patients and their families. In short, they are integral to the cancer care delivery system. Therefore, it is essential that we assure that Medicare payment policies recognize the full range of health professionals who contribute to the delivery of quality cancer care to beneficiaries in need.

In addition to updating Medicare payment for the administration of chemotherapy and supportive care services provided by oncology nurses and other health professionals, ONS urges Congress and CMS to ensure that the Medicare program does not unintentionally devalue the work of oncology nurses and other non-physician clinical staff. Specifically, we call upon you to eliminate the use of the term "zero work pool" for those services provided by nurses and other non-physician health professionals. While we realize that the actual name for services without physician work Relative Value Units (RVUs) is "zero physician work pool," the vernacular used by agency and Congressional staff and other stakeholders is "zero work pool." This nomenclature suggests that the work done by oncology nurses and other clinical staff is without value—that their work is of "zero" value. We understand that while it is not the intention of Congress or CMS to connote a zero value for oncology nurses' contributions, the reality is that our organization, our members, and others—such as oncology social workers and radiology technicians—take offense at its use. Moreover, in a time in which our country is facing a nursing shortage—the nature and scope of which we have never before experienced—we must make positive policy changes that work to elevate the visibility and express the importance of nursing. One of the causes of the current nursing shortage is low morale within the profession. Now more than ever is the time to highlight the range of work done by our nation's nurses, not to diminish it.

Therefore, as you consider changes to the Medicare program, we urge that you and your colleagues take actions to ensure that the Medicare program better acknowledge the essential and unique role of oncology nurses in the provision of quality cancer care. Through official comments to CMS on the 2003 Physician Fee Schedule, we have asked the agency to rename the "zero physician work pool" in the final rule for the 2003 Physician Fee Schedule. We are advocating a title that better reflects the significant contributions made by nurses and other non-physician cancer care providers in outpatient settings. We understand that the "zero work pool" may be eliminated altogether and/or oncology services may be pulled out from it. However, in the interim, while the methodology is still being used, we propose the following as possible appropriate alternative titles:

- Non-physician clinical staff time;
- Non-physician work components; or
- Non-physician work pool;
- Non-physician health professional pool.

We would appreciate it if you and your committee colleagues would please contact CMS to voice your support of this change. We welcome an opportunity to discuss these or other suggested titles with you as well as agency staff as they review and consider modifications for the final rule. A change such as this would send a strong message to the oncology nursing community that the nation values their work. Such a step would help boost morale within the nursing community in a time when our nation is facing a nursing shortage of serious proportion.

Again, ONS would like to express its gratitude to you and the Subcommittee for this opportunity to provide comments on these issues of priority for our organization. We believe that bringing Medicare payments for drugs more in line with actual costs—coupled with increasing and expanding practice expense payments for chemotherapy administration and supportive care and recognizing the contributions of oncology nurses—will help ensure that Medicare beneficiaries will have access to the quality care they need and deserve.

If ONS can be of any assistance to the agency on these or other nursing or oncology matters, please do not hesitate to contact our Health Policy Associate, Ilisa Halpern (202/857–8968, halperni@arentfox.com).

Sincerely,

Judy E. Lundgren, RN, MSN, AOCN
President
Pearl Moore, RN, MN, FAAN
Chief Executive Officer

Attachments

Guiding Principles: [1]

- The system should not adversely affect patient access to quality health care.
- Medicare reimbursement for drugs should be closely linked to the cost of the drugs.
- Reimbursement for services should be based on actual expenses.
- Drug reimbursement should not impact medical decision-making.
- Payments should be equalized to ensure there is no incentive to choose one setting for receiving care over another.

Additional Policy Positions:

- The role of oncology nurses in the provision of cancer care should be reflected explicitly in Medicare legislation, statute, regulation and other policies.
- Nursing specifically should be included—and named in statutes, regulations, and other policies as included participants—in any policy making, policy analysis, and policy review processes in which the Centers for Medicare and Medicaid Services, the General Accounting Office, and other Federal agencies engage with regards to Medicare reimbursement for care involving the direct or indirect contribution of nurses.
- Medicare reimbursement for oncology nursing practice expenses should be based on current practice data using a bottom-up methodology. The Centers for Medicare and Medicaid Services (CMS) should support "work sampling" studies and incorporate the results into its practice expense calculations to

[1] These principles are the same as outlined earlier this year by House Energy and Commerce Oversight and Investigations Subcommittee Chairman Jim Greenwood.

ensure that Medicare reimbursement is based on real costs and real practice patterns.

- Changes to Medicare policy and associated reimbursement must be considered in aggregate to ensure that adjustments in one area do not have unintended consequences with regards to patient access to quality care. The Medicare program should monitor and evaluate—on an ongoing basis—the impact that reimbursement policy changes have on patient migration, access, and outcomes. Such tracking studies involve the Agency for Healthcare Research and Quality (AHRQ), the Institute of Medicine (IOM), and the Medicare Payment Advisory Commission (MedPAC).
- If the CMS maintains the "zero work pool" alternative methodology, the "zero work pool" should be renamed to reflect more accurately the substantive contributions that nurses and other non-physicians make to the provision of care to Medicare beneficiaries. The current nomenclature connotes a lack of value of the critical contribution that nurses make and further exacerbates a misconception that the work that nurses do is not quantifiable or significant.
- As nursing specialty organizations typically lack the resources of physician specialty groups, regulatory and statutory requirements relating to public input into policymaking processes should be reasonable, accommodating, and flexible to ensure that nurses are not disenfranchised.
- With the current and impending shortage of nurses coupled with the expected growth in cancer incidence over the next two decades, all Medicare policy and reimbursement must be crafted with the goal of preserving and strengthening the nation's system of community-based cancer care.
- To ensure long-term solvency, Medicare policy should prove fiscally responsible; however, changes to Medicare reimbursement should not result in such financial pressures that patients would lose access to nurses specially trained in oncology. Oncology nurses are an integral part of a comprehensive cancer care team and studies have shown that patients fare much better when they receive care from health care providers specially trained in oncology. To ensure the highest quality of cancer care for Medicare beneficiaries, Medicare policy should seek to safeguard the provision of chemotherapy administration and related services by nurses specially trained in oncology.
- The Medicare program should provide adequate reimbursement for the full-range of supportive care services provided to oncology patients. Such services include: patient counseling/psychosocial support, oncology social work, oncology case management, medical nutrition therapy, and investigating and enrolling patients in cancer clinical trials.

Endorsing Organizations:

Alliance for Lung Cancer Advocacy, Support, and Education
Association of Community Cancer Centers
Cancer Care, Inc.
Cancer Research Foundation of America
Candlelighters Childhood Cancer Foundation
Colorectal Cancer Network
International Myeloma Foundation
Kidney Cancer Association
Leukemia & Lymphoma Society
Men's Health Network
National Association of Pediatric Oncology Nurses
National Association of Social Workers
National Patient Advocate Foundation
North American Brain Tumor Coalition
Oncology Nursing Society
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network, Inc.
US Oncology

National Patient Advocate Foundation, and
Oncology Nursing Society
September 30, 2002

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Chairman:

On behalf of our organizations committed to ensuring access to the full-range of quality cancer care for all individuals in need, we are writing to voice our concerns about linking the reform of the Average Wholesale Price (AWP) for drugs with the provision of coverage for oral anti-cancer therapies under Medicare. While we support both reform of the current AWP system and the expansion of Medicare coverage to include all oral anti-cancer drugs, we have serious concerns about the possibility of a proposal to do so without the necessary and appropriate adjustments to Medicare practice expenses for the actual provision of oncology care. Unless Medicare provides adequate reimbursement for the full-range of oncology care associated with chemotherapy, such a dramatic change in the Medicare program could have devastating effects on beneficiary access to the care they need and deserve.

Due to the tremendous progress that has been achieved in biomedical research, significant advances have been made in the development of new cancer therapeutics that are having a dramatic impact on the quality of cancer care in America. However, as you know, many of the newest anti-cancer drugs are not covered under Medicare because they are available only in oral form and there is no injectable equivalent. To address this inequity, Senator Olympia Snowe has introduced S. 913, the "Access to Cancer Therapies Act," which will provide Medicare coverage for these life-saving oral anti-cancer therapies. More than half of your colleagues in the United States Senate have co-sponsored this legislation. While we strongly support a comprehensive Medicare prescription drug benefit, we believe Medicare coverage for oral anti-cancer drugs would serve as an important first step. We advocate passage of S. 913 either as a free-standing bill or as part of other Medicare legislation enacted this year.

We are concerned, however, that some are considering that an expansion of Medicare coverage to include oral anti-cancer drugs should be funded by an overall reduction in payments for chemotherapy. As you know, the issue of reforming the payment methodology for chemotherapy and related practice expenses has been discussed for many years. Our organizations have participated in numerous meetings with your colleagues and your staff to highlight the concerns of cancer patients and their families surrounding this issue. We strongly support balanced reform of the current Medicare reimbursement system for cancer care. However, we are extremely concerned that access to quality cancer care will be endangered if balanced reform is not achieved.

The key to balanced reform is ensuring that the providers of cancer care to our nation's seniors have the resources necessary to ensure that Medicare beneficiaries with cancer can receive high quality care in their own communities. Currently, the Medicare system wrongly and grossly overpays for drugs while simultaneously dramatically underpays for chemotherapy administration and the practice expenses associated with cancer treatment and supportive care. This distorted reimbursement system must be remedied by decreasing drug payments to a level more aligned with actual cost while at the same time increasing practice expense payments so they more accurately cover real expenditures.

Using the "savings" from AWP reform to fund coverage of oral anti-cancer drugs without a commensurate increase in the oncology nursing and related practice expenses is a short-sighted and flawed approach. First, it fails to ensure that community-based cancer providers will have the overall resources necessary to continue to provide quality cancer care. Second, the use of oral anti-cancer therapies necessitates the active involvement of a multi-disciplinary cancer care team involved in patient and therapy management. Many erroneously believe that Medicare beneficiaries will just get a prescription filled and disappear from the cancer care system. Those individuals taking oral therapies will need to be trained and educated as to how to take their therapy regimen, monitored by their cancer care team to ensure compliance and manage side-effects, and counseled regarding other prescription drugs they may be taking as the average Medicare beneficiary takes four prescriptions a day and fills 18 a year. Providing oral-drug coverage without also allocating the resources necessary to oncology practices so they can provide their patients with the supportive care they need is irresponsible and not to the benefit of our nation's seniors.

We believe, however, that balanced reform can be achieved and we have worked with our colleagues in the cancer community to develop the attached comprehensive reform proposal for your consideration. We welcome the opportunity to speak with you and your staff about our proposal and believe we can strike a much-needed balance in proving fiscally responsible while ensuring access to quality cancer care that Medicare beneficiaries need and deserve.

We strongly encourage you to resist efforts to provide Medicare coverage for oral anti-cancer drugs by reducing payments to physicians for chemotherapy and related practice expenses. One is not a replacement for the other. Coverage for traditional chemotherapy and the full range of oral anti-cancer drugs coupled with adequate reimbursement for care provided by a multi-disciplinary oncology care team are essential if Medicare beneficiaries with cancer are to continue to have access to quality cancer care in their communities.

Thank you for your consideration of our viewpoint on this important issue. Should you have any questions on this or other cancer-related matters, please do not hesitate to contact any of our organizations.

Sincerely,

Nancy Davenport-Ennis
President & CEO
Pearl Moore, RN, MN, FAAN
Chief Executive Officer

(Similar correspondence was sent to Senate Finance Committee Ranking Member Charles Grassley.)

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