

S. HRG. 107-684

**REIMBURSEMENT AND ACCESS TO PRESCRIPTION  
DRUGS UNDER MEDICARE PART B**

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**HEARING**  
BEFORE THE  
SUBCOMMITTEE ON HEALTH CARE  
OF THE  
COMMITTEE ON FINANCE  
UNITED STATES SENATE  
ONE HUNDRED SEVENTH CONGRESS  
SECOND SESSION

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MARCH 14, 2002  
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## **REIMBURSEMENT AND ACCESS TO PRESCRIPTION DRUGS UNDER MEDICARE PART B**

**THURSDAY, MARCH 14, 2002**

U.S. SENATE,  
SUBCOMMITTEE ON HEALTH CARE,  
COMMITTEE ON FINANCE,  
*Washington, DC.*

The hearing was convened, pursuant to notice, at 10:09 a.m., in room 215, Dirksen Senate Office Building, Hon. John D. Rockefeller IV presiding.

### **OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER IV, A U.S. SENATOR FROM WEST VIRGINIA, CHAIRMAN, SUBCOMMITTEE ON HEALTH CARE**

Senator ROCKEFELLER. I want to thank our witnesses, obviously, for testifying today. Tom Scully and I spent some very good time together last evening discussing the world and its future, and its possibilities.

The problem this morning that I think those of us who are here want to talk about—and I want to point out that we do have several panels. When you have somebody rich and famous like Tom Scully, when he has finished testifying, there is a tendency for people to get up and walk out. Well, you, too, Janet.

I do not want that to happen, because the second and third panel are terribly, terribly important. So, to the extent that you can stay and listen and be a part of this, obviously it will be very helpful.

The Medicare program is basically over-paying drugs, the cost of drugs, to the tune of about \$1 billion a year, which means that Medicare beneficiaries are overcharged in their co-payments, which would probably come to about \$200 million a year.

That means that there is less money available for the prescription drugs that they need to buy and that are available, particularly those not covered by Medicare.

Now, in some cases, the 20 percent co-insurance alone exceeds 100 percent of the true cost of the drug. This is unacceptable. We are here today to highlight possible solutions so that Congress can take action on this problem this year.

It is an easy thing to do and we can do it without passing the entire prescription drug bill, which is something we also want to pass, but we cannot say we done one or we do the other. We will do both. We will pass the whole prescription drug bill and this will already have been covered, and people will get help, and will have been getting help.

The Medicare program currently provides coverage for a very small number of drugs. They are listed under the law. This is not something that Tom Scully can simply order to happen. The Congress has to do this.

Those drugs are limited principally to those that are administered, as they say, incident to a physician's treatment or in conjunction with coverable durable medical equipment, such as inhalation drugs used with a nebulizer.

Medicare is required, under the law, to pay 95 percent of the average wholesale price, AWP, for these drugs. No matter what the discount cost might be, they are required to pay 95 percent.

So the AWP, average wholesale price, is a number that direct manufacturers do not make up, but they determine, and do not necessarily report, or to the extent they do report, it is what the government accepts. There is no independent verification of any sort.

So it is a little bit like sticker price on a car. You have your suggested retail price, but very few people pay the sticker price on a car and no physicians or suppliers are paying for the AWP, the average wholesale price, for drugs.

They are paying a lot less and are not making money off of it in a deliberate or wrong way. But it is inefficient and we are forcing the system to work against coverage for seniors.

In fact, the General Accounting Office, the Inspector General, the Department of Justice, physicians, and suppliers are paying far less than the AWP. But, again, Medicare continues to reimburse them at 95 percent of the AWP, regardless of what they are paying.

So this means that physicians and suppliers are making huge profits on Medicare's overpayments. Meanwhile, the Medicare program and its beneficiaries are being harmed.

We need to correct Medicare's payment for these drugs and ensure that providers are paid the right amount to administer these drugs. This will ensure access to services that we need, such as chemotherapy treatments, to make sure that they are not compromised.

Now, ideally, we can do lots of things at the same time. But this hearing is about doing one thing, and doing it this year for sure.

Another way to ensure that our correction of Medicare's payments for drugs does not adversely affect access to cancer therapies is to use part of the savings that we achieve to cover all oral cancer drugs under the Medicare program. There is no witness today who will not be asked whether they support this. And since they are all going to answer yes, we all look forward to that.

Now, 8 years ago, Congress created a unique Medicare benefit for oral anti-cancer drugs, but, again, Congress had to do it. There were only seven. There are now 40 drugs, most of them much better, much more used, much less toxic, much more cost-effective and efficient.

And there are 40 of them, but none of them are covered unless you take it out of home in a physician's office, in the hospital setting, that kind of thing. In other words, incident to a physician visit. Drugs, in other words, have to be injected. They cannot be taken orally. That is wrong.

At present, upwards of 95 percent of cancer drug therapy is covered by Medicare either in physician offices or in reimbursed oral form, but in the near future, as I indicated, as much as 25 percent of cancer drug therapy will be in the form of oral drugs that are not covered. In fact, this is already happening. As I indicated, they have 40, and only 7 are covered.

So that is why Senator Snowe and I have introduced a bill that would cover all cancer therapies under Medicare. I urge my colleagues to consider co-sponsoring this bill because it makes a whole lot of sense.

Now, we have good witnesses today, but we also have very good Senators. Senator Snowe, who is my colleague in so many things, I would hope would have some remarks to make.

**OPENING STATEMENT OF HON. OLYMPIA J. SNOWE, A U.S.  
SENATOR FROM MAINE**

Senator SNOWE. Thank you, Mr. Chairman. I most certainly do.

First of all, I want to commend your leadership in holding this hearing today and putting appropriate focus on the issue of access to prescription drugs under the Medicare program, and also the issue of examining the reimbursement problems that obviously have manifested themselves in that program that we need to address expeditiously and efficiently.

I certainly appreciate the witnesses that we have here today that can give us their input as to how best to tackle this most vital, but intricate, problem with respect to one dimension of our health care delivery system in America.

While the so-called retro look may be all the rage in some quarters, there is nothing desirable about a Medicare reimbursement system that is stuck in the past. This is a system in dire need of modernization, both in terms of the amount the program spends to purchase prescription drugs and also the drugs that are considered acceptable for reimbursement.

If we do not bring this component of Medicare into the 21st century, it will continue to unnecessarily add to Medicare spending and continue to cost patients their lives because they cannot pay for the most effective state-of-the-art medications.

The facts are that Medicare is over-spending for prescription drugs by hundreds of millions of dollars each year, and that will be confirmed by reports that have been done by the Inspector General, the General Accounting Office.

Physicians and pharmacy suppliers have access to enormous discounts on their prescription drug purchases. We know about Medicare. As the Chairman indicated, they are paying the sticker price, essentially, for the cost of prescription drugs under Medicare.

While Medicare pays 95 percent of the average wholesale price, GAO reports that physicians routinely have access to discounts ranging from 13 to 14 percent below the average wholesale price, with some drugs discounted up to 86 percent.

While Medicare currently has license to be taken for a ride, other suppliers in Medicare-covered drugs are also able to purchase drugs at prices significantly below the published AWP.

For instance, pharmacy suppliers routinely have access to discounts of 78 to 85 percent for two inhalation therapy drugs that ac-

count for most of their Medicare payments. As we are working on how to create a comprehensive prescription drug benefit program under Medicare, it is unacceptable that the Medicare payment system for drugs that are already covered is so fundamentally flawed.

Medicare, with all of its collective purchasing power, ought to be exercising that power so that the program pays not a penny more than necessary for covered services.

Medicare Part B ought to be reimbursing physicians fairly for the delivery of cancer treatments they provide. Our health care system should not have to rely on Medicare overpayments for prescription drugs to make up for the cost of delivering the drugs.

Specifically, we understand from the work by the GAO and the Inspector General that there are problems with how oncologists are paying for administering cancer therapy, and in many cases Medicare Part B's current home infusion benefit program does not provide any payment for the cost of administering the drug. As a result, these providers are relying on the flawed overpayment for drugs to cover the cost of providing the drugs to patients.

This obviously is not a way of doing business. The CMS and the former Health Care Financing Administration have tried for over 10 years to reform this payment system, so it is obviously out of control, and it is obviously hopelessly outdated and it needs to be fixed.

In addition to what the Chairman indicated, we have introduced legislation to provide coverage for all of the oral anti-cancer drug treatments. It just does not make sense to exclude some because of the way in which they are administered.

When, over the next decade, 25 percent of the drug cancer treatments are going to be administered orally, it seems to me that Medicare needs to get with the program and begin to reimburse for those types of drugs administered orally for cancer treatments now. That is an issue that we will be addressing as we proceed with this overall problem with respect to this system.

So, again, Mr. Chairman, I thank you for your leadership on this most significant issue affecting so many seniors in this country.

Senator ROCKEFELLER. Thank you, Senator Snowe.

Senator Graham?

**OPENING STATEMENT OF HON. BOB GRAHAM, A U.S. SENATOR  
FROM FLORIDA**

Senator GRAHAM. Thank you very much, Mr. Chairman and our Ranking Member. I wish to thank both of you for the leadership that you have provided on the Medicare reform issue, and this specific aspect of that agenda.

I understand that the average wholesale price, the AWP, which is the basis for Medicare reimbursements for Part B drugs meets none of the words in its description. It is, in fact, not an average. It is not a price that wholesalers actually charge, nor is it a price that providers and suppliers actually pay.

I believe that we all are in agreement that to continue to rely on an index that holds no meaning in the marketplace will continue to refuse to this aspect of Medicare the benefits of a competitive market, will continue to overcharge American taxpayers, and



continue to overcharge cancer, dialysis, organ transplant, and other Medicare patients.

We have known for at least 5 years that Medicare is significantly overpaying for the drugs that are covered. The reimbursement system has outlived any usefulness it may have had, and it must be modified. This is the year to do so.

There is no reason that the Medicare program should continue to pay nearly \$1 billion annually, and \$200 million a year by the beneficiaries, more than the purchasers do for the very same drugs in other settings.

I have begun to study this issue that must necessarily be considered in the development of a new reimbursement system. I agree with the statement of our Chairman, that AWP, in itself, is a simple and rather direct issue.

However, placed in the context of all of the other issues which are affected by AWP, it becomes more complex. These questions include the effects on patients and providers who serve them, the appropriateness of the current practice expense system, reporting and confidentiality requirements, and data availability and reliability.

I intend to continue to work with my colleagues, oncologists, and other providers and suppliers of Part B drugs, pharmaceutical manufacturers, and patients and beneficiary groups to develop a proposal to bring market prices to Medicare's system for paying for these drugs, as well as a reasonable reimbursement for the services of those who provide and deliver the drugs.

I urge all involved parties to commit to finding a resolution and to do so this year. We have a short Congressional year in 2002, but we simply cannot continue to knowingly over-pay for prescription drugs and under-pay practice expenses.

Those resources can and should be used instead to finance expanded coverage of oral cancer drugs, such as the legislation that Senator Rockefeller and Senator Snowe have introduced. Also, to expand to self-injectable drugs and to appropriately compensate providers for their expenses.

As we move forward with these efforts, I will continue to push for the enactment of a universal, comprehensive, affordable prescription drug benefit for all Medicare beneficiaries.

Expanded coverage for oral drugs and self-injectable drugs through savings achieved by rationalizing the reimbursement system for Part B would in no way substitute or divert from our overall goal of covering all necessary prescription drugs.

But these efforts are related. The type of prescription drug benefits seniors need, one that is universal, comprehensive, and affordable, will not come cheaply. We need to look at all the aspects of the Medicare program, both fee-for-service and Medicare Plus Choice, to assure that we are paying appropriately for all services and capturing efficiencies where possible.

This is necessary to accommodate a prescription drug benefit, as well as to assure the long-term sustainability of the Medicare program. Using market-based prices to pay for Part B drugs is one step in this overall effort of greater efficiency through the use of the marketplace.

Again, I wish to thank my colleagues for their leadership, and I will have some questions as we turn to our witnesses.

Senator ROCKEFELLER. Thank you, Senator Graham.

Tom Scully presides over the largest health insurance organization in the world, at less reimbursement than he had previously been accustomed to. But he does us a great service by doing that, because he is somebody who wants to get things done.

I just have to say this, Tom. In my years of working with you, you have helped me on so many issues, from coal miners to steel. You are a problem-solver. You want to see things done. You were confirmed in May of 2001 as the administrator. We are extremely pleased that you are here.

I am going to introduce you, and I am also going to introduce Janet, and then you can both give your testimony.

Janet Rehnquist was sworn in as Inspector General of the U.S. Department of Health and Human Services on August 8. As Inspector General, she is responsible for overseeing the work of the OIG, the Office of Inspector General, through its audits, its evaluations, and its civil and criminal investigations.

Before that, she served several years as U.S. Attorney for the Eastern District of Virginia, where she focused on health care fraud enforcement.

So, we welcome both of you. Mr. Scully, we would turn to you.

**STATEMENT OF HON. TOM SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, DC**

Mr. SCULLY. Thank you, Mr. Chairman. I look forward to hopefully getting a lot more good health care policy done this time around in this administration. But thank you, Mr. Chairman, Senator Snowe, and Senator Graham, for having us here today.

I think, Senator, as you know, I was involved in this issue in 1991, the first time the President Bush 41 administration tried to fix AWP. I have been involved with you in the Medicaid rebid issues, and lots of other related issues on trying to figure out how the government pays appropriately for prescription drugs for a long time.

It is very clear that the average wholesale price is seriously flawed. I am excited that this committee, along with both committees in the House, seem to be very determined to working on this and fixing it together this year.

We would like to offer whatever help we can from CMS on a technical basis to help you fix it, to work with your staffs and the committee to make sure that this gets fixed this year. This issue cries out for a legislative solution, and I am glad that you have introduced one.

This has been an issue that the last two administrations have tried to fix. As you well know, in the last administration, Secretary Shalala and Nancy Ann Min DeParle, who is my predecessor and friend, tried to fix this 3 years ago and had an outcry, whether appropriate or inappropriate, from virtually every party involved. Then Congress prohibited the HCFA, now CMS, from making any further changes until GAO studied the matter. That report was released to Congress last fall.

Today, I would like to talk about a variety of different ways that we think that this can be fixed. But I also think that when we look

at this, it is important that we realize we should, and must, fix this.

But, as all of you have mentioned, there are a lot of side effects on various providers that are fairly legitimate. If we are going to lower prices that Medicare pays for outpatient drugs, then I think we also need to make appropriate adjustments—it is certainly not a one-for-one swap, it is significantly less than that.

But if you can save, whether it is \$800 million or \$1 billion on AWP, I think we probably have—GAO said it was about \$50 million; it may be around that area, or a little higher—to put back into oncology, probably ESRD clinics, hemophiliac agencies, some DME providers. Many of these providers rely on cross subsidies to survive, basically, in the Medicare business.

So, I do not think it is necessarily that they all should have their rates increased, but there is a substantial amount of money that could, and should, be saved in this area. I think we need to go back and look at putting a little bit of it back in the base of these providers.

I would also note that last fall I testified at the House Commerce Committee. In my 23 years here, I do not think I have ever seen more bipartisan interest in an issue, from Chairman Tozen and Ranking Member Dingle. They were extremely excited, and I would say angry, about this issue and wanted it fixed.

So, I believe that there is very fertile ground in the House as well to work with the administration and this committee, hopefully, to fix this issue this year.

If I could make a couple of quick points. One, is this is not, as you pointed out, Chairman Rockefeller, not a problem just for the program. It is a huge problem for beneficiaries. When we are overpaying for drugs, they are overpaying for their 20 percent co-payments. That is a very significant issue for all seniors and the disabled.

The second point, is this is a complicated issue, but the reality is that there are only 20 drugs that apply to about 75 percent of the spending in this area. So, the number of drugs you are dealing with is really pretty small. In fact, single-source drugs apply for about 60 percent of all the drug spending in this area.

So the number of drugs that are affected, the spending that is affected, are a relatively small pot of drugs. I think it is not as difficult to deal with as many have argued over the years.

The third point, is I think we need to realize—and I am going to go through some of the suggested fixes that we have talked about. The first fix that we had in 1991 was to go to 85 percent AWP. As I will mention in a minute, I think AWP is largely air and is a meaningless figure.

But in that case, a lot of the physicians said, we cannot get access to the drugs for AWP. I think in Medicare, what you are really talking about, very different from VA, which I know you are very familiar with, Senator, is this is not a government program. The doctors actually have to go out and buy this on the market.

So, as we try to substantially reduce the payments that we have in these programs, which we need to do, it is a lot different from VA or DOD where we can just go out and buy in bulk and give

them to government facilities. Physicians actually have to buy this for their offices on the market.

So, in a number of cases people suggested the Federal supply schedule. I know VA has done a great job, and Janet is going to talk in her testimony about VA savings. But I am not sure that the government model necessarily always works.

Another option is average manufacturers price, which we do collect and GAO has talked about, which is a very reasonable number. It works in the Medicaid program. It is a much lower price, so it generates substantial savings. But, again, it potentially could have problems with physicians' access to drugs.

Wholesale acquisition costs is another measurement that has been mentioned, but I am not sure that wholesale acquisition costs is different from AWP. AWP is very easily manipulated, as is wholesale acquisition costs. I am not sure. As a short-term fix it may be a lower price, but in the long run I believe manufacturers can move that number out as well.

A number of people, including a CMS contract that we let, had suggested doing a market survey. That generally is a 1- or 2-year look-back, which also makes things difficult, but could, in fact, work. That just is one indication of how badly and what a mess this program is.

If we simply went to a market survey where we hired one of our contractors, we have 23 carriers in Part B to make these payments and four durable medical equipment carriers, so there are 27 Medicare carriers that make these payments, the inconsistencies—and if we just picked one, let us say we picked Palmetto, which is Blue Cross of South Carolina, which happens to be both in Part B and in durable medical equipment.

If we picked one and just said to them, go out and come up with a consistent price across the country in the median of what we pay, because there is so much variation between contractors. That alone would save \$500 million a year.

That would not even be requiring lowering prices, that would just tell our contractors to go out and basically come up with a consistent policy. That would be \$500 million a year. So, I think that alone is one minor step that you could take that clearly shows how much money there is to be saved in here.

The Commerce Committee approach, at least right now, seems to be average sales price, which also may be an appropriate number, but it would be average sales price plus a number. We have spent a lot of time working with the Commerce Committee on various options on this. It is certainly a workable number, and one that I would encourage the committee to at least look at.

The bottom line is, there are a variety of ways to do this. But the manufacturers who sell us drugs know how many drugs they sell us, they know how many units they are selling to us. There is a mechanism, regardless of which one we pick, to make sure that we save a significant amount of money in this area.

In the President's budget, there is an assumption. We would greatly, greatly, greatly prefer to do this with Congress. We can, in fact, in a more limited way, do this administratively. The President's budget said that if Congress does not act this year, that we will attempt to do it administratively.

There is no question, however, that the one thing that Congress can do, is reduce payments by \$700 million, \$1 billion, whatever the reduction is. But only Congress can put money back in to oncologists, ESRD clinics, and others in a non-budget neutral way. That is not something the administration can do.

So, we are greatly encouraged by the action on both the House and the Senate. We are very anxious to work with you and make sure that it is done this year. We think it is most appropriately done legislatively. There is no question that the system is a mess and needs to be fixed.

One of the problems over the years, is the Senate, the Finance Committee, has had an idea, the Commerce Committee has had an idea, the Ways and Means Committee has had an idea, all of them legitimate, but nothing has happened because of the slightly difference substance.

We are very anxious to work with the committee this year to try to get the three committees of jurisdiction in this area and the administration to come up with a fix, because we believe that virtually any of the fixes that are being discussed are substantially better for seniors, substantially better for the program, and will fix a mess that is about a decade overdue for being cleaned up.

Thank you very much.

Senator ROCKEFELLER. Thank you, Tom Scully.

[The prepared statement of Mr. Scully appears in the appendix.]

Senator ROCKEFELLER. Janet Rehnquist?

**STATEMENT OF HON. JANET REHNQUIST, INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC**

Ms. REHNQUIST. Thank you. Good morning, Mr. Chairman, Senator Snowe, Senator Graham, Senator Hatch.

I am Janet Rehnquist, Inspector General for the Department of Health and Human Services. I appreciate the opportunity to appear before you today regarding the important issue of Medicare reimbursement for prescription drugs.

The OIG has consistently found that Medicare pays too much for prescription drugs, more than most other payors. Medicare's current payment methodology for prescription drugs adversely affects the Medicare trust fund and Medicare's beneficiaries who, as you know, are responsible for 20 percent of the allowed amounts.

Medicare's payment system, based on average wholesale price, is neither average nor wholesale. Until this problem is corrected, Medicare and its beneficiaries will unnecessarily pay more and more each year.

Medicare's coverage of outpatient drugs is limited primarily to drugs used in dialysis, organ transplantation, and cancer treatment. Physicians and suppliers purchase these drugs, administer or provide them to Medicare beneficiaries, and then submit a bill to Medicare for reimbursement.

In general, Medicare reimburses physicians and suppliers for 95 percent of their average wholesale price, or AWP, published by the drug manufacturers.

Medicare's total payments for prescription drugs have risen steadily over the past decade. In 1992, Medicare paid about \$700

million for prescription drugs, but by the year 2000, it paid \$5 billion. Between 1999 and 2000 alone, payments increased by \$1 billion.

Our reports have shown again and again that Medicare pays too much for drugs. Why does Medicare pay so much? We believe that it is because the payment methodology is fundamentally flawed. For the most part, AWP's are reported by manufacturers to companies that compile drug pricing data.

As our reports have indicated, the published AWP's that Medicare uses to establish drug reimbursement bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers.

Aside from the obvious problem of inflated AWP's resulting in Medicare paying too much, the use of AWP also has other potential adverse implications. 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 be an inducement for suppliers or physicians to use one brand of 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 drug product, it does increase the manufacturer's market share because of the higher profits made by the physicians and suppliers who choose that drug. This, in turn, increases the profits of the drug company. All of this occurs at the expense of the Medicare program and its beneficiaries.

Although Medicare is the primary focus of my testimony today, problems resulting from the publication of misleading AWP's have also plagued the Medicaid program because the payment methods are so fundamentally flawed.

This is illustrated by a report we are releasing today related to Medicaid drug reimbursement. As a follow-up to our previous work, we conducted a nationwide review of pharmacy acquisition costs for generic drugs reimbursed under Medicaid.

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 this review was to develop an estimate of the discount below AWP at which pharmacies actually purchase generic drugs.

In thinking about how to approach the inequities of AWP, I believe a number of factors need to be considered. These factors provide a basis for considering how to change the Medicare drug payment system.

First, we should of course focus on market prices. A drug reimbursement system should be based on real prices available in the marketplace. Physicians and suppliers 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 should also consider data availability and reliability. We need a practical way to obtain data which can be used to set reimbursement. Further, there needs to be confidence that the data are reliable and cannot be misrepresented.

We also must consider the importance of periodic updates. Reimbursement needs to be periodically updated to reflect market changes. This will also impact how monitoring is conducted to ensure that access problems do not occur, and how payment revisions are made if this does occur, or if individual payments continue to be inflated.

Another important consideration, is proprietary information. We need to consider how to protect the proprietary data of the drug manufacturers.

Finally, we must consider practice costs of the physicians. We recognize that some physician groups have raised concerns about Medicare's attempt to lower reimbursement for prescription drugs.

We also 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 physicians.

Mr. Chairman, this concludes my testimony. I appreciate the opportunity to address this important issue with you today, and I would ask you to have my full written testimony entered into the record.

I would be happy to answer any questions.

Senator ROCKEFELLER. Of course. Thank you both very much.

[The prepared statement of Ms. Rehnquist appears in the appendix.]

Senator ROCKEFELLER. Mr. Scully, let me start with you. The President's budget assumes a \$12 billion savings in terms of this so-called reform of the Medicare payment system for Part B covered drugs.

The first question I want to ask you, is can you explain what it is? You have not, so far.

The second question, is one that you brought up in your statement when you said that there are parts of this that we can do by ourselves. We can do it even if we were not to, which I hope we will. I would be very interested if you could describe that also.

Mr. SCULLY. Well, there are a variety of ways to do it. Obviously, the Clinton administration chose to basically send directions out to the contractors just telling them to use a different market level price, and that led to a significant backlash that, arguably, the cross subsidies were disappearing without additional payments to oncologists, hematologists, ESRD clinics, hemophiliac agencies, and others.

We clearly could just, administratively, go out and change our direction and lower the definition of what we pay at AWP, arguably. We can also go out and give direction to the contractors, as the Clinton administration has done in the past.

You can, as a legal matter, arguably, do this. The real issue is, you do not have the flexibility to add back into Part B additional payments to oncologists and other people. Obviously we have an additional problem with physician payments and Part B this year.

So, going back into the Part B RBRVS pool and further reducing it to raise oncology payments or other payments, at the same time to make up for reduction in payments to AWP, would be particularly difficult this year.

We think it could be done legislatively. It is scored in our budget based on what the traditional proposal had been, and the similar way it was done in the Clinton administration, which is just basically to tell the contractors to pay significantly lower prices. I believe the score is \$12 billion over 10 years. I think the first year was about \$700 million.

Senator ROCKEFELLER. You are saying that is based upon what the Clinton administration did?

Mr. SCULLY. It is a little bit of a hybrid of what the Clinton administration was going to do. But I think that is the mid-range projection from our actuaries of what you can save with a fairly modest proposal. Now one of the versions of the House bill has been scored as high as \$1 billion a year.

Senator ROCKEFELLER. But if you do not have an exact program that you can explain to us, how can you assume savings?

Mr. SCULLY. Well, as I said, Senator, if we did nothing more than send that direction—

Senator ROCKEFELLER. You assume precise savings, the \$12 billion.

Mr. SCULLY. Yes. We do have some assumptions that our actuaries put into the budget. To be honest with you, we would much prefer to work with you on the Hill and the Congress to come up with one that is palatable to all parties.

As I said, the Commerce Committee has a fairly thoroughly spelled out approach. That is, average sales price plus, I think it is now about 15 percent. The numbers vary by the day.

The scoring areas, whether it is ASP plus 8, 10, 15. We really want to get this fixed. We have a proposal that is a plug in our budget, which we have assumed we will do this summer if Congress does not act.

But we would greatly prefer to work with Congress to do it legislatively. We think it is a much neater and cleaner process.

Senator ROCKEFELLER. And I understand that. But it is like so many things when Congress is trying to do something. If we know that the administration is working with us, we are much more likely to do it.

Mr. SCULLY. Yes. The plug number, Senator, is very close to average manufacturers' price, which is the number we have in Medicaid. I think you can have a significant policy to balance the right way to go, but the savings number in the budget is parallel to the average manufacturers' price.

Senator ROCKEFELLER. If I were to ask you to send to us, as closely as you can, how you would describe your program that leads to those savings, would you be willing to do that?

Mr. SCULLY. I think, Senator, to be honest with you, the administration has not formally decided on which policy.

Senator ROCKEFELLER. Then how can you assume savings?

Mr. SCULLY. Well, we assumed in the budget, and it says in the budget, that we did it based on a variation of average manufacturers' price. So, we did assume those savings.



Senator ROCKEFELLER. You admit, that is a little tricky. I do not mean devious.

Mr. SCULLY. No. Well, I think, Senator, average manufacturers' price has some problems with it, primarily that, arguably, it could cause some problems with physician access. It is clearly the number we use in Medicaid. It is audited. We have those numbers. The manufacturers, under Medicaid law, give them to us, and we could use them.

The manufacturers are not going to like it very much, but that is not our number-one concern, to be honest. But, roughly, that is actually a slightly watered down number. If you put in pure AMP, you would actually save a little more money in the summer budget.

Senator ROCKEFELLER. Two more quick questions to you.

Mr. SCULLY. The answer, by the way, Senator, if you want me to send you a more thorough description, I can.

Senator ROCKEFELLER. The best you can. I would appreciate that.

We talked about, you take from one, you take away from another. Oncologists. And RBRVS, of course, was the history of taking away from some for another, but it was to do generalists more and specialists less, and everybody was not happy. Generally speaking, I think people felt it was a good thing.

Do you not agree that if somebody, whether it is an oncologist—one of whom, a distinguished one, is going to be testifying in our next panel—if they make that complaint, or any particular physician group makes that complaint, that they should send in data that verifies that?

We do not have data. You do not have data. I mean, we do not have any way of verifying the figures that we receive, or we do not get any figures on which to make those kinds of decisions.

Am I not right?

Mr. SCULLY. We do. We have done some studies on it, and GAO has done some on oncology. I do not want to throw out the wrong number. We have, to some degree, the acknowledged transfer and cross subsidy from AWP for oncologists has resulted in our RBRVS payments being somewhat artificially low for practice expenses.

I think the number that our staff came up with was about \$49 million a year, is what they thought practice expenses should go up in oncology if you were to take away or significantly reduce AWP for oncology drugs. I think GAO's number was about \$52 million.

So, I think those are pretty surprisingly close, given the fact that we did two completely independent surveys on what we thought were oncology practice expenses.

Senator ROCKEFELLER. All right. Then I will take advantage. You were just about to say that you are for this access act for oral cancer, are you not?

Mr. SCULLY. I would love to work with you, Senator. We would be happy to work with you. I hope we get a Medicare drug and reform package this year. I think there are a lot of cancer drugs that are not paid for.

The current law obviously says that drugs are not usually self-injectable, we cannot pay for, so the program does not. I hope, in the context of a larger negotiation of prescription drugs, we can work out better coverage for cancer drugs.

Senator ROCKEFELLER. I am just going to argue for a second that, if we do it in the larger context, and then if the larger context should, hopefully, unrealistically, not happen to pass, then we are left with nothing. This is a precise, carefully targeted matter.

As I indicated to you, if an administration indicates on something, which I think is relatively straightforward and not terribly costly, that they are sympathetic, it can have an enormous effect on whether or not we pass it up here. That is why I really would hope that the administration would be for it. Then you would be for it, as the health care advocate in the administration.

Mr. SCULLY. I am spending a lot of time right now trying to adjust the self-injectable language from two years ago that was modestly changed. We will have a proposal out on that shortly. But which drugs are covered and which are not?

Self-injectable is extremely complicated. Congress made a slight change on that that was scored at about \$1.2 billion in the last reconciliation bill. Obviously, I was here last week and the administration very strongly wants to do access expansions, Medicare reform, prescription drugs this year.

I hope we get to a bigger context. If we do not, it seems likely that there is also going to be a narrower provider bill, which we are planning to work on, which we would like to do and think can be done in a budget-neutral way.

There was a fix to expand, a little bit, prescription drugs 2 years ago. I think, in that context, it can be discussed as well.

Senator ROCKEFELLER. All right. I will try to think through what you said. [Laughter.]

Senator Snowe?

Senator SNOWE. I will give you time, Mr. Chairman.

Mr. Scully, it really is mystifying why this problem has not been corrected previously. As you indicated, it has been a decade-long problem. How is it that other purchasers, other physicians, other providers, large purchasing organizations have managed to find a way in not overpaying for prescription drugs and the government has been unable to do so?

I mean, I am concerned that we might take a guess-work approach. This seems to me anything less than guess work. It can be a precise measurement of what the drugs cost and what we ought to be paying. It should be as simple as that.

So why is it that we have not been able to fix this problem prior to this?

Mr. SCULLY. Well, part of it, to be honest with you, Senator, is in the past when there were legitimate efforts made to address this, the push-back from the affected providers and other folks was pretty loud, and the substantive level of interest in Congress was nowhere near as high as it is now.

So, I am very optimistic we can finally fix it. I think that the level of substantive detail in both the House and Senate is much higher than it has ever been in the 10 years that I have followed this issue. I think it needs to be fixed.

I think, whether you are a private insurance company that generally buys these drugs through group purchasing efforts in an out-patient setting or through PBMs, clearly they get much better mar-

ket prices. There is no question that the VA and DOD get much better prices.

We basically buy through 27 contractors who do not have a very good incentive or ability to figure out what the appropriate price is.

Senator SNOWE. Speaking of the Veterans Administration, obviously they have managed to be very successful in this regard, another government agency. Why is it that one government agency has been so successful and effective and one has not with respect to the purchasing ability?

Mr. SCULLY. Well, I think it is a very different mechanism. I do not think it would be wise to track the Federal Supply Schedule, because DOD and VA buy drugs for big facilities for physicians that are employed by them. In this case, the individual physician buy drugs basically for their patients. So, I think it is a totally different market mechanism. But there is no question that we are paying vast amounts.

Senator SNOWE. Right. But by any measurement, there is not a measurement yet that could redeem the way in which we are now approaching purchasing prescription drugs under the Medicare program.

Mr. SCULLY. Well, essentially most of our contractors are Blue Cross plans. I mean, we have Mutual of Omaha and some others. Most of these Blue Cross plans, on one side of the building, work for the government as a contractor, and on the other side of the building they run significant commercial insurance plans where they pay much less, and know exactly what is going on.

So, part of it, I think, is just having the ability to change the way we manage the purchasing and to direct them to find ways to contract with them to use their otherwise commercial knowledge of what they are paying for these drugs to get better prices.

Senator SNOWE. Could we adopt a competitive system?

Mr. SCULLY. It is a problem. We could, but a lot of these drugs are sole-source, single drugs. Many are patented drugs. You could do it through PBMs, if that is what you mean by a competitive system. You could certainly use third party payors to do that. You could use our existing Medicare contracts if you incentivize them differently.

Senator SNOWE. Ms. Rehnquist, in your report you indicated that Medicare could have saved, if they had been reimbursed at the actual prices available to providers, \$886 million. Does that include rebates, volume discounts?

Ms. REHNQUIST. I am not sure of the actual number. As you know, in Medicaid there is the reimbursement based on the acquisition cost, and then the rebates are on top of that, which are statutorily mandated.

Senator SNOWE. Medicare.

Ms. REHNQUIST. No. The Medicare numbers would not include rebates. Medicare does not have rebates.

Senator SNOWE. So it would have been substantially higher if there had been any type, but there are not any volume discounts. Nothing has been included.

Ms. REHNQUIST. That is right. Rebates are a feature of Medicaid reimbursement.

Senator SNOWE. How is that we do not have access to reliable data in order to make our best evaluation in terms of the prices that we are paying?

Ms. REHNQUIST. Well, I think there are a number of factors that explain that. Part of it is the history of AWP, which was, initially, Medicare used to reimburse at 100 percent of it. It was thought to be reliable when it first started.

Then as these compendia which established the prices collected the pricing data, it became clearer, I think, kind of as we got better at it, that the data did not reflect the actual prices. This was just something that the manufacturers established for the benefit of the physician or supplier reimbursement.

Mr. SCULLY. Senator, if I could just add.

Senator SNOWE. Yes.

Mr. SCULLY. We do have pretty good data. We collect AMP data from Medicaid on one side of my agency. We have it. We know what every drug company charges us for Medicaid, what their average manufacturers' price is. But, by statute, we are not allowed to share that with the Medicare side of the agency. It is proprietary data, just for the purpose of the Medicaid program.

Ms. REHNQUIST. So Medicare uses something different. They use AWP in Medicare. Medicaid uses AMP for the Medicaid reimbursement process.

Senator SNOWE. All right. So can Medicare have access to that information? If Medicaid can have access, why can Medicare not have access?

Mr. SCULLY. The law that created it prohibited us from using AMP for Medicare.

Senator SNOWE. So there is no other way of getting information from the manufacturers with respect to pricing?

Mr. SCULLY. No. I am saying you could, certainly, get information other ways. We could do market surveys and other things. AMP provides a pretty good source of data. But by statute, it is limited to the use of the Medicaid program. The Medicare side of my agency does not have access to it, by law.

Senator SNOWE. Well, I think, frankly, it is rather remarkable that we are in this situation, and for so long. In the private sector, this just would not stand. It just does not stand to reason that we are in this kind of situation, trying to find out information about the prices and who is getting what, and why we are paying so much more than those in the private sector.

I understand what has happened over the years and why that may be, but clearly it is not anything that we can continue to perpetuate any longer.

Thank you, Mr. Chairman.

Senator ROCKEFELLER. Thank you, Senator.

Senator Graham?

Senator GRAHAM. Thank you, Mr. Chairman.

Mr. Scully, we will hear later from Dr. Norton, as well as others, that the overpayment for drugs help compensate physicians and suppliers for the underpayment for their services.

In your testimony, you, I think, rejected the concept of using AWP overpayments as a means of substituting for reimbursement,

while expressing some empathy for the need for increased reimbursement for practice expenses.

The \$5 billion which you have included on page 298 of the President's budget for savings by shifting away from AWP, does that include any offsetting costs for increased payments to physicians or suppliers?

Mr. SCULLY. Senator, the policy, as I mentioned, was based on a slightly watered down version of AMP. I believe that the assumption in the budget does not include add-backs for practice expenses. But we have publicly said in a number of forums that we would support doing that in the context of an AWP reduction.

Senator GRAHAM. So you believe that some additional practice expense reimbursement would be an appropriate part of moving away from AWP?

Mr. SCULLY. Yes, Senator, we do.

Senator GRAHAM. Do you have any thoughts as to how you would go about that calculation? I understand that the GAO has suggested that it maybe should be in the range of \$50 to \$100 million a year. We will hear testimony later that it should be 98 percent of the current benefit derived by practitioners and suppliers through the use of the AWP.

Which number, or how would you go about arriving at what is the appropriate level of add-back for practice expenses?

Mr. SCULLY. Our internal study that CMS did suggests that about a \$50 million add-back for oncology practice expenses, and probably smaller amounts are appropriate—and we have not yet determined the exact amount, but certainly smaller—for some DME suppliers, probably ESRD, hemophiliacs, some other areas where, clearly, AWP pricing is a significant cross subsidy that they rely on to have a reasonable margin as Medicare contractors.

Senator GRAHAM. Is that based on, for instance, some bringing oncologists up to a consistent standard with other providers who have similar training or complexity in their practices?

Mr. SCULLY. I think, in fairness, this has probably never been discussed publicly, but I have gone through it with my staff extensively. As you know, Senator Rockefeller spent many, many months with me on this in 1989.

Under the Physician Payment Reform System from 1989, the ROCK, which is the AMA's creative committee, they basically sit down with all of the specialty groups and decides whether oncologists, pathologists, internists, whatever their practice expenses should be and the relative payments. Everybody has acknowledged for years that oncologists have a significant cross subsidy through AWP.

So, I think there was a subconscious effort within the rug to not fully and completely consider all the practice expenses for oncologists because of the acknowledged cross subsidy from AWP over-pricing. I believe you have taken that away.

There is a strong argument within the physician community and within the physician payment system to put a little more money back into the practice expense base. So, we think \$50 million is about the right amount.

Senator GRAHAM. Are there any other areas in practice expense reimbursement where there is a similar reduction of the expense

level in recognition of some supplementary source of income that comes into the practice, or is this unique to oncology?

Mr. SCULLY. I think this is pretty unique, certainly, to the scale to oncologists. I am not aware of any other place within the RBRVS system where there has been this kind of acknowledged cross subsidy.

Senator GRAHAM. Ms. Rehnquist, I personally would like to see us move away from AWP and towards something that might have the title "Market Price for Drugs," and attempt to arrive at, what is the competitive marketplace statement as to what the cost of this particular drug should be.

If we were to go to an MPD format, what should that definition include or exclude in its application to Part B drugs? Are there any purchases that should be excluded when determining the price that is actually available in the market?

Should we exempt, as an example, purchases from the definition of best price, which are used in the Medicaid statute? What are the implications of such exclusions or inclusions?

Ms. REHNQUIST. Well, Senator, I think that, as Tom Scully has pointed out, that the price used by Medicaid is the price at which we have the most data that we have collected over the years, meaning collectively, the government.

So, we have, I think, about 10 years' worth of data to be able to determine fairly accurately what the average manufacturers' price is. That data is audited, so that is checked and rechecked, and I believe that there are periodic updates to those prices. So, that might be just one possibility for what you market data price could be based on.

There are a lot of other factors to be considered. I think that the formularies used in Medicaid, such as excluding certain large group purchasers, those are just an effort to make the price as fair as possible. The auditors throw out the top price, the lowest price, and really try to find out, what is the average price?

So I think in terms of what you are suggesting, as you say, market data price, I think that AMP would be a good data point to consider. I think you would want to include some of the same things that Medicaid looks at, some of the same things that they exclude when they determine the AMP. I think you would also want to be sure that you would have some means of auditing to be sure that it is accurate.

Senator GRAHAM. Thank you, Mr. Chairman.

Senator ROCKEFELLER. Senator Hatch?

Senator HATCH. Thank you, Mr. Chairman.

Mr. Scully, in December you received a letter from all of the committee chairmen and ranking members of the committees with jurisdiction over Medicare which outlined the specific problems with the planned implementation of the 2002 hospital outpatient prospective system.

The letter expressed widely-held concern in Congress that insufficient payments for drug costs could impede beneficiary access to needed treatments. The letter said, "we strongly urge that CMS revise its assumptions to provide that 75 percent of AWP, the cross single-source, multiple-source, and generic drugs, represents the acquisition cost of drugs."

Now, it is my understanding that moving drugs to the APC rate of 75 percent of AWP on April 1 would be a relatively simple adjustment fix for CMS. What I would like to know, is how your agency will respond to this issue, especially since the rule has been released by CMS. I am worried that the beneficiaries could suffer if this issue is not addressed.

Mr. SCULLY. The outpatient rule is effective April 1. It was delayed 3 months due to some significant coding and billing errors, as you know.

Senator HATCH. Right.

Mr. SCULLY. I apologize, Senator. I have tried to get back to all of the Congressional letters quickly. If I have not gotten back on that one, I certainly apologize and I will get on it today with my crack legislative staff who used to work for you.

But to be honest with you, we probably could implement it, just go out and lower the AWP from 95 percent to 75 percent. I think that would send significant tremors through certainly oncology and ESRD, DME providers, and all the others I have mentioned.

There is no question that I think you need to ratchet down the payment. I think if you did it that abruptly, right away, you would certainly have some significant side effects in the provision of care to people.

I am sorry. Maybe you are talking about the folding in of the across-the-board—that is a totally different issue. I apologize. The high-cost new technology drugs is a completely different issue, something we have worked on a couple of years ago when we went to PPS for outpatient.

There was a carve-out in the outpatient PPS system, which I was very involved in when I was in the hospital business, of 2.5 percent of all the outpatient, which is about a \$17 billion a year system. Two and a half percent of that was carved out for new drugs and devices.

The amount that was allocated for that, however, in the budget was about \$450 million a year. As it turned out, later in the year, because we had so many new drugs and devices that came into the system, the actual budget amount for that turned out to be \$1.6 billion. So, we had an allocation of \$480 million, I think the number was, and a demand of \$1.6 billion.

The law required us to do a pro rata cut. So, we were presented with doing about an 75 percent or 80 percent pro rata cut, which would have essentially wiped out all the drugs and devices.

What we basically did, and Secretary Thompson was very involved in this policy as well, is we basically recalculated all the APC rates and folded in as much as we possible could. So, we ended up doing a modest pro rata reduction, but it was required under the law.

We basically had an allocation of \$480 million and we were significantly over it. We were basically going to spend about \$1.5 billion a year on new drugs that were not allocated in the budget.

I think we did the most artful job we could at folding into the base rates the high-cost drugs, and we ended up doing about a 25 percent reduction in new drugs and devices.

Senator HATCH. All right.

Ms. Rehnquist, welcome to the committee. We appreciate your taking time to be with us this morning. I would like for you to go into more detail about how you believe this problem could be resolved. I am hearing about general recommendations, but what do you believe should be the price or the prices the Medicare program should be paying?

Ms. REHNQUIST. Well, Senator, I think that in the context of the work that my office has done, we have done studies over the years that have shown time and time again how Medicare is overpaying, how Medicaid is overpaying. We have suggested certain data points, if you will.

One data point, I think, is the Federal Supply Schedule. Another data point would be the actual acquisition cost. Another data point would be the AMP, the average manufacturers' price.

These are different data points that I think bear consideration and are worthy of consideration. I think, as Tom pointed out in his earlier testimony, virtually any of these other data points would be an improvement over what Medicare is currently paying.

In terms of recommending a comprehensive vision for where we go from here, that is kind of beyond the scope of what we do. We publish studies of the audits that look at what the savings could be if other prices were looked at.

I think, again, sort of getting back to what Senator Graham was talking about earlier, that collectively we do have a lot of experience with Medicaid using AMP. So, we have some mechanisms in place. We know how to look at that information. We know that it is collected by CMS. It is not releasable, by statute, right now because it is proprietary information that the manufacturers supply.

But we do audit that information. We know that that is accurate, in terms of the average AMP, for what it purports to be. So that, I think, can either serve as a structural framework or it could actually be used more comprehensively for a Medicare benefit.

Senator HATCH. All right. Thank you.

Thank you, Mr. Chairman.

Senator ROCKEFELLER. Thank you, Senator.

Senator Grassley?

Senator GRASSLEY. Thank you, Mr. Chairman.

I am going to start with Mr. Scully. I have had an opportunity to review your testimony of about 6 months ago before the House Energy and Commerce Committee on the issue of AWP, the average wholesale price. In comparing that testimony with the testimony you gave today, I do not see much difference between the two on that issue.

So, I would like to give you an opportunity to state if there is development of any policy by elaborating on the work that has been done at CMS over the past six months to develop recommended changes in the current average wholesale price reimbursement system.

Mr. SCULLY. Senator, to be honest, I think I probably have 15 people in CMS that have spent a lot of time on this over the last decade. A number of times I have had all 15 of them in my office, including my former policy director who is now on the committee. You can get about 15 different opinions about the right way to do it. I think you could pick AMP.



Senator GRASSLEY. So there is not any change in policy yet then.

Mr. SCULLY. I think if you asked today what I thought was the most immediate way to do it, I would suggest personally that the quickest way to significantly improve it would be to just pick one of our DME contractors and one of our Part B carriers—there are four DME contractors and 23 Part B carriers—and basically direct one of them to come up with a consistent national coverage policy.

That alone would save about \$500 million a year. I think that is a significant first step. You certainly could also come up with a statutory mechanism to reduce the payment to a more appropriate level as well.

I think we spent a lot of time with the House Commerce Committee on their concept, which is currently average sales price, which is very close to average manufacturers' price, plus a certain amount to make sure that there is a margin in there for physicians to go out and buy it from distributors.

There are a variety of ways to do it. My own view is, any way is better than where we are now. If the committees could come together, the administration agree on it, probably ASP would work, ASP plus the right number. Any of them would be significant savings.

Senator GRASSLEY. Then you are in the process of developing a policy. Do you have a date when it might be enunciated?

Mr. SCULLY. If you would like us to develop an administration policy on this, I am sure we could. I believe probably some variation—

Senator GRASSLEY. Or specific recommendations to Congress. Either are appropriate.

Mr. SCULLY. Senator, I would suggest right now, if we had to approve something, the closest would probably be to the House Commerce Committee's average sales price plus. The issue would be to identify the appropriate number above that to make sure physicians had access to the drugs.

Senator GRASSLEY. I guess it is such an important issue that I would expect the administration and the President to have a policy.

Ms. Rehnquist, I am pleased to note that the government's success in extracting settlements from pharmaceutical companies that have inflated their AWP's is going along well. I think I need to commend the teams of State and Federal enforcement officials for their hard work in returning almost \$900 million to the U.S. Treasury.

I am going to ask you, though, if you intend to continue utilizing the Federal False Claims QUITAM provisions in this area, as you did in the Bayer Corporation case, to impose price discipline and compliance practices on pharmaceutical companies via corporate integrity agreements.

The reason I ask that, is because you put out a recent letter saying, "Open Letter to Health Care Providers." It suggested in some circumstances requirements for corporate integrity agreements being able to be eased to account for a provider's good behavior.

Now, I guess my judgment is, that could weaken QUITAM. So I am concerned about the effect of this change on provider behavior, if it might invite negative behavior, and on the False Claims Act itself.

So I would like to have some assurance from you that the False Claims Act will not be affected or in any way undermined by the open letter to health care providers.

Then I guess I would finalize it this way, for further affirmation from you that you made to me privately last year to consult with me and the committees I serve on, meaning Judiciary as well as this committee, before you take any action that impacts the False Claims Act or the corporate integrity agreement process in any way.

It seems to me that was a commitment I got from you in our private meetings pre-confirmation times, and that you were very open to total commitment to the False Claims Act. Then I see the open letter, and then I have my doubts.

So, could you give some assurance, please, or what your mode of thinking is now, if it is different from what you told me a year ago?

Ms. REHNQUIST. No, Senator. As you know, the corporate integrity agreements are something that the Office of Inspector General imposes on defendants in the context of a settlement of a QUITAM suit, or False Claims Act lawsuit.

The corporate integrity agreement is in exchange for the Office of Inspector General releasing its administrative authorities that it might have against a defendant, which would be an exclusion authority.

The Bayer Corporation is in a corporate integrity agreement, as is TAP Pharmaceuticals. Although you have to evaluate these cases on a case-by-case basis, certainly if the allegations against a drug manufacturer amount to False Claims Act violations and that determination is made by the Justice Department's Assistant U.S. Attorneys in the field, they pursue those cases.

Now, if they pursue them to trial, there would, of course, be no corporate integrity agreement. The corporate integrity agreement is an aspect of a False Claims Act settlement. But there is no backing down of corporate integrity agreements when we find that the defendant does not have an adequate compliance plan in place.

Senator GRASSLEY. Mr. Chairman, could I ask one more question?

Senator ROCKEFELLER. Yes.

Senator GRASSLEY. This is along the lines of QUITAM, but it is directed to Mr. Scully.

Again, I had a private meeting with you prior to your confirmation. I highlighted the great importance of QUITAM and the benefit of QUITAM. I think we have gotten enough examples of the benefit for it.

But currently the Justice Department is conducting a review of the QUITAM suit against Columbia HCA that deals with the average wholesale price. In the Justice Department's review of the Columbia HCA, they have sought the cooperation of your shop, the CMS.

It is my understanding from sources of mine at the Justice Department that the Center for Medicaid Services has not been fully cooperative with the Justice Department in its investigation of Columbia HCA.

I would ask your assurances that CMS is fully cooperating with the Justice Department on this investigation, and all QUITAM in-

vestigations conducted by the Justice Department in addition to Columbia.

So, I think the best way to make sure, and you probably would say this is being done, but I would like to have you instruct your staff, in writing, to provide all information requested by the Justice Department and make everybody available who works on this at CMS, as requested by Justice.

Mr. SCULLY. Senator, first, I am not recused from Columbia HCA issues, believe it or not, but I did run the trade association, of which they are members. So, I generally do not get involved in that specific issue at all and leave it to my staff.

I will say that we are totally cooperative with the Justice Department on everything. I do not think it is the False Claims Act. I will say I am spending two hours with Justice this afternoon, and I would happy to come and spend an hour's meeting with you and your staff.

I used to be a lawyer. I think some of the interpretations Justice has made of some of the ways they are prosecuting these statements—and it is not just me, it is also the department and the General Counsel's department—are beyond comprehension.

So, I would be happy to come discuss this with you, and some of the approaches they are taking in some of the other cases. And I have no knowledge of what is going on in HCA and Columbia.

Senator GRASSLEY. All right. Well, you do not have to come and discuss anything with me. I just would like to have everybody at CMS who can help Justice, help Justice. I would like to have everybody know that. If you can do that, that is going to satisfy me.

Mr. SCULLY. We have a very good relationship with Justice. I think we have a very good relationship with Attorney General Ashcroft's staff. We have every intention of cooperating with them. But there are some significant legal issues that we do not agree on with Justice.

Senator GRASSLEY. But are you going to question the Justice Department's judgment of whether somebody ought to be prosecuted? And if you are not going to because you do not like what they are doing, that seems to me to be not cooperating.

Mr. SCULLY. Senator, with all due respect, I would be happy to discuss the legal issue with you. But the reality is, in these cases, the Department is the client. We have significant legal differences on issues every day. I think we discuss them in a very friendly, cooperative way.

Senator ROCKEFELLER. Thank you, Senator Grassley.

Senator Lincoln?

Senator LINCOLN. Thank you, Mr. Chairman, for holding such an important hearing today. Welcome to our folks here testifying.

I think it is really unbelievable to all of us that Medicare and Medicare beneficiaries are be overpaying for prescription drugs covered by Part B. We all want to work together to ensure that we fix Medicare's reimbursement methodology, while ensuring that we pay health care providers appropriately.

I am sorry that I was late, but I believe that Senator Snowe brought up some of the points that I wanted to make.

Ms. Rehnquist, in your latest report, you compared the Medicare reimbursement for the 24 prescription drugs to the prices available

in the physician community, the Department of Veteran's Affairs, and in Medicaid. You found, obviously, that Medicare and its beneficiaries paid more for these drugs than any of the other entities.

So, our hope is that we can look to what these other entities are doing, particularly the VA, I think, who has done a good job. I know there has been some comment, and if you all could just briefly give me the idea of why it is that that is happening and why it is that you feel, if you do, that we cannot use better methodology, something similar to what the VA does, in order to be able to reach some of those savings?

Mr. SCULLY. Senator, I think the VA does a great job of purchasing a lot of supplies, including drugs and other things, much like DOD. They probably do a better job than DOD. They buy it in large amounts for multiple hospitals and multiple facilities. The physicians that use them, and the patients, are generally within the VA system, so they can buy them in bulk in this situation.

The concern is, clearly, the VA gets good prices, and that is one indicator. But if you are a physician in rural Arkansas and you have to actually go and buy it for your patients, frequently you are not going to get as good a price as the VA. You actually have to go out and buy it from a wholesaler. So, we want to make sure we do not deny physicians access.

On the other hand, what is happening now is, there are intentionally inflated prices. Clearly, in at least some cases, companies have gone out and intentionally inflated prices to Medicare, with the understanding that physicians would make a significant margin on it.

So the last thing we want to do is find that providers, especially in rural areas, do not have access to go out and buy drugs for their patients. If we picked a price that a large purchasing entity like VA could get when they are buying for a \$24 billion organization, it is probably going to be lower than a physician is going to get out in the rural community. So, we need to make sure that we do not overly squeeze the prices, so I think we need to look at a number of factors.

Senator LINCOLN. Good. I hope we will. That is a point we have been trying to make for a long time, is that rural providers, particularly in reimbursement rates, unfortunately are not able to capitalize on many of the savings that come to other entities out there that are larger groups, particularly in more urban areas.

But I do hope that what Ms. Rehnquist has found certainly, in what she has presented in her report gives us enough initiative to go out and find a better way and a better methodology for those prescription drugs in Medicare Part B.

Just one quick question, Mr. Scully. I have visited with you about this before, and I am concerned that CMS has not yet issued a program memorandum implementing the language from BIPA that we included on the Medicare injectable drug coverage about a year ago.

Mr. SCULLY. I mentioned last week, I had hoped to get a decision made by March 1st. I spent some time talking to the Secretary about it yesterday. It is a very, very complicated issue. The Congress passed a modest expansion of self-injectable coverage that I believe was scored at about \$1.1 billion.

Obviously, it is a dicey issue. There are a lot of drugs, particularly AMS drugs, that people like to see covered. We are trying to live within the intent of Congress. The new language says, "not usually self-injectable." It is a very complicated issue as to whether patients self-administer or have physicians administer 40, 50, 60 percent of the time.

Each one of these drugs has very different utilization rates and we are trying to figure out appropriately which drugs should be covered. We are also trying to figure out whether we should make a national coverage decision, whether the Department would say these are the drugs we are going to cover and these are the ones we do not.

Right now, those decisions are made by 23 carriers. Whether we should take it to a national decision process, or at least some flexibility of the carriers, I hope that we are going to have a decision in the next few years.

Senator LINCOLN. In the form of a decision, are you talking about a rule?

Mr. SCULLY. It depends. It is another issue I am working with the General Counsel on. There are some variations, depending on what the Secretary decides. It could be done by program memorandum and it would happen immediately, or there are others that would probably require a rule. It depends on how much we change the policy.

Senator LINCOLN. It was very clear in what we sent through BIPA, and I would think that a program memorandum would be absolutely appropriate in just implementing the will of Congress as we sent it to you.

But we would love to work with you, and encourage you, again, that we move forward and come to some conclusion on that.

Mr. SCULLY. I know it is frustrating. I am spending a large part of my days on it right now. Thank you.

Senator LINCOLN. Thank you very much.

Thank you, Mr. Chairman.

Senator ROCKEFELLER. I want to ask a question, a final question. Actually, three quick questions, all the same. We have discussed a lot of things here, auditing, overpayments, AWP, AMP, all kinds of things. Part of the point of this, for Senator Snowe and myself, is the Access to Cancer Therapies Act. We have gotten just a bit away from this, at least in my judgment.

So, I just want to ask both of you the same three questions. I can understand, Janet Rehnquist, you will say that is not so much in my area. But you are a health care person and I am going to ask it, because you are in the administration and HHS.

Ms. REHNQUIST. You are the chairman.

Senator ROCKEFELLER. You indicated that there are a lot of things you can do, but you cannot include oral reimbursement without Congressional action. We can talk about a prescription drug benefit coming, in which case none of this will be necessary.

We cannot prove it will come. You and I have spent an hour last night talking about how we hoped, and would work together to make sure that we did everything could that it could come.

But, in the meantime, we have people who have problems and who cannot necessarily afford to wait on Congress' ability to act or

not act. We have had a good record on some things, and not such a good record on some things.

So I want to know, does the administration support expanding Medicare coverage to all cancer groups, whether they are injectable or oral?

Mr. SCULLY. Certainly, in a prescription drug program, there is no question we would, Senator.

Senator ROCKEFELLER. No. I am talking about where we are now.

Mr. SCULLY. Well, Senator, I think the bill that you and Senator Snowe introduced, from what I have seen, was at a score of probably about \$2.8 billion over five years, which is probably about \$9 billion over 10.

I think there are many things we want to accomplish in a drug program. Obviously, whether we are at \$190 billion over 10, or \$300 billion over 10, or other numbers, I think in that context that is probably a group of drugs that will be covered.

In a narrower bill, I think if we are talking about a provider adjustment bill, which is probably a much smaller amount of money this year, I think that would be more difficult to accomplish. So, I think it depends on a lot of things.

Senator ROCKEFELLER. You said last night that \$2.8 billion is not going to be, then you said what it will be. You may be right, and you may be wrong. I would still like to know. It is scored at \$2.8 billion.

Mr. SCULLY. Conceptually, there is no question that we would like to get all prescription drugs covered, including, certainly, cancer drugs. For example, Glevec, which is a drug that I mentioned to you last night. I saw a terrific presentation by the head of the National Human Genome Project the other night.

Glevec is a fabulous drug that has done incredible things for people with leukemia. I think it is appropriate to find ways to cover it. But that drug, for instance, probably is \$50,000 per patient per year. So, the issues beyond this are incredibly complicated.

Senator ROCKEFELLER. Janet Rehnquist?

Ms. REHNQUIST. Senator, I apologize. I have not read the bill that you and Senator Snowe have introduced. As I understand from what we have discussed today, I think that the common sense is, there is much facial appeal to having a comprehensive prescription drug benefit.

But we have to develop a reimbursement method so that we can make it budget neutral, I think, to revise the way we reimburse for drugs, or else I would expect that something like that would be just prohibitively costly and it just would not work.

Senator ROCKEFELLER. So far, the answer is maybe, or perhaps not. So I want to ask my second question of both of you. Do you believe that expanding Medicare coverage to include all orally-taken cancer drugs will ensure access to cancer treatments for Medicare beneficiaries? That is a question of fact, not of opinion.

Mr. SCULLY. I think we certainly should do that, Senator. I think, as we have discussed a lot—

Senator ROCKEFELLER. But do you believe it would lead to that if we covered them all?

Mr. SCULLY. Yes. Yes. I think certainly any of these variations of drugs—and we had a great debate last year whether you do a comprehensive drug benefit in year one or whether you start out with a catastrophic cap like we had years ago. A lot of these cancer drugs will go way beyond \$4,000, \$5,000, \$6,000 a year. Any cancer patient will be significantly—

Senator ROCKEFELLER. And I understand your cost implications, because you have mentioned them many times. I am simply asking a fundamental question.

Janet Rehnquist?

Ms. REHNQUIST. Senator, as I understand it, your question is, if you have a comprehensive drug benefit with Medicare, would that mean access to all Medicare beneficiaries.

Senator ROCKEFELLER. Yes.

Ms. REHNQUIST. Well, I would respond that I think it would depend on how you priced it.

Senator ROCKEFELLER. All right. I wish your answer had been yes.

Ms. REHNQUIST. Sorry.

Senator ROCKEFELLER. I just think that is the only way one can answer that question.

Ms. REHNQUIST. Well, but you would have access problems if you price it too low.

Senator ROCKEFELLER. I know. But, you see, we have been talking about AWP, AMP, all kinds of things, data, auditing, all these things.

I am asking here, I am walking away from that, getting down to the nature of the act itself. I am not including price for the moment. You have to, we have to. We will get to that. I am asking about the fundamental integrity and purpose of the Act itself. I would think, does this ensure access for all people? The answer would have to be yes.

Mr. SCULLY. I think the answer is, there is no question that the administration, Senator, wants to have a Medicare benefit that most under 65-year-old patients have in commercial plans. They have all these drugs covered.

We clearly think that the Medicare program is flawed without drug coverage, and we need to reform the whole program and include drug coverage. So, clearly, in a fixed Medicare program, we believe patients ought to have all these drugs covered.

Senator ROCKEFELLER. And you both, I would assume, would, as a matter of philosophy, support increased access to Medicare beneficiaries for all treatments for cancer, both oral and injectable?

Ms. REHNQUIST. As a matter of philosophy, yes.

Senator ROCKEFELLER. Philosophy determines what you decide to work for.

Mr. SCULLY. I think there is obviously a great deal of sympathy for all patients, but particularly cancer patients. I think there is no question that is one of the major reasons you need a drug benefit.

Senator ROCKEFELLER. Thank you.

Senator SNOWE?

Senator SNOWE. Thank you, Mr. Chairman.

To follow up, I would hope that we could advance the issue this year. Obviously, we would like to see a prescription drug benefit in-

cluded as part of the Medicare program. We are certainly going to strive for that.

But, in addition, there is no reason why we cannot pursue this avenue of including both types of cancer treatments under the Medicare program. I mean, I see it as cost effective.

In fact, whatever changes that are made to the payment system ought to be able to yield savings that could offset any increased costs in providing this reimbursement under the Medicare program.

So do you foresee any problem with moving ahead on this legislation, irrespective of what happens in a comprehensive prescription drug benefit program and/or Medicare modernization?

Mr. SCULLY. We would like to move forward. I think the issue is, you can see we are not particularly artistic at paying for drugs in the Medicare program with AWP.

If we expanded it, Senator Graham knows and you all know from trying to draft these bills in the last couple of years, trying to find a way when you get to a drug like Glevec, which is at least \$50,000 a year and is a terrific drug, to make sure, as we drive these drugs for a large number of seniors in large quantities, that we are paying an appropriate amount.

I think that is one of the great concerns as you develop the drug benefit, is how do we make sure that we have a good drug benefit for seniors and it does not blow up financially, because we do not have a real good mechanism right now to figure out the most cost effective way to buy it. I testified on that last week. We are certainly extremely committed to doing that.

I can tell you, I discussed this with Senator Rockefeller yesterday, there is a strong commitment in the administration to try and get something done this year on prescription drugs. Can we fix everything this year? We would like to try. Can we agree on it? We certainly want to get something done this year.

Senator SNOWE. I think the question is, if for some reason we did not pass a prescription drug benefit and/or Medicare modernization, would the administration be willing to advance this issue and support it outside of that?

Mr. SCULLY. Senator, I think the administration's position is, our strongly-held view is that, if we do a provider package—and we are sending a letter up to Mr. Thomas this afternoon in response to his questions about similar issues—that we have a budget-neutral package so that we do make sure we do not spend money that should be allocated towards Medicare prescription drugs and reform, and knocking down the number of 40 million-plus uninsured for access. If we do a provider package, it ought to be budget neutral.

Within that context, if you did not do a broader drug benefit bill, I think we would be happy to discuss expansions for things like cancer drugs in the context of a more normal year reconciliation bill.

Senator SNOWE. Did you mention earlier that there would be a savings in using average manufacturers' price of \$12 billion over 10 years?

Mr. SCULLY. Ten years. Yes.



Senator SNOWE. Now, I understand the House is developing a proposal they call the average sales price. They are also considering the average sales price plus 15 percent, or plus 8 percent.

What are your thoughts on that?

Mr. SCULLY. I think average sales price is similar to average market price, we believe. I think we have spent a lot of time talking to them. I think it is a good concept. Whether it is average sales price plus 8 or plus 15, is obviously a big difference. We are trying to figure out what the right number is to make sure that there is access for oncologists and other providers.

But, personally, I think that is as workable a mechanism as I have seen, and my hope is that the three committees involved will pick one of the mechanisms and go forward with it.

But I think that is certainly the one that I think, of the legislative proposals that I have seen so far, average sales price plus, pick the right number, is probably the best one I have seen.

Senator SNOWE. So would that yield more or less savings with the ASP?

Mr. SCULLY. It probably would yield a little less, but not very much. Probably close to about \$800 million in the first year, so it would probably be a little less than \$12 billion.

Senator SNOWE. One other issue. As you know, more than 52 members of the Congress had contacted you and the Secretary concerning the enactment of BIPA, the Benefits Improvement and Protect Act, urging the CMS to issue a program memorandum implementing statutory language that would clarify the coverage of drugs under Medicare Part B.

How close are you to doing that?

Mr. SCULLY. We are very close. As I tried to explain, maybe not too coherently earlier, the issues of—for instance, probably the drug that has gotten the most attention over the years is Avonex, which is an MS drug.

The language in the law says, “not usually self-injectable.” Is that 50 percent of the time? How much? We have no data on, for instance, that particular drug, which is a high-volume MS drug as to how often a physician administers it as opposed to it being self-injected. There are extremely complicated questions that involve probably 25 fairly high-volume drugs.

I had hoped to get it done by March 1. We are very actively working on it. I have to sit down with the Secretary—I started last night—and make some decisions.

Senator SNOWE. All right.

Thank you, Mr. Chairman.

Senator ROCKEFELLER. Thank you, Senator Snowe.

Final questions from Senator Graham for this panel.

Senator GRAHAM. Mr. Chairman, this is really a question of you. I am afraid I am going to have to leave. Will we be able to submit written questions for the next panel for subsequent response?

Senator ROCKEFELLER. I think the answer to that would be, absolutely.

Senator GRAHAM. Is that a yes?

Senator ROCKEFELLER. Yes.

Senator GRAHAM. Thank you.

Senator ROCKEFELLER. In that case, I want to thank both of you, Tom Scully and Janet Rehnquist, for testifying before us and being helpful, and making us think, ponder, and prepare. Thank you both.

Ms. REHNQUIST. Thank you, Mr. Chairman.

Senator ROCKEFELLER. The second panel is made up of Laura Dummit, who is the Director of Health Care-Medicare Payment Issues in the U.S. General Accounting Office. She is responsible for overseeing the body of work related to Medicare payment policies and health care delivery.

Dr. Larry Norton, who is a renowned clinical oncologist and internationally recognized leader of drug treatments for breast cancer. He is attending physician and member of Memorial Hospital and the head of the Solid Tumor Division at Memorial Sloane-Kettering Cancer Center in New York.

Ellen Stovall is a 30-year survivor of two bouts with cancer and is present and CEO of the National Coalition for Cancer Survivorship, the Nation's only patient-led advocacy organization representing people with all types of cancer and their families.

Lisa Getson is senior vice president of Business Development and Clinical Services for Apria Healthcare. Ms. Getson manages Apria's Clinical Respiratory High-Tech Infusion Nursing and Pharmacy Services.

I thank you all for coming. You all know what question you are going to get at some point in the questioning from Senator Snowe and myself.

So, we look forward to your testimony. We will start with you, Laura.

**STATEMENT OF LAURA DUMMIT, DIRECTOR, HEALTH CARE-MEDICARE PAYMENT ISSUES, GENERAL ACCOUNTING OFFICE, WASHINGTON, DC**

Ms. DUMMIT. Thank you, Chairman Rockefeller and Senator Snowe. I am pleased to be here today as you discuss the important issue of how Medicare pays for outpatient covered prescription drugs.

In September of last year, the GAO issued a report with recommendations on this topic, and 1 month later, a related report on the adequacy of Medicare's payments to oncologists for chemotherapy administration.

Today I will provide highlights from both of these studies which underscore the need to modify Medicare's payment methods. Our drug pricing study findings echo those of the Inspector General, Justice Department, and CMS. All reveal that Medicare's payment method for establishing drug payments is flawed.

Simply put, tying Medicare's payment to a drug's average wholesale price is a recipe for inflation and excess payment. Even though AWP is often labeled a retailer sticker price, it is not even that.

A price is what a purchaser pays for a product. AWP, however, is a number manufacturers specify without rules or criteria, a number that is not constrained by any purchaser's willingness to pay that price.

Like the Inspector General, we found that wholesaler catalogue prices available to any physician or pharmacy supplier were considerably below AWP.

Average discounts on physician-billed drugs, mostly chemotherapy drugs, generally range from 13 percent to 34 percent less than AWP, compared to Medicare's payment of 5 percent less than AWP. Discounts on two important inhalation therapy drugs were even greater, 78 percent for one and 85 percent for another.

Moreover, we heard from purchasers and sellers that such wholesale catalog prices were often merely the starting point. Actual net prices after rebates and additional negotiated discounts could be even lower.

While concerns have been expressed that small practices might not have access to significant discounts, we found that even physicians who billed Medicare for low volumes of chemotherapy drugs got similar or better discounts than the widely available prices we had documented.

Medicare's experience is often contrasted with that of the Veterans Administration. As the VA is essentially a health care provider, not a third party payor like Medicare, its approach cannot be simply transferred. But its key elements can.

VA uses the leverage of Federal purchasing volume to get verifiable data from drug manufacturers on actual market transactions to private purchasers. These data are then used to establish the Federal supply schedule prices. For selected drugs, the VA has consolidated its purchasing power even more and used competition to secure even lower prices.

CMS has comparable information on market prices through the Medicaid drug rebate program, although it would need Congressional sanction to use these data as a basis for Medicare payments.

We are recommending that CMS assess how it can use those data to ensure that Medicare's payments more closely reflect market prices and to explore how competitive procurements might be effectively used.

Our findings about drug prices are not controversial. Providers acknowledge the generosity of Medicare's payments, but they contend that the excess drug payments make up for inappropriately low Medicare payments for dispensing and administration.

In particular, oncology representatives have claimed that Medicare's payments for chemotherapy administration, which are made under Medicare's physician fee schedule, typically through the practice expense component, do not cover their costs.

So I will now turn to our second report which examines those payments made to oncologists who account for the bulk of physician-billed drugs.

In our evaluations, we have concluded that CMS' basic method of computing resource-based physician fees is sound. It achieves the goal laid out by the Congress, which is to align physician fees with the relative amount of resources needed to provide each service, rather than according to what physicians historically charge for their services, as had been the case.

However, the implement of the revised fee schedule has been controversial. Since the Congress required that the new fees be budget neutral, if one specialty's fees increased on average, then

some others would have to decline. Such redistributions have occurred and some are significant.

Oncology, however, is one of the specialties to gain in the change to the resource-based practice expense fee schedule. Its practice expense payments are eight percent higher than what they would have been if the prior method of setting fees had remained in place.

However, we do believe that there is a problem in the way fees for services like chemotherapy administration by nurses are calculated. HCFA modified its basic method in computing payments for certain services, including chemotherapy administration.

The modifications were intended to correct for perceived low payments for these services, yet some fees, including some for chemotherapy administration, were lowered even further. The modifications moved the fee schedule away from the resource-based approach that Congress intended.

We do not believe that the changes to the basic method were appropriate and we recommend that CMS use the basic method to determine practice expense payments for all services. Such a change would increase Medicare's payments for most chemotherapy administration services.

Overall, we believe that it would be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some services to offset inadequate payments for complimentary services. An efficiently operated Medicare program needs payments that reflect market prices so that it benefits from the discipline imposed by other payors.

At the same time, however, it must balance its responsibilities to be efficient with its responsibilities to ensure access for beneficiaries and to treat providers fairly.

Any changes to Medicare's payments, particularly a reduction in fees, needs to be accompanied by ongoing examinations of recent service use so that prompt fee adjustments can be made if access problems are found.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions.

Senator ROCKEFELLER. Thank you very much, Ms. Dummit.

[The prepared statement of Ms. Dummit appears in the appendix.]

Senator ROCKEFELLER. Dr. Norton?

**STATEMENT OF DR. LARRY NORTON, PRESIDENT, AMERICAN SOCIETY OF CLINICAL ONCOLOGISTS, NEW YORK, NY**

Dr. NORTON. It is a great pleasure to be here, not only to talk about this important topic, but also to congratulate you, Mr. Chairman and Senator Snowe, for championing the cause of access to quality cancer care for older Americans, something that we all seek.

I really want to underscore how important this is. I have dedicated my life to the treatment of breast cancer. One of the most commonly used drugs that we use is Tamoxifen, which helps essentially all stages of the disease. It is just unbelievable that that drug is not reimbursed.

We have seen situations where patients share their prescriptions, so they all get under-dosed by 25 or 50 percent, thinking that it is not going to make a difference. It does make a difference.

I know of one patient who was recently prescribed a romatase inhibitor, a whole new class of very exciting drugs for breast cancer that is going to be in even wider use based on recent data that has become available. She was taking the drug every other day, thinking that would really do the trick.

Dosage is extremely important for cancer drugs. Not being able to have access—and we are not even talking about Glevec, which has lifted patients right out of their death bed with diseases like the GI stromal tumors.

The most incredible thing that we see in oncology is where patients are on the verge of death, taking two or four pills a day and just getting up from their death bed and going home. For that not to be paid for is just extraordinary.

So, I think this is a very important topic and something really has to be done right away. I am very supportive, as we all are, of your efforts to achieve that.

I think it goes along with the whole topic of access to quality care. Of course, not all quality care is going to be oral. A lot of it now is intravenous, most of it. We hope as little as possible, but even in the far future, some of it will have to be intravenous because not all these medications can be made in an oral form. They will not be absorbed, for a whole variety of chemical reasons.

So, access to intravenous medications is also of critical importance. That gets us into the whole area of the AWP and the reimbursement of the actual cost of administration of drugs by the doctors.

I just want to underscore something that I do not think has come up clearly. We are talking a lot about numbers. But the fact is, oncology is not like any other practice in internal medicine.

The doctors have to buy the drugs, they have to buy the IV tubing, they have to buy the needles, they have to pay for the nurses, they have to pay for the social workers. They have to do all of this before the first patient walks in the door.

These are all out-of-pocket expenses. The government's own estimate has been that doctors are now being reimbursed at 25 percent or less of the actual cost of the administration of the medications. The money that is coming out of their pocket is coming back, to some extent—and we do not know to what extent—from the AWP issue.

We support what everybody said here before, that AWP has to change. But it has to change commensurate with a change in the reimbursement for the actual cost of administering the chemotherapy or else we could be in real trouble here. I really want to emphasize that this is a very, very serious issue.

All the costs we are talking about, nursing costs, monitoring for toxicities, the phone calls involved, nutritional counseling, social work counseling, family counseling, all of these critical issues right now are working, to some extent.

Patients are being treated because of this equilibrium we have with basically two unfair things going on, a dramatic reimbursement on one side and overpayment on the other. We all agree.

A sudden change, without carefully thinking out the consequences, could be disastrous. When I started looking into the issue when I was elected to the presidency of the American Society of Clinical Oncology, I interviewed dozens of doctors in New York State and throughout the country, probably hundreds at this point. I have been doing this for 2 years.

The doctors and the patients—and I think you will be hearing from the patient side in a moment—are really terrified of the implications. Can you start reducing the costs of administering chemotherapy? You can give some of these drugs by direct injection rather than through IV tubing, but you risk extravasation of some of these drugs.

This means that the drug gets into the tissue and the tissue will die and actually turn black and fall off. It is a horrible consequence, and it can happen because of efforts to reduce the cost of administering the chemotherapy. We just cannot let that happen. The nursing time is essential to make sure that quality is being part of the system.

Senator ROCKEFELLER. With Senator Snowe's permission, can I just interrupt you to make this point? You indicated earlier that you have to pay for practice expense, nurses, space, all kinds of things.

Oncologists, insofar as I remember from my RBRVS days—and nothing, I do not think, has changed that much since then—along with anesthesiologists and some others, are still pretty well reimbursed. Does everybody else not have to pay pretty much those same costs?

Dr. NORTON. Well, the difference in oncology, is that it is most of the patients that require this very extensive system for administering chemotherapy, drug therapy.

Cardiology, rheumatology, nephrology. It would be a small percentage of the patients that would require this as opposed to the bulk of the practice of oncology. Oncology really is special among oncologic practices and has to be looked at that way.

Senator ROCKEFELLER. I would be interested—and I am going to apologize to my colleague—and would like to get some data on that.

Dr. NORTON. Sure.

Senator ROCKEFELLER. Because getting data, as Janet Rehnquist was saying, we can do it, audit it, and all the rest of it. But some of the rest of us are a little bit more skeptical about what data has been submitted. So, we more or less have to rely on the data we are given.

I think, without being audited, sometimes it just comes from physicians or pharmaceutical companies and is not necessarily audited as well as we think.

So, for me, without any pre-assumption here, I would like to get some information from you about the differences between you and, let us say, some other kinds of physicians in terms of practice expenses.

Dr. NORTON. Absolutely. In fact, that is a very important topic of conversation. Oncologists are telling me that if the system gets thrown out of whack here, that they are not going to be able to afford to do it.

Some have said that they refer the patients to hospitals. But I called hospitals all through New York State when I looked into this 2 years ago, and they cannot afford it either.

I can tell you, at Memorial Sloane-Kettering we have an obligation to our own patients. We could not take an influx of hundreds or thousands of patients to treat. We have the same economic pressures, the hospitals have, that the community-based oncologists have. So, it is a huge issue.

Senator ROCKEFELLER. Again, with apologies to my colleague, I hear so many doctors over so many years, both as a Governor and as a Senator, making statements like that.

If we do not get reimbursed when we start doing health care cost review in West Virginia, if we do not get reimbursement to a certain level, we are going to have to stop.

I have gotten a little, sort of, harder about my reaction to that. People go into a profession to do certain things and I am a little more skeptical about it.

Dr. NORTON. What they are saying is, they will do consultations and plan for the treatment, but not be able to afford the administration of it. These are out-of-pocket expenses for these doctors.

Senator ROCKEFELLER. So just leave the patients and then walk away.

Dr. NORTON. They are not going to walk away. They are going to try to see if they can arrange it. But I can tell you, calling cancer centers and hospitals, it is not going to be easily arranged. In fact, we could have a disaster here.

It is a very, very serious issue. These are out-of-pocket expenses, expensive issues. They are paying for it before the patient even walks in the door. And there are a lot of other costs, hidden costs.

But I want to get to your point, really, which is that we do not know a lot of those numbers. We have been trying to get those numbers. I agree with you. I do not think the data is good. I am just speaking as a scientist here in terms of what it actually costs.

Senator ROCKEFELLER. Then get good data and get it to us, for heaven's sake. For your own sake, and for ours.

Dr. NORTON. We actually have been trying to. The House asked us to work together with CMS to do this. We have been trying to. There have been discussions about methodology and differences of opinion. There are data out there.

There is a clinical practice expert panel that came up with that number—and this is back a few years—where doctors were only getting about 25 percent reimbursement for what they actually had to spend to treat a patient with chemotherapy. These are numbers that exist out there. I think it is worse today.

Senator ROCKEFELLER. That may be, Doctor. But if you are telling me that there is about to be a catastrophe, or there could be a catastrophe, and at the same time you are telling me that you do not have data because there is so many different kinds of data available, it is not very convincing.

Dr. NORTON. Mr. Chairman, we are trying to work to get you that data. We really are. We are trying to work with CMS. They do not agree with the methodology. GAO was asked to do this in 1999, and again in 2000. They did not give the data. We did not do it independently.

We are planning to do it independently. We want to do it independently. But we have been asked to work with the government on this and we are having difficulty doing that because there is no agreement on methodology.

The only way to find out what a syringe costs is to look at the cost of a syringe. There are other ways of doing it, but it does not give you an accurate number.

So, we are trying to do that. I agree with you 100 percent. We need data to know what we are dealing with. I heard quotes earlier today that any way is better than what we have here now. That was an exact quote I heard. I do not think that that is necessarily the case.

There are ways that can make it very difficult or impossible for patients to actually be treated. We have to avoid that. The oral drug part is critical, but we cannot forget the IV drug part.

If doctors in the community cannot afford to give the drugs, you can just pour out so much money from your pocket for so long before there is just no more money there. We could be in very, very serious trouble. This is the statement. Any changes that are made have to be thought through very, very, very carefully to make sure that we do not start, really, a disastrous situation.

Thank you very much.

[The prepared statement of Dr. Norton appears in the appendix.]  
Senator ROCKEFELLER. Ellen Stovall?

**STATEMENT OF ELLEN STOVALL, EXECUTIVE DIRECTOR, NATIONAL COALITION FOR CANCER SURVIVORSHIP, SILVER SPRING, MD**

Ms. STOVALL. Yes. I would like to comment on the whole AWP issue. It may be at the end of my remarks very briefly, but I really feel that the issue that I want to discuss today has gotten a little bit short shrift. That is, the important bill that you and Senator Snowe have pending with many of your colleagues in the Senate.

My name is Ellen Stovall. I am a 30-year survivor of Hodgkin's Disease, diagnosed in 1971. I had a recurrence in 1984. I am really able to appear before you today because I was fortunate to receive some of the best cancer treatment that our country can provide. I did not have access to health care issues, I did not have financial problems. I had cancer under the best of circumstances.

The treatment that I received in 1971 was really considered the best that there was at the time. It was radiation alone. There was no chemotherapy for my cancer that was not in clinical trial.

When I had a recurrence of my cancer in 1984, the drugs that were in clinical trial in 1971 were used to treat my cancer. I was ineligible to take advantage of the trial.

The personal commitment that I have to advancing new cancer treatment through the conduct of high-quality cancer clinical trials is what I bring to my work as the president of the National Coalition for Cancer Survivorship.

NCCS considers itself an honest broker of very sound health policy and views this approach as the most efficient way to ensure quality cancer care for all Americans, which is our core mission. Both the access to quality that I had and my ability to live long



enough to take advantage of the progress in cancer research are what you are addressing today.

I want to begin my remarks by thanking both you, Senator Rockefeller and Senator Snowe. Both of you have well-established records on the issue of oral drug coverage for Medicare beneficiaries.

I want to pay a special tribute to Senator Rockefeller for your perpetual bipartisan support over many years that resulted in President Clinton's June, 2000 executive memorandum requiring Medicare to pay for the routine patient care costs associated with clinical trials.

I want to mention the limited coverage of oral drugs currently available under Medicare, which is due almost exclusively to the hard work and dedication of Senator Rockefeller over a decade when his bill to cover oral anti-cancer agents that have an injectable equivalent became law in 1993. We believe this legislation provides clear precedent for cancer drugs to be covered differently under Medicare.

Senator Snowe, your leadership is evident in your effort to extend Medicare coverage to Tamoxifen and other agents. These drugs were not covered by Senator Rockefeller's legislation in 1993 because they have no IV equivalent.

The Access to Cancer Therapies Act will not only provide much-needed reimbursement to many of our senior citizens on this very important anti-cancer hormone, but to many of my friends with prostate cancer who depend on oral hormonal agents, and to your former colleague Senator Geraldine Ferraro, who, with multiple myeloma, is taking relief from taking thalidomide.

Coverage of these existing drugs is very important to us. An equal passion we have for this bill is the prospect of coverage for the many new, promising oral anti-cancer agents that will move through the FDA over the next few years as scientists are designing drugs that specifically target the receptors that cause cancer and disrupt the growth of cancer without collateral damage to surrounding tissues.

On Glevec, which you have heard a lot about, unfortunately, I am a little bit worried about the calculus Mr. Scully is using. If he is using the calculus to price this drug, it could explain a lot of the reasons why we are having difficulty communicating with him on the over-payment of drugs and the under-payment of services.

Glevec, from the folks I know who take it, costs \$25,000 a year, not \$50,000. That is a clear 50 percent differential that needs to be corrected.

Prior to Glevec, these patients faced two unpleasant and highly debilitating and costly therapies: bone marrow transplantation or high-dose interferon, both of which pose great risk and physical distress for seniors, which render these treatments all but unbearable for them.

Another one of Glevec's targets is a rare, but deadly tumor known as gastrointestinal stromal tumor, or GST. A patient with GST told my colleague Richard Palmer, of the Life Raft Group, that her bottle of Glevec sits on her dresser. She has labeled the bottle "Extra Time."

If Richard himself were here, he would tell you that, 15 months ago, he had incurable cancer that was not fazed by conventional chemotherapy or radiation. That is when he started Glevec.

Last month, his clinical trial doctor told him that his GST tumor would not kill him anytime soon, if ever. He would go on to tell you that the hardest part of taking this drug is learning to live with hope again.

I hope that that is a message that we could all take home with us and that learning to live with hope again becomes the hardest thing cancer patients have to do in the future.

These drugs literally are “hope in a bottle,” providing therapies for people, for Richard, that seemed all but out of their grasp a few years ago. This is why your legislation, that enjoys the co-sponsorship of more than 30 of your colleagues, is so timely and important.

You have the will of the American people behind you, as NCCS discovered when we conducted a Harris poll of 1,000 Americans over the weekend. They tell us that 9 in 10 of them want Medicare to pay for all medically-approved cancer therapies.

They also tell us that 4 in 5 believe your legislation should be passed in this session of Congress. Four in five Americans would support adding 1 percent to the cost of cancer care paid by Medicare if it meant that Medicare patients could have better access to cancer therapies.

My message to you, and to the entire Congress, is to pass this legislation now so that Medicare patients, our citizens who are most disproportionately affected by cancer, can rest assured that they will have access to these therapies.

Can I make a comment in closing about the issues raised by Ms. Rehnquist and Mr. Scully? They are in my formal testimony.

But the inequities in the Medicare drug payment system, namely AWP, really, the overpayment for drugs is something that we all want to see changed. I am worried that Mr. Scully and CMS are using a calculus that is really off-base, as I said to you. If there is no methodology that starts at the bottom and works its way back, we really have no idea what we are paying for out there.

I am sorry Senator Grassley had to leave early, because we talked to his staff a couple of weeks ago and we asked him to go and visit the practice of the chairman of my board, Dr. Dean Gesme in Cedar Rapids, Iowa, one of his constituents. He is going to be visiting there in the next couple of weeks.

I would love to arrange for the two of you to visit an oncology practice before making any precipitous decision about this issue of AWP and what it is paying for.

The reason is, because until you can see how people are being treated and what the gross under-payments are on the side of the other end of the spectrum for a physician practice expense, Larry's comment about a disaster on our hands, I do not believe is overstated.

I can tell you for a fact that Dr. Gesme, who also sees patients in rural Iowa—he has a practice in Cedar Rapids—pays for the offices in rural Iowa, the rental on those offices, based on the margin he gets from that chemotherapy. He knows that that margin, and the calculus for it, is perverse.

He really wants to see that payment methodology go away. But he is very, very worried that if it happens immediately, that he will have to close those offices because that is where he is getting the money from. Most of his oncology nurses are not going to be able to stay with him and it is literally going to gut his practice.

This is an honest, good, hardworking oncologist. Most cancer patients in this country are treated by people like Dr. Gesme. I really am concerned.

We all want to see this payment methodology changed, but we really want to work constructively with the people, both patients and doctors. We are really in this together. We are inextricably linked in trying to get our cancer treated, and we ask you to please pay due consideration to this as you consider this whole issue.

Thank you.

Senator ROCKEFELLER. Thank you, Ms. Stovall. I hear exactly what you are saying. We have been living with this problem for some time now, as have oncologists. I continue to think that it is not in the nature of those that have studied and spent all their years becoming physicians to walk away from their patients, to put it crudely.

Dr. Gesme is not going to do that. I do not like it when people say that kind of thing. I react to it more warmly when you say that. I think he is right. I also understand that there is a very close relationship between you and an oncologist, just by definition.

But you go down what RBRVS did, the adjustments that were made, what people make. We think of rural physicians and what they do, and what they do not get paid, and the nurses they do not have, and the syringes they do not have, the space they do not have, and the air conditioning that they do not have, and everything has to be put into context. People have to do what they have to do. So, the catastrophe factor, we will discuss when we do more questions, but I maintain my view on that.

[The prepared statement of Ms. Stovall appears in the appendix.]

Senator ROCKEFELLER. Ms. Getson, please.

**STATEMENT OF LISA GETSON, EXECUTIVE VICE PRESIDENT  
OF CLINICAL SERVICES, APRIA HEALTHCARE, LAKE FOREST,  
CA**

Ms. GETSON. Mr. Chairman and Senator Snowe, my name is Lisa M. Getson. Thank you for inviting me to appear at this hearing on behalf of Apria Healthcare.

Headquartered in Lake Forest, California, Apria Healthcare is one of the Nation's largest home health care providers of oxygen and respiratory therapies, home infusion therapies, and home medical equipment.

My testimony this morning can be summarized quite simply. There is no question that drug payments for home inhalation and home infusion therapies subsidize other important functions and costs that are not directly reimbursed.

But we are extremely concerned that drug payment reform may occur without a corresponding change in how these other vital services and functions are covered and paid for as they are in other Medicare-covered settings.

We strongly urge the committee to couple drug payment reform with coverage reform for these home-delivered therapies. If that does not occur, then it may become impossible for responsible home care providers to serve Medicare beneficiaries.

Inhalation therapy is the process through which a drug, or a combination of drugs, is delivered into the airways directly into the lungs via a device called a nebulizer. These drugs are used to treat chronic obstructive pulmonary disease, the fourth leading cause of death in the United States according to the National Institutes of Health.

The clinical literature also shows that patients are being diagnosed earlier and treated proactively to reduce other medical expenses. Infusion therapy involves the administration of the drug into the body through a needle or a catheter. Patients and their caregivers, on these therapies, prefer the comfort of their own homes for these treatments.

In addition, private payors have realized that home health care is significantly less expensive than either hospitalization or emergency room visits, and they have saved millions of dollars each year as a result.

But, unlike private payors, Medicare Part B covers very few of these therapies. Current Medicare policy limits payment for these therapies to what is covered and paid for under the Durable Medical Equipment, or DME, benefit, which only explicitly covers the drugs, supplies, and equipment. It does not reflect any other services or any other costs that are integral to the provision of these therapies.

Patients receiving these therapies must also receive services as part of their care. This is the community standard of care across the country, and it would be reckless for Medicare to ignore that standard.

For these therapies, this debate is not simply a reimbursement issue. Rather, it is a coverage issue. Clarification of Medicare coverage in this area is long overdue.

The acquisition costs of the drug is only a small part of the cost that we incur when caring for Medicare beneficiaries at home. We have legitimate clinical and operating costs that generally are recognized by Medicare for providers in other care settings.

For example, these therapies require staff to be available around the clock to respond to emergencies and questions. They may require the services of a licensed pharmacist, nurse, or respiratory therapist to perform a variety of functions, often in the home. We also deliver directly to patient homes using company vehicles or overnight delivery services.

Although Medicare does not currently require accreditation as a condition of participation currently, the Medicare program and beneficiaries do benefit from working with accredited providers.

It is important to note that most private payors do require the providers to be accredited. This offers the public the assurance that an accredited provider meets or exceeds a verifiable standard of care.

There are also costs we incur associated with complying with numerous government agencies, such as the Food and Drug Administration, the Drug Enforcement Agency, the Department of Trans-

portation, and State Medicaid programs. Home care pharmacies also incur significant costs in complying with program rules related to billing and documentation.

So to study industry costs, in the summer of 2001 the American Association for Homecare contracted with the Lewin Group to conduct what we believe is the most definitive study ever conducted on this subject.

The study included statistically valid data from 19 home care pharmacies across the country. The study found that the acquisition cost of the drug represented only 26 percent of the total cost of caring for Medicare Part B beneficiaries.

The remaining 74 percent of the costs were comprised of the administrative labor, clinical, billing and collection costs, indirect or overhead costs, inventory warehouse delivery expenses, and bad debt. I have submitted the study to the committee.

In conclusion, we understand the committee's interest in reforming Medicare reimbursement for drugs. However, there must be a corresponding creation of a payment structure for the services required to furnish inhalation and infusion therapies in the home. Thus, we need another step.

Congress has to clarify coverage for these therapies in the home care setting before reimbursement changes are implemented. We believe that the Lewin Group study contains the most accurate and up-to-date information about the total cost borne by providers.

If there is to be further study, we recommend that Medpac or the Institute of Medicine work with the home care pharmacy industry to conduct a formal study.

Mr. Chairman, Senator Snowe, thank you for the opportunity to present this information to the committee. I will be happy to answer any questions.

Senator ROCKEFELLER. Thank you, Ms. Getson.

[The prepared statement of Ms. Getson appears in the appendix.]

Senator ROCKEFELLER. Senator Snowe is going to have the first round of questions.

Senator SNOWE. Thank you, Mr. Chairman.

Ms. Getson, would you support the legislation that Senator Rockefeller and I have introduced with respect to anti-cancer oral drug treatments?

Ms. GETSON. Given the fact that Apria Healthcare services tens of thousands of patients with cancer nationwide every year, given the fact that lung cancer deaths, for example, in women, have jumped 600 percent since the 1950's, and the fact that our patients who are on infusion or inhalation therapies with us would also be taking the oral, then, yes, we would support that expansion.

Senator SNOWE. Is there a way to measure the cost with respect to what you are suggesting? I gather you are saying that basically now the reimbursement is based on the acquisition cost, but not all the other additional costs with respect to labor, administrative, clinical, and all the other issues that add to the cost of providing inhalation therapy. Is that correct?

Ms. GETSON. Yes. I am not sure I understand your question, though.

Senator SNOWE. Is there a way to measure it precisely, obviously, in terms of the additional costs that are associated beyond the ac-

quisition costs? You have said it has come down to, 74 percent of all of the extra costs in providing this kind of therapy at home are not reimbursed. Is that correct?

Ms. GETSON. That is correct. The current methodology for durable medical equipment providers, under Part B, relies solely on the AWP minus 5 percent factor, plus a small dispensing fee. That is unlike other care settings.

The Lewin study does break down the 74 percent and provides both the committee, as well as other groups to whom we have submitted that data, the breakdown of nursing, respiratory therapy, overhead, pharmacy, and other costs.

Senator SNOWE. Is this an issue that your organization has pursued before with Health and Human Services or with Congress?

Ms. GETSON. In the past 18 months, since the former Secretary first issued notice that changes might occur, we have been working very proactively through the American Association for Home Care, with various committee members, and CMS, and also worked with the GAO as they prepared their study last summer.

Senator SNOWE. All right. So really it has just been in the last 2 years, essentially, that you have been working on making this change with respect to this issue.

Ms. GETSON. Yes.

Senator SNOWE. All right. What has been the response from the Department?

Ms. GETSON. I would say that they have acknowledged that they have not had enough time to adequately study this issue, that most of the time and attention has been spent on the physician component, since that is where the bulk of the spending for these drugs has actually occurred.

But they have been very receptive to our information. The GAO, for example, had staff visit a home infusion pharmacy to gain a better understanding of the various service components.

Senator SNOWE. For Dr. Norton and Ms. Dummit, since you both focus obviously on the same areas, and the GAO obviously examined the issues of oncology expenses. Dr. Norton, first of all, would you agree that some of the issues concerning reimbursement for oncology services started with the previous methodology changes under HCFA at that time? I am trying to get an understanding.

Is that when this problem manifested itself? Was it always present, but was exacerbated by the changes that were made by HCFA or the administration?

Dr. NORTON. It kind of grew around us. But, clearly, decisions were made by HCFA that brought us to the current state, yes.

Senator SNOWE. I see. And do you agree with the assessment that has been made by the General Accounting Office in terms of what could address the problems that are being faced by your group?

Dr. NORTON. I think that we need more data, frankly. I am just speaking as somebody who looks at data professionally. When I make a decision to treat a patient with a drug, and I know the dose of the drug, that dose for that drug is based on a lot of solid data.

I do not see enough data here to feel very confident that I know what the real costs are and what the real reimbursement situation is. Nobody has really done a bottom's up approach where you look

at how many syringes and how much nursing time is involved. I think that is really what is needed here so that we know what the true costs are.

Senator SNOWE. I see. So the basic methodology proposed by the General Accounting Office, combined, would yield an additional \$51 million. You are not necessarily in agreement or disagreement?

Dr. NORTON. I think that you and I should both get an accounting of how they come up with that number to see if it is a satisfactory number.

Senator SNOWE. Ms. Dummit, can you respond to that?

Ms. DUMMIT. Yes. What we did in reaching that \$50 million number, was we looked at the basic method that HCFA used in establishing the practice expense fees.

Our earlier analysis and our current analysis confirmed that that is a reasonable approach to setting practice expense payments for physician services.

CMS used the best available data that they had on both specialties' total practice expense costs, as well as CPAP data, which are physician groups that determine the resources that are used for each particular service.

I will add that CMS has stated that physician specialties can submit revised practice expense data, that is, data that sets the entire pool of payments for a particular specialty.

They have that specialties can submit those data, and if it meets particular requirements, they will use those data in setting the fees. Furthermore, CMS regularly updates the service-specific information it uses to set the fees.

As I said, GAO did a very detailed analysis of CMS's method for calculating fees for particular services. There were two variations from their specific basic methodology that, in particular, affected oncologists. One, is most chemotherapy services are performed by nurses. That is, they are non-physician services and do not include a physician work component.

CMS separated out those services and developed a different method for paying for those services, a methodology that is not resource-based as the Congress intended, but is rather based on the old charge-based system.

We believe that that is not the right way to go. We have recommended that CMS fix the underlying problems with those fees, which we believe have to do with overhead allocation, and pay for them using the basic methodology.

Furthermore, CMS reduced the practice expenses attributed to supplies that oncologists reported. Everyone acknowledges that oncology supply expense data included some numbers for drugs, which, as we know, are paid for separately.

CMS, rather than gathering the correct information, substituted the all physician average. This further lowered oncologists' payments. We believe if these two payment problems were fixed, that payments to oncologists in 2001 would have been about \$50 million higher than they were now.

Senator SNOWE. Dr. Norton?

Dr. NORTON. I am really not sure of the number. I mean, I think it is the number. What we are hearing here, is there are some problems that have already been identified with the way these are

calculated. I am not convinced that the number is an accurate number, unless you look at the whole picture and everything that is really involved.

Once you see some problems in the way the estimation is, you have to look at the whole picture and see whether it is a fair, accurate, scientifically valid way of deriving these numbers.

I do not know whether that is an accurate number. I would have to be convinced—I am not convinced yet—that that number is accurately derived.

Senator SNOWE. Well, obviously this is something we are going to have to follow up on. I know my time has expired. But I would be interested in your response to the specifics of what Ms. Dummit has raised and how she reached her calculations on that.

Dr. NORTON. Well, frankly, there is a lot of jargon that I do not understand. The statement that “we looked at it and we think it is fair,” is sort of a statement that does not mean much to me unless you have the specifics of how it is done.

So, I would have to look at that. Frankly, I think if you want to know how much something costs, you look at what the pieces cost. I have yet to see an accounting that does that. How much does it cost for the equipment? What is the nursing time? What do the nurses earn? And everything else that is involved.

Doctors are not taking this AWP thing and putting it in their pocket. They are trying to reimburse things that are actually absolutely obligatory and necessary to take care of the patients. I think obligatory is the key word here, frankly. It is not a matter of trying to make it cheaper by cutting. We are talking about essential services.

If you do not talk to a patient about toxicity, the patient may not know to report to you that they have toxicity, and that could have fatal consequences. So, we are talking about essential things here, not things that can be trimmed safely. I have yet to see hard data, hard information that really makes me comfortable that that \$50 million is an accurate number.

Senator ROCKEFELLER. Thank you, Senator Snowe.

Senator SNOWE. Thank you.

Senator ROCKEFELLER. I have three questions and I am going to ask them all at once to three of you. They relate.

One, Laura Dummit, you make a very interesting statement in your testimony. You say that “overall payments to oncologists relative to their estimated practice expenses,” and I also think nursing comes in here, “were comparable to those for all specialties.” I want you to comment on that in a moment.

Then I am going to say to Dr. Norton, I am running out of patience with, we have got to be paid more, but we do not know what the data is. So, I would just like to say to you that I would like to have you present to the Finance Committee, in about a month, how much more you have to be paid in order not to have a catastrophe.

And if oncologists cannot, through your national association, come up with a way—and I have a payment schedule of all different specialties here. Data is always complicated, but so is your profession.



In fact, your profession is far more complicated than data, and far more critical in many ways. You ought to be able to come up with some data that tells us how much more we have to pay you, in your judgment, so that you will not present to us a catastrophe.

I do not think that is a particularly unfair request. It is a request that I am making, and I hope that you will have it to this committee within a month.

Dr. NORTON. May I respond?

Senator ROCKEFELLER. In a minute, after I ask my third question.

Dr. NORTON. All right. Thank you.

Senator ROCKEFELLER. That is to Ellen Stovall. That is, I want you to make the point, why are we singling out cancer for oral special treatment here?

In other words, I do not know how much oral, injected, or invasive, or whatever treatments are available for diabetes, for example, or heart disease. But we are not talking about that. We are talking about cancer. We are singling out cancer here.

Now, I am very glad that we are, but I would like to have you make the case why it is all right to single out cancer, even as there may be others that are not being singled out. I am sure that they will come pouring in, because everybody always does around here.

Ms. STOVALL. I hope they do. I hope that that will lead to an omnibus comprehensive reform that we all want. Epidemiologically, Senator, we know that 1 in 2 men and 1 in 3 women, are going to develop cancer. People, at the rate of 1.2 million a year, are being diagnosed with this disease. Over half of them will die, many of them needlessly, because they did not have access to treatments that we know can be life-saving for them.

I think that, as we knew with clinical trials when we were having to answer these same questions to you with your colleagues and me with my friends in other health associations, that I think if we can do this well and demonstrate it works well for cancer, that it is going to be a lot easier for us to demonstrate doing this, and the savings that might come from doing this under Medicare for other diseases as well.

I really believe that this is not something that would be difficult.

Senator ROCKEFELLER. I admire your answer, but you are not telling me what I wanted to hear. What I am asking you to say, is to make the case for cancer and oral treatment.

Ms. STOVALL. I think we have already made the case for cancer. We made it in 1993. We showed it was cost neutral to the system, so as far as cost goes we know this will not have a big impact on an overall budget. Less than one-half of 1 percent of the total cost of treating people under Medicare next year would be due to this benefit, which is really not a very big impact. I think we can do it and show that we are doing something for people on Medicare who are disproportionately affected by this disease.

Senator ROCKEFELLER. Fair enough. Thank you.

Doctor, you are welcome to respond, keeping in mind what Laura Dummit said. That is, there does not appear to be any reimbursement difference between oncologists and other specialties.

Dr. NORTON. Well, I want to answer all three questions, actually, if I could, just very briefly. We will show you how oncology—be-

cause you have asked for it. Basically, I want to thank you for asking these questions. When we had similar opportunity before the House, they asked us to work with CMS in terms of answering your question, and we have been trying to do so.

Senator ROCKEFELLER. But do not work with CMS, work with us. CMS does not seem to have a position.

Dr. NORTON. In fact, I just want to thank you for asking the question, because we will provide the answer to that question. We will provide you with all of the reasons why that question has not been answered adequately to the present time.

Senator ROCKEFELLER. Oh. Are you saying, therefore, that you will not answer it?

Dr. NORTON. Oh, yes.

Senator ROCKEFELLER. You will answer it. And you will give us data?

Dr. NORTON. Mr. Chairman, you asked me a question and I will answer it.

Senator ROCKEFELLER. Good. All right.

Dr. NORTON. In addition to that, we will answer your question about why oncology is different than other specialties. The answer to that is very similar to your third question, as to what makes cancer special in terms of the oral drug, which is the complexity of the disease, the time sensitivity of the disease, the emotional impact of the disease. All of those are really key factors.

All of those, in addition to the inventory issue with doctors really having to have an inventory to take care of their patients that they have to pay out of their pockets, all makes oncology a very different specialty than other medical specialties. So, we will provide you with that answer as well, and I just thank you for asking that question so we will have an opportunity to answer them.

Senator ROCKEFELLER. Thank you, Dr. Norton.

Ms. Dummit, Dr. Norton has challenged your statement.

Ms. DUMMIT. To reach our conclusion that oncologists fare as well as other specialties under the practice expense component of the payment, what we did was we compared practice expense data submitted by the various specialties and compared those to practice expense payments under the fee schedule.

If you set the average at one, oncologists come out at 1.04, which means slightly above the average. Now, what, of course, that encompasses, however, is the whole notion of budget neutrality.

As you know, the fee schedule was implemented to be budget neutral to what payments were under the previous payment system. So, physician groups will argue that 100 percent of their costs are not covered under the fee schedule. But Congress deemed that budget neutrality was appropriate, given that access was not a problem when the fee schedule was implemented.

So, again, my statement stands relative to other physician specialties. Oncologists are doing as well, if not a little better, than other specialties under the practice expense component of the fee schedule.

Ms. STOVALL. Senator Rockefeller, could I make a statement about the GAO report?

Senator ROCKEFELLER. Yes. This will be the final statement.

Ms. STOVALL. All right. A lot of people asked us on the House side, when we were dealing with this issue, why are the patients even interested in AWP? It is just a doctor's pocketbook issue. The reason we got involved, is we were all waiting for the GAO report to come out.

For us, it was an access to care issue all along, knowing how oncology has grown up in this country and the way it is practiced. We were waiting for the GAO report. When the GAO reports came out, they did not address this practice expense side. The study was not done.

In an effort to try and get a study done, we went to Nancy Johnson, who expressed some interest in getting some kind of a study done. She had originally asked for it in the BIPA language in 1999 and did not feel satisfied she had gotten a response.

So, I went to the IOM and asked them if they would be interested in doing such a study. They said they would. I know that your group also approached the IOM.

The Board on Health Care Services at the Institute of Medicine, and also the National Cancer Policy Board of that Institute, which I co-chair, are very interested in helping us get a picture of what is going on out there in the community, which is what I was asking you and Senator Snowe to consider doing. We really do not know what we are paying for. I think, as citizens, all of us deserve to know where our money is going from CMS, and I do not think we have a clue.

Senator ROCKEFELLER. Well, I think Laura Dummit might argue with you. She works for a pretty respected organization. But let us not worry about that right now.

Let me thank all of you for coming. These are the kinds of hearings, I think, which I love, because everybody leaves and then you get to ask the questions. [Laughter.] But this will lead to something. I think we can pass this this year. I really do.

Then dealing with the whole practice expense issue, AWP, and all the rest of it, of course, is going to depend on data and auditing and data coming, getting it. It is a little hard to deal with it if you do not get it. But that is going to happen.

So, I thank you all very, very much.

[Whereupon, at 12:34 p.m. the hearing was concluded.]



# APPENDIX

## ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

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United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Health, Committee on  
Finance, U.S. Senate

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For Release on Delivery  
Expected at 10:00 a.m.  
Thursday, March 14, 2002

## MEDICARE OUTPATIENT DRUGS

### Program Payments Should Better Reflect Market Prices

Statement of Laura A. Dummit  
Director, Health Care—Medicare Payment Issues



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GAO-02-531T

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here as you discuss Medicare's payments for covered outpatient prescription drugs. As you know, Medicare pays for only a limited number of outpatient drugs and biologicals—largely those that cannot be self-administered or require certain medical equipment to be administered.<sup>1</sup> The covered drugs are typically provided by a physician, as is the case for chemotherapy drugs, or through pharmacy suppliers, as for respiratory drugs.

Medicare's payments for covered drugs have been scrutinized for several years. Recent studies by the Department of Justice and the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) show that Medicare's payment for covered outpatient drugs in some cases is significantly higher than the actual costs to the physicians and pharmacy suppliers who bill Medicare for them.<sup>2</sup> Yet attempts to reduce these payments have been met with provider claims that overpayments for the drugs are needed to cover underpayments for administering or delivering them. In September 2000, the Health Care Financing Administration (HCFA)—now the Centers for Medicare and Medicaid Services (CMS)<sup>3</sup>—took steps to reduce Medicare's payment for covered outpatient drugs by authorizing Medicare carriers, the contractors that pay drug claims, to use prices obtained in Justice Department investigations of providers' drug acquisition costs in setting payment rates. HCFA retracted this authority in November 2000 following concerns raised by providers that reducing Medicare's drug payments could affect beneficiary access to these drugs and related services. In December 2000, as part of recent Medicare legislation,<sup>4</sup> the Congress directed us to study Medicare's payments for covered outpatient drugs and make recommendations for payment methodology refinements. In September 2001, we reported our

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<sup>1</sup>For the remainder of this statement, we will refer to "drugs and biologicals" covered under Medicare part B, which generally covers physician and outpatient hospital services, as "outpatient drugs."

<sup>2</sup>For example, see U.S. Department of Health and Human Services, Office of the Inspector General, *Medicare Reimbursement of Albuterol*, OEI-03-00-00311 (Washington, DC: June 2000) and *Medicare Reimbursement of Prescription Drugs*, OEI-03-00-00310 (Jan. 2001).

<sup>3</sup>Our statement refers to HCFA when discussing actions taken under that name.

<sup>4</sup>The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. No. 106-554, App. F, 106 Stat. 2763, 2763A-522).

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findings and made recommendations.<sup>4</sup> In October 2001, we also reported on the adequacy of Medicare payments to oncologists for administering chemotherapy drugs as directed by the Congress.<sup>5</sup>

My remarks today will focus on (1) Medicare payment policies for covered outpatient drugs and related services to administer or deliver the drugs and (2) opportunities to improve the appropriateness of Medicare's payments by adapting key features of other federal payers' reimbursement policies. My comments are based primarily on our studies of Medicare payments for covered outpatient drugs and for administering chemotherapy.

In summary, Medicare's payment for covered outpatient drugs is significantly higher than prices widely available to providers. Medicare's method for establishing drug payments is flawed. Medicare pays 95 percent of the average wholesale price (AWP), which, despite its name, is neither an average nor a price that wholesalers charge. Instead, it is a number that manufacturers derive using their own criteria; there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Manufacturers report AWPs to organizations that publish them in drug price compendia, and Medicare carriers base providers' payments on these published AWPs.

We found that widely available prices at which providers could purchase drugs in 2001 were substantially below AWP. For both physician-billed drugs and pharmacy supplier-billed drugs, Medicare payments often far exceeded widely available prices. Despite concerns that the discounts available to large purchasers would not be available to physicians with a small number of drug claims, these physicians with low volumes reported that their purchase prices were the same or less than the widely available prices we documented.

Physicians and pharmacy suppliers contend that the excess payments for covered drugs are necessary to offset what they claim to be

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<sup>4</sup>U.S. General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs*, GAO-01-1118 (Washington, D.C.: Sept. 21, 2001).

<sup>5</sup>This study was mandated in section 213 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. No. 106-113, App. F, 113 Stat. 1501, 1501A-350). See U.S. General Accounting Office, *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements*, GAO-02-53 (Washington, DC: Oct. 31, 2001).

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inappropriately low Medicare payments or no such payments for services related to the administration or delivery of these drugs. For administering physician-billed drugs, such as those used in chemotherapy, Medicare makes explicit payments under the physician fee schedule, typically through the practice expense component of the payment. Our October 2001 report on practice expense payments under the fee schedule showed that, overall, payments to oncologists relative to their estimated practice expenses were comparable to those for all specialties. But we also found that HCFA made inappropriate modifications to its basic method of setting these payments, which resulted in a lowering of the average fees paid for the administration of chemotherapy.

While physicians receive an explicit payment for administering drugs, Medicare's payment policies for delivering pharmacy supplier-billed drugs and related equipment are uneven. Pharmacy suppliers billing Medicare receive a dispensing fee for one drug type—inhalation therapy drugs—but there are no similar payments for the other covered drugs, such as infusion therapy or covered oral drugs. Suppliers do receive an additional Medicare payment for the rental or purchase of durable medical equipment (DME) and related supplies that are used to administer drugs, such as inhalation and infusion therapy, that require DME. However, in 1998 we reported two problems with the program's payments for DME—a wide variety of products may be covered under a single fee and fee schedule allowances were out of line with current market prices.<sup>7</sup> These problems may result in overpayments that implicitly compensate for some service delivery costs not covered by Medicare.

Other payers and purchasers, such as private health plans and the Department of Veterans Affairs (VA), employ different approaches in paying for or purchasing drugs that may be instructive for Medicare. In particular, VA uses the leverage from the volume of federal drug purchases to secure verifiable data on actual market transactions and it uses the prices paid by manufacturers' best customers to set Federal Supply Schedule (FSS) prices. VA also uses competitive bidding to obtain lower prices for certain products for its own facilities. These approaches may be instructive for Medicare provided that they are adopted in ways that reflect Medicare's unique responsibilities and characteristics.

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<sup>7</sup>See U.S. General Accounting Office, *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies*, GAO/HEHS-98-102 (Washington, DC: May 12, 1998).



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In our view, Medicare should pay for each service appropriately and not rely on overpayments for some services to offset inadequate payments for complementary services. Our recommendation that Medicare begin to establish payment rates using information about actual market transactions for covered drugs at levels that reflect providers' acquisition costs is consistent with this principle. We have also recommended that the CMS administrator use consistent methods in setting physician practice expense fees for all services, including those for administering chemotherapy.

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## Background

While the traditional Medicare program does not have a comprehensive outpatient prescription drug benefit, the program does cover roughly 450 outpatient drugs. The outpatient drugs with the highest Medicare payments and billing volume fall into three categories: those that physicians bill for and that are typically provided in a physician office (such as chemotherapy drugs); those that pharmacy suppliers bill for and that are administered through DME, such as a respiratory drug given in conjunction with a nebulizer;<sup>8</sup> and those that are also billed by pharmacy suppliers but are patient-administered and covered explicitly in statute.<sup>9</sup> In 1999, spending for Medicare-covered outpatient prescription drugs totaled almost \$4 billion.<sup>10</sup>

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## Small Number of Products Accounts for Majority of Program Spending and Volume

Although Medicare reimburses providers for roughly 450 outpatient drugs, spending is concentrated on a small number of products billed by pharmacy suppliers and a few physician specialties. For example, just 35 drugs accounted for 82 percent of Medicare spending and 95 percent of the claims volume in 1999. These 35 products included certain injectible drugs to treat cancer, inhalation therapy drugs, and oral immunosuppressive drugs, such as those used by organ transplant patients. Physician-billed drugs accounted for the largest share of Medicare program spending, while pharmacy supplier-billed drugs

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<sup>8</sup>A nebulizer is a device driven by a compressed air machine. It allows the patient to take medicine in the form of a mist (wet aerosol).

<sup>9</sup>Medicare-covered outpatient drugs that can be self-administered include such drugs as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy.

<sup>10</sup>Spending is defined as Medicare's total payment, of which the program's share is 80 percent and the beneficiaries' share is 20 percent.

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constituted the largest share of the billing volume. Drugs provided in physician offices accounted for more than 75 percent of total Medicare spending for drugs in 1999 and just three specialties—hematology oncology, medical oncology, and urology—submitted claims for 80 percent of the total physician billings for outpatient drugs. By contrast, pharmacy suppliers accounted for more than 80 percent of Medicare drug billing volume and less than 20 percent of corresponding payments. Two inhalation therapy drugs accounted for 88 percent of the Medicare billing volume for pharmacy-supplied drugs administered in a patient's home.<sup>11</sup>

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**Medicare Payments for Drugs Are Based on "Prices" Set by Manufacturer**

Medicare bases its reimbursements to physicians and other providers for a covered outpatient drug on the product's AWP, with Medicare beneficiaries contributing 20 percent of the payment. The AWP, however, is neither "average" nor "wholesale;" it is simply a number assigned by the product's manufacturer. The AWP is often described as a "list price," "sticker price," or "suggested retail price," reflecting that it is not necessarily the price paid by a purchaser or a consistently low, or "wholesale," price.

Because the term AWP is not defined in law or regulation, the manufacturer is free to set an AWP at any level, regardless of the actual price that purchasers pay. Manufacturers periodically report AWPs to publishers of drug pricing data. While there is no required frequency for manufacturers to report AWPs, most publishers said they attempt to update AWPs at least annually. The Medicare-allowed amount, or payment level, for each HCFA Common Procedure Coding System (HCPCS) -coded drug is 95 percent of its AWP.<sup>12</sup> Given the latitude manufacturers have in setting AWPs, these payments need not be related to market prices that physicians and suppliers actually pay for the products.

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<sup>11</sup>These two drugs are ipratropium bromide and albuterol (unit dose form).

<sup>12</sup>The payment is based on the AWP for all the drugs having the same HCPCS code. A National Drug Code (NDC) identifies an individual drug. The Food and Drug Administration assigns the NDCs, which are the universal product identifiers for drugs for human use. Each NDC specifies a chemical entity, manufacturer, dosage form, strength, and package size. For example, a single drug—marketed by one manufacturer in one form and strength but in three package sizes—would have three NDCs. HCFA defines HCPCS codes, which generally include multiple NDCs. For single-source drugs, Medicare's payment is 95 percent of the drug's AWP. For multisource drugs, generally those available from multiple manufacturers, the payment allowance is 95 percent of the lower of (1) the median AWP of all generic forms of the drug or (2) the lowest brand name product's AWP.

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**Varying Payment Arrangements Affect Providers' Final Purchase Price**

Common drug purchasing arrangements can substantially reduce a provider's actual acquisition price for a drug. Physicians and suppliers may belong to group purchasing organizations (GPO) that negotiate prices with wholesalers or manufacturers on behalf of GPO members. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In addition, providers can purchase covered outpatient drugs from general or specialty pharmaceutical wholesalers or can have direct purchase agreements with manufacturers. In these arrangements, providers may benefit from transactions, including rebates and "chargebacks" that also reduce the actual costs providers incur. Rebates offered by drug manufacturers or wholesalers may be based on the number of different products purchased over an extended period. Under a chargeback arrangement, the provider negotiates a price with the manufacturer that is lower than the price the wholesaler normally charges for the product, and the provider pays the wholesaler the negotiated price. The manufacturer then pays the wholesaler the difference between the wholesale price and the price negotiated between the manufacturer and provider.

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**Medicare's Payment for Covered Outpatient Drugs Is Significantly Higher than Prices Widely Available to Providers**

For the outpatient drugs accounting for the bulk of Medicare spending and claims, Medicare payments in 2001 were almost always considerably higher than wholesalers' prices widely available to physicians and suppliers.<sup>13</sup> This was true regardless of whether there were competing drug products or whether a particular drug was available from only one manufacturer. Physicians who had few Medicare claims for covered drugs were able to obtain these wholesalers' prices or even more favorable prices. Physicians and pharmacy suppliers told us that the higher payments are necessary to cover costs of administering and dispensing their drugs that Medicare does not pay. Our work indicates that CMS's method of computing Medicare fees for physician-administered drug claims, which are submitted primarily by oncologists, inappropriately reduced those fees. Furthermore, Medicare's coverage and payment policies for pharmacy supplier-billed drugs are uneven: Medicare pays a dispensing fee for delivering some pharmacy supplier-billed drugs; for

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<sup>13</sup>We attempted to analyze prices for 35 high-volume and high-expenditure outpatient drugs, however, our analysis excluded some high-volume and high-expenditure drugs because of inadequate pricing data. Our results are based on wholesaler and GPO prices for 19 physician-administered drugs and 6 drugs provided primarily by pharmacy suppliers. Volume for a drug is measured in terms of the number of units provided.

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others, however, Medicare makes no explicit payment for delivery and administration services.

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**Wide Disparities Exist  
Between Drug Acquisition  
Costs and Medicare  
Payments**

Physician-billed drugs account for the bulk of Medicare spending on outpatient drugs. Of those billed by physicians, drugs used to treat cancer accounted for most of Medicare's expenditures. The prices available to physicians through wholesaler and GPO catalogues are far lower than Medicare's payment. The catalogue prices ranged from 13 percent to 34 percent less than AWP for most drugs that we examined and up to 86 percent less for one. These prices indicate that Medicare's payments for physician-administered outpatient drugs were at least \$532 million higher than providers' potential acquisition costs in 2000. Further, the overpayment is likely even greater because additional reductions provided to certain purchasers through chargebacks, rebates, and other discounts drive down the actual acquisition costs to providers even more.

Concerns have been expressed that providers who had few beneficiaries requiring chemotherapy drugs either could not or do not obtain such favorable prices. Therefore, we surveyed a sample of physicians who billed Medicare for low volumes of chemotherapy drugs to see if they were able to obtain discounts similar to those of providers with a high volume of claims. More than one-third of these physicians who billed for a low volume of drugs actually belonged to large, hospital-based, or national chain oncology practices that likely had access to widely available drug discounts. The low-volume providers who responded to our survey reported similar or better discounts than the widely available prices we documented, although these discounts may not be as high as those obtained by high-volume purchasers.

Inhalation therapy drugs administered through DME and oral immunosuppressive drugs represent most of the high-expenditure, high-volume drugs billed to Medicare by pharmacy suppliers. As with physician-billed drugs, Medicare's payments for pharmacy supplier-billed drugs generally far exceeded the prices available to these suppliers. Further, the discounts we found were largest for products that could be obtained from more than one source. Based on the discounts for six drugs billed primarily by pharmacy suppliers, we found that Medicare's payments were at least \$483 million more than what the suppliers potentially paid in 2000. Specifically, two DME-administered drugs, albuterol and ipratropium bromide, that accounted for most of the pharmacy supplier-billed drugs paid for by Medicare were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP. Two

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other high-volume DME-administered drugs had prices averaging 69 percent and 72 percent less than AWP. Two of the high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent. Although wholesale price information on the two other oral drugs was not available, retail prices from online pharmacies were as much as 13 percent and 8 percent below AWP.

Based on our findings, we recommended that Medicare revise its drug payment policies to more closely parallel market prices that providers actually pay to acquire drugs. To set such prices, Medicare needs to use information on actual market prices, accounting for rebates and other discounts. It is important in setting payment levels to be mindful that providers' ability to secure discounts likely varies, and that prices need to be sufficient to ensure that beneficiary access is not compromised.

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**Current Drug Payments Called Necessary to Offset Inadequate Payments for Related Services**

Physicians and pharmacy suppliers contend that the excess in Medicare's payments for covered outpatient drugs compensates for related service costs inadequately reimbursed or not explicitly covered at all. Medicare payment policies for administering or delivering a drug vary, depending on who provides the drug to the patient. Physicians are compensated directly for drug administration through the physician fee schedule. Pharmacy suppliers are compensated for dispensing inhalation therapy drugs used with a nebulizer, which make up the majority of their Medicare outpatient drug claims. No explicit payments are made to pharmacy suppliers for dispensing other drugs, but the suppliers receive payments for equipment and supplies associated with DME-administered drugs.

Medicare pays physicians based on a fee schedule that includes rates for administering chemotherapy. Payments for chemotherapy administration are important because chemotherapy drugs represent the bulk of Medicare payments for physician-administered drugs. Medicare's payment for chemotherapy administration is usually determined by the practice expense component of the fee schedule, as there is generally no direct physician involvement with these services.<sup>14</sup> Payments for practice expenses were revised beginning in 1999. These payments, which had

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<sup>14</sup>Practice expenses include the salaries of nurses, technicians, and administrative staff, and rent, utilities, equipment, and supplies. Practice expenses constitute one of three components in Medicare's physician fee schedule. The other two are the physician work component and the malpractice component.

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been based on charges physicians had billed in prior years, were recomputed to reflect the relative resources required to provide each service. Implementation of these resource-based practice expense payments has been controversial. This is in part because the Congress required that payments be budget neutral so that if one specialty's fees increased on average, some others would have to be reduced. Such redistributions have occurred, and some are significant. However, Medicare's physician payments were deemed adequate in the aggregate, as almost all physicians participated in Medicare and accepted the program's fees as payment in full, so that budget neutrality appeared unlikely to cause access problems for beneficiaries.

Oncologists argue that Medicare's payments for administering chemotherapy are inappropriately low and that the excess Medicare drug payments based on the AWP are needed to offset their losses. Yet, oncology is one of the specialties to gain from the introduction of new practice expense payments under the physician fee schedule. In our October 2001 study on physicians' practice expenses under Medicare's fee schedule, we showed that practice expense payments to oncologists were 8 percent higher than they would have been if the prior payment method had been maintained; we also showed that overall oncologists' payments relative to their estimated practice expenses were close to the average for all specialties.

While oncologists do not appear disadvantaged overall under the fee schedule, adjustments that HCFA made to the basic method of computing payments reduced fees for some oncologists' services, particularly chemotherapy administration. In those adjustments, HCFA modified the basic method in computing payments for services delivered without direct physician involvement, like much of chemotherapy administration.<sup>15</sup> The modifications were intended to correct perceived low payments for these services, but instead resulted in reduced payments for some of these services, particularly those provided by oncologists. Further, the agency reduced oncology's reported supply expenses, one of the data elements used to compute fees, to keep from paying twice for drugs that are reimbursed separately by Medicare. Oncologists acknowledge that the supply expense estimate needed to be reduced, but argue that the reduction was too large. We recommended in our October 2001 report that

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<sup>15</sup>In the case of chemotherapy drugs, the common practice is for a nurse employed by a physician to administer the drug and for the physician to bill Medicare.

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CMS revert to using the basic methodology to determine practice expense payments for all services and develop the appropriate data to more accurately estimate oncology supply expenses. If these recommendations had been followed in 2001, we estimate that payments to oncologists would have been about \$51 million higher.

Similar to the physicians who bill for outpatient drugs, pharmacy suppliers and their representatives contend that the overpayments for DME-related drugs are needed to compensate them for costs not covered by Medicare—that is, clinical, administrative, and other labor costs associated with delivering the drug. These include costs for billing and collection; facility and employee accreditation; licensing and certifications; and printed patient education materials. Medicare pays a \$5 dispensing fee for inhalation therapy drugs used with a nebulizer, the vast majority of the pharmacy-supplied drugs. The fee is higher than dispensing fees paid by pharmacy benefit managers for private insurance plans, which average around \$2, and comparable to fees paid by state Medicaid programs, which range from \$2 to more than \$6.

Besides payments for the DME-related drugs, pharmacy suppliers may receive additional compensation through the payment for DME and related supplies. Our prior work shows that, for two reasons, Medicare DME and supply payments may exceed market prices.<sup>16</sup> First, because of an imprecise coding system, Medicare carriers cannot determine from the DME claims they process which specific products the program is paying for. Medicare's coding system groups products that may have significantly different characteristics and, therefore, different prices. Medicare, however, pays one fee for all products classified under a single billing code, regardless of whether their market prices are below or above that fee.<sup>17</sup> Second, DME fees are often out of line with current market prices. Until recently, DME fees had generally been adjusted only for inflation since the process required to change the fees for any other reason was lengthy and cumbersome. As a result, payment levels may not reflect changes in technology and other factors that could significantly change market prices.

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<sup>16</sup> U.S. General Accounting Office, *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies*, GAO/HEHS-98-102 (Washington, DC: May 12, 1998).

<sup>17</sup> The equipment and supply payment is determined from a DME fee schedule, whose rates are based on a state-specific fee schedule and subject to national minimum and maximum payment limits.

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### Other Purchasers' Practices Are Instructive for Reforming Medicare Payments for Covered Outpatient Drugs

Private insurers and federal agencies, notably VA, employ varying approaches in paying for drugs, generally using the leverage of their volume and competition to secure better prices. While private payers can negotiate with some suppliers to the exclusion of others and arrive at terms without clear criteria or a transparent process to secure lower prices, some of these practices would not be acceptable for a public program like Medicare, given the program's size and need to ensure access for providers and beneficiaries. VA uses the leverage of federal purchasers to secure verifiable data on actual market transactions by private purchasers to establish FSS prices for federal agency and public hospital purchasers. VA also uses competition to secure even lower prices in purchasing selected drugs for its own facilities. In considering how these approaches might prove instructive for Medicare, the program's unique responsibilities and characteristics need to be carefully considered to avoid untoward consequences for beneficiaries and providers.

VA sets FSS prices based on actual prices paid by private purchasers—specifically, the prices that drug manufacturers charge their “most-favored” private customers.<sup>18</sup> In exchange for state Medicaid programs covering their drugs, manufacturers agree to offer VA and other government purchasers drugs at these prices. To enable VA to determine the most-favored customer price, manufacturers provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices.<sup>19</sup> Manufacturers must also be willing to supply similar information to CMS to have their drugs covered by Medicaid. The information is the basis for rebates required by the Medicaid program. With Congressional sanction, CMS might utilize this information to determine appropriate prices for Medicare that would be based on actual prices being paid in the market. Medicare prices most likely could not be the prices paid by most favored customers, but would need to be high enough to assure access for all beneficiaries.

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<sup>18</sup>Under federal procurement regulations, the government seeks to obtain a price that is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.

<sup>19</sup>Because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the regulations, VA may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable and (2) awarding the contract is otherwise in the best interest of the government.



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VA has been successful in using competitive bidding to obtain even more favorable prices for certain drugs for its own facilities.<sup>20</sup> Through these competitive bids, VA has obtained national contracts for selected drugs at prices that are even lower than FSS prices. These contracts seek to concentrate the agency's purchase on one drug within a class of therapeutically equivalent products for the agency's national formulary. In 2000, VA contract prices averaged 33 percent lower than corresponding FSS prices.

Medicare's use of competition has been restricted to several demonstration projects authorized by the Balanced Budget Act of 1997.<sup>21</sup> In one of these demonstrations under way in San Antonio, Texas, suppliers bid to provide nebulizer drugs, such as albuterol, to Medicare beneficiaries. While Medicare normally allows any qualified provider to participate in the program, only 11 bidders for nebulizer drugs were selected to participate under the demonstration. In exchange for restricting their choice of providers to the 11 suppliers, beneficiaries are not liable for any differences between what suppliers charge and what Medicare allows. Preliminary CMS information on the San Antonio competitive bidding demonstration suggests no reported problems with access and a savings of about 26 percent for the inhalation drugs. Expanding competitive bidding for additional drugs could be beneficial. However, use of competitive bidding would not be feasible for all drugs, for example, those that have no or few therapeutic equivalent alternatives, which is the case for many chemotherapy drugs.

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## Concluding Observations

Our September 2001 study on Medicare payments for outpatient drugs shows that Medicare payments and Medicare beneficiary copayments to providers for these drugs are much higher than necessary, given what the providers likely paid to purchase these drugs from manufacturers, wholesalers, or other suppliers. Unlike the market-based fees paid by VA and other federal agencies, Medicare's fees are based on AWP, which is a manufacturer-reported amount that generally does not reflect actual transactions between seller and purchaser. Physicians contend that the profits they receive from Medicare's payments for outpatient drugs are needed to compensate for inappropriately low Medicare fees for most

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<sup>20</sup>U.S. General Accounting Office, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, GAO/HEHS-00-118 (Washington, DC: August 7, 2000).

<sup>21</sup>Pub. L. No. 105-33, §4319, 111 Stat. 251, 392.

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drug administration services. Similarly, the case argued by some pharmacy suppliers for Medicare's high drug payments is that not all of their costs of dispensing the drugs are covered.

If Medicare were to follow the principle of paying for each service appropriately and incorporate lessons from other payers in setting fees for outpatient drugs, the program would use information on actual market prices, accounting for rebates and discounts, to establish its payments for drugs. Manufacturers whose drugs are used by veterans or Medicaid recipients are already required to provide this information to VA and CMS. Medicare could also determine market-based fees for certain drugs through competitive bidding. If drug payments are tied closer to providers' likely acquisition costs, Medicare would need to ensure that separate and appropriate payments are made to pay for the administration and delivery of covered drugs. Changes to Medicare payments for chemotherapy administration under the current physician fee schedule are needed to make these payments comparable to payments for other services. While Medicare also provides a separate payment for the dispensing of inhalation therapy drugs, dispensing fees for other drugs that physicians do not administer need to be considered. Different methods of determining these payments may be necessary because of differences in the way certain drugs are supplied and administered. Paying for these services explicitly would enable Medicare to eliminate implicit payments that may have been made through excessive payments for DME and the drugs associated with the DME payment.

Any change to Medicare's payments, particularly a reduction in fees, for covered outpatient drugs or related administration or delivery services needs to be accompanied by an ongoing assessment of whether the new fees adequately support Medicare beneficiaries' access to the drugs and services. Such monitoring should involve examining recent use of these services so that prompt fee adjustments can be made if access problems are found.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions that you or other Subcommittee Members may have.

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### Contact and Acknowledgments

For further information regarding this testimony, please contact me at (202) 512-7119. Kathryn Linehan, James Mathews, and Michael Rose made contributions to this statement.

(290174)

### RESPONSES TO QUESTIONS FROM SENATOR BAUCUS

*Question 1:* Ms. Stovall testified that GAO did not answer the questions required by the 1999 Benefits Improvement and Protection Act (BIPA), and others have voiced similar complaints. Will you please comment on this? Do you believe we must find a way to answer those questions before proceeding? Do you believe it is possible to answer those questions?

*Answer:* In BIPA, we were asked to provide information on the adequacy of Medicare's payments for covered outpatient drugs and related services. We reported on Medicare's payments for covered outpatient drugs and related services in *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO 01-1118). We provided a more detailed analysis of payments to oncologists for chemotherapy services in the Balanced Budget Refinement Act-mandated report, *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements* (GAO-02-53).

In conducting our analyses, we obtained sufficient data to indicate that Medicare's payments for outpatient drugs were substantially above providers' acquisition costs. We also obtained sufficient data to identify shortcomings in Medicare's payments for physician practice expenses that affect payments to oncologists for chemotherapy administration. Based on these data, we made recommendations regarding alternative ways of establishing more appropriate payments for outpatient drugs and physician's practice expenses.

*Question 2:* I understand that some believe the data used to calculate physician costs is not representative of oncologists costs, and is too old to be of use. Does the GAO agree with those assertions? What are the implications given that the physician reimbursement system is a relative system? Is there any reason to believe that oncologists' costs have increased more than those of other physician specialties? Does the GAO believe that we have acceptable data to allow us to develop and enact an alternative reimbursement system for Part B drugs and any necessary modifications to physician payments this year?

*Answer:* Based on our analysis, we believe that the Centers for Medicare and Medicaid Services (CMS) used the best available data on practice expenses for most services to establish physician fees. Furthermore, all specialty societies have the opportunity to submit additional data to improve the underlying estimates of total practice expenses and the practice expenses for individual services. Specialties may submit supplemental practice expense survey data to CMS for consideration in establishing their total practice expense estimates. To date, the American Society of Clinical Oncology (ASCO) has not submitted supplemental data to CMS. The American Medical Association has established a process by which the practice expense estimates for individual services are reviewed and refined. CMS receives recommendations on these refinements and has implemented many of them.

Our report on Medicare payments for physician practice expenses (GAO-02-53) noted a particular problem with the adjustment made to the medical supply data for oncology and recommended that CMS validate the adjustment and consider revising it. Using a methodology recommended by ASCO, we estimated that payments to oncologists would increase 1 percent if alternative data were used.

Some specialties have raised concerns about the data used to establish total practice expenses—for example, the age of the data, that the data may not include certain costs, and that it may not be representative of actual expenses of a particular specialty. We stated that it is not clear that improvements in the data would increase payments to oncologists, since these payments would change only if oncologists' costs increased or decreased relative to the costs of all other specialties. We estimated that if oncology's practice expenses were increased or decreased by 10 percent, its payments would change by 1 percent.

In our report on outpatient drug payments (GAO-01-1118) we recommended that CMS take steps to begin reimbursing providers for these drugs and related services using price information from actual market transactions. Data on drug acquisition costs are available and could be used to set more appropriate payments for outpatient drugs.

*Question 3:* Is it correct that the GAO believes some refinements to payments for oncology services are necessary? I believe there may be problems with the overhead allocation, and with expenses for supplies? Would you please elaborate on this, the time necessary to collect the data to correct the problems, and also give me your estimate of the cost if we were to adopt GAO's recommendations in these areas?

*Answer:* GAO believes that there are problems with allocation of overhead expenses in establishing Medicare payments for certain physician services and with the estimate of oncology's medical supply expenses. In our report (GAO-02-53), we discussed the problems with the current method of allocating overhead expenses and recommend that it be changed. Using an alternative method of allocating services that are not physician administered. Implementing this recommendation would not require additional data.

We also recommended that CMS validate the adjustment to oncologists' medical supply cost estimates to exclude the costs of prescription drugs. Using the methodology recommended by ASCO to estimate medical supply expenses for oncologists is likely to increase payments to them. Our analysis showed that doubling the supply expense would increase payments by 1 percent. Based on other specialty societies' experiences of gathering and submitting supplemental practice expense data to CMS for consideration, it is likely that better medical supply information could be gathered within a year.

Total Medicare payments would not increase by implementing either of these improvements because the fee schedule must be budget neutral; rather, any increased payments to oncology would be funded by decreased in payments to other specialties, all other factors being equal. Given the interrelated nature of the fee schedule,

it is important to emphasize that refinements to the current practice expense methodology will affect payments across all specialties and all services.

*Question 4:* I understand that US Oncology, the largest non-governmental purchaser of cancer drugs in the country, made their data available to you in Chicago, in August of 2001. Did you use the data for your September or October 2001 reports? Why or why not?

*Answer:* GAO received information from US Oncology in August 2001 on the direct and indirect expenses for its cancer drug administration services and a comparison of these costs to Medicare payments. US Oncology informed us that this information would not be representative of all oncology practices because it included only practices the company owned or managed. US Oncology also provided us with drug prices for some of the drugs included in our study.

The information provided to us by US Oncology reflected its estimates of practice expenses of practices that the company owned or managed, and these estimates did not conform to the methodology used by CMS to calculate practice expenses. US Oncology's estimates included a 30 percent increase in the hourly rate for clinical labor for "non-clinical patient care activities" that US Oncology's auditor, Ernst & Young, did not confirm was appropriate. In addition, US Oncology calculated indirect costs using a different method than the one used by CMS for all other services, resulting in higher estimates. US Oncology's estimate also did not incorporate the 30 percent reduction made to all payments for physician services to achieve budget neutrality. Because these cost estimates and the methodology of estimating practice expenses deviated from that used by CMS to establish practice expense estimates, we could not use the company's data for the practice expense report (GAO-02-53).

We did use US Oncology's more general data on drug acquisition costs to verify and validate our own estimates based on data we collected independently for our report on Medicare payments for outpatient drugs covered under part B (GAO-01-1118).

*Question 5:* Some critics of GAO's report say that you analyzed only the subset of cancer care services that are currently recognized and reimbursed by Medicare. They say that your analysis is incomplete because it did not address the many costs of cancer care that were left out of the Resource Based Relative Value System (RBRVS) when it was created in the early 1990s. It appears that HCFA agreed with these critics when they published the following statement in the Federal Register.

"Current Medicare Part B payment rules for physicians' services may fail to compensate adequately for these services because the usual reasonable charge methodology may not fully recognize the overhead costs involved in these procedures."

Did the GAO analysis focus on the subset of services currently recognized by Medicare or did it account for all costs associated with the appropriate delivery of cancer care in free-standing facilities?

*Answer:* In our report on Medicare payments for physician practice expenses (GAO-02-53), we analyzed the total costs to provide services, as reflected in physician-provided practice expense data. We reported on the total costs of providing all services provided by oncologists, including all cancer care.

There are currently two processes to refine the estimates of total specialty and service-specific costs. First, all specialties may submit supplemental data on the actual costs incurred in running physician practices to CMS for consideration in updating CMS's estimate of total specialty practice expenses. To date, oncology representatives have not pursued this option for revising the estimate of its total specialty practice expenses. Second, the Practice Expense Advisory Committee (PEAC), a subcommittee of the AMA's Relative Value Update Committee, considers refinements to the direct practice expense estimates for individual services brought to the panel by specialty societies. CMS receives recommendations on these refinements and has implemented many of them. Oncology representatives may pursue both strategies to ensure that the estimates of its services' costs are accurate.

*Question 6:* Looking at all physician specialties, what percent of practice costs does the Medicare program cover? Is the percentage of oncologist practice expenses covered significantly different than that of other comparable specialties? US Oncology, the largest non-governmental purchaser of cancer drugs in the United States, has told my staff that Medicare reimburses oncologists for only 24% of their practice expenses—far below the percentage reimbursed for other specialties. [This analysis is based on a weighted average of Medicare reimbursement for 4 codes representing cancer care], and that Medicare overpayments for drugs are only 2.3% greater than the underpayments for practice expenses. What is your reaction to their analysis?

*Answer:* Our report (GAO-02-53) notes that Medicare practice expense payments are approximately 70 percent of estimated practice expenses for the average physician practice across all specialties. This is primarily due to the requirement that

total payments to physicians be based on what would have been paid under the previous methodology, termed budget neutrality. Practice expense payments to oncologists are 4 percent higher than average.

US Oncology's comparison of Medicare payments with its estimate of its practice expenses is lower than ours primarily due to the methodology US Oncology used to estimate its costs (see question #4). As previously noted, US Oncology's estimate does not include the budget neutrality adjustment, includes higher clinical labor costs than those used by CMS, and uses a different overhead allocation method than that used by CMS. For these reasons, US Oncology's estimate results in higher costs.

Our analysis of drugs predominantly provided by oncology specialties—hematology/oncology and medical oncology—indicated that Medicare paid \$371 million more than the estimated acquisition cost. We estimate that implementing our recommendations regarding practice expense payments would increase payment to oncologists by \$51 million.

*Question 7:* Payments for drugs to treat cancer account for 62% of spending on Part B drugs. The GAO has commented on problems with the way Medicare pays oncologists for their practice expenses. Are there similar problems with payments to other physicians and suppliers of Part B drugs that we should be aware of?

*Answer:* As we reported, Medicare covers outpatient drugs if they cannot be self-administered and are related to a physician's services, or are provided by pharmacy suppliers in conjunction with covered durable medical equipment (DME), such as inhalation drugs used with a nebulizer. Pharmacy suppliers were the predominant billers for 10 of the drugs in the sample of high-expenditure, high-volume drugs we studied for our report (GAO-01-1118). These drugs include inhalation therapy drugs used with DME and oral immunosuppressive drugs. We found that pharmacy suppliers can obtain these drugs at prices far lower than Medicare payment levels. While physicians are reimbursed for administering drugs under Medicare's physician fee schedule, reimbursements to pharmacy suppliers for dispensing drugs used with DME vary. Pharmacy suppliers who bill for inhalation drugs used with a nebulizer, which account for the majority of Medicare drug volume and spending in the home setting, may separately bill a \$5 monthly dispensing fee, but receive no dispensing fee for providing other types of drugs. Medicare also pays pharmacy suppliers a separate fee for the DME based on a state-specific fee schedule. We have not recently analyzed suppliers' costs of providing DME relative to Medicare's payment. However, a prior GAO report (*Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies*, GAO/HEHS-98-102) indicated problems with Medicare's DME fees that could lead to inappropriately high payments. In our report on Medicare's outpatient drug payments (GAO-01-1118), we recommended that payments for delivery and administration of drugs should be commensurate with providers' costs of dispensing or administering each type of drug.

*Question 8:* I gather from your testimony that part of the problem we now face using AWP for reimbursement purposes occurs when manufacturers and physicians use the spread between the AWP and acquisition costs to their benefit—the manufacturers can use the spread as a marketing tool to encourage physicians to use their products, and physicians can use the products that provide them with the largest spread to cover their practice expenses.

Are there similar dynamics with drugs dispensed by pharmacists? What is the spread between Medicare's payments to pharmacists, and pharmacists' acquisition costs? Is it as large as the spread for physician-dispensed drugs? Would it make sense to create one reimbursement system for physician-dispensed drugs, and a different reimbursement system for pharmacist-dispensed drugs?

You state in your testimony that inhalation therapy drugs used with a nebulizer make up the majority of pharmacy suppliers' Part B drug claims. Will you please clarify the percentage of Part B drugs provided by pharmacists and pharmacy providers represented by these nebulizer drugs? Pharmacists receive a dispensing fee for these drugs, correct? How do those fees compare to those paid by other purchasers?

*Answer:* The high-expenditure, high-volume drugs we examined in our study were billed primarily by physicians or pharmacy suppliers and exhibited significant but varying degrees of difference between average wholesale price and acquisition costs from manufacturers. There is no evidence to suggest that there should be separate reimbursement systems for drugs dispensed by physicians and drugs dispensed by pharmacy suppliers. Rather, our findings strongly suggest that Medicare needs to use information on actual market prices, to determine program payments for drugs.

In 1999, 82 percent of Medicare-allowed spending and 94 percent of allowed services for drugs provided by pharmacy suppliers were for drugs used with a nebulizer. Medicare pays a monthly dispensing fee of \$5 for these drugs. We found that Med-

icaid dispensing fees per prescription ranged from \$2 to \$6 in 2000 and that dispensing fees paid by pharmacy benefit managers average about \$2.

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PREPARED STATEMENT OF LISA M. GETSON

Mr. Chairman and members of this Committee, thank you for inviting me to appear at this hearing on behalf of Apria Healthcare, the homecare pharmacy industry, and the 1200 Apria clinicians who care for thousands of Medicare and Medicaid patients daily.

My name is Lisa M. Getson. I am senior vice president of business development and clinical services for Apria Healthcare, headquartered in Lake Forest, California. Apria Healthcare is one of the nation's largest home healthcare providers of oxygen and other respiratory therapies; home-delivered respiratory medications, home medical equipment and home infusion therapies, including chemotherapy. Every year, Apria provides service to over 1.2 million patients in all 50 states. Our 380 branch locations and 32 regional pharmacies serve urban areas such as Boston, Philadelphia, Atlanta, Houston, Los Angeles and here in the Washington area, as well as the most rural reaches of America such as Moosehead Lake, Maine; rural Wyoming County, West Virginia; Live Oak, Florida; Storm Lake, Iowa; and even Soldotna, Alaska.

My responsibilities at Apria Healthcare include managing the two homecare pharmacies that provide home-delivered inhalation therapies to 46,000 Medicare, Medicaid and managed care patients and the company's 32 regional home infusion pharmacies, which serve over 10,000 patients on any given day. I also provide executive oversight to the clinical respiratory, pharmacy and nursing functions as well as to the marketing department.

I will limit my oral comments to five minutes but have provided additional documentation for the official record. My testimony this morning can be summarized quite simply. There is no question that drug payments for home infusion and inhalation therapies subsidize other important functions and costs that are not directly reimbursed. We have no quarrel whatsoever with the effort to reform Medicare payments for outpatient drugs, but we are extremely concerned that such reform may occur without a corresponding change in how these other vital services and functions are covered and paid for. We strongly urge the Committee to couple drug payment reform with coverage reform for these home-delivered therapies. If that does not occur, then it may become impossible for responsible homecare providers to serve Medicare beneficiaries.

*Definitions of Inhalation and Infusion Therapy*

At the outset, permit me to describe briefly what inhalation and infusion therapies are. Inhalation therapy is the process through which a drug or a combination of drugs are delivered into the airways and inhaled directly into the lungs via a device called a nebulizer. These drugs may include bronchodilators (help open narrowed airways, corticosteroids (lessen inflammation of the airway walls); antibiotics (to fight lung infections); expectorants (help loosen and expel mucus secretions); and other drugs. These drugs are used to treat chronic obstructive pulmonary disease (COPD), the fourth leading cause of death in the U.S. which is also on the increase.

Infusion therapy involves the administration of the drug into the body through a needle or a catheter. Typically, infusion drug therapy means that a drug is administered intravenously, but it may also apply to drugs that are provided through other parenteral (non-oral) routes, such as injectables. Examples include intravenous chemotherapy, antibiotics, anti-nausea agents, pain management and other therapies for terminal or chronic illnesses. The drugs must be prepared by licensed pharmacists in hospital-quality clean rooms or with laminar airflow hoods. Many advances in technology and drug therapy have occurred since the late 1970s when home infusion therapy was introduced that have allowed many more therapies to be delivered in the home setting than were possible in the 1970s and 1980s. This is significant for two reasons. Patients and their caregivers prefer that whenever possible, their medical treatment be provided in the comfort of their homes. In addition, managed care organizations have realized that home healthcare is 30% to 50% less expensive than either inpatient hospitalization or unplanned emergency room visits. Since the 1980s homecare, as a percent of total healthcare expenditures has grown from three to four percent. It is therefore not surprising to me to see that Medicare Part B expenditures continue to increase.

Unlike private payors, Medicare Part B covers very few inhalation and infusion therapies. Current Medicare policy limits payment for these therapies to what is covered and paid for under the durable medical equipment (DME) benefit. The DME

benefit only explicitly covers the drugs, supplies and equipment and does not reflect any other services or any other costs integral to the provision of these therapies. This means that the Medicare program does not directly reimburse homecare pharmacies for the complex array of services necessary to furnish these therapies safely and effectively to patients in their homes. There is no question that the payment for the drug subsidizes these services and other related costs. They have to, since under the Part B benefit there is no alternative. Patients receiving infusion and inhalation therapies must receive these services as part of their care. Without question, this is the community standard of care across the country, and it would be reckless for Medicare to deviate from that standard.

For that reason, if our concerns could be reduced to one sentence, it would be that any policy changes to the drug payments must include a corresponding change in how these medically necessary services and functions are defined and paid for. For these therapies, this debate is not simply a reimbursement issue; rather, it is a coverage issue. Clarification of Medicare coverage in this area is long overdue. The deficiencies in the current system are illuminated by the AWP debate, but did not begin there.

#### *Acquisition Costs and Service Costs Incurred by Providers*

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. Provided safely and properly, these therapies require a complex array of services and ancillary functions provided by licensed health professionals such as pharmacists, high-tech infusion nurses with oncology or geriatric certifications; and respiratory care practitioners. While not separately acknowledged or paid for by the Medicare program under the current reimbursement structure, these services and functions are inextricably linked to the delivery of the covered drugs. In fact, through various state and federal legislation and the requirements of accrediting bodies, providers must include most of these services in their daily operations, must have one set of operating procedures and cannot discriminate among patients based on the payor source.

These expenses are legitimate clinical and operating costs that generally are recognized by Medicare for providers in other care settings. For example, these therapies require staff to be available 24 hours a day, seven days a week to respond to emergencies and questions regarding therapy, 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 using company vehicles, overnight delivery services or certified courier services. At Apria Healthcare, one out of every four home infusion patients calls us after 5 p.m. during any given month, often resulting in an after-hours visit or delivery.

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. Examples include quality improvement programs, utilization review, medical records management, coordination of insurance benefits, claims processing, medical waste management, personnel management, inventory control, and patient education materials in multiple languages.

Although Medicare does not currently require accreditation as a condition of participation, the Medicare program and beneficiaries do benefit from working with accredited providers. It is important to note that many, if not most, private payors require their providers and suppliers to be accredited. 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 provider meets or exceeds a verifiable standard of care. If the Medicare program discourages private accreditation as a result of its payment policies, then Medicare beneficiaries ultimately will lose the enhanced quality of care that accreditation achieves for patients. There are no comparable Medicare standards of care, a result of the illogical and incomplete coverage of Part B items and services. The value of accreditation was never more evident than on September 11, when we activated our disaster preparedness plan nationwide. Such a plan is a requirement of the Joint Commission on Accreditation of Healthcare Organizations. Within hours, we provided a range of nebulizers, oxygen, respiratory and home medical equipment to hospitals in New York City, northern New Jersey, Philadelphia and Washington, DC, prepared our clinical staff to assist local hospitals and were referred patients

who were discharged quickly from area hospitals to free up hospital beds for the wounded.

In addition to accreditation, there are costs associated with complying with state licensure and professional board requirements. We must comply with the extensive requirements of the following agencies: Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), Department of Justice (DOJ), Office of Inspector General (OIG); Department of Transportation (DOT), state Medicaid programs; state pharmacy, nursing and respiratory boards.

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;
- Preparing claims;
- Communicating with physicians regarding completion of certificates of medical necessity (CMNs) and other documents required by the program of physicians;
- Communicating with carriers regarding claims, documentation and inexplicable denials;
- Participating in medical review process with carriers on particular claims;
- Delays in payment from the program.

There are other costs of doing business that cannot normally be passed along to any payor. These include: 1) A nationwide pharmacist and nursing shortage causing increased labor expenses and benefit expansions; 2) Uncontrolled and variable fuel increases; 3) Fuel surcharges on business-related travel; 4) Annual rate increases by UPS, FedEx and other carriers; 5) Nominal salary increases to remain competitive; 6) Double-digit increases in business insurance expenses; 7) Increases in real estate and other overhead.

In the summer of 2001, the American Association of Homecare (AAHomecare) contracted with The Lewin Group to conduct what we believe is the most definitive study ever conducted on this subject. Entitled *“Product and Service Costs of Providing Respiratory and Infusion Therapies to Medicare Patients in the Home”* September 10, 2001, 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 the drug represented only 26% of the total costs of caring for Medicare Part B beneficiaries. The remaining 74% 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. I have submitted the study to the Committee.

#### *Increased Utilization of Inhalation Therapies*

What is driving the increased utilization in respiratory medications? 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. Please keep in mind that homecare pharmacies fulfill legal prescriptions written by licensed physicians who diagnose and treat patients in their offices. We believe the increased utilization is due to three primary factors:

(1) **The increased incidence of Chronic Obstructive Pulmonary Disease (COPD) in America.** According to a report recently released by the National Institutes of Health, 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. These death rates exceed those of diabetes and Alzheimer's. The number of lung cancer (highly linked to COPD) cases among women has jumped more than 600 percent since 1950, and in fact about 53% of Apria's patients are women. Patients with Black Lung Disease are aging and require many respiratory services. Overall 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.

(2) **The approval of generic ipratropium bromide by the Food and Drug Administration in 1995.** Not unlike other newly-approved drugs, the growth in utilization of inhalation therapies is related to increased physician demand for the drug. Over 1400 clinical studies have been published during the 1990s and overwhelmingly affirmed the efficacy of early treatment with ipratropium, particularly in conjunction with albuterol sulfate. Utilization for ipratropium has been driven by the clinical needs of the patient group and physician prescribing patterns. Historical factors have influenced the relationship between this drug's AWP and the acquisition



cost of the drug. Specifically, when it was first released, the manufacturer encountered severe production shortages. As the manufacturers' increased production, a generic became available causing supplies to increase dramatically, resulting in lower prices for the drug.

(3) **COPD is incurable but can be managed as the disease progresses.** As patients worsen or experience exacerbations, the number of treatments per patient increases, accounting for the higher volume for these drugs. COPD patients are being 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 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. Again, the government agencies have not studied the additional cost savings that could be afforded under Part B when compared with ER visits or inpatient hospitalization under Part A.

#### *Patients Benefit from Homecare*

I would like to briefly outline how two Medicare beneficiaries benefited from home infusion and home inhalation therapies in rural parts of West Virginia and Maine. In rural Wyoming County, West Virginia, Apria respiratory therapists often have to meet a family member in the mouth of the local hollow to transfer the respiratory equipment to their tractor or four-wheel drive to get up the mountain where patient education and assessment can ensue. In bad weather, we have to use the National Guard to deliver back-up oxygen to these patients and we even deliver to two Medicare patients currently by carrying equipment over two swinging bridges to reach their homes. They have been able to be treated at home for over two years rather than being hospitalized intermittently in the city hospital.

In Boothbay, Maine, we took care of a Medicare patient who was at the end of his 20-year battle with cancer. After being admitted to homecare about 1.5 years ago with severe malnutrition and anemia, the Apria clinical team conducted weekly teleconferences with his primary care physician to stabilize his condition and increase his weight gain. By the end of his life, he was able to enjoy a reasonable quality of life with his family by being treated largely at home until his death last month.

#### *Conclusion*

In conclusion, we understand the Committee's interest in reforming Medicare reimbursement for drugs. Any system where reimbursement for important services or functions is subsidized by the reimbursement for some other item cries out for reform. However, in the process of achieving that reform, there must be a corresponding creation of a payment structure for the services required to furnish inhalation and infusion therapies in the home. Thus, we need another step. Congress has to clarify coverage for these therapies in the homecare setting before reimbursement changes are implemented. We believe that the Lewin Group study I described earlier contains the most accurate and up-to-date information about the total costs borne by providers. If, however, the Medicare program believes that further study of these service costs is necessary, some of the analysis to date regarding physicians' office costs could establish useful benchmarks for similar costs. In a number of areas, the costs probably are not materially different between physicians and providers. In fact, in some areas we incur additional costs that the physicians do not, such as delivery, accreditation and certain clinical support services. If there is to be further study, we recommend that a credible organization such as MedPAC or the Institute of Medicine work with the homecare pharmacy industry to conduct a formal study of the service components and related costs that homecare pharmacies incur when providing care to Medicare beneficiaries.

Finally, we recommend that Congress adopt the approach proposed in the Engels bill, H.R. 2750, that would define the items and services covered under a Medicare benefit for home infusion therapy. A similar approach would work equally well for inhalation therapy.

Mr. Chairman, thank you for the opportunity to present this information to the Committee. I will be happy to answer any questions you have today or respond to written questions after the conclusion of this hearing.

**Product and Service Costs of  
Providing Respiratory and Infusion  
Therapies to Medicare Patients  
in the Home**

Prepared for:  
**American Association for Homecare**  
*September 10, 2000*

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## BACKGROUND AND SIGNIFICANCE

The issue of Medicare payments for prescription drugs is receiving considerable and increasing attention among public and private policymakers. Medicare Part B does cover some prescription drugs, including the medications necessary for the effective use of durable medical equipment (DME). These drugs are administered to patients who require respiratory or infusion drug therapy in the home. The level of Medicare's payment for a covered drug is based on the drug's average wholesale price (AWP)<sup>1</sup>. Respiratory and infusion drugs are different from simple drugs, such as pills, because they require an associated complex array of services in order to be safely administered to patients in their homes. Among the services homecare pharmacies provide to Medicare beneficiaries are monitoring and oversight of the homecare patient including, patient training and education, 24 hour on-call services, delivery of the drug to the patient in the home, as well as pharmacy services, such as compounding drugs.

For Medicare patients, respiratory and home infusion therapies vary greatly depending on the disease being treated, the level of patient acuity, the stability of the drug used in therapy, and the frequency of drug deliveries made to the home. Typical Part B-covered respiratory therapy patients have some type of chronic obstructive pulmonary disease (COPD) such as emphysema, chronic bronchitis, or asthma. Other disease states include environmentally induced COPD and congestive heart failure in combination with COPD. Patients vary in severity between those who may be moderately active and those unable to perform the most basic activities of daily living. Part B-covered home infusion patients may have many diagnoses: cancer requiring continuous or intermittent chemotherapy; chronic intractable pain due to advanced stages of cancer; chronic digestive diseases requiring a pump to provide intravenous or enteral nutrition through surgically-implanted tubes or catheters; or a limited list of acute infections that cannot be treated with oral antibiotics. Patients vary in the severity of their symptoms and some are homebound.

Concern is being expressed by members of Congress, the Office of Inspector General (OIG), the General Accounting Office (GAO), and the Department of Justice about the use of the AWP as a basis for Medicare (and Medicaid) reimbursement of drugs covered under Part B. Some public policymakers assert that Medicare's payments for these drugs are unnecessarily high because prices providers pay for these drugs are typically far below AWP levels. Large purchasers of pharmaceuticals often receive substantial discounts from the AWP. Medicare's payments for certain drug products may indeed appear high, if considered in isolation. This perspective is arguably narrow, however, given the complex set of services that are required to safely administer these drugs to patients in their homes and the economics of the home pharmacy industry.

Providers and suppliers of home infusion and respiratory drug therapies maintain that the so-called "excessive reimbursements" are, in reality, covering patient service and clinical costs associated with the safe and effective administration of these drugs. Unlike the private sector,

<sup>1</sup> AWP is the average of prices charged by the national drug wholesalers for a given product. Medicare's reimbursement is calculated by allowing 95 percent of the drug's AWP. If there is more than one seller of a drug, the median AWP for all generic versions of the drug product is used less 5 percent. Of this amount, Medicare pays 80 percent and the beneficiary is responsible for a 20 percent co-payment.

where these services -- integral to quality patient care -- are defined as part of the benefit and paid for accordingly, the Medicare program neither recognizes nor reimburses for them apart from its payment for the drug itself. The difference between what companies are paid by Medicare Part B and their "true" drug acquisition costs (often referred to as the "spread") is the only way providers of home drug therapies cover the costs of the clinical and support services necessary to furnish these drugs to patients in their homes. Thus, while the acquisition cost of drugs may seem small in comparison to other homecare pharmacy operating costs, the difference between the drug's acquisition cost and Medicare reimbursement underwrites clinical and support services that make home administration of these therapies possible for Medicare beneficiaries.

Given the controversy surrounding Medicare payment for Part B drugs, Congress mandated the General Accounting Office (GAO) to conduct a study of Part B reimbursement for drugs and biologicals. (This study was required by the Medicare, Medicaid, and SCHIP Benefits and Improvement Act of 2000.) The GAO has been asked to determine, in part, whether Medicare payment is adequate to compensate providers for costs incurred in the "administration, handling, or storage of such drugs." That study is expected in the Fall of 2001.

Because of the importance of understanding Medicare Part B payment issues as they relate to the scope and the costs of the services furnished to patients receiving drug therapies in the home, the American Association for Homecare commissioned The Lewin Group to conduct a study of the economics of homecare pharmacies in the United States. The study was conducted during July-August 2001.

## **ANALYSIS AND APPROACH**

### **Study Objectives**

The purpose of the Lewin study was to estimate the costs of providing respiratory and infusion drug therapies in the home to Medicare Part B patients in the calendar year 2000. The survey was designed to identify the cost of pharmaceutical products, scope of clinical and other patient service costs, and other costs associated with providing drug therapies in the home under the Medicare program. The study builds upon last year's study by The Lewin Group for the Association that was designed to estimate the impact of proposed reductions in Medicare Part B and Medicaid payments for up to 400 national drug codes.

### **Sample**

The survey sample was selected with the intent of being generally representative of homecare pharmacy companies nationwide. Data were obtained from a purposeful sample of 19 homecare pharmacy companies across the United States. Providers were identified as potential sample recruits through Lewin Group professional contacts, American Association for Homecare membership lists, and other industry representatives. Not all sampled companies are members of the Association.

As a group, sampled companies serve Medicare patients in all geographic regions of the United States; their various headquarter offices are located in 13 states (*Figure 1*).

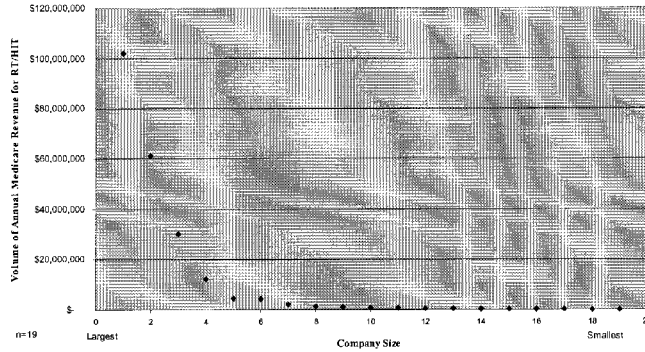
**Figure 1:  
Geographic Distribution of Sample  
by Homecare Pharmacy Headquarters\***



\*The 19 sampled companies together, provide services in all 50 states.

The companies range in size from less than \$1 million to greater than \$1 billion annual net revenue from all sources. The companies' combined respiratory and infusion Medicare revenue ranges from less than \$1 million to greater than \$100 million (*Figure 2*). All sampled companies provide respiratory therapies and eight companies provide home infusion therapies. Sampled companies in CY 2000 served 164,782 Medicare respiratory patients and 2,400 Medicare home infusion patients.

**Figure 2:  
Distribution of Sample by Medicare Revenue for  
Respiratory and Home Infusion Therapies, CY 2000**



### Survey Design

The Lewin survey instrument, designed in conjunction with pharmacy and financial experts, identified Medicare revenues, cost of pharmaceutical products, categories of professional services, and other major costs that accompany the provision of respiratory and infusion therapies in the home (Detailed cost allocation categories and definitions can be found in Appendix 1. Actual survey is Appendix 2). From company financial records, a chief financial officer (or his/her designee) or the head pharmacist from each participating company completed the mail-in survey and participated in a follow-up telephone interview to verify data submitted. To further assure the reasonableness of financial data submitted, Lewin staff compared them with available Wall Street equity research documents if the homecare company was publicly traded.

Companies provided revenue and cost data separately for respiratory and home infusion services. Revenue from Medicare for these two groups of therapies was also identified. For each service, the Lewin survey identified major categories of professional services that accompany the provision of drug therapies in the home (such as pharmacy operations, direct patient services, and others) as well as other corporate costs. For example, pharmacy operations include labor, delivery, and storage. Direct patient services includes those necessary to administer the drugs safely, such as patient training and education, patient monitoring, and 24-hour on-call services. Respondents were directed to exclude any costs and revenues associated with skilled nursing services that are reimbursed through home health agency provisions of Medicare. Cost data, submitted by companies, were proportionately allocated based on the volume of Medicare patients served.

The survey design enabled the calculation of various cost components as a percent of total costs, with particular emphasis on cost of services in relation to total costs and pre-tax operating and after-tax margins for the two therapies (individually and then combined).

### Analysis

The Lewin Group identified the cost of goods for respiratory and home infusion pharmacy products and analyzed the various service costs associated with these drug therapies. To calculate Medicare margins, revenue and costs for respiratory and home infusion were separately identified because of the differences in relative drug acquisition costs and associated service requirements. Four infusion therapy categories were analyzed: Chemotherapy, Pain Therapy and Management, Anti-Infectives, and Inotropic Therapy.<sup>2</sup> Although information was gathered at the individual company level, The Lewin Group assured confidentiality to encourage participation in the survey. Thus individual company results are not reported.

In a study such as this, it is important to assure that findings are not skewed by a small sample size. Lewin calculations of Medicare product and service costs for respiratory and home infusion therapies and Medicare operating margins were made with the intent of representing the homecare pharmacy industry as a whole. To achieve this objective, a double weighting process was developed for our analysis. First the sample of homecare pharmacies was divided into two groups, large and small, based on volume of their respiratory and home infusion business. "Large" consisted of the six sampled companies with the highest combined Medicare revenue for respiratory and home infusion therapies. The remaining thirteen sampled companies comprised the "small" group. Revenues and costs were then pooled at the "large" and "small" company levels and sample respiratory and home infusion service costs and margins were calculated from these numbers. Then, in order to reflect the *industry's* distribution of large and small firms with respect to Medicare respiratory and home infusion services, an additional set of weights was used. For respiratory therapy, a ratio of 70 percent "large" and 30 percent "small" was used.<sup>3</sup> For home infusion therapies, a ratio of 40 percent "large" and 60 percent "small" was adopted.<sup>4</sup>

In order to maintain the ongoing viability of a healthcare provider, an operating margin of net patient care revenues in excess of operating expenses must be maintained. The net operating margin reflects the revenue and total costs generated by the core activities of a healthcare business. Another important measure for our analysis is the after tax margin, which represents the earnings of a firm after accounting for other expenses, including federal and state corporate

<sup>2</sup> Information was gathered on seven home infusion therapies but only four were included in this analysis. In two cases, only one company in the sample provided a specific infusion therapy; thus, these individual company data were not reported. Total Parental Nutrition was excluded from this analysis because reimbursement for it is not based on AWP.

<sup>3</sup> Ratio based on the following sources: sampled companies' reported respiratory therapy Medicare revenue, Office of Inspector General's (OIG) identification of total allowable Medicare payments in 1999 for albuterol (June 2000), and Medicare data from the OIG's report *Medicare Reimbursement of Prescription Drugs* (January 2001).

<sup>4</sup> Of the \$4.8 billion home infusion market today, large providers (greater than \$40 million a year) comprise 40 percent of the total, yielding a 40/60 ratio. Source: Public filings of publicly traded providers, company finance departments, and Medical Data International.

income taxes. This study calculated margins in both ways. After tax margins for respiratory and home infusion therapies were calculated by first subtracting five percentage points for interest expense and corporate depreciation and then adjusting the resulting amount to account for combined national and state corporate income taxes (at 40.75 percent).<sup>5</sup>

In all calculation of costs and margins, bad debt associated with Medicare patients was included in the calculations because it is a significant expense borne by providers who are required to collect deductibles and co-payments from patients.

### STUDY RESULTS

As noted above, policy analysts have frequently asserted that Medicare reimbursement for Part B covered drugs results in windfalls to providers because of the “spread” between the provider’s acquisition costs for the drug and Medicare’s AWP based payment. The results of this study indicate that the acquisition cost for drugs is relatively small in comparison to other operating expenses of the homecare pharmacy. These results support the assertion that Medicare Part B payments, as currently constructed, offset costs for services which have no corresponding Medicare reimbursement at this time.

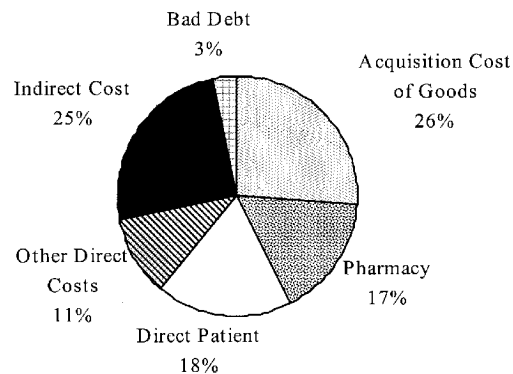
Homecare pharmacy operating costs, including patient-related services, far exceed the costs of acquiring respiratory and infusion drugs under the Medicare program. This study found that the acquisition cost for the drugs themselves was equal to 26 percent of total costs for respiratory and infusion therapies provided in the home setting to Medicare patients by homecare providers. Pharmacy, labor and delivery, patient care and education, and other direct costs account for nearly half (46 percent) of the total costs incurred by homecare pharmacies providing respiratory and infusion therapies to Medicare patients. Bad debt associated with Medicare patients is an estimated 3 percent of operating costs. Finally, indirect costs, such as management systems, regulatory compliance programs, and field administration, make up another 25 percent of homecare pharmacy costs. *Figure 3* summarizes these results.

<sup>5</sup> Calculations were made based on industry financial expert’s judgements that, for the pharmacy homehealth sector on average, five percentage points off of an operating margin would properly account for interest and depreciation. While corporate income tax rates vary from state to state, on average, state and local corporate income taxes amount to 8.84 percent of income and, on average, national corporate income taxes are 31.94 percent of income. Source: International Comparison of Effective Tax Rate of Corporate Income Taxation: [www.mof.go.jp/english/zei/report2/zc001d02.htm](http://www.mof.go.jp/english/zei/report2/zc001d02.htm)



**Figure 3:  
Homecare Operating Cost Components as Percent of  
Total Costs for Medicare Patients, CY2000**

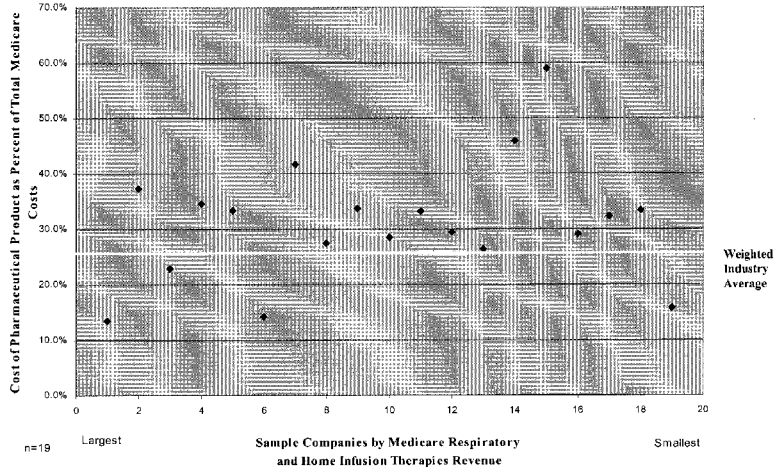
**Respiratory and Home Infusion Therapies Combined**



**Note: Definitions of cost components can be found in Appendix 1.**

The distribution of homecare pharmacy cost of goods for respiratory and home infusion medications, as a percent of total costs incurred serving Medicare patients, varied by homecare pharmacy company, depending on whether they were large or small in size. The cost of goods ranged from 13 percent to nearly 60 percent of all costs associated with providing homecare to Medicare patients. As *Figure 4* indicates, large firms and respiratory therapy results influence our findings, but the raw unweighted data clearly indicates that the acquisition cost of goods is typically around 30 percent and rarely much above 40 percent. Our findings are unequivocal on this key point.

**Figure 4:  
Distribution of Homecare Pharmacy Cost of Goods  
as Percent of Total Costs for Medicare Patients, CY2000,  
Respiratory and Home Infusion Therapies Combined**



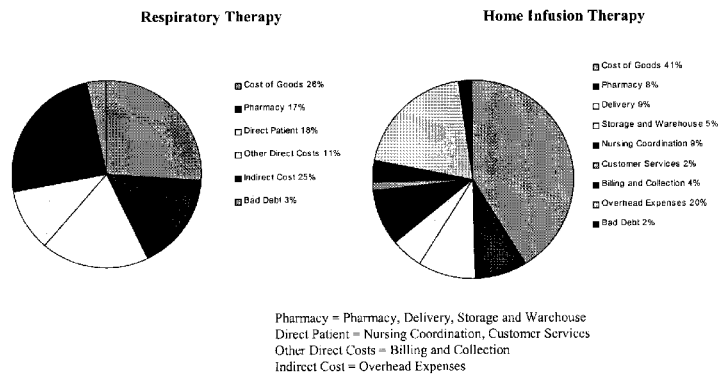
Survey results revealed that companies provide many essential professional services as part of delivering respiratory and infusion therapies in the home. These services include nursing and respiratory therapy coordination, clinical monitoring of patients, medication delivery, patient education services, and others.

Assuring quality patient care and meeting established patient quality standards (e.g., Joint Commission on Accreditation of Healthcare organizations (JCAHO), Community Health Accreditation Program (CHAP) or equivalent, federal and state licensure and regulatory requirements, customer service, education and training, emergency response, patient/employee needlestick and other safety guidelines, hazardous waste disposal and so forth) is an essential dimension of the service homecare pharmacy providers offer to *all* patients and is often required for Medicare participation. Providers are not permitted under law to offer a different level of service to Medicare patients as policies and procedures must be standard for all patients thus the service cost for *all* patients is equal regardless of the specifics of individual payer coverage.

The distribution of costs for nursing coordination, pharmacy, customer services, delivery, medication storage, and other services varies by type of therapy. For respiratory therapy these service costs equal 46 percent of the total cost of providing the treatment; the drugs themselves

equal 26 percent. For home infusion therapies, service costs equal 35 percent of the total cost of providing the treatment and the acquisition of the drugs average 41 percent (*Figure 5*).

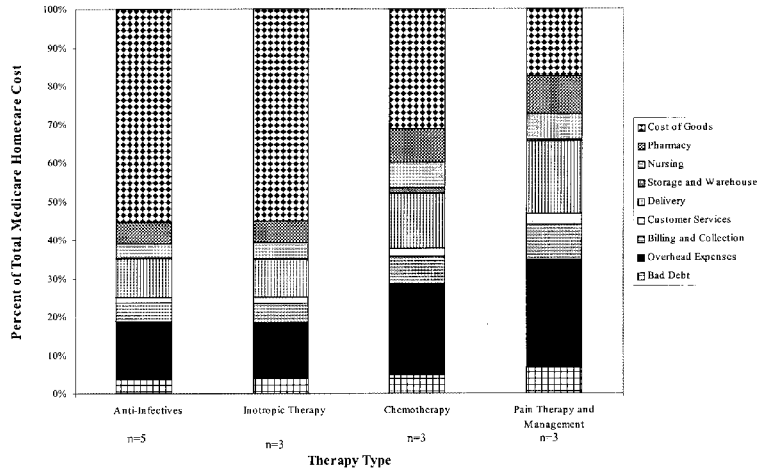
**Figure 5:  
Homecare Cost Components as Percent of Total Costs for Medicare Patients, CY 2000**



**Note: Home infusion therapy has little impact on the combined distribution of cost components (in *Figure 3*) because respiratory dwarfs infusion in volume of Medicare patients.**

Among the various home infusion therapies included in the survey, percentages fluctuate by type of infusion treatment. The cost of pharmaceutical products equals 55 percent for Anti-Infectives, 55 percent for Inotropic Therapy, 31 percent for Chemotherapy, and 17 percent for Pain Therapy and Management (*Figure 6*).

**Figure 6:  
Home Infusion: Cost of Product and Services in Relation  
to Total Cost, by Therapy, CY2000**



The cost of assuring quality care is considerably greater than the cost of “a reasonable handling fee” that some policymakers have stated they would consider negotiating with providers. Unless full provider costs are otherwise paid for, the only way these costs can be recovered under the existing Medicare payment structure is through reimbursement for the pharmaceuticals provided.

**Margins**

Another major finding of this study is the estimated margin for respiratory and home infusion therapies provided to Medicare patients by homecare pharmacies. We learned that companies have, on average, a 20.4 percent pre-tax operating margin for respiratory and home infusion therapies combined. When viewed alone, Medicare home infusion therapies generate a negative

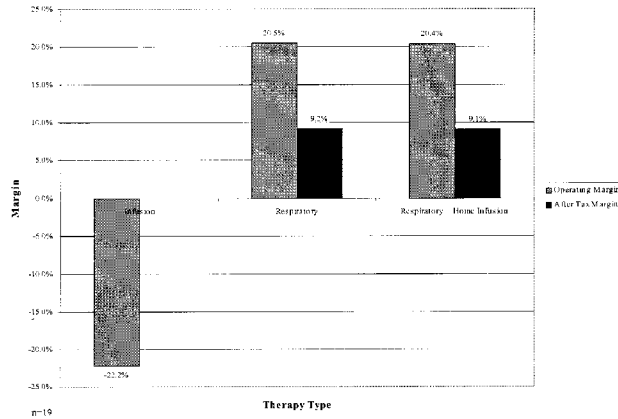
<sup>6</sup> Why would companies continue to offer home infusion therapies to Medicare patients if the operating margin from these services is negative? Companies report that physicians and hospitals expect homecare pharmacy companies to accept referrals for all patients, regardless of payer source. One respondent wrote, “We don’t take many [home infusion] patients who are strictly Medicare, as coverage under Medicare is limited. Those patients we do service who have no secondary insurance are done as charity cases to maintain referral relationships.” For surveyed companies, the fact that Medicare home infusion patients are a small portion of their total home infusion business

22 percent margin, while the operating margin for respiratory therapy is 20.5 percent.<sup>6</sup>

When interest and depreciation expenses are subtracted from the combined operating margin, it drops to an estimated 15.5 percent. When federal and state corporate income taxes are also included in the calculation, the bottom line after-tax margin for these companies drops to 9.1 percent for the services provided to Medicare patients (*Figure 7*). The after-tax margin of 9.1 percent is at a level sufficient to attract debt and equity capital which allows homecare pharmacies to continue to offer patients a high degree of access.

This study presents the financial realities of the pharmacy sector that provides respiratory and infusion services to Medicare patients in the home. In a previous Lewin report, we reported that several companies had ceased accepting referrals from Medicaid programs for new patients on a specific list of respiratory and infusion therapies after approximately 10 states reduced the AWP-based reimbursement without an offset for services incurred. Thus, it is clear that service lines at the payer level can be discontinued as companies review their operational results.

**Figure 7:**  
**Estimated Margins for Respiratory and Home Infusion Therapies to Medicare Patients by U.S. Homecare Pharmacy Providers**



makes it possible for them to continue these arrangements.

## CONCLUSION

This study is significant in that it provides the most current and extensive estimates of the relative cost of respiratory and infusion drugs and the cost of associated services provided to Medicare patients in the home by homecare pharmacy providers. Assuring quality patient services and meeting established federal, state, and private quality standards is a commitment homecare pharmacy providers offer to all patients, including Medicare beneficiaries, even though Medicare reimbursement policies do not expressly recognize these services. Continued assurance that Medicare patients have access to quality service and drug therapies in the home depends upon the financial viability of homecare pharmacy product lines. As policymakers fashion potential Medicare Part B payment changes, the ramifications of these financial realities merit consideration.

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### PREPARED STATEMENT OF LARRY NORTON, M.D.

My name is Larry Norton. I am head of the Division of Solid Tumor Oncology at Memorial Sloan-Kettering Cancer Center in New York, specializing in breast cancer, and am presently serving as President of the American Society of Clinical Oncology (ASCO). ASCO is the medical society representing physicians who specialize in cancer treatment and clinical cancer research. Its 18,000 membership is international in reach and includes many nonphysician healthcare professionals.

I appreciate the opportunity to appear before the Finance Committee today to address issues of great concern to cancer physicians and their patients. Two of these issues—coverage by Medicare of oral anti-cancer drugs and payments by Medicare for chemotherapy drugs and services furnished in physician offices—have an inevitable link to quality cancer care for Medicare beneficiaries. They are thus highly appropriate and timely topics for consideration by this Committee.

I want to thank Senator Rockefeller and Senator Snowe for convening this hearing. Both Senator Rockefeller and Senator Snowe have commendable legislative records in support of quality cancer care. It was Senator Rockefeller's 1993 legislation that established a precedent for Medicare coverage of oral anti-cancer drugs by covering oral drugs that have an injectable version, and Senator Snowe has long been an advocate for coverage of oral breast cancer drugs. The cancer community is pleased that you are still pressing for these important coverage provisions and feels confident that you will provide thoughtful leadership on the overarching question of how to ensure Medicare beneficiaries access to quality cancer care.

### MEDICARE COVERAGE OF ORAL ANTI-CANCER DRUGS

As I mentioned earlier, at Memorial Sloan-Kettering, I specialize in the treatment of breast cancer. With the benefits of screening and early diagnosis as well as improvements in therapy, mortality from breast cancer is declining, though not nearly so fast as we would like. One of the important drug therapies that has improved the chances for women diagnosed with breast cancer is tamoxifen, a hormonal agent that has been demonstrated to prevent the recurrence of breast cancer. I have prescribed that drug for my patients for years and have seen its benefits.

It is truly shocking that such an effective therapy is not covered by Medicare, leaving patients to fend for themselves for the five years that the drug is typically prescribed. Yet tamoxifen is just one of a number of anti-cancer drugs not covered by Medicare solely because they are not available in an injectable dosage form.

Noncoverage of oral anti-cancer drugs has long been a gap in quality cancer care for Medicare beneficiaries. Last year that gap became even more noticeable with the approval of the first in what we hope will be a series of targeted anti-cancer drugs that are less toxic than current treatment as well as more effective. But, because many of these drugs are available only in oral form, they will not be covered by Medicare unless Congress passes the Access to Cancer Therapies Act, introduced as S. 913 by Senators Rockefeller and Snowe and co-sponsored by many others in both the Senate and the House of Representatives.

The first of these targeted oral drugs is known as STI-571, or Gleevec. The drug was tested in patients with chronic myeloid leukemia (CML) because it has the ability to block the effect of a protein that had been shown through basic research as

essential to the growth of CML cells. Clinical trials have shown thus far that the drug has remarkable ability to induce remission in CML patients. As such, this drug's success is an important "proof of principle" that drugs targeting specific protein interactions or other cellular mechanisms can in fact be used effectively to treat cancer with fewer side effects than with traditional chemotherapy drugs. Additionally, this drug has just been approved for use in gastrointestinal stromal tumors (GIST), which was a previously untreatable and fatal disease.

Other targeted oral drugs are in the product pipeline and are showing impressive results in clinical trials. Within the next few years, we should see such products used for the treatment of a variety of cancers, not just cancers of the blood like CML but also solid tumors of the breast, colon, lung, pancreas and prostate. The anticipated success of these drugs is a resounding confirmation of this country's strategy of funding biomedical research. Through outstanding translational and clinical research, and with the continued efforts of industry, we now can create patient benefit from the many basic science discoveries of the past several decades.

As these new drugs increasingly take the place of drugs covered by Medicare, it will become obvious to beneficiaries with cancer that, while cancer research is doing more for them, the Medicare program will be doing less. For example, the new drug for CML can be used by many patients in place of bone marrow transplantation or high-dose interferon, both very costly and very toxic treatments and both of them covered by Medicare in appropriate circumstances. Most patients will choose the new drug, but that means Medicare will not cover much of the cost of their care even though it would cover the perhaps less optimal therapies.

At present, most cancer treatment of Medicare beneficiaries is covered because it is administered by providers and drug costs are covered as incident to the provider service. As drug therapy is increasingly delivered in oral form, however, the financial burden will be shifted from the Medicare program to the individual beneficiary. This is clearly not an acceptable trend.

Medicare policy must be reformed to ensure that continued advances in cancer treatment that may result in less toxic, more effective and more cost-effective therapies are not stymied by coverage limitations that deny access to patients.

#### NEED TO PRESERVE OUTPATIENT CHEMOTHERAPY

As we consider the prospect of improved cancer therapies that can be administered orally, it is also important to preserve the current system of outpatient chemotherapy administration in physician offices and hospital outpatient departments. There has been much discussion over a number of years about Medicare payment of the drugs and related services furnished in outpatient cancer treatment.

As President of ASCO, I want to make clear our belief that the payment methodology should be reformed, but it must be done without disrupting patient care. ASCO agrees that Medicare payment for both drugs and related services should be restructured to more closely align payment amounts with the cost of providing care. Payments for drugs should be reduced; payments for related services should be increased. Reform should be comprehensive with simultaneous changes to drug payments and to payments for related services so as to ensure that treatment for beneficiaries with cancer is not threatened.

Chemotherapy is central to modern cancer treatment and is likely to be even more important in the coming years. Chemotherapy once required extensive hospital stays. Now, with better drugs to control side effects, patients can receive treatments in outpatient settings most convenient for them—and for their families. This is usually in physician offices.

In restructuring the Medicare payment system for chemotherapy, the net result must be aggregate payment amounts that enable physicians to continue offering office-based chemotherapy. It has been estimated that 70% or more of chemotherapy treatments are furnished in physician offices. If Medicare payments are not adequate to cover the costs of this service, physicians will be forced to try to have chemotherapy delivered in some other setting. It is far from clear, however, whether hospital outpatient departments have the capacity or the resources to handle a large inflow of chemotherapy patients. Any significant reduction in office-based chemotherapy could therefore result in a massive disruption in the care of Medicare patients with cancer.

#### PAYMENTS FOR DRUG-RELATED SERVICES

As I stated earlier, ASCO supports a reduction in the Medicare payments for drugs. Before discussing that aspect, however, I want to speak first about the simultaneous change that must be made to ensure that Medicare cancer patients will still be able to obtain chemotherapy treatment after the drug payments have been re-

duced. Under the current reimbursement system, the payments for drugs compensate at least in part for the underpayment or lack of payment for the related services, and all parts of the system must therefore be reformed at the same time.

In the 1970s, there were few drug treatments available for cancer and, as I mentioned earlier, those that were available were generally administered to hospital inpatients. The few types of chemotherapy that were first furnished in the office setting were relatively simple, but they established the basis for the low Medicare payment levels for chemotherapy administration services that continue to exist today. There has been no major revision, even though the complexity of chemotherapy furnished in the outpatient setting has increased enormously. This problem was noted by Congress as early as 1987, when the Omnibus Budget and Reconciliation Act required the Department of Health and Human Services to conduct a study of the costs of furnishing chemotherapy in the office and assess whether payments are adequate. Unfortunately, this study was never conducted.

In 2000, however, the Health Care Financing Administration, now the Centers for Medicare & Medicaid Services (CMS), reviewed the matter and wrote Congress that “Medicare payments for services related to the provision of chemotherapy drugs. . . are inadequate.”

The inadequacy of the Medicare payment amounts is illustrated by the costs of one of the principal services. Under the physician fee schedule, the current Medicare payment level for the first hour of a chemotherapy infusion (CPT 96410) averages about \$56. The cost of the supplies and equipment used in this procedure are estimated to be about \$29, based on the 1994–95 prices used by CMS for these estimates. The salary and benefits of the oncology certified nurses who furnish chemotherapy are currently estimated by CMS to average about \$35 an hour, and the total nurse time involved in furnishing an hour of infusion is estimated at about two hours. Among other elements, this work includes reviewing the patient’s medical history, verifying the drug orders, preparing the drug, educating the patient, assembling the necessary supplies, administering the drug, documenting the procedure, and follow-up phone calls.

Thus, the costs of the supplies, equipment, and nurse time for an infusion by themselves significantly exceed the Medicare payment amount. Moreover, there is nothing in the Medicare payment to cover the other costs of the office, including the administrative staff and the overhead, which CMS, using American Medical Association data, estimates to be about two-thirds of a physician’s costs. The Medicare payment amount for chemotherapy services are far less than the costs incurred to furnish the services. ASCO estimates that Medicare pays less than one-fourth of the total costs of the principal chemotherapy procedures.

ASCO believes that this underpayment results at least in part because of the way in which the methodology for the Medicare physician fee schedule sets payment amounts for services that may represent significant expense to a practice but are not directly furnished by the physician. Chemotherapy is one example. At the time that CMS adopted this methodology in 1998, it characterized its approach as “interim” but the methodology has not yet been revised.

ASCO believes that the payment amounts for services of this kind—those that do not have a physician work component—should be based on information about the costs of providing those services, and not on the current “top-down” methodology that is used in general to set payment amounts. Although it would be desirable to collect new cost data, any restructuring in the near future must depend on information that currently exists or can be promptly developed. Consequently, ASCO recommends use of the data on costs that was initially developed by the Clinical Practice Expert Panels (CPEP) and has subsequently undergone review in the American Medical Association refinement process and analysis by CMS. Medicare should pay the full direct and indirect costs of chemotherapy services as estimated in that process. If the CPEP data are not viewed as acceptable, then there should be a process for acquiring new data, or for analyzing proposed payment amounts, prior to any payment reform being approved by Congress.

There should also be a new type of Medicare payment for services that are related to chemotherapy but are not part of the chemotherapy procedure itself. Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement. These services include the extensive support that seriously ill cancer patients frequently require, including social worker services, psychosocial services, and nutrition counseling. Social worker services encompass a variety of services intended to help patients carry out their therapy, such as help with insurance, arranging transportation to treatment, and filling prescriptions. Psychosocial support includes services such as counseling patients on their activities of daily living, support groups that meet in the physician’s office, and grief counseling. In addition, physicians treating cancer patients perform an extraor-



dinarily high amount of work outside the patient's presence, including family counseling, telephone calls, arranging for entry into clinical trials, and so forth. While other types of physician specialists may provide such services to occasional patients, oncologists and their staffs typically provide these services to the bulk of their entire patient load. If the Medicare payments for the drugs and drug administration are aligned closely with their costs, there will not be sufficient funds available to continue these services, which are so important to the seriously ill cancer patient population. Medicare patients need to continue to receive these services to deal with their disease, and the services should not be cut off to save money.

#### PAYMENTS FOR DRUGS

Finally, let me turn to the Medicare payments for the drugs themselves. The current Medicare payment amount for covered drugs is based on 95% of published average wholesale price (AWP). As is widely known, published AWP overstates, by a varying amount, the prices at which drugs can actually be purchased. This circumstance does not necessarily make AWP useless, however, and AWP is widely used by public and private insurance programs in their reimbursement methods for drugs that are dispensed by pharmacies or administered in physician offices.

In recent years, the difference between AWP and actual prices for some drugs has become very large. This situation typically occurs for multiple-source drugs or drugs with close competitors, where competition forces down the actual price even though the list price, on which AWP is based, remains high. The large discrepancy between price and reimbursement amount for some drugs is not an appropriate situation.

As part of restructuring the Medicare payment system, ASCO recommends one of two approaches to revising the payments for drugs. First, Medicare could determine the market prices of each drug. Instead of using AWP, the law could require drug wholesalers to report to a Medicare contractor the prices at which they sold each Medicare-covered drug, considering all discounts, and the quantity sold at that price. The contractor could then compile those reports into a picture of the range of market prices for each drug and set a Medicare payment level accordingly.

If this market approach is adopted, ASCO believes that a number of features should be included to ensure that the survey results in an appropriate payment level:

- The price reports should be frequent so that they reflect changing market conditions. ASCO recommends that the wholesalers submit reports every month and that the contractor process the data promptly so that it can be used for reimbursement purposes in the second following month. For example, prices of drugs sold in January would be used to set the payment amounts for March.
- Since there will be a variation in the prices, the Medicare payment level for each drug should be set at an amount that will cover the prices actually paid by the vast majority of physicians. ASCO recommends the 95th percentile. Prices actually paid may vary greatly because physicians in larger groups are able to negotiate lower prices based on their volume purchases. It would be extremely unfair to pay based on the median price or some similar price because that would systematically discriminate against physicians who are unable to negotiate lower prices. Oncologists who are routinely reimbursed less than what they pay for a drug would be unable to continue furnishing drugs to their patients.
- The payment methodology should be flexible enough to take known manufacturer price increases into account immediately. For example, if data on wholesale prices is collected during January for use in March, but the manufacturer raises the price of a drug by 5% on February 1, that should be taken into account in setting the March payment amounts.
- There should be an add-on amount to reflect certain costs associated with use of the drug. These include costs such as spillage, wastage, the opportunity cost of the capital tied up in drug inventory, procurement and storage costs, and unpaid patient coinsurance (bad debt). Although Medicare Part B does not ordinarily cover bad debt, bad debt here represents an out-of-pocket loss to the physician and should be treated specially. The various components of these extra costs are difficult to estimate, so ASCO recommends a flat 10% add-on to cover them.
- Sometimes physicians will encounter especially high prices for drugs, such as if they have to purchase a drug from a pharmacy in an emergency. The system should always allow a physician to be reimbursed for the actual acquisition cost by submitting documentation as to the purchase price.

- In states that impose a sales or gross receipts tax on physician-administered drugs, Medicare should also cover that amount so as to keep the physician financially whole.

An alternative approach to using a survey of market prices would be to make the published prices used by Medicare more accurate. The main concern expressed about the published prices has been the particularly large differences between the published prices and actual prices for some drugs. The law could be changed to require manufacturers to submit accurate prices to the publishers. This approach would have the advantage of not requiring a government contractor to compile data.

ASCO could support either of these approaches. Our concern is only that the resulting Medicare payment must be adequate to cover the full costs incurred by oncologists. Oncologists pay varying amounts for drugs, with large practices and entities able to obtain volume discounts not available to everyone. The methodology adopted must be adequate to ensure that all oncology practices, regardless of size, obtain full reimbursement of all their drug-related costs.

#### HOSPITAL OUTPATIENT DEPARTMENTS

The Medicare statute ties payments under the hospital outpatient prospective payment system to AWP by paying for drugs used in cancer therapy based on 95% of AWP for a two to three year transitional period. As the payment methodology for drugs furnished in physician offices is revised, it is important that possible effects on payments for services in hospital outpatient departments be kept in mind. Hospital outpatient departments are an essential part of the delivery system for cancer care, and Medicare payments must be adequate to support their continued operation.

#### CONCLUSION

The Medicare program should be reformed by:

- Extending coverage to all oral anti-cancer drugs so that patients may have access to new targeted oral drugs as well as proven drugs like tamoxifen for breast cancer;
- Reducing payments for drugs to more closely approximate their acquisition and others costs; and
- Simultaneously increasing payments for services related to the provision of chemotherapy to Medicare beneficiaries in order to cover the costs of providing such services.

In undertaking such reform, the Congress should be guided by what will maintain quality cancer care for beneficiaries. We look forward to continued work with the Congress to achieve reform without disrupting patient care for beneficiaries with cancer.

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#### PREPARED STATEMENT OF JANET REHNQUIST

Good morning, Mr. Chairman. I am Janet Rehnquist, Inspector General for the Department of Health and Human Services. I appreciate the opportunity to appear before you today regarding the important issue of Medicare reimbursement for prescription drugs.

We have consistently found that Medicare pays too much for prescription drugs—more than most other payers. For example, we found that Medicare's authorized payments for 24 leading drugs in the year 2000 were \$887 million more than actual wholesale prices available to physicians and suppliers and \$1.9 billion more than prices available through the Federal Supply Schedule. We believe that this has occurred because Medicare's reimbursement methodology is flawed. Until the system is changed, Medicare and its beneficiaries will continue to pay excessive amounts for prescription drugs, and the amount of excessive payments will increase every year.

#### *Medicare Coverage and Payments for Prescription Drugs*

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. In general, Medicare reimburses physicians and suppliers for 95 percent of the average wholesale price (AWP) published by the drug manufacturers. Of this

amount, Medicare beneficiaries are responsible for a 20 percent coinsurance payment.

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 2000, it paid \$5 billion. Between 1999 and 2000 alone, payments increased by \$1 billion.

#### *Excessive Payments*

Since 1997, the Office of Inspector General has produced a number of reports, all of which have concluded that Medicare and its beneficiaries pay too much for prescription drugs. Today I am issuing three new reports. Two of these are related to Medicare payments for the drugs albuterol and ipratropium bromide. The third focuses on Medicaid reimbursement for generic drugs. It shows that the Medicaid program faces the same kinds of problems as Medicare when paying for prescription drugs.

The following summarizes the results of our many reports on Medicare payments for prescription drugs.

*Medicare Reimbursement for Prescription Drugs.* In a January 2001 report, 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.

In June 2001, we updated the findings of this report with more current drug pricing information. 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 some cases, the VA price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. 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. Beneficiaries would pay over \$175 million less in coinsurance if Medicare paid for these drugs based on catalog prices. The potential total savings available to both Medicare and its beneficiaries is probably higher, assuming data for all Medicare drugs is similar to that for the 24 we analyzed.

*Nebulizer Drugs.* In June 2000, 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 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 for around \$52. 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.

In a report that we are releasing today, we show that the VA price for albuterol has continued to decrease. 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. In 2000, published wholesale acquisition costs for albuterol ranged from \$0.09 to \$0.18 per mg. These wholesale acquisition costs were provided by manufacturers to drug compendiums such as the Red Book. The Medicare reimbursement rate of \$0.47 per mg was anywhere from three to five times the wholesale acquisition costs reported by manufacturers.

Also in this report, we looked at who actually supplies albuterol to Medicare beneficiaries. We found that Medicare reimbursed more than 6,500 pharmaceutical suppliers for albuterol claims in 2000. However, less than 3 percent of these suppliers (184) accounted for approximately 80 percent of albuterol reimbursement. Each of these suppliers had over \$150,000 in paid Medicare claims for albuterol last year. Thirty-four of these suppliers were each responsible for more than \$1 million in Medicare reimbursement for albuterol in 2000, with five having between \$11 million and \$35 million in reimbursement. Thus, the vast majority of the albuterol supplied

to Medicare beneficiaries was provided by suppliers that purchase and bill for a large quantity of the product. We believe that suppliers that purchase albuterol in such large quantities are likely to receive volume discounts similar to those provided to the VA and other large purchasers.

We are releasing a separate report today in which we 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. Furthermore, we found that less than 1 percent of the 5,652 pharmaceutical suppliers that were reimbursed by Medicare for ipratropium bromide accounted for the majority of the drug's reimbursement that year. Each of these high-volume suppliers provided home-delivery/mail-order services to Medicare beneficiaries.

#### *Flawed Payment Method*

Our reports have shown time after time that Medicare pays too much for drugs. Why does Medicare pay so much? We believe that it is because Medicare's payment methodology is fundamentally flawed. By statutory requirement, Medicare's payment for a drug is equal to 95 percent of the drug's average wholesale price (AWP). However, the AWP's which Medicare uses are not really wholesale prices.

For the most part, AWP's are reported by manufacturers to companies that compile drug pricing data, such as First DataBank and Medical Economics, which publishes the Red Book. As our reports have indicated, the published AWP's that Medicare uses to establish drug prices bear little or no resemblance to actual wholesale prices available to physicians, suppliers, and large government purchasers.

Aside from the obvious problem of inflated AWP's resulting in inappropriate Medicare payments, the use of AWP also has other potential adverse implications. 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" serves as an inducement for suppliers or physicians to use one brand of the drug over another. Thus, publishing an artificially high AWP is 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, it does increase the manufacturer's market share because of the higher profits made by physicians and suppliers. This in turn increases the profits of the drug company. All of this occurs at the expense of the Medicare program and its beneficiaries.

#### *Recent Settlements*

Recent settlements further illustrate some of the problems associated with Medicare's current reimbursement methodology. Because 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 kickback 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 AWP's were also associated with recent settlements involving Bayer Corporation and TAP Pharmaceutical.

*Bayer Corporation.* In January of 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 AWP's for these drugs at levels far higher than the actual acquisition cost of the majority of its cus-

tomers 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 sale 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, travel and entertainment, and other items to induce them to purchase Lupron. In addition, TAP allegedly set and reported AWP's 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.

#### *Medicaid Drugs*

Although Medicare is the primary focus of my testimony today, problems resulting from the publication of misleading AWP's have also plagued the Medicaid program because the payment methods based on AWP's are fundamentally flawed. This is illustrated by a report we are releasing today related to Medicaid drug reimbursement. As a follow-up to our previous work, we conducted a nationwide review of pharmacy acquisition costs for generic drugs reimbursed under the Medicaid prescription drug program. 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 this review was to develop an estimate of the discount below AWP at which pharmacies purchase generic drugs.

We obtained pricing information from 217 pharmacies in 8 States, which resulted in an analysis of 8,728 invoice prices for 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. We estimated that the actual generic drug acquisition cost was a national average of 65.93 percent below AWP. Our previous estimate, based on calendar year 1994 pricing data, showed a discount of 42.45 percent below AWP for generic drugs. As a result, this review showed an increase of 55.31 percent in the average discount below AWP for generic drugs from 1994 to 1999.

Unlike brand name drugs for which Medicaid reimbursement is based predominantly on a discounted AWP, reimbursement for generic drugs can be limited by Federal upper limit amounts. Taking the discounts below AWP, as well as those generic drugs for which upper limits could be applied, we calculated that as much as \$470 million could have been saved for the 200 generic drugs with the greatest amount of Medicaid reimbursements in CY 1999, if reimbursement had been based on the discount percentages below AWP as identified in this report. Accordingly, 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 generic drug products, which we identified as being 65.93 percent below AWP.

Similarly, in August 2001 we issued a report on pharmacy acquisition costs for brand name drugs reimbursed under the Medicaid prescription drug program. The objective of the review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name drugs. We estimated that nationally, pharmacy actual acquisition cost was an average of 21.84 percent below AWP. Our previous estimate, based on CY 1994 pricing data, showed a discount of 18.30 percent below AWP for brand name drugs. Therefore, this review showed that from 1994 to 1999 there was an increase of 19.3 percent in the average discount below AWP for brand name drugs. We estimated that the Medicaid program could have saved as much as \$1.08 billion if reimbursement had been based on a 21.84 percent average discount below AWP.

#### *Correcting the Current Payment System*

I believe a number of factors need to be considered when deciding how to correct Medicare's reimbursement method for prescription drugs. These factors provide a basis for considering how to change the Medicare drug payment system.

*Market Prices.* A drug reimbursement system should be based on real prices available in the marketplace. Physicians and suppliers 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.

*Data Availability and Reliability.* We need a practical way to obtain data which can be used to set reimbursement. Further, there needs to be confidence that the data are reliable and cannot be misrepresented.

*Periodic Updates.* Reimbursement needs to be periodically updated to reflect market changes. This will also impact how monitoring is conducted to ensure that access problems do not occur, and how payment revisions are made if this does occur or if individual payments continue to be inflated.

*Proprietary Information.* We need to consider how to protect proprietary data.

*Physician Practice Costs.* Finally, we recognize that some physician groups have raised concerns about Medicare's attempts to lower reimbursement for prescription drugs. For example, some oncologists have stated that Medicare does not adequately reimburse physicians for the practice costs associated with providing treatment to cancer patients. 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. The Medicare program already has a procedure for determining the amount physicians should be reimbursed for their practice costs. If the current calculations are incorrect, they should be modified. Physicians deserve fair reimbursement for their valuable services.

#### *Conclusion*

Our reports, including the ones that I am releasing today, contain numerous options to reform Medicare's drug pricing method. Each has its own advantages and disadvantages. We recognize that there may not be one perfect solution to solving all of Medicare's drug pricing issues. We hope that these are helpful as the Congress and the Administration move forward to address this pressing problem.

Mr. Chairman, this concludes my testimony. I appreciate the opportunity to address this important issue with you today. 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. The payment system is based on the AWP, a list price reported by the drug manufacturers that is neither average nor wholesale and bears little or no resemblance to the actual wholesale prices available to physicians and suppliers who participate in the Medicare program. Until this problem is corrected, Medicare and its beneficiaries will unnecessarily pay more and more each year. I welcome your questions.

#### RESPONSES TO QUESTIONS FROM SENATOR BAUCUS

*Question 1:* I believe we need to replace the average wholesale price (AWP) with a market price for drugs (MPD). What should the definition of "MPD" include or exclude if it were to be used to pay for Part B drugs? Are there any purchasers that should be excluded when determining the price actually available in the market? Should we exempt the same types of purchasers exempt from the definition of best price in Medicaid statute? What are the implications of exempting or including those purchasers? The Bayer and TAP corporate integrity agreements exclude direct sales to hospitals, and the average manufacturer price (AMP), used in the Medicaid rebate system, excludes sales to health maintenance organizations (HMOs). Should either of those purchasers be excluded when creating a system for Part B drugs? Why or why not? The Bayer and TAP agreements require the price to be net of all price concessions—charge backs, prompt pay discounts, volume discounts, free goods, and others. The AMP is only net of prompt pay discounts. Is there any reason the Medicare definition should not be net of all price concessions?

*Answer:* We believe that Medicare reimbursement for prescription drugs should be based on real prices available in the marketplace. These real prices can be described using any term (e.g., average sales price, wholesale acquisition cost, market price data) as long as the term is strictly defined. By "strictly defined", we mean that the industry, the Government, and providers must understand what, how, and when the information will be reported and updated. It should also provide for a process to determine if the new prices are causing access problems for beneficiaries. As a general principle, we believe that the new definition should allow for very few exemptions for purchasers. One exemption should be for Federal Government programs such as the Federal Supply Schedule and Department of Defense. Along the same lines, Medicare pricing definitions should have few exceptions for price concessions. By allowing for few exemptions, chances are increased that the government receives ac-

tual base prices, thereby making it easier to determine the appropriate payment amount.

*Question 2:* I gather from your testimony that part of the problem we now face with using AWP for reimbursement purposes occurs when manufacturers and physicians use the spread between the AWP and acquisition costs to their benefit—the manufacturers can use the spread as a marketing tool to encourage physicians to use their products, and physicians can use the products that provide them with the largest spread to cover their practice expenses. Are there similar dynamics with drugs dispensed by pharmacists? What is the spread between Medicare’s payments to pharmacists, and pharmacists’ acquisition costs? Is it as large as the spread for physician-dispensed drugs? Would it make sense to create one reimbursement system for physician-dispensed drugs, and a different reimbursement system for pharmacist-dispensed drugs?

*Answer:* With a few exceptions, our work has found the spreads between the AWP and the acquisition cost were generally higher for nebulizer drugs (albuterol, ipratropium bromide, etc.) provided by pharmacies compared to physician-administered drugs. We believe that pharmacies need to make a profit from the drugs they provide. Physicians, on the other hand, need to be reimbursed accurately for the cost of the drug while also getting appropriate payments for patient care. Any new reimbursement system should account for these differences.

*Question 3:* Has CMS used their audit authority for AMP? What have the outputs been? I understand there is some variation in how different manufacturers calculate AMP, perhaps in part because regulations were not issued on the definition so there is some confusion, new types of entities have evolved since OBRA–90, and accounting systems are different. What effect does this have? I understand that prices to health maintenance organizations are excluded from the definition of AMP. What effect does excluding discounts to managed care plans have?

*Answer:* The AMP is a calculation that can be audited. CMS has not performed any reviews of AMP but has asked the OIG to audit a few manufacturers. The results showed that AMP, although defined as sales by drug manufacturer’s to wholesaler’s for resale to the retail class of trade, was being interpreted differently as to what a retail class represented. For example, sales to hospital buying groups should be excluded from AMP calculations if those sales were used for hospital inpatient use. However, if the hospital pharmacy also sold those drugs as a retail pharmacy, then those sales could be included in AMP and should be separately identified. There is a definite need for clarification of the definition of “retail class.” Sales to health maintenance organizations, for example, are also specifically excluded from AMP. However, if the manufacturers do not have a means to obtain those sales from the wholesalers as sales to an HMO, those sales could very well be included in AMP which would have the effect of reducing the amount of the Medicaid rebate owned by the manufacturer. The logic of excluding those sales for the non-retail class was based on the fact that those classes could buy drugs in bulk and at much better prices than the traditional retail pharmacy. Since Medicaid dispenses drugs through the retail setting, we believe that the law was correct in basing rebates on retail sales.

*Question 4:* In both your testimony and that of the GAO, there are discussions of manufacturers submitting their AWP to entities such as the Red Book. Yet I have also been told that the manufacturers submit a list price to the Red Book, and that then their prices are marked up substantially. Will you please clarify for me who it is that determines the AWP, and what the role is of the Red Book?

*Answer:* We understand that the primary source of information for the published AWP is the drug manufacturers. We are not intimately familiar with the role of the Red Book, and they would be a better source to clearly delineate how they arrive at their published figures.

*Question 5:* What would be the effect of using wholesale acquisition cost as a replacement for AWP?

*Answer:* Whatever system is implemented, terms have to be strictly defined as I discussed in my first answer. Without a strict definition, wholesale acquisition cost can mean different things to different manufacturers. This will allow the wholesale acquisition cost price data to be vulnerable to gaming. In addition, wholesale acquisition cost prices do not exist for all drugs. Also, in our recent report on generic drugs, we estimated that the invoice for generic drugs was a national average of 30 percent below the wholesale acquisition cost.

## PREPARED STATEMENT OF THOMAS A. SCULLY

Chairman Rockefeller, Senator Snowe, distinguished Subcommittee members, thank you for inviting me to discuss Medicare payment for outpatient 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 disabled from high drug costs, and we are continuing to work closely with Congress to modernize Medicare to include a comprehensive prescription drug benefit as we discussed at the hearing before this Committee just last week. It also is critically important, as the President's budget proposal provides, that we improve the payment system for the limited outpatient drugs that are now covered by Medicare. It is clear that this system, based on average wholesale price, or "AWP," is seriously flawed and I appreciate the Committee's interest in this issue. I look forward to working with you and your colleagues to ensure that Medicare and beneficiaries pay competitive prices for these prescription drugs and Medicare beneficiaries have access to the drugs they need.

Medicare pays more than many other purchasers for the drugs we cover because of Medicare's payment policies and the way that drug manufacturers report their prices. We all agree that Medicare should pay appropriately for all of Medicare's benefits, including the limited drugs the program currently covers. The current system, which results in Medicare and beneficiaries paying excessive prices for certain prescription drugs, must be fixed. At the same time, we need to be certain that Medicare pays providers appropriately for their services when they furnish drugs to beneficiaries.

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 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 drug payments are based, are vastly higher than the amounts drug manufacturers and wholesalers actually charge 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. Some affected physicians and providers have suggested that they need these Medicare "drug profits" 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. A better approach is to pay appropriately for both the drugs and the services related to furnishing those drugs, and we need to take action this year to implement an appropriate payment system.

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 limited number of prescription drugs that Medicare covers, and that providers are compensated appropriately for their services. We continue to believe that an effective legislative remedy to this problem would be acceptable, and we intend to 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 even more important to 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 you, and all of Congress to ensure that Medicare pays appropriately for all benefits, including the limited drugs Medicare 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 we were creating the Medicare program today, we would certainly include a prescription drug benefit. However, in 1965 when the Medicare program was enacted, prescription drugs played a less prominent role in health care than it does today. The emphasis in 1965 was on ensuring access to inpatient hospital care in Medicare Part A and providing ac-



cess to physicians in Medicare Part B. Today, Medicare beneficiaries rely on prescription drugs as an integral part of their health care. 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 as part of 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 following organ transplants;
  - Erythropoietin (EPO), far and away the drug Medicare spends the most money on, 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 provider. Additionally, vaccines for diseases like influenza, pneumonia, and hepatitis are considered drugs and are covered by Medicare.

By law, we generally pay for these drugs based on 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 for from the Medicare Trust Funds. In general, Medicare beneficiaries must also share in the cost of purchasing these drugs through their Part B premiums, and except for the flu and pneumonia vaccines, 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 reported by drug manufacturers and published in compendia such as the *Red Book*, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers competitive discounts that reduce the actual amount the physician or provider actually pays for the drugs. But Medicare’s regulated payment system leaves the program behind in obtaining competitive discounts for drugs. These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the *Red Book*. Furthermore, use of the AWP, as reported by manufacturers to companies which 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.”

This Committee, CMS, the Department’s Office of the Inspector General (IG), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. 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 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 amount. The deep competitive discounts offered to physicians and providers by drug manufacturers, compared to the reported AWP, could give physicians and providers an incentive to use the manufacturer’s products for Medicare beneficiaries. It is simply unacceptable for Medicare to continue paying for drugs in an outdated, noncompetitive 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 competitively by physicians and providers. However, these efforts have not been successful. 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 very high volume drugs be reimbursed at levels equal to the lesser of 85 percent of AWP or the physician’s or provider’s 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. Others 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,

a policy was established for Medicare to pay 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 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 accurate 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 provider community, reflected the actual Average Wholesale Prices for these drugs far more accurately than the drug manufacturers' 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. However, 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. The Agency postponed Medicare carriers' use of the DOJ data, because in December 2000, Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), which established a moratorium on decreases in Medicare drug reimbursement rates, 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.

As I stated, the Administration wants to work with Congress on a legislative remedy that benefits from competition in drug pricing. However, I am sure you will agree that needed improvements in Medicare's drug payment system are overdue, and the Administration is prepared to take action. Let me reiterate that we are committed to providing assistance to this Committee and Congress as you seek solutions to AWP and we look forward to working with you in the weeks ahead.

#### CONCLUSION

Medicare beneficiaries rely on prescription drugs, and the coinsurance they pay for covered drugs is tied directly to the prices that Medicare pays. We must find a competitive way to ensure that Medicare beneficiaries and taxpayers are no longer paying excessive prices for drugs that are far above the competitive discounts that are widely available today. We need to pay appropriately for all Medicare benefits, including the prescription drugs we cover and the services required to furnish those drugs. We look forward to working with you Mr. Chairman, this Committee, and the Congress to revise 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.

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#### PREPARED STATEMENT OF ELLEN STOVALL

Good morning, my name is Ellen Stovall. I am an almost 30-year two-time survivor of Hodgkin's disease, a cancer of the lymphatic system. As President and CEO of the National Coalition for Cancer Survivorship, or NCCS, I have the privilege of translating my personal commitment to cancer care into an enriching professional experience. One of the oldest patient advocacy organizations, NCCS was founded in 1986 by and for people with cancer and those who care for them. Since 1992, when our headquarters moved to Washington, NCCS has increasingly focused on public policy as the most efficient way to ensure quality cancer care for all Americans, which is our core mission.

Given that mission, I am delighted to have the opportunity to address the question of quality cancer care from two perspectives: first, the impact on patients of potential changes to payment for chemotherapy in physician offices; and second, the shortfall in cancer drug coverage for Medicare beneficiaries who seek any of the life-extending drugs that are available only in oral form.

I am particularly pleased that these issues are being reviewed under the Subcommittee Leadership of Senator Rockefeller and Senator Snowe, both of whom have well-established track records on the issue of oral drug coverage for Medicare beneficiaries with cancer, as well as the more general question of access to quality care for people with cancer and other chronic diseases.

The limited coverage of oral cancer drugs currently available under the Medicare statute is almost exclusively due to the hard work and dedication of Senator Rockefeller from 1991, when his bill was first introduced, to 1993, when it became law. As a result of that legislation, Medicare covers oral anti-cancer drugs that also have an injectable dosage form. Unfortunately, there are only 7 such drugs, but they establish a clear precedent for cancer drugs to be treated differently by Medicare, and we are pleased that the Access to Cancer Therapies Act builds on that precedent. (I should also add that the entire cancer community is grateful for the strong, and ultimately successful, effort by Senator Rockefeller throughout the 1990's to persuade the Medicare program to cover routine patient care costs in cancer clinical trials.)

Senator Snowe has also been involved in a later, parallel effort to extend Medicare coverage to tamoxifen and other hormonal agents that successfully prevent recurrence of breast cancer but are not covered by the program because they are available only in oral form. S. 913 will address this shortfall and will also include other important drugs not currently covered, including hormonal agents for prostate cancer and thalidomide for multiple myeloma.

Coverage of these existing anti-cancer drugs will provide welcome relief to beneficiaries struggling to obtain access to life-extending cancer therapies. An equal or perhaps even greater cause for excitement is the prospect of coverage for the many promising new agents in the product pipeline. Our nation's substantial investment in biomedical research is finally beginning to pay dividends as translational and clinical research find ways to utilize our new understanding, through basic science, of the biological activity that leads to cancer.

With this new knowledge, scientists are able to design drugs that specifically target the gene or protein or cellular receptor that cause cancer and disrupt growth of cancer cells without collateral damage to surrounding tissue. These targeted drugs are a vast improvement over traditional chemotherapy, which threaten all cells in order to attack the more rapidly dividing cancer cells. The new drugs feature few and only relatively minor side effects.

The first of these drugs to emerge was STI-571, or Gleevec, approved last year for the treatment of chronic myelogenous leukemia, or CML, a rare but deadly blood cancer. CML patients taking this drug have been in remission for months with virtually no side effects. Previously, patients with CML faced two unpleasant alternatives that were both costly and toxic, bone marrow transplantation or high dose interferon therapy.

This year the Food and Drug Administration approved Gleevec for treatment of another rare cancer, known as gastrointestinal stromal tumor or GIST, for which there was previously no reliable treatment. The drug could also show activity in a variety of other solid tumors that express the same protein as CML and GIST, including cancers of the breast, lung and prostate and some of the most deadly forms of brain tumor. A second targeted therapy, indicated for non-small cell lung cancer, is expected to be approved later this year.

All of this remarkable research and development activity will be for naught if patients cannot afford to access these new drugs. That is why this legislation introduced by Senators Rockefeller and Snowe (and currently enjoying more than 30 cosponsors) is so timely and important. The need of beneficiaries with cancer is immediate, and the relief should also be immediate.

This leads to the question that begs to be answered by all of us who favor immediate passage of S. 913: why not wait for enactment of a comprehensive Medicare drug benefit that will cover these drugs as well as those to treat every other disease. In answering that question, I believe that each of us who support the Rockefeller-Snowe legislation also seeks comprehensive coverage. The fiscal and political hurdles to achieving that goal in the short run seem daunting, however, and, like the 20 national senior citizen advocacy groups that support this legislation, we would rather have a significant first step toward coverage than no movement at all.

It is important to recognize that, even if comprehensive coverage became law this year, the absence of an implementation strategy in place and the necessary infra-

structure to support such comprehensive change would mean that seniors in all likelihood would not see the fruits of the legislation for several years. In contrast, your legislation would envision immediate coverage under the existing payment mechanisms of Medicare Part B. Some oral cancer drugs are already being reimbursed under that system; adding more should pose no problem. (As an aside, let me say that this direct straightforward solution to a potential conundrum is completely characteristic of the effective pragmatic approach of both Senators Rockefeller and Snowe.)

My message, then, to you, Senators Rockefeller and Snowe, and to the Finance Committee, the Senate and the entire Congress, is: pass this legislation now so that beneficiaries with cancer can rest assured that they will have access to the best quality cancer care. The cost is relatively modest and will represent a down-payment on the cost of an eventual comprehensive Medicare drug benefit.

This leads me to the other topic for this hearing—reimbursement for chemotherapy services in physician offices—another matter of extreme concern to cancer patients. As we all know, the problem is that Medicare is paying too much for drugs and too little for the services required to administer the drugs in physician offices. The excessive payment for drugs is not something that anyone defends or wants to continue. At the same time, no one has suggested an orderly and effective way to reform payment for the associated services to correct what everyone perceives as a shortfall.

The position of patient advocates—not just my organization but the overwhelming majority of the groups comprising the Cancer Leadership Council—is that further study is needed before the system should be changed. The important background to the issue of further study is that Congresswoman Nancy Johnson drafted very specific legislation that was included in the 1999 Benefits Improvement and Protection Act detailing what questions should be answered by the General Accounting Office (GAO) before Medicare sought to address the drug overpayments and physician services underpayments. Unfortunately, GAO did not answer those questions, and Medicare is thus left ill-equipped to take action.

As a member of the National Cancer Policy Board—an arm of the Institute of Medicine (IOM), I have worked with Mrs. Johnson's office and with the IOM staff to enlist the expert analysis of the IOM in addressing those unanswered questions. We should not underestimate the difficulty of assessing what services are necessary and at what cost in order to administer chemotherapy in a non-hospital setting. Even the GAO, with all its resources, essentially said it could not answer the questions that Mrs. Johnson inserted in the 1999 legislation, but I have not heard anyone assert that these are not important questions.

At the same time that we are told that overall payment to physicians for administering chemotherapy should be significantly reduced and further told that life-extending new oral cancer drugs will not be covered by Medicare, it is also being reported that hospital outpatient departments are not being paid adequately for new breakthrough drugs for cancer because pass-through payments under the new outpatient prospective payment system are either capped or not timely available or both. Thus, it seems that cancer treatment is under siege regardless of the setting in which that treatment is delivered. We have great concern about taking from one sector of the overall treatment system to pay for shortfalls in another sector.

Instead, I wonder if we couldn't recognize that we have an aging population increasingly subject to cancer, which is a disease of the elderly, and admit that more resources are correspondingly required to keep the treatment system functional. To some degree, we are the victims of our own success. Death can be a cheap alternative to treatment, and advances in cancer therapy have kept death at bay in many cancers. But that leaves more people dealing with cancer as a chronic disease.

Senator Rockefeller and Senator Snowe, regrettably I don't know where to find additional resources to meet what I think is a clear need. But I think it is important that patient advocates keep reminding our political leadership of the tremendous burden that cancer imposes on our people and the responsibility of government to assume its appropriate share of that burden.

Thank you for your time and the energy that you devote to these important issues.

