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Session 134PD
Prescription Drug Update

Track: Health

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Summary: Prescription drug trends continue to outpace other medical cost trends. These costs are a major driver of the return to double digit medical care premium increases and renewed interest in Congress to add prescription drug coverage to Medicare. Panelists look at the following issues for both the commercial and Medicare markets:

- *Recent trends in prescription drug costs*
- *What factors are behind these trends*
- *Expectations for future trends*
- *Strategies insurers and health plans are using to manage prescription drug costs*

Mr. Bryan F. Miller: Amy Companik is the actuarial manager of AdvancePCS, a health improvement company. In her current role, she assists AdvancePCS clients with prescription drug and risk issues including plan design and drug trends. Prior to joining AdvancePCS, Amy worked in managed health care managing actuarial analysis for both commercial and Medicare business. Before her work in managed care, she was involved with individual health insurance. Amy is a graduate of Purdue University with a major in mathematics and actuarial science.

Gordon Trapnell is president of the Actuarial Research Corporation. He has devoted several decades to advising national health policy makers concerning the operation of insurance markets and the cost impacts of proposed legislation. In this capacity, he has estimated the cost of a variety of prescription drug coverages including commercial, Medicaid and Medicare programs. He has prepared estimates for a number of proposals to cover prescriptions in Medicare and to revise payment methods in Medicaid beginning in the late 1960s and continuing to the present. He chaired the subcommittee responsible for drafting the American Academy of Actuaries public policy monograph on covering prescriptions in Medicare.

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†Ms. Companik, not a member of the sponsoring organizations, is the actuarial manager of AdvancePCS in Irving, TX.

Note: The chart referred to in the text can be found at the end of the manuscript.

I'm the vice president and chief actuary of Blue Cross and Blue Shield of Kansas City, having been named to that position in May 2000. I've spent about 11 years in Kansas City. Prior to that, I worked in the actuarial development program with The Prudential in Newark, New Jersey. In my current position, I have general rating authority for our commercial, Medicare and Medicaid managed care business. The focus of my presentation today will be on our commercial block.

Our basic program builds on what you've heard in previous sessions. One of our concerns in laying out the design for this session was not to overlap too much with what you have already heard. There has been an awful lot of discussion of prescription drugs, and rightly so.

Amy and I will be more strategic in focus, looking at the kinds of things we, as actuaries, can do within our companies to either stem the tide or try to hold back a little bit on the rising cost of prescription drugs. Then we'll let Gordon give us an idea of how the proposals for the Medicare prescription drug coverage came about and why we are where we are.

I'll begin with the view of a commercial market HMO actuary. One of the more popular plan designs among commercial programs is a three-tier prescription drug program. A study by Scott-Levin indicates that 80% of HMOs and pharmacy benefit managers (PBMs) are now offering a three-tier prescription drug program. That's up from just 60% last year and only 35% two years ago. However, only 35% of lives are currently covered in a three-tier prescription drug program, so there's a gap between the offering of those programs and who is actually accepting it.

Blue Cross and Blue Shield of Kansas City first implemented a three-tier drug program in March 1998. As many of you who insure commercial blocks know, your largest accounts generally renew on a calendar basis. So it's well over a year before the true impacts of plan design changes can be understood.

The drivers behind this change are probably the same drivers that you see. Certainly, the trend in drugs was something that we have acknowledged for a long period of time. It contributed to the unfortunate task of delivering significant rate increases to a lot of our accounts. As a result of that, consultants, brokers, and accountants themselves were asking, "What can you do to help manage these costs?" This was certainly one of the primary drivers of moving to this kind of program.

There was an increasing trend over the 1990s of moving drugs out of a major medical indemnity approach where they're paid in the same manner as other claims. The convenience and the savings that prescription drug cards offer also led to significant plan designs as the decade evolved.

From a customer service standpoint, the concept of coinsurance may be one that we, as actuaries, understand much more readily adapts to changes in cost because the insured's share of the cost would increase as the price of the drugs would

increase. However, when insureds go in to a pharmacy, they prefer to know how much they're going to pay for a prescription drug and not be surprised at the counter. This was another element. As I go through some of our historical plan design development, you'll see this dissatisfaction and its effect on plan design.

Another element of our benefit design that was increasingly becoming bothersome to a lot of our customers was the fact that we had fairly low annual limits. Certainly, the primary impact was to hold down costs, but it was still an issue among our customers that many of them wanted to avoid. They would be willing to accept higher payments on the front end if you wouldn't shut those people off who are in the greatest need of drugs.

Let me take you through a four-year period of the evolution of our basic drug plan designs. I hope it's similar to what many of you have experienced, but I also hope that it gives you an idea of some of the issues that I've mentioned already and how they worked their way into our basic plan designs.

I tallied the most popular plan designs of our medium-sized groups, say 50–500 employee cases, over the period 1996 to 1999. In 1996 the most common plan design started with a $5 generic and $8 brand co-payment, and then the insured was responsible for 20% of the remaining cost. The mail order co-payments at that time did not favor brand or generic. There was simply a flat $10 co-payment. We still had a fairly low annual benefit limit of $3,500.

As we move to 1997, to fight the inflation that was occurring, the flat co-payments in advance of the coinsurance moved from $5 and $8 to $8 and $12. The other thing you begin to see in 1997 is the removal of some of the coinsurance as certain accounts wanted to do away with that aspect. Moving the co-payments from $5 to $8 and $8 to $12 should result in some offset of the drug trend. But the removal of the coinsurance may actually result in an increase in benefits, which may have exacerbated the claim trends we were experiencing.

As I said, in March 1988, we began to implement a three-tier drug co-payment system. For those of you who may not have been through this process, you simply split your brand name drugs into two categories. For the most part, although it's not absolutely true, single-source drugs for which there is no generic equivalent go into the second tier. Multi-source drugs for which there generally is an equivalent on the generic side goes into the third and highest tier with the intent of moving folks to the generic equivalents when they're available.

There was a significant change in the mail order co-payments for the first time. While in the past we showed no preference for mail order between generics and brands, now we set up a two times co-payment. A 30-day supply of generic was $5, for example, and the mail order of a 90-day supply was $10. So we charged two times the co-payment for three times the product. From the customer's viewpoint, it seemed like a good deal.

The annual limits were still in place. But by the time we get to 1999, the most popular plan had no drug limit. The pressure to increase those limits finally bore fruit. The co-payments increased again in 1999 to a $10/20/30 with $20/40/60 on the mail order with no limit. The evolution over just a three-year period showed significant change from a coinsurance system to a co-payment system. At each interval between the two years, you see significant changes in the amount of those co-payments.

What I want to do now is to show you our results in Chart 1. If they are not indicative of your experience, I certainly hope you will contradict any conclusions I might draw from our experiment with three-tier drug programs. I want to show you what has happened with our per member per month (PMPM) drug claims by segment because I think there are some significant differences; some in plan design, but also some in the nature of certain segments of our business, and why they result in different drug trends.

Our individual PPO program seems to be bucking the trend of most segments in that the trend is fairly flat on a PMPM basis. Part of that I think is due to the inherent characteristics of the individual PPO market. First, it's more tightly underwritten than other programs. Second, there's greater turnover in this product than there will be in most group products.

The combination of those two effects means that your underwriting takes much longer to wear off. The fact that people use this product as a transitional product between group coverages or as a temporary coverage means that the average duration never gets to be as great as in group coverages. So you see that despite the significant trends that we all have experienced in the industry, that particular line held its own.

As you look in the middle of the chart, you see our small group coverages. I think this makes sense as you move from the smallest product (individual) up to the large group products in that market we do have some underwriting latitude in small group. The effect of going to the three-tier program in 1998 and 1999 may have had an impact, but the slope of the line continues pretty much unabated into 2000.

The more noticeable effect of our three-tier conversion can be seen in the large group market. You see that although we began this process in early 1998, the PPO products showed a decrease that year. A lot of that can be attributed, I think, to the benefit design changes. Our large group plans, as I'm sure do yours, had richer benefits than in the small group and individual markets. Many large employers took the opportunity, when we presented them with a new set of plan designs, to step back somewhat by raising the co-payments. That is evident in the results. The HMO product in the large group segment didn't show any cost reduction in 1998. This has to do with what I mentioned earlier in that many of them did not renew with us until January 1999, so the conversion of the plan didn't occur until then. Therefore, it took an extra year for the impact to emerge.

But the other thing to notice about this chart is that the trends, once the program was implemented, started right back up again.

My conclusion from our move to the three-tier benefit design was that a significant adjustment period occurred as people tried to understand what the formulary looked like, where my drug was, why did my co-payment go up so much, etc. So you have to deal with the adjustment process of going from a flat co-payment or a coinsurance system to a three-tier design.

There seems to have been little or no impact on the individual and small group cost PMPM. This probably has more to do with the underwriting value you have in these market segments, and also that the plan designs we converted to were probably not that much different from the basis of actuarial equivalency than we had before.

There was a reduction in the large account drug cost. There's no question about that, but it appears to have been a temporary one. As we look at year 2000 data, that cost has marched right back up to where it was a couple of years ago.

The bottom line, I believe, of the three-tier drug benefit design comes in looking at the nature of the drugs themselves. Our figures from 1999 indicate that non-preferred brands (the third tier) comprised only 11% of our total prescriptions and 7% of the total plan cost. How much can you affect your total drug cost by focusing your efforts on the third tier alone?

Let's look at it a different way. Let's look at the percentage of your total claims that drug costs make up. I'm looking at three different years; 1995, 1997, and 1999. I mentioned that the flat drug cost in our individual PPO has actually reduced the proportion of claims that drugs comprised. In the small group and large group segments there is some variability there. They've hovered in the 10-15% range. As plan designs have changed, sometimes they've gone up at times and sometimes down.

I've added one additional segment that I did not discuss earlier. We have two of the big three automakers with significant HMO enrollments. As many of you know who work with collectively bargained programs, changes in benefits are rather hard to come by, and most of those decisions are out of our hands—they're made in Detroit. So our hands are tied in the ability to manage these folks' costs through benefit design. For the auto industry the proportion of claims that drugs comprised increased tremendously in 1999 to 30%. I'll tell you, thus far in 2000, it's at 34% and climbing.

The major issue that's driving this is the fact that there are very few disincentives for employees and dependents of the auto manufacturers to continue using drugs. The aggregate co-payment per prescription for the auto industry is about $1.46. It was that in 1999, and it's the same exact amount in 2000. Although we've been successful to some extent at moderating the increase in drug costs in many of our local segments, there are some segments for which this is getting out of hand and we have very few weapons at our disposal to use in helping to manage that cost.

That brings us to another option that many carriers are taking. That's going to a closed formulary. As I mentioned, it's prompted, in large part, by our automotive experience and, to some extent, by our wanting to continue in the Medicare Risk HMO Program. I'm not going to address Medicare much. I'll leave the discussion of Medicare drugs to Gordon later on. But it was certainly one of the drivers behind our consideration of a closed drug formulary.

The approach that we took around October 1999, was not to go back and try to redesign a formulary, but simply to take the three tiers that we had and just provide no benefit for the third tier. It was as simple as we could make it at that time. At this time, we undertook two different approaches to reviewing whether this was a good move for us to make. One, in which I was involved, was the analysis of the cost savings. The other portion of it dealt with looking at our competition and looking at our local customers and whether they would tolerate a closed formulary drug program.

The first attempt was in October 1999. I came up with an estimate of about 5% of the drug cost that could be saved. Some of that would be from an increased generic substitution rate, which for our plan was hovering near 40% and had not improved much for several years. So we felt there was some room for some additional substitution of generics. The other part of it is that you may have some risk selection savings in that certain groups who need particular name brand drugs won't find it on your formulary and will go somewhere else. My estimate of 5% has more to do with our actual data which showed that about 9% of our payout is for generics, another 9% for the third tier, and 82% for single source drugs, which a closed formulary doesn't even attempt to go after. So my estimate came in a lot lower than a lot of what our decision makers hoped it would be.

The other major internal conflict that we faced was making this mandatory for our business segments versus allowing groups the option to stick with the three-tier co-payment or go with a closed formulary. Our marketing folks on the large group side said, "You're not going to mandate anything for our customers. You're going to let them make the call." That leaves us with a difficult situation in customer service in that you have people trying to explain two very different drug programs.

At the same time as this was being discussed, we were in the middle of a massive system conversion taking seven systems to one platform. We were re-contracting with all of our providers. The timing of this change could not have been any worse than it was. We decided about a year ago at this time that the cost, and the effort to implement this kind of change to our business, was not worth the limited savings we expected to realize from it.

So we scrapped that approach and tinkered with the system instead, and raised some of our third-tier co-payments. I mentioned an $8/18/28 co-payment earlier. We raised the third tier to the $36 level which made it twice the co-payment in the second tier, again, with limited impact. The 2000 figures went right back up to the same growth rate they had before.

We also decided to change our mail order co-payments, and I should address mail order for a second. We did an internal study based on what we felt was our unfavorable contracting of mail order drugs versus retail. We decided that for a 90-day supply, we would have to charge at least 2.5 months of co-payment. In 1998 we implemented a 90-day supply for two times the 30-day retail co-payment, and it turned out that we lost money on it.

What we decided to do in some of our segments is supply three months of the drug for three times the co-payment, which doesn't save the members anything and, in fact, if you think of the cash flow implications, they're putting out more money up front. It's not a very customer-friendly approach, but it was the only one that allowed us to hold our cost levels where they were.

That takes us to today, to a second attempt at a closed formulary. It is driven primarily by the automakers, which we're in the process of trying to renew. We said, "We are not going to renew your accounts at the drug program you've got now. If you want us to be in your account, you're going to have to have a closed formulary." They didn't take to it too well. But one of the two has agreed. The other one is still fighting with us, but we took an all-or-nothing position.

We want to link the formulary between Medicare and our commercial plans. We don't want two different programs. We don't want to deal with the hassles of having multiple things going on. We want to have a standard from which certain options can be made.

An internal pharmacy and therapeutics committee will make quarterly changes to the list of covered brand name drugs. This is a departure from where we were before, when we simply accepted the three-tier program where it was and just knocked off the third tier, the non-preferred drugs. This time we're focusing more at what's in the second tier because, as I mentioned, it's 82% of our total drug cost. You've got to attack that tier if you're going to really make any kind of progress holding the cost down.

The other reason to make changes on a pretty rapid basis has to do with the nature of the drug business. Some major brand name drugs are coming off of patent protection next year. Our internal pharmacist mentioned three of them, Prozac, Claritin, and Prilosec. Something will happen with each of these next year. If you're late in responding to new generics or new brand name drugs, you may be at a significant disadvantage in the market.

The other thing that we will be doing is proposing some alternatives which are not strictly equivalents. This is going to cause some problems from our customers. We expect some pain out of this when we say that a brand name drug that does not have a generic equivalent won't be covered. We expect some problems handling the complaints that this is likely to cause. There will be an exception process for physicians who say, "This is the only drug that's working for this patient." So it's not an absolute ban on these drugs, but it's a major step forward for us anyway in

saying, "We've got to get a handle on this thing. We have nibbled at the edges of this process for a long time. Now it's time that we really make some effort at controlling this cost on behalf of our customers."
I have drawn some conclusions from our three-year experiment at changing prescription drug benefit programs. Over these three years, we have tried to make significant changes to our benefits to offset the high drug trends that we've experienced. To truly fight this trending would force annual increases to co-payments. If we have a $10 generic co-payment, which is becoming more and more common, the total cost of the drug is only about $13. There's a practical limit to the value you can derive from hiking up flat dollar co-payments over and over again. You get to the point where you're asking the customer to pay almost the entire cost of your generics and your non-preferred drugs, and you're still not going after the drugs in that second tier. The single-source brands, in our case, average $67 a prescription and you're only charging a co-payment of $20. That's a significant issue. You've got to focus on single-source drugs if you want to realize significant savings because that's where the dollars are.

A final thing is there are a number of non-actuarial impacts you'll have to consider as you make these changes, such as regulatory, contractual, claims, customer service, system, etc. But you can't do these things without some degree of discomfort. However, given that these have continued relatively unchecked for a number of years now, we need to take some steps on behalf of our customers and on behalf of our companies to try to mitigate these costs. I've given you just a few of them. I hope that at the end of the session, if you have some other ideas about controlling these costs, you'll share them.

While my presentation was at more of a macro level, Amy will give you more of a micro look from a PBM viewpoint as to other things that you might try.

Ms. Amy Companik: For those of you who are unfamiliar with AdvancePCS, it is the company formed by the recent acquisition of PCS Health Systems by Advance Paradigm.

I'm going to talk to you about an issue that's been on many people's minds lately, and that's how we manage our drug spending.

First, I'm going to talk briefly on how drug spending is influenced by many different factors, among the most significant of which being utilization and innovation.

Second, we have reason to believe that members and employees are going to continue to value prescription benefits highly and that they're also going to be of high value to employers because they support retention and productivity.

Finally, I will talk about strategies for keeping drug spending from getting out of control: strategies that allow members and employees to get the drugs they need when they need them, while managing how those drugs are delivered and paid for.

As I mentioned, drug spending is mainly due to a couple of factors. First is increased cost. We've been seeing that this is particularly due to the new agents. Studies have shown that research and development expenditures have nearly tripled in the past decade, and newer drugs tend to cost about twice as much as older therapies.

Increased utilization is due to many factors; among them is increased third-party coverage. For many Americans, prescription drugs have become more accessible as third-party coverage has increased. We also have more aggressive diagnosis and prevention.

For example, the American Diabetes Association recently lowered the blood glucose level threshold for diabetes, in effect increasing by two million the number of people who meet the guidelines for treatment.

Of course, we also have the aging population. The aging of the population is a significant driver of increased drug cost and will continue to be so for several years. People over age 65 now account for 13% of the population and, by 2030, they will account for a full 20%. We know drug use and spend rise dramatically as people grow older and develop age related illnesses. The average over age 65 patient fills approximately 20 prescriptions per year compared to about 3 prescriptions for a person in his or her 20s. In addition, the average per member per year cost for someone between the ages of 65–70 is $700. That's about 9 times higher than the yearly cost per person under the age of 20.

Another factor in increased utilization is the availability of new drugs to treat previously untreatable conditions. Recent examples of this include Relenza and Tamiflu for the treatment of influenza, and Lotronex, which, in February 2000, became the first drug approved by the Food and Drug Administration (FDA) for the treatment of irritable bowel syndrome.

Pharmaceutical marketing spending has increased fairly steadily over the last several years. In 1998, pharmaceutical companies spent almost $5.9 billion in marketing, a 19% increase over the prior year. Much of this, or $4.5 billion was spent on marketing to health care professionals.

So because of all those factors we just discussed, we believe that drug spending is going to continue to increase by about 16–20% per year for the next few years. While some of the drivers of drug spending are beyond client control, there are some effective ways to manage drivers of spending. We'll talk about those now.

There are many tools that we can use to manage drug spending. While we can't talk about all of them, I'd like to provide some information about a few key ones, including: how your pharmacy network can save you money, use of a formulary and member cost sharing, how to manage member utilization, use of generic substitution as a cost savings strategy, a tool called step therapy, case management and, finally, how to use provider education to reduce your drug spending.

As you probably know, many pharmacy benefit plans use pharmacy networks, including chain and independent pharmacies, to fill their members' prescriptions. In general, the more limited the size of the pharmacy network or the smaller the network, the greater savings that can be negotiated with the member pharmacies. However, members tend to complain if they have to travel too far to get their prescription filled.

Because they generally process high volumes of prescriptions, mail pharmacies can negotiate deep discounts with manufacturers. Mail service pharmacies also have greater success in making generic and therapeutic substitutions than do retail pharmacies. So for these reasons, the use of a mail pharmacy can save money as well. If cost savings is paramount, members can be required to fill chronic prescriptions through the mail; however, many states prohibit this practice.

Today, most pharmacy benefit plans make use of a formulary or a list of preferred drugs for specific diseases. This list encourages the use of the most cost effective drugs and also qualifies plans to receive rebates from manufacturers which can also help reduce their overall drug spend. A formulary can be used to support a therapeutic substitution program in which physicians need to be educated so that they understand the cost savings offered by generics. This will encourage them to allow for generic substitution when writing a prescription. The AdvancePCS Program involves both the patient and the physician in the decision to switch to a lower cost, yet still clinically effective drug.

Bryan touched on differential co-payments. In a plan with differential co-payments, members pay a slightly higher co-payment for a brand name or non-formulary drug than they do for generics. For example, members can pay $5 for a generic drug and $10 for a brand name drug. Many plans, as Bryan mentioned, now have three-tier co-payment designs where the lowest tier is for generics, the middle tier, for example, could be for preferred or formulary drugs, and the highest tier would be for either non-preferred or non-formulary drugs. Such plans encourage the members to select the lower cost drug as well as formulary drugs.

Bryan also touched on coinsurance plans where you require a member to pay a percentage of the total cost for the drug, for example, 20%. The advantage of this system is that it's self regulating. As prescription drug costs increase, so does the amount that the member has to pay. Its disadvantages, again, as Bryan mentioned, is that it's not very well liked by members and that members don't know what they're going to have to pay until they get to the pharmacy.

A well designed formulary and formulary related programs can help payers save money on life enhancing and life lengthening drugs, and these are the areas of great spending increases. In choosing the type of formulary to use, member impact needs to be balanced with cost saving goals. An open formulary does not exclude specific drugs, but uses physician education, voluntary therapeutic substitution and member communication to increase the use of drugs in the formulary.

A managed or incentive formulary uses all those same tools and also requires the member to pay a higher share of the cost in order to receive a non-formulary drug. A closed formulary excludes specific drugs from coverage, so that a patient receiving a non-formulary drug would have to pay the entire cost of the prescription, although even plans with closed formularies generally allow members access to non-formulary drugs when medically necessary.

There are many different utilization management tools, and we'll talk about just a few of them. Concurrent utilization review happens at the time the prescription is being filled. The computer system at the pharmacy is linked to the AdvancePCS system and automatically checks the prescription against the host of criteria. For example, it would make sure that the prescription isn't being filled too soon, or that the patient isn't on another drug that might interact badly with the new prescription, or that the drug isn't counter-indicated by the patient's age or gender as well as additional tests.

Prior authorization is used to allow members limited access to specific non-formulary drugs. In general, coverage is denied for prior authorization drugs unless the patient meets specific criteria. Drugs, which are often managed by prior authorization, include fertility drugs, cosmetic drugs, growth hormones and anti-obesity drugs.

Managed drug limits (MDL) is typically used for drugs that would normally be prescribed only a few times a year, for example, for influenza or for other drugs that the plan might want to limit, such as treatment for erectile dysfunction, infertility, and smoking cessation.

We did a case study of a client using managed drug limitations. The projected usage for the affected drugs had an upward trend. But since the client put MDL in place, the trend actually flattened out quite a bit. The client saved $165,000 over 9 months.

Substituting generic drugs for multi-source brand name drugs can also offer substantial cost savings to payers. Generic substitution is really a utilization management tool. It can help manage what drugs are being prescribed and taken by patients.

There are generic versions of many brand name drugs available today, but first it's important to educate physicians so that they understand the cost savings offered by generics. This will encourage them to allow for generic substitution when they're writing a prescription.

Patients can also be encouraged to use generics through education and differential co-payments. The co-payment for a generic can be significantly less than that for a brand name drug, or the member could be required to pay the difference in cost between the brand and the generic drug.

Pharmacists also need encouragement so that they will suggest the use of generics to patients. Education is helpful.

Another utilization management tool is called step therapy. In step therapy physicians try the least expensive treatment alternative first before moving on to more costly alternatives. Some plans require the use of step therapy and others simply encourage their use. For example, a patient being treated for ulcers might be encouraged to first change her diet, maybe exercise, and learn to manage stress better. If that didn't improve the condition, then she might be prescribed a generic ulcer medication, and only if the generic medication failed would a brand name, new generation ulcer medicine be prescribed.

Another utilization management tool is called case management. This is a care approach, which provides case-by-case attention to patients with complex and chronic conditions that are greatly affected by lifestyle choices. Diabetes and heart disease are good examples of this. Much of the suffering and costs associated with such diseases can be avoided by proper and consistent management. Such patients might receive education on available treatments, information on beneficial lifestyle changes, or education on the importance of compliance, as well as follow-up contacts to encourage their compliance.

Provider education is also an effective tool to manage utilization. It's important to provide physicians with new product updates as well as information on drug indications and treatment regimens. Physicians also benefit from information on how well their patients are complying with their treatment, and information which shows physicians how their prescribing habits compare to those of their colleagues, as well as detailed patient profiling, when it is appropriate.

We looked at a lot of different tools that can help manage drug spending now, but it's also important to keep an eye on what's coming up down the road. What innovations, demographic trends or new treatment protocols might be coming up that could affect your drug spending? We'll talk about a few of those now.

There are several drug classes that deserve some attention including arthritis and chronic pain treatment, cancer treatment, diabetes, gastrointestinal agents, and hypertension. We'll go through each of them in a little bit of detail.

We expect significant growth in the next few years in the class of drugs used to treat arthritis and chronic pain. In the past, treatment for these conditions has typically been through the use of non-steroidal anti-inflammatory drugs (NSAIDs), which cost only pennies per day, but can cause severe stomach problems in chronic users. A new class of painkillers called Cox-2 inhibitors became available in 1999. While these new drugs lessen the chance of stomach problems, they cost about $2.40 per day.

Due to population growth and aging, the occurrence of cancer is expected to increase markedly. In 1997, 6 million people died of cancer. Over the next 20 years, that number is expected to double to about 12 million. Because of these

trends, it is expected that over the next 8 years sales of cancer drugs will almost double reaching about $15 billion worldwide.

We also expect to see a growing trend in diabetes treatments for several years to come due to the dramatic increase in the number of patients with Type 2 Diabetes and the introduction of new diabetes treatments. The increase in the number of patients we talked about a little earlier is due to the new treatment protocols. Several new expensive products were recently added. These include Rezulin, Glucophage, Prandin, and most recently Avandia and Actos. These drugs can be used by patients with even mild diabetes and are being highly accepted. Any future drugs which simplify the self-management regimen of Type 1 patients can also be expected to generate high demand.

Related to gastrointestinal agents, manufacturers are developing a new generation of drugs used for the treatment of the multiple symptoms of irritable bowel syndrome. This is the most common functional gastrointestinal disorder. New therapies for irritable bowel syndrome can be expected to contribute to increased sales in this class over the next several years.

Another therapy to watch is hypertension. A new class of medications called angiotension receptor blockers (ARBs) is changing the way high blood pressure is treated. ARBs are similar to ACE inhibitors in their effectiveness, but have a better side effect profile because they don't cause the dry cough often associated with ACE inhibitors. While ARBs are more expensive than ACE inhibitors, they're slightly less expensive than calcium channel blockers. The ARB class has been expanding significantly over the past several years. The first drugs in the class were launched in mid-1995 with several others being launched in 1997 and 1998.

In summary, certainly we've seen that drug spending is influenced by many factors and, again, the most significant being innovation and utilization.

We know that members and employees are going to continue to value prescription benefits highly—and they are of high value to employers because they support retention and productivity.

Finally, we saw some strategies for keeping the drug spending from getting out of control. Again, these were strategies that allow members to get the drugs they need when they need them, while managing how the drugs are delivered and paid for. So what it basically comes down to is encouraging proper drug use while lowering the cost of the drugs.

Mr. Gordon R. Trapnell: When I was preparing for this session, I fully expected there to be some movement in the Congress and something looking like a Roth Bill moving through the Senate in some form.

But I didn't want to talk about the bills anyway. Instead, I want to talk from the perspective of where this is coming from and help you evaluate where we are and where we are likely to go.

One perspective is to compare our situation with the Biblical fat and lean years. Demographically, the United States has been going through the equivalent of the fat years; people born between 1929 and 1942 are going through the ages that are most expensive for retirement and medical benefits. The result is that from 1980 to sometime after 2010, we're having this once only drop in the cost of all these expensive programs that our politicians have promised retirees. The facts that people are living ever longer and that we are spending more and more on the very aged has dramatically increased this impact.

Politicians love programs that have the characteristics that you promise people benefits now, and some other politician sometime in the future is responsible for the taxes to pay for them. Somehow the press never holds those responsible for the costs. The structure of our social benefit programs is replete with examples of this. Social Security, Medicare, et cetera are just the leading examples that everybody knows about. There's a host of others, and many union contracts have a lot of the same characteristics.

But these fat years will be followed by lean years, demographically. From sometime before 2020, it gets worse until 2045, and then it improves slightly through 2050, and stays at a somewhat constant level thereafter. Of course, instead of shoring up our finances and finding ways to pre-fund these huge benefit obligations, we have so far totally squandered the opportunity. It looks like we'll continue to squander it in the future.

The Titanic analogy I like to make is that about 20 years ago, when John Wilken and I wrote a series of articles; one of which appeared in *Contingencies*, about how the total cost of the benefit programs was going to more than double or triple by 2045 and reach a huge percentage of gross national product (GNP). It was like being on the bridge of the Titanic and warning the captain: "Just over the horizon, there's a big iceberg and we're headed right toward it."

I think the way that we expressed it was that if all of Social Security, Medicare, and Medicaid long-term care were financed with a payroll tax similar to Social Security and Part A of Medicare, it would reach close to 50% of GNP, which we thought, obviously, couldn't happen. There's going to be a revolution. But then a year or two later, I had a job consulting in Hungary, when it was still under communism, and I found that it did have a Social Security tax of 50%. But it had a different reason for a Social Security tax of 50%. It wanted to soak up all the spending power because there weren't enough goods and services for people to buy with all that money, and so it wanted to take it out of the economy. So a 50% tax rate is not impossible. It just seems quite unlikely.

But following the Titanic image, about 20 years ago when people like us were writing these articles, it was sort of like being on the Titanic and warning the captain of an iceberg ahead. But now that the media is full of articles about the coming financial catastrophe, it's as if everyone on the bridge was running around yelling "Gee! That's an iceberg, and we are headed right toward it." But then the Captain

says: "Let's don't worry about icebergs. Let's have a party." The party is a prescription benefit in Medicare. Well, this is the Washington attitude.

I would like to read you something from the monograph that we did on prescriptions because I wish we could say this sort of thing a little more loudly: "Since under federal budgetary procedures, federal transfers to the program to pay the interest on the trust funds and to fund the redeeming of the special Treasury bonds in which trust funds are invested require a major increase in budgeted expenditures that are likely to prove a burden on the economy. Should a prescription drug benefit be provided under Medicare in the absence of an overall reform of the program? Even if the prescription drug benefit is partially funded through participant premiums, paying the government share will have a substantial impact on the federal budget, especially during the retirement years of the 'baby-boomers.' Further, a prescription drug benefit may have features that will lead to its cost rising faster than that for the other acute care services covered by Medicare. Adding another expensive benefit to Medicare is not prudent when the source of funding for the current benefit structure is uncertain. Assuring adequate financing for the program needs to be addressed in a comprehensive way." I really recommend this monograph if you are interested in pursuing it further.

You have to really credit the Clinton Administration for their astute political timing in utilizing a political opportunity. It came up with this prescription benefit almost two years ago, which has given it enough time and gathered enough attention so that it became a primary issue in this election, which is a pivotal election for the Administration, both Houses of Congress, and in many state capitols. It is going to affect reapportionment for the next ten years. It is designed to address the strengths of the Democrats and the weaknesses of the Republicans.

The Republicans have sort of gone through a transformation similar to what I heard in another session on reinsurance, in which somebody was talking about risk evaluation. I remember he said that the first mistake was "denial", that something just can't be true. Then there are other stages, other bad ways to react to actuarial developments that should be alarms.

But the first Republican reaction was a kind of staged denial. At first they offered programs to help the poor and subsidize private insurance to make sure everybody has access to a plan. They thought that would take care of it. The Republicans would lose control of the House if they did not come up with a substantive benefit for prescription drugs through Medicare. They have assured me again and again that they have polled this thing to death and researched it with focus groups. As long as they take care of the low income and assure access it does not present a political problem.

Well, as the spring wore on and as it became more and more evident that control of the House and their prerequisites in Congress depended on as few as a half dozen or so races, and prescriptions started emerging as an issue of the magnitude that I had expected it to be all along, the Republicans did act. As far as I'm concerned, the Thomas Bill is a real bill that would actually provide substantial

coverage for nearly all persons over 65 even though it's ostensibly voluntary and through private insurance. I would expect enrollment above 75%, maybe as high as 90%. My basis for believing that is the enrollment that took place in Part B in 1965 when we really didn't know what to expect from this completely new program. Where the only guides to go on were the over 65 programs that were sponsored by the insurance companies (such as "Connecticut 65"), which never got more than 10% in any state.

But the Republicans are still not getting credit for the level of their effort, or some of the elements that would lead to relatively effective cost controls, depending on how it's administered, which is the secret to the cost of any of these proposals.

The Democrats are making hay claiming that the Republicans want to propose something for the insurance companies, despite testimony from the Health Insurance Association of America (HIAA) saying that insurance companies can't do it, that it won't work. The Republicans compare their prescription proposal to Part B, which evokes that the coverage is real. In point of fact it would provide real coverage. It's not like Medicare supplement where anti-selection drives the premiums up, or HMOs which may terminate prescription benefits, or any other private insurance. The level of debate never concerns what's really important.

Well, what is important to determine the cost? What really matters are several key elements of the proposal. Obviously, the benefit plan is important. If you cover more, it costs more. The scope of drugs covered could conceivably be limited to a bundle of maintenance drugs as passed by the Senate in 1972. But it almost certainly is going to include all acute care drugs, biologicals that are self administered, and certain drugs which are usually referred to as "life saving" drugs, insulin being the leading example. The right people will take it if it were free and there's no point in requiring a prescription.

There are also over-the-counter drugs that are alleged to substitute effectively for prescription drugs in a way that will lower the cost. I'm always a bit skeptical of that. You have the dimensions that Amy brought up; lifestyle drugs with whatever the name that you all came up with to distinguish between ones that are life preserving and life enhancing but not necessary to treat an acute illness, and ones that just make you enjoy your life more.

But there are other design elements that will probably have a dramatic effect on the potential cost of the program, especially the flexibility and freedom for the administrating organization to implement an effective formulary, and through an effective formulary to capture low net prices from manufacturers. By net price, I mean net of discounts, rebates, incentives, and whatever else.

The capacity to do that depends primarily on four elements; (1) how narrowly the therapeutic categories are defined, (2) the minimum coverage that the organization is required to have within each therapeutic category, and (3) perhaps the most critical element of all, the criteria for overriding the formulary and paying for a non-formulary drug. It's a question of what determines medical necessity and how it's

implemented, and how difficult it is, and how much burden it is on the physician to obtain the approval—that figures into how effective a formulary is. The pharmaceutical companies are the most expert players politically in these negotiations. They're aware of how effective any formulary is, especially in a public setting where everything is known and fully disclosed. Finally, (4) if a non-formulary drug is approved for some payment, what's the payment? I'm not sure if Amy mentioned this, but one approach is to cover any non-formulary drug, but raise the co-payment, for example to $50 instead of $20 when it is approved.

Another important feature that determines the value of the program to beneficiaries will be whether pharmacies charge the program negotiated price for non-covered prescriptions, i.e., before a deductible is met, after a benefit maximum is reached, or for non-formulary drugs that are not approved on the grounds of medical necessity.

Another cost determining feature will be the approach to generic substitution. Although the magnitude of savings on a particular drug is typically huge, approximately 25–30% or even less of the price of the drug for which it's being substituted, the saving is even larger when the effect on the originator's price is taken into consideration.

However, generic use is so imbedded in medical practice now that the potential for savings from even the most rigorous generic approach is relatively small simply because not that much is now being spent on multiple source drugs for the innovator's version. Although more are feasible, the discounts that have already been captured are relatively large. There's probably no more than about 3–5% of total expenditures by the aged that are for the innovator's version of multiple source drugs. Approximately 20–25% is spent on generics, another 5% on innovators' versions of multiple source drugs and the rest is for single source drugs where there's no generic equivalent. There may be therapeutic equivalents, but then that's in formulary territory, not in generic substitution.

There's the network, another major source of saving. There's a significance source of savings if you have the freedom to use a limited network. Limited networks can limit distribution to pharmacies that have low costs and obtain a great deal of assistance in implementing a formulary. Obtaining savings depends on being able to set up a network and compete with it and not have it overridden by state "any willing provider" laws or, in this case, a federal any willing provider law.

Finally, there's that series of measures, usually called drug utilization review (DUR) types of management techniques that Amy covered very effectively. These don't generate anything like the order of magnitude of savings that you can get from formularies, generic substitution, or network selection.

What matters most to the cost of any proposal is the flexibility and incentives to actually do these things, given the approach and administrating organization. The proposals can be roughly divided into those that I call "single payer" and those in

which there are multiple, competitive payers, such as the House (Thomas) bill and probably the Roth bill, if it ever emerges.

The Clinton proposal, both the original and the revised, would rely on a single payer in each area, which means that there's almost no room for a genuine formulary. PBMs would bid to be the administrator in each area, proposing a formulary which would affect the price for which they are willing to provide the coverage. In theory, there could be different formularies in different parts of the U.S., but that would generate media stories of how unfair it was to patients in some areas not to have drugs available in others. That would probably lead to a single national formulary. But the media would then produce stories of how some one who desperately needed some drug did not have access to it, making it politically difficult to exclude any drug from the national formulary. The upshot would be that virtually all drugs would be either included in the formulary or there would be easy access to non-formulary drugs for patients whose doctors would certify they needed them. Manufacturers, assured that patients would have full access to their products, would have little incentives to discount prices or offer large rebates. I conclude that there's not going to be significant savings from formularies in a single payer program.

As far as pharmacy networks are concerned, if you have a single administering organization, for most pharmacies not being in a limited network and not being able to offer Medicare prescriptions would be a death sentence. It's simply too major a sanction. For that reason, I think any attempt to limit networks with any real savings elements would quickly unravel politically in a single payer approach.

In the Thomas approach, at least you have the potential, although that doesn't mean it would be realized, for competitors to offer different formularies, different networks and different approaches to generic substitution. There would at least be the political cover from the rationale that if you didn't like what you had in one plan, another plan may offer something better.

But even in the Thomas approach real competition among different formularies may not materialize. The combination of long term prescribing and annual enrollment periods would result in almost perfect anti-selection by beneficiaries choosing the formulary that offered the drugs they need. My extrapolation from that is that if you did have competing plans offering different formularies, they'd all quickly look an awful lot alike. But even if the differences disappeared pretty quickly, there might still be enough political cover for flexibility in the formulary.

Then you have to worry about the Congress itself. Is there any way of protecting the Congress from itself? Congress can adopt a cost saving feature which in theory will save a lot of money, but when it hurts constituents, they adopt piecemeal actions that offset the source of the savings. Thus it's perfectly possible that there will be no savings on any of these approaches because of the combination of effective, targeted political lobbying. By contributing to most Congressional campaigns, the pharmaceutical research companies who want to get their drugs covered in a mandatory fashion can take advantage of the tendency of

the Congress to make these piecemeal changes that can undermine cost saving features.

My only observation is there's the potential with multiple payers that these savings might accrue. But it is still a long way from the reality of savings even if those things are passed.

Mr. Robert G. Lynch: I was at an earlier session and I'm repeating much of what I said then. As far as the Medicare prescription drug plans go that are being offered right now, I hate to be Mr. Doom and Gloom, but I see them following the same path to failure as has been followed in the state of Wisconsin for the last 10-15 years because it's very similar to the situation there. Wisconsin's prescription drug coverage, which is required to be a $250 deductible and 50% of the next $6,000 with mandatory catastrophic coverage beyond that for all plans, is purchased as a separate rider much in the way that the bills proposed by Mr. Thomas and Governor Bush have been laid out.

You pointed out that this is very similar to Medicare Part B. I think the flaw in that comparison is that in Medicare Part B there was only one level of decision making and that was the beneficiaries' decision whether to buy in or not. With these plans, there are two levels of decision making. The beneficiaries, of course, still have to decide whether to take the plan, but you also have carriers deciding whether to be involved and offer a plan.

Adverse selection is the killer. It isn't the adverse selection on the drug costs, it's those people with a back end benefit where there's a fairly high deductible, so it takes a while to get their benefit. Those people who would benefit from the coverage on the Medicare part also have very high medical expenses. Carriers in Wisconsin found that, although they could price for the adverse selection of the prescription drug part, the costs for other medical benefits ran 50% higher and you're guaranteed to lose large amounts of money if you participated and offered a prescription drug rider.

As a result, it has been quite a while since any Medicare supplement beneficiary in Wisconsin has been able to purchase prescription drug coverage there. I'll point out that there is one insurance company supposedly offering this prescription drug rider, but in surveying insurance agents myself, I couldn't find anybody who was aware of that company. The uniform answer I got from them was that there's nobody selling prescription drug coverage in Wisconsin.

So my doom and gloom forecast for these plans is if they're enacted that the smart carriers will simply say, "This is a loser for us to participate, and we'll refuse to participate." So the beneficiaries will not have a chance to buy this. So it will do absolutely nothing. That's my opinion.

Mr. Trapnell: Let me respond to a couple of aspects of that. First, when I mentioned that the Democrats were claiming that the Thomas Bill would not

provide drugs through Medicare like Part B does, it was at the propaganda level. I wasn't really talking about the substance of the proposal.

The Clinton Administration's benefit design was originally capped at a relatively low level and there was no catastrophic coverage. The catastrophic coverage was added in response to the House Republican bill in order to have everything in their bill that the Republicans had in their bill. The results are very strange benefit designs to say the least because they wanted to promise some benefits to everybody. You end up with a basic benefit program that has first dollar coverage. Everybody understands that. That's going to help everybody.

Then you have this large—what they used to call in the grand old days when major medical was first coming into play—corridor deductible. Finally, this 100% paid catastrophic, which is really a dumb idea. Drugs can be extraordinarily expensive to develop for two reasons. One is that it is very expensive to develop the drug and the other is that not very many people need it. So it doesn't take a very high expenditure, if you target it to relatively few people, to get up in the hundreds of thousands of dollars for each one that does. Five thousand dollars could prove to be almost a throwaway proportion of the cost.

As to the degree to which anti-selection is important, what matters is selection against the whole program, which depends entirely on how much flexibility the plans are given and the degree of federal subsidy.

Now, as far as the whole program incentive is concerned, I believe 50% subsidy from the federal government is enough to assure participation at the 90% level or higher. The Thomas Bill produces somewhat less than that, but the subsidy is primarily directed to higher levels of expenditure, and the subsidy to the catastrophic is complete. They also made provision because of the HIAA testimony that the amount of subsidy will be increased until they have enough players.

I have no doubt that there will be options offered everywhere in the country under that proposal. They may not be insurance companies. It may be AdvancePCS. It may be Merck and Medco everywhere and at least one other. But there will be options. I expect all the offers to be very similar because of the danger of anti-selection because there are a lot of smart people like you that are going to help point these problems out.

From the Floor: If the policy makers are looking for a model, I present Wisconsin as an example of what not to do. If they're looking for an example of what to do, look for the private sector, the Medicare+Choice HMO plans which offer front end benefits with co-payments. It's because of the adverse selection. You do not get an adverse selection nearly as bad with the front end benefit as a back end benefit.

Mr. Dale C. Griffin: Bryan, you emphasized the need to do something about the vast middle tier, 80% of the cost. It just seems to me that a coinsurance form is a very good thing to do there because it gives an incentive to members to watch the costs or to switch drugs, and also updates automatically.

Bryan, when you switched to three tier, how long did it take? Did you notice a length of time for the switch from the third tier to the second tier, or from the third tier to generics to materialize? Did it happen immediately, or did it take a while?

Is there ever a circumstance where rebates from manufacturers come into play in the member cost sharing? That is if you have a coinsurance benefit, has anyone experienced situations where you actually have to reflect that in what you make the member pay?

Mr. Miller: Let me address the first two questions. Your point about coinsurance is very well taken, and I'm in full agreement with you that coinsurance is the best way, rather than updating flat dollar co-payments. I think the issue that I tried to make clear was that that's not very marketable. You're going to go through a period of some pain trying to convince other folks in your company that you need to make people aware of how much their drugs cost when they're standing at the counter. It's a tougher thing to sell internally. Then it's exacerbated by having to sell it externally.

I'll tell you about our three-tier program in terms of the utilization—it basically has not moved. The third tier in 1998 had 11% of prescriptions and 7% of costs. It's now 12% of prescriptions and 9% of costs. It's not moving. Our generic substitution rate is not moving either. So the habits seem to be very hard to change. Even if you hit them a little harder in the pocketbook, it's not moving many of them.

Ms. Companik: I can actually comment on a recent example of a client we had, and this is a large managed care client who on January 1, 2000 moved to a three-tier co-payment design from a two tier. It experienced a significant shift from the third tier to the second tier. It noticed that almost instantly within the first couple of months 30% of its non-preferred drugs were moving to preferred drugs, and it did have a tremendous impact on its drug spend. So that was just one success story that I can think of.

With regards to your question on the rebates, I am not aware yet of any programs or plans requesting that rebates somehow be taken in consideration on member co-payments. So if they exist, I'm just not aware of them right now.

Mr. Brian G. Small: First, I'd like to thank Mr. Trapnell for alerting the politicians to the iceberg on the horizon. Even if they fail to listen to you, at least I'm glad you're doing that. My question is on generic substitution. We're experiencing generic substitution around 39–40%. I was wondering what is the highest it could get? I've heard rumors of up to 50%. I haven't seen those numbers.

Mr. Miller: I think 50% was a practical target that we shot for. I'll tell you our aggregate figure right now is 38%, and it's only 33% in the automotive accounts, and that's obviously dragging the average down. Our goal was to be in the upper

forties by now, and we're not there. We tried to get it through benefit design changes and, as I said, behavior seems to be adjusting very slowly, if at all.
Ms. Companik: Yeah. I don't have a feel for what the maximum is on that, but we definitely see some clients in the mid-forties.

Mr. Bruce N. Vander Els: Gordon, what I thought I heard in your presentation, correct me if I heard it wrong, was the idea that in a multiple payer system there would be more opportunities for discounts. I thought about that, and I would agree that it would be true over the short term, but I thought that what we've seen from the government in single payer systems is that over the longer term, the discounts tended to be what the government would take rather than what the providers would give. In a single-payer system, the government had a lot of potential over the longer term, given the price structure in the pharmaceutical industry right now, to be taking some fairly massive discounts relative to what the commercial drug plans are able to. Can you comment?

Mr. Trapnell: My observation is that whatever the design is it can be politically overridden, and that the lobbying expertise is there on the part of the manufacturers to do so, especially in the long run. I'm far from saying that even with a multiple payer system that the flexibility will be there to start with and remain there in the long run against the political pressures. But I think that with a single-payer system, it won't be very long before we see price controls with the kind of cost increases that are likely. Price controls never work out the way their proponents expect them to. That's the only other observation I have.

Ms. Sharon Roberts Rivais: I wanted to share that we moved to a three-tier co-payment voluntarily in mid-1999 and then more in 2000 to a lot of our large groups. We had the experience of going from about 40% to around 45% generic compliance, which was very good.

As new drugs are being moved into the third tier, or as generics become available were there isn't competition yet, and the price of these is a lot higher, so it's raising the average cost of our generics. I wanted to hear some comments from anyone on that.

Mr. Miller: We've seen a rise in the average cost of generic drugs, and it may be due to the very reason that you've talked about. But that's an interesting thought. I'm actually happy that you've been able to increase your substitution rate that much because we have become pessimistic that anything we do is going to have any effect anymore.

CHART 1

PMPM Drug Claims by Business Segment