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INCREASING GENERIC DRUG USE: SAVINGS FOR SENIORS AND MEDICARE

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THURSDAY, SEPTEMBER 21, 2006

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 10:06 a.m., in room SD–562, Dirksen Senate Office Building, Hon. Herb Kohl presiding.

Present: Senators Kohl, Smith, Collins, Talent, Nelson and Lincoln.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. We will call this hearing to order now and welcome our witnesses. As always, I thank Chairman Smith for allowing us to put together this hearing.

Everywhere I go in my State of Wisconsin, I see how prescription drug costs are a drain on seniors, families and businesses, all of whom are struggling to pay their health care bills. They need help, and we can respond by expanding access to generic drugs. Generics, which on average cost 63 percent less than their brand-name counterparts, are a big part of the solution to health care costs that we all know are spiraling out of control.

Prescription drugs make up 11 percent of national health care spending, but are one of the largest and fastest growing health care expenditures. The U.S. spent over $250 billion on prescription drugs in 2005, with generics accounting for 56 percent of the prescriptions, but only less than 13 percent of the cost. One study estimates that every 1-percent increase in generic use can save up to $4 billion. That means that a modest 5-percent increase in generic use could save as much as $20 billion.

The private and public sectors are looking for relief, and our Committee has heard some remarkable success stories from some who have turned to generic drugs. General Motors, for example, testified that in 2005 they spent $1.9 billion on prescription drugs—40 percent of their total health care spending—and their program to use generics first saves General Motors nearly $400 million a year.

We know generic drugs have the potential to save seniors thousands of dollars and curb health care spending for the Federal Government, States, employers and families. Every year, more blockbuster drugs are coming off patent, setting up the potential for billions of dollars in savings, and so the question is what are we going to do about it.

Well, first, we need to get the word out to Medicare beneficiaries. This month, millions will exceed the initial $2,250 drug benefit and will fall into what is called the donut hole, where they must pay full price for their drugs. CMS needs to steer seniors more so toward generic drugs to help them survive the donut hole and publicize the 13 percent of drug plans that actually cover generic drugs during this gap so that seniors can seek out those plans during the open season.

Second, we need to do a better job of educating seniors. Many are still reluctant to switch to generic drugs because they think that expensive or brand name means better. Many don't know or don't believe that generic drugs are just as safe and effective as the brand-name drug that they see advertised on television. Often, their own physicians compound the problem. With little information available to doctors comparing brand name to generics and patients demanding the newest drugs, doctors too often prescribe medications that are more expensive, but not necessarily more effective.

CMS and HARQ are currently compiling some comparative information about different drugs that treat the same diseases, but we need more comprehensive studies. We need to get this information into the hands of doctors so that they can prescribe better, and we should get it to the Medicare drug plans, also, so they can consider it when designing their formularies.

It is clear that generic drugs can be a big part of reining in health care costs. The first battle in this fight is to break through the roadblocks that stop generics from reaching patients. In the agricultural appropriations bills, we are boosting funding for the FDA to reduce their backlog in approving generics, and I and others are also sponsoring legislation to end back-room deals and frivolous citizen petitions used by the pharmaceutical industry to prevent generics from coming to market faster. It is also time to create a system to approve generic biologics which are increasingly used to treat disease, but currently have no generic equivalents at all.

Once generics are on the market, it is just as important to win the next battle, which is to make sure that every senior, every family, every business and every government program knows the value of generics and uses them to bring costs down. So we look forward to hearing more from our panels.

Now, we turn to our Chairman, Gordon Smith, for his opening comments.

OPENING STATEMENT OF SENATOR GORDON H. SMITH, CHAIRMAN

The CHAIRMAN. Thank you, Senator Kohl, and my thanks to you for helping to organize this hearing and to your staff. We appreciate so much the working relationship we have with you. But, more, we thank you for all that you have done to help seniors reduce their prescription drug costs and what you continue to do.

I also want to make note of what I have been told. This may be Dr. Mark McClellan's last Senate hearing. I don't know whether that makes you happy or sad, but we are honored that you would come here, Mark, to this Committee, it being one of your last hearings, if not the last. You have presided over this enormous program, this enormous agency, at a historic and important time, and I know you have had your full measure of challenges. But I just think heart-felt thanks are due on behalf of the Senate, on behalf of this Senator, and certainly on behalf of the seniors of this country, who I think in increasing numbers are recognizing that while we didn't pass a perfect bill for you to administer, we have passed a bill that is proving already a real benefit to their lives and to their quality of living.

Today, we turn our focus to the demand side of the equation by exploring ways generic drugs can be used more frequently when they are deemed medically appropriate. We are familiar with the skyrocketing costs of prescription drugs and the potential savings that could be achieved if generics were used more effectively in our Nation's health care system. This is true both for individual consumers and the government, but neither can achieve those savings unless we continue working to break down the barriers that Senator Kohl just talked about.

Medicare's new prescription drug benefit is saving seniors a great deal of money on their health costs, but they could save even more by choosing to use generic alternatives their plans offer. Considering some reports show that drug prices and Medicare Part D are increasing at rates equal to or even faster than the rest of the market, the gains seniors have made with their new benefit may soon be lost.

We cannot afford to allow out-of-control drug prices to erode seniors' access to vital drug therapies. But simply getting more prescription alternatives to the market will not guarantee that they will be used by doctors or patients. The savings generics could provide our health care system can only be fully realized if we raise awareness about their effectiveness and their affordability.

In order to accomplish this, there needs to be more information available to the public regarding generic drug benefits. Fortunately, interest from the government and other health care purchasers has sparked more research in this area. Programs like the Drug Effectiveness Review Project, spearheaded by the Oregon Health Sciences University, are providing policymakers and health care purchasers a wealth of evidence-based materials about the effectiveness and safety of prescription drugs, including generics.

We are all aware of concerns that brand-name marketing efforts influence physicians' prescribing behavior. Since generic drug companies typically do not engage in such activities, a doctor may not be aware of the availability of more affordable drug options. If we

expect to realize all the benefits generics have to offer, both providers and patients need greater access to objective prescription drug information.

The Internet is one source consumers are using to make comparisons between brand-name and generic drugs. Hopefully, as seniors learn more about their options, they will more readily talk to their doctors about finding the prescription drugs that are not only most effective, but most affordable.

So I look forward to our discussion today and I expect it will provide us with more ideas on how we can further raise awareness about the value and safety of generic prescription drugs. Senator Kohl has assembled a fine group of witnesses and I know their input will be very useful.

Senator KOHL. Thank you very much for your fine statement, Mr. Chairman. Now, we turn to Senator Talent.

OPENING STATEMENT OF SENATOR JAMES TALENT

Senator TALENT. I want to join Senator Kohl and the Chairman in welcoming Dr. McClellan. Thank you for your tireless efforts in implementing the Medicare prescription drug program which is benefiting over 700,000 seniors in Missouri. While there are certainly things about the bill that I want to improve—and you and I have talked about some of them—I am pleased about the benefit to Missourians and the fact that the model has succeeded in getting prescription drug costs discounted and then paying a part of the discounted price for our seniors around the country.

I also join with you in the belief that in addition to just providing a benefit that people need, it is going to be very important in moving Medicare toward a system that focuses on helping people manage their health and manage any diseases they may have so they stay as healthy as possible, rather than just paying bills when they get sick. That is the key to the health of our seniors in the future. Certainly, increased reliance on generics is an important part of that and we need to keep emphasizing that, and I am glad you are here today to talk about what you think we can do.

Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Talent.

We will turn now to our first witness, Dr. Mark McClellan. Dr. McClellan has been the Administrator of the Centers for Medicare and Medicaid Services, known as CMS, since March 2004. Unfortunately, as we know, Dr. McClellan recently announced that he will be leaving his job. Of course, we wish you the very best. We certainly appreciate how accessible you have been to this Committee, and we thank you for agreeing to come here today.

Dr. McClellan will discuss CMS' efforts to encourage generic drug use under Medicare and their preparations for the upcoming open season, when beneficiaries can switch their drug plans.

We welcome you here today and we look forward to your testimony.

STATEMENT OF MARK McCLELLAN, M.D., Ph.D., ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. McCLELLAN. Thank you, Senator Kohl, and Mr. Chairman, Senator Talent. Thank you very much for your kind words, for your bipartisan leadership on the issue of generic drugs, and especially for your leadership on safe and effective ways to lower drug costs for Americans.

Generic drugs are just as safe and effective as the brand name version, they are inexpensive in the United States as a result of our competitive pricing system, and they are a critical element to providing health care to Americans that is effective and affordable. As a result of the new Medicare prescription drug benefit, generic drug use is up significantly, leading to billions of dollars more in savings for people with Medicare and taxpayers.

I am pleased to report that the Medicare drug benefit is proving less expensive than anticipated at any previous time and that we expect continued savings throughout 2007. These savings are in part being driven by promoting the use of generics, where appropriate, in the design and implementation of the drug benefit, and I am pleased to have the opportunity to discuss how we can do even more in this area.

Based on updated figures from the 2006 mid-session budget review, the estimated cost of the drug benefit over 5 years is down by $35 billion compared to the estimates earlier this year, and is $110 billion lower than the estimates just a year ago. The average Part D premium for 2006, now estimated to be under $24 a month, is lower than estimates from last year which came in at over $37 a month. Based in part on these strong competitive bids for 2007, average premiums next year will again be around $24 if beneficiaries stay in their current plan.

Because the vast majority of beneficiaries will have access to Medicare drug plans that have lower premiums, actual premiums in 2007 are likely to be even lower if some beneficiaries decide to switch. With lower bids and smart choices by our beneficiaries, costs to taxpayers will be even lower in 2007 than the much lower than expected costs we are already seeing in 2006.

Along with aggressive drug price negotiation and effective benefit design, the utilization of generics has played an important role in bringing down these Medicare drug benefit costs. As you pointed out, generic drugs typically cost 50 to 70 percent less than their brand-name counterparts, and prices for generic drugs in the United States, drugs that account for most of the prescriptions in this country, are much lower than in many other countries. For example, a study by the National Opinion Research Center at the University of Chicago reported that people living in Canada pay 37 percent more for generic drugs than people living in the United States.

Because of these low prices and strong competition, the Medicare drug plans are providing excellent low-cost coverage for generic drugs. Generics are widely available on planned formularies and co-pays for these drugs are typically low, often just a few dollars,

and some Part D plans are even providing generic prescriptions for free.

Because of the low prices and because of the personalized information that Medicare beneficiaries are getting about how they can save using generics, Medicare beneficiaries are using generics at a high rate. Nationwide, the proportion of generic usage stands at 51.9 percent. Data that CMS is gathering on the drug benefit show that generic usage among all types of Part D plans was 60.1 percent in the first two quarters of 2006.

In addition, many Part D plans report an increased growth rate of generic utilization that is faster than in the overall market. This is very good news for Medicare beneficiaries in the Medicare program because it translates into billions of dollars in savings, while still delivering the same high quality of health care.

One of the most important tools in helping beneficiaries find out about how much they can save using generics is our Drug Plan Finder tool which is available online at Medicare.gov and on the phone at 1–800–MEDICARE. Millions of beneficiaries and the family members and counselors who work with them have seen how much they can save personally by switching to generic versions of their drugs. We are enhancing this tool for 2007 for the upcoming fall open enrollment period, and we will also highlight generic availability in the Medicare & You Handbook which is being sent out next month.

Additionally, during our outreach events and through our extensive partner network, we are advising beneficiaries that asking their doctor or pharmacist about generics or lower-cost brand-name drugs that treat the same condition can help them delay reaching the coverage gap if they choose a plan that doesn't fill in the coverage gap. Consumers Union has concluded that seniors can save hundreds, if not thousands of dollars by switching to generics, potentially enabling them to avoid any coverage gap altogether. Other studies have found similar savings of 60 to 75 percent by switching to generics, and next year I am pleased to report that even more plans will offer coverage of generics in the gap.

CMS is also working with a broad range of stakeholders in the Pharmacy Quality Alliance to develop consensus measures of pharmacy quality that will be available starting later this year. Generic utilization is expected to be one of these key quality measures. Low-cost generic drugs are one of the reasons why a broad range of recent surveys, including J.D. Power and the Kaiser Foundation, are consistently showing high beneficiary satisfaction rates with the new drug benefit. Satisfaction rates are consistently over 80 percent, with even higher rates for dual-eligible beneficiaries.

We are continuing to work hard to build on these successes and improve the benefit further. For example, in 2007 more plans will be offering options with coverage in the gap, and as I have already mentioned, Part D costs will be lower for taxpayers. The cost savings are due in no small part to price negotiation on drugs, and also to effective use of generics that cost much less than drugs that seniors have used in the past.

Mr. Chairman, Senator Kohl, Senator Talent, thank you again for inviting me to speak with you today about generic drugs and how we can work to continue providing a high-quality, low-cost pre-

scription drug benefit for people with Medicare. The drug benefit provides much-needed coverage for our beneficiaries, and generic drugs serve as an important and safe way to save a lot of money for beneficiaries and the Medicare program. I look forward to any questions that you all may have.

Senator KOHL. Thank you for your statement. You say that generic drug use rates under all Part D plans during the first two quarters were just a bit above 60 percent, which is very good. I assume that that is an average and that there are some plans which did a better job and others which did not do so well.

What kind of range are we talking about here? In other words, what were the generic use rates of the plans with the lowest and the highest generic use? Do you have some information on that?

Dr. MCCLELLAN. This is preliminary data, Senator. We have just gotten second quarter data recently. In the first quarter, I am not sure that is going to be real representative because that was the transition period for many people onto the benefit and many people continued their previous drugs for the first 3 months of 2006.

We are going to keep analyzing these data and we do want to make them available by plan. We hope to do so by November, so we should have those numbers for you by plan soon. What I can tell you is that some of the Medicare Advantage plans, the HMO and PPO and private fee-for-service plans in Medicare, tend to have a somewhat rate of use of generic drugs, over 60 percent, but we don't have any systematic numbers on that quite yet. We will have them soon.

Senator KOHL. Will that information be available to seniors by the time the open season starts in November so that they and we and everyone can know which plans are doing a better job and which are not doing well?

Dr. MCCLELLAN. That is exactly our goal. I know that is very important to you from our staff discussions and we intend to make that information available by mid-November.

Senator KOHL. For those plans with well below the average generic use, what is CMS intending to do to encourage them to increase their use of generic drugs?

Dr. MCCLELLAN. Well, I think that those plans are going to have a hard time doing well in this program in the longer term because we are seeing strong competition. The premiums are very low. The cost of the overall drug coverage is much lower than expected and if plans aren't implementing effective ways of telling people about the savings with generics and helping people switch over, then they are not going to do well.

That is why I think we are seeing such good coverage for generic drug use, with many plans having generic drugs available for no cost at all. We are going to highlight those plans this fall, and I think the most important message for the drug plans is because we are making available information on generic use, because we are telling people how much they personally can save on their drug needs by switching to safe and effective generic drugs, the plans that don't do well with generics are not going to do well in this program.

Senator KOHL. Dr. McClellan, a growing number of drugs that seniors take today, as you know, are biotechnology drugs, which

have been a growing expense under Medicare Part B and are now also covered under Part D. Today, as you know, there are no generic versions of biotech drugs because the FDA has no system to approve them.

Don't you believe it is time that we do create a system to approve generic biotech drugs, and wouldn't those generics produce additional real savings for Medicare and for seniors?

Dr. MCCLELLAN. Senator, during my time at FDA, we spent a good deal of effort starting to look into what would be required for generic biologics to be available safely and effectively and I know FDA is continuing to work very hard on that issue.

The challenge that biologics present is, as you know, they are much more complicated molecules. They are not a simple, small-molecule drug. Many biologics are complex. They are part of complex formulations with complex manufacturing processes, and what that means is that they present some more challenging safety issues.

The FDA is working hard to find ways to address those safety issues, but frankly I think we need to put some resources into developing methods that can assure the safety of generic versions of biologic drugs and maybe focus first on some of the relatively simple generic biologics. FDA has already got a process underway for a generic version of Omnitrope, which is a relatively small biologic molecule. There are several other biologics that were approved a long time ago under the FDA's new drug authority, as opposed to the BLA, the biologics authorities, and that might be a good place to start. But I agree with you that it is time to look closely at the safety issues, and if we can address those safety issues, then this is an important policy to consider.

Senator KOHL. Thank you.

Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kohl.

I wonder, Mark, in your view, to the degree that there is resistance to generics, is it just perhaps a placebo belief that the brands are just better, because, in fact, aren't the medicines darn near identical?

Dr. MCCLELLAN. They are identical; the active ingredients are identical. They are regulated in the same way. They have to meet the same safety and effectiveness standards. According to the FDA, the oversight is tight.

I think, Mr. Chairman, it is maybe a bit of a carryover from when people hear the term "generic," they think about knock-off purses or watches that you might buy on the street that aren't the same as the brand-name version. It is very important for the public to know that that is absolutely not the case when it comes to FDA-approved generic drugs in the United States. These drugs are just as safe and just as effective as the brand-name version.

We have been making that information available every opportunity we get. It is on our website. It is in, as I mentioned, our outreach materials to beneficiaries, and I think as long as we have a concerted effort with all of us focusing on this very important education message about safe and effective and low-cost medicines, we can make sure that all Americans are aware of it.

The CHAIRMAN. Ultimately, will the best educator be the price savings that people individually can enjoy?

Dr. MCCLELLAN. What we have found is what seems to motivate a lot of seniors is being able to give them personalized information about the price savings, not just telling them, in general, that generics are 50 to 70 percent, or more, savings compared to the brand-name drug, but being able to give them a print-out when they call us 1–800–MEDICARE or when they go to Medicare.gov. If you tell us what drugs you are on, we will tell you if there is a generic version available and we will tell you how much you can save each month by switching to that drug.

That is a print-out that you can take with you the next time you see your doctor or pharmacist. In many States, you don't even need to go to the doctor to switch over to a generic version of your drug; you can just do it. So that has proved to be a strong motivator for many of our beneficiaries.

The CHAIRMAN. It keeps them out of the donut hole for a lot longer, doesn't it?

Dr. MCCLELLAN. It sure does. That is what Consumers Union has said that you can save hundreds or thousands of dollars by switching over, and that can keep you out of the donut hole if you choose a plan that has a donut hole.

The CHAIRMAN. If I hear any complaint at this point on Medicare Part D. it is the donut hole. I think that was foreseeable, but again I hope your Department is getting that message out. If you want to stay out of the donut hole for a lot longer, use generics.

Dr. MCCLELLAN. It is very important. On our website and when people call us at 1–800–MEDICARE, we have a whole set of steps that people can take to lower their drug costs. Even if they are not in the donut hole, these are important things to look at anyway to keep your drug costs down. It includes getting this personalized information about generic drug availability and lower-cost brand-name drugs for your medical needs, something you can talk about with your doctor and pharmacist.

It includes using your Medicare card because you get discounts on the drug prices when you do that. It includes looking at a lot of programs that are out there to help you with costs in the donut hole. So we want people to get in touch with us about all of these opportunities for saving.

The CHAIRMAN. I describe generics as nearly identical, and I want to emphasize your response was that they are identical.

Dr. MCCLELLAN. Just as safe and effective. They have the same active ingredient, they work in the same way in the body as the brand-name drug.

The CHAIRMAN. Mark, something that is not specifically to generics, but Medicaid, and a concern I have on Medicaid. I want to talk to you about some recent news reports that I am aware of that a couple of States, specifically Kentucky and Idaho, are offering Medicaid so-called benchmark plans without describing to the beneficiaries that that doesn't disqualify them from Medicaid. Frankly, they need to be told what the differences are, and they shouldn't be asked to make a choice between a benchmark plan and Medicaid. If they are going to make that choice, they need to be given the choice.

I am wondering, has CMS authorized these two States to pursue these alternatives without making clear their choice?

Dr. MCCLELLAN. Mr. Chairman, under the Deficit Reduction Act, as you know, because I know this is a provision very important to you, for certain populations the States must continue to offer a traditional Medicaid option as well as these new kinds of benefit plans.

What we have heard from beneficiaries in the two States is that they are pleased by the new benefits coming along. In Idaho, there are some additional benefits to help people stay well that they didn't get before. In Kentucky, there are new home and community-based services that are very important and very much supported by many advocates for people with a disability to help people get services that they need in their homes.

But I want to be very clear that under the law and under our interpretation of the law, the States must offer the basic traditional Medicaid version, too, for people who want it. For beneficiaries that feel that they are not getting access to needed benefits, they have appeals rights and we intend to enforce that provision.

The CHAIRMAN. As far as you know, are Kentucky and Idaho making clear——

Dr. MCCLELLAN. Well, Idaho has not yet even initiated their program. It is not even underway yet. In Kentucky, people do have the option of staying in the traditional Medicaid program, and we will be happy to provide you with additional information on this.

The CHAIRMAN. You have provided no waiver from the statute?

Dr. MCCLELLAN. No. I want to be very clear that the States must provide the basic traditional Medicaid approach as an alternative for beneficiaries.

The CHAIRMAN. One other comment I have. My staff is working with your agency to try and work out a solution to the problems that have occurred with Part D premium withholding. I appreciate your willingness to develop solutions, but I want to make clear that CMS and SSA need to work with beneficiaries to develop options to repay past-due premiums over a period of time. This is a problem not of their making.

Dr. MCCLELLAN. Absolutely.

The CHAIRMAN. So I hope, come November, or whatever the deadline is for an individual, they won't have their check confiscated in one lump sum. I think too many seniors would face a real financial burden.

Dr. MCCLELLAN. If I can just say a word about that, this was our mistake and it is our responsibility to fix it and to make sure that the money that the seniors wanted to go to pay their drug plan premium does go to do that, but does it in a way that is not burdensome on the senior.

The CHAIRMAN. So you are not proposing a—you are not just going to grab their money?

Dr. MCCLELLAN. You know, some people do want to just get the money back and be done with it, and that is fine. For most people, the amount of money involved was under $200, and so many people just want to be done with it. None of our low-income beneficiaries were affected. But some people want to have the option of paying it out over time and we have made available an option of paying

out for as much as 7 months, and we will talk to beneficiaries about even longer if they have concerns.

We have a toll-free number set up for people to call in if they have any questions about this, and we definitely want to work with our beneficiaries to make sure the money goes where they intended it to go in the least burdensome way possible.

The CHAIRMAN. Well, I thank you for your flexibility on that very much.

Thanks, Mr. Chairman.

Senator KOHL. Thank you, Mr. Chairman.

Senator Nelson from Florida.

Senator NELSON. Thank you, Mr. Chairman.

Dr. McClellan, as you know, there have been 45 of us Senators that have introduced what is called the Medicare Late Enrollment Assistance Act, including several of the members of this Committee. It is headed up by Senator Grassley and Senator Baucus.

We filed this bill the day after the deadline, the deadline having been May 15, in order to eliminate the 1-percent-a-month penalty which, in effect, for senior citizens that did not sign up, as they sign up at the end of the year for the Part D Medicare prescription drug benefit, they are going to be penalized with a 7-percent increase in their premium. It is estimated by one of the agencies—I think it might be CBO—that this includes 3 million senior citizens in the country.

So I would like to know if your outfit, CMS, supports waiving this late enrollment fee for these seniors at this particular time.

Dr. MCCLELLAN. Senator, we have very strong interests in making sure that everyone takes advantage of this benefit, so we certainly share your goal of getting more people into the program. I think we did have some concerns about the way that this bill might be paid for by taking away money that is needed for providing other benefits to seniors, Medicare Advantage support and things like that that many seniors are counting on.

What I can tell you, as well, is that we have been looking at these numbers closely and it is not, we don't think, 3 million beneficiaries that would be subject to the penalty. Remember that because of our authority, we have been able to waive the penalty for any low-income beneficiaries that have not yet enrolled, and that is a very hard population to reach and they actually account for probably most of the people who have not yet signed up, most of the few million people who are not yet in good drug coverage.

We also want to emphasize that everybody who is in drug coverage now can switch to a different plan with no penalty at all later this year if they are not happy with their current coverage. So it is a pretty small population that is subject to this penalty. It is actually fewer people, we think, than would be subject to the Part B penalty if they ended up enrolling in Part B. So we will try to continue to work with you on this.

Senator NELSON. Well, I hope so because 3 million is not a trifling number of people.

Dr. MCCLELLAN. It is less than that. I agree any population, even if it is a few hundred thousand, that is something that we are concerned about; we want to get them into the coverage.

Senator NELSON. Particularly when you are dealing with senior citizens who sometimes have to make the tough choices of how they are going to make financial ends meet. If you wanted to hang that penalty over their head in order to get them into the system, OK, the system deadline came and went. Now, for whatever reason, a number of them, many of them confused, did not sign up. Now, they are going to sign up at the end of the year. Why have that penalty of 7 percent on these people forever?

Oh, by the way, you can pay for it with an offset because there was a sinking fund, a set-aside fund that was to help the private companies enroll people. Because people went ahead and enrolled, there is money left there that can be used to offset this penalty, so you have got a net no additional money. If it is for the good of the seniors, we ought to do it.

Dr. MCCLELLAN. We definitely agree with you that we should be doing what is for the good of the seniors. We are concerned about taking away funds for other programs that may be needed and make sure we continue to provide the best possible coverage to seniors. Again, we have been watching the numbers closely. Ninety percent of people already have drug coverage. Most of those who don't, we have already said do not have to pay any penalty at all.

If you are a low-income senior, there is no penalty. Please find out about this program and enroll in it right away. So it is only that smaller group, and again we do want to keep working with you on this to make sure we are using the dollars that we have as effectively as possible to help as many seniors as possible.

Senator NELSON. Why can't you just say yes? [Laughter.]

Dr. MCCLELLAN. People ask me that a lot, but there is——

Senator NELSON. Well, I mean it is not funny.

Dr. MCCLELLAN. I don't think it is funny. I think that the issue is a very important one and that is why we have tried to get the word out and that is why we are very pleased that so many people did enroll in drug coverage, and that is why we have done all we can under the authority we have to eliminate the penalty for low-income seniors. It is that remaining group, and again we want to continue to work with you. I just don't want to take money away from one important priority and put it on this one unless we are sure that that is the best thing to do.

Senator NELSON. Well, since I have an opportunity to give you a little advice here, I would suggest also, since we have had a discussion here about the donut hole and I think a good discussion has come out here about how you can avoid having seniors go into the donut hole with the generic drugs—and by the way, Wal-Mart is starting a pilot project in my State, in Tampa, FL, in which they are going to start promoting the generics giving people prescriptions at something like four bucks a prescription. So on the basis of this experiment, this pilot project, maybe it will work.

But over and above that, I would, Mr. Chairman, like to take the privilege of suggesting that one way that we could pay for the donut hole is to let the free market private enterprise work by having Medicare be able to negotiate through bulk purchases the price of the drugs down and take those savings and start to plug the donut hole.

Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Nelson.

Senator TALENT.

Senator TALENT. Dr. McClellan, in your testimony you gave some figures about savings on the Part D program, updated figures, and I was writing them down and I didn't see them in your written testimony. Would you give me that again?

Dr. MCCLELLAN. Sure, and we can give you a full report. This was included in the President's mid-session budget review update for 2007, and then we also made some further announcements in August when we released information on the 2007 bids, the costs that the plans will have for the drug coverage in 2007.

Based on the numbers that we saw through the budget in 2006, the costs for the drug benefit in the first 5 years, starting in 2006, are $110 billion lower than had been projected just a year ago.

Senator TALENT. That is over 5 years?

Dr. MCCLELLAN. That is over 5 years. The costs in 2006 are 25 percent lower than had been projected just a year ago. That is billions of dollars in savings for beneficiaries through lower premiums and savings for taxpayers.

Senator TALENT. So the taxpayers are spending less than we thought?

Dr. MCCLELLAN. Taxpayers are spending a lot less. Now, those numbers don't yet account for the fact that the cost of the prescription drug benefit is going to go down in 2007, and that is because the average bid, the average cost for providing a drug plan to beneficiaries—the average cost to taxpayers is going to go down by 10 percent. It may go down even more if seniors do what they did this year, which is look into the program and take some effort.

I know it wasn't easy especially this first time for many of them, but they looked into it and they overwhelmingly chose low-cost plans. They are very satisfied with those plans, and so we could see even more savings.

Senator TALENT. The cost to the taxpayers is $110 billion less over 5 years than we thought?

Dr. MCCLELLAN. Yes, and again I think those numbers are going to be down——

Senator TALENT. The cost to the seniors, because the average premium is staying the same——

Dr. MCCLELLAN. It is 40 percent lower than had been projected.

Senator TALENT. Yes, 40 percent lower. It sounds like there is some bargaining going on someplace, isn't there?

Dr. MCCLELLAN. There is a lot of bargaining going on and we are going to see even more savings.

Senator TALENT. So it is costing the taxpayers less and it is costing the seniors less.

Dr. MCCLELLAN. A lot less.

Senator TALENT. The two objects of the bill were to force the prescription drug companies to discount their prices, which they have, and then pay a part of the discounted price for the seniors. It is an insurance feature.

Dr. MCCLELLAN. If I could just add to that, we have an update. We have been tracking the cost of drugs in the program and tracking the prices that the plans are negotiating over time. We are going to have an update on those numbers released this afternoon.

What we are seeing is large and stable savings of typically 50 to 70 percent for commonly used combinations of drugs by seniors. In the drug plans, the average price of the drugs for the first 8 months of the program has increased by less than one percent. So it is not only below medical inflation, it is below general inflation.

Senator TALENT. Of the folks who haven't signed up—and I support waiving the penalty, too, in part because the cost of that will be so much less than we think since there are just not that many people that we haven't already waived it for anyway.

Dr. MCCLELLAN. Yes.

Senator TALENT. But in any event, most of the folks who did not sign up are eligible for the more generous benefit that lower-income Americans can get. Isn't that right?

Dr. MCCLELLAN. That is correct.

Senator TALENT. My experience in Missouri was that part of the problem was there were so many allegations about the plan being thrown out there that a lot of people, I think, were afraid. They just didn't get the information adequately, and now that they have got it, I am hopeful that they will sign up because those are exactly the folks who need it.

Now, you mentioned in your testimony on page 7 that the Pharmaceutical Care Management Association released a study earlier this year indicating that Medicare drug plans offer significant price discounts compared to what beneficiaries would pay without coverage. Now, you are talking about just the discounts off the original prescription drug price. Is that what study——

Dr. MCCLELLAN. That study was looking just at the discounts off the price.

Senator TALENT. Not the insurance feature that the government pays?

Dr. MCCLELLAN. Not the insurance, not the payments.

Senator TALENT. Did that study give an average discount? I mean, can I get some figures on that?

Dr. MCCLELLAN. They did, and I am sure PCMA would be happy to talk about it. I think they have actually testified before this Committee, too, and I think the numbers are in the range of 30 to 50 percent.

Senator TALENT. OK, that would be good. Now, one other thing you mentioned—and it was kind of you to talk about the strong support that Members of Congress gave. I know that you are testifying before members of the Senate, and so I understand why you said that. But I want to just point out—and I am sure you will agree with this—that we had tremendous help on the ground, and continue to have it, from our community pharmacists and from our senior centers and those who implement the Older Americans Act.

Dr. MCCLELLAN. Yes.

Senator TALENT. We found in Missouri that those two groups absolutely were priceless and indispensable in getting information about the Medicare benefit, and I hope you feel the same way.

Dr. MCCLELLAN. They have been phenomenal, and I think they are going to be so. The No. 1 source for beneficiaries was pharmacists and these local counselors. Senator, we are continuing that same grass-roots approach for the open enrollment period for 2007. We have launched a new initiative called My Health, My Medicare.

We looked at what happened this past year and we found that this personalized support really helps people get better care. It is, as you were saying earlier, turning Medicare from a program that just pays the bills when people get sick to a program that is a partner to help them stay well.

In addition to the information about lower-cost drug coverage options for next year and generics, they will also be helping us get the word out about our new preventive benefits. Medicare has closed the preventive benefits gap, but we still have a prevention gap among our seniors where many seniors aren't taking advantage of it. I know you know about the fact that we have got free screening for heart disease and diabetes and many types of cancers.

Senator TALENT. One more comment and then I am done. Thank you for your patience, Senator Kohl.

I have been talking a lot with pharmacists about the medicine management program, the pilot program that we put in the Medicare Modernization Act, and I want to encourage you to continue moving in this direction and I am going to do this with your successor. Also, you are talking about wellness and it is very important to move Medicare in that direction.

It is very important that we have people who have regular contact with their patients, helping them to understand wellness programming and move in that direction. Well, who is that if not the pharmacists? As we begin to implement electronic medical records more and more, we can network in all these health care professionals. I just want to urge you to think in these terms. Getting these pharmacists more involved and expanding that pilot program so they get compensation for how they work with seniors is not going to cost us money. It is going to save us money because they are part of the group of people who will show these seniors how to do these wellness aspects. So think in those terms about it because we have had some resistance on that.

Dr. MCCLELLAN. I agree completely with you, and because of your interest in this issue, we helped support a new Pharmacy Quality Alliance that is being led by pharmacy groups that includes all the health care stakeholders to help make these better medication therapy management and other quality pharmacy services available not just to Medicare beneficiaries, but we need this throughout our health care system, Senator.

Senator TALENT. I completely agree, and one of the things I regret about the bill is that the pharmacists have borne such a burden under it and, as you know, they are economically squeezed and this would be a great way to help them, but also to help move this progress toward a wellness system.

Dr. MCCLELLAN. We will follow up on this.

Senator TALENT. Thank you and your staff.

Thank you, Senator.

Senator KOHL. Thank you, Senator Talent.

Senator Susan Collins from Maine.

Senator COLLINS. Thank you.

Dr. McClellan, the debate over the use of generic drugs versus brand-name drugs becomes largely an academic debate if patients don't have access to physicians that can diagnose them and write

the appropriate prescription. So though I am extremely interested in this issue and very concerned about it, I am going to use my time this morning to question you about policies that the Department is pursuing that threaten a number of small medical residency programs in the State of Maine that provide absolutely critical family physicians for the most rural areas of my State.

I also have to express some frustration to you because I have called your office every single day for a week to talk to you about this issue and have been unable to get a return call. So with the Chairman's indulgence, I am going to use my time here today to pursue this issue and then I will submit my questions for the record on the generic drug issue, which is an extraordinarily important issue.

As I have said, we have five small medical residency programs in Maine. They have been the subject of audits by the fiscal intermediary focusing on their graduate medical education programs, specifically their use of non-hospital teaching sites. Over the past 4 years, they have been asked to repay millions of dollars and have had the cap on their overall FTE reduced.

Most recently, the fiscal intermediary has told two of the programs that they may have to pay $5.4 million. I have to tell you, Doctor, if that stands, these programs will close; they will be forced to close their doors. I am not crying wolf about that; that is the financial reality. These hospitals and teaching programs have dedicated themselves to training primary care physicians and placing their graduates in rural Maine communities. They are non-profit institutions that provide health care to Maine's most vulnerable populations. With all due respect to your fiscal intermediaries, they are doing their best to comply with a set of regulations that are inconsistent, vague and contradictory.

If we lose the two teaching programs that are at issue right now, we will lose approximately one-third of our graduate medical education population and our major pipeline for future primary care physicians. The result of that is that citizens in my State are going to have reduced access to health care. I understand that CMS has a fiduciary responsibility, but I just plead with you to take a look at the implications of the decisions that are being made. I think your agency is not seeing the forest for the trees.

Over the past 4 years, I have written letters to you. I have talked to you personally about this, I have talked to Secretary Leavitt, I have talked to your predecessor, and I believe that CMS' actions are in direct conflict with congressional intent, as expressed in the 1997 and 1999 Balanced Budget Act which were designed to encouraged rural and out-of-hospital experiences in these residency programs.

Congress put in place a 1-year moratorium on the kinds of payment denials as part of the Medicare Modernization Act. Yet, the recent audits threaten to deny payments for rotations that occurred during the moratorium. I don't even think you can legally do that. It is extremely frustrating. I don't want to take the time of this Committee to go into it in more detail, but this has to be resolved.

These are small residency programs. They are not large teaching hospitals, and we have reached a level of technicality here that none of them, even with the best of intentions, can meet. When my

staff looks at the regulations, we can't figure out why the denials are being issued.

Let me just give you one example. The most recent audit of the Maine-Dartmouth Family Residency programs denies the reimbursement for time if the written agreement between the teaching program and the supervising physician is not dated prior to the time training was begun even though everything else was fine. Yet, we can't find any regulation that stipulates that requirement. So this is extremely serious.

I would ask that you at least consider delaying the issuance of the notice of program reimbursement by the fiscal intermediary for Maine General Medical Center and Southern Maine Medical Center so we can continue to work to resolve these issues. I have to tell you the situation is dire. These programs will close if we can't get this to be resolved, and that means that senior citizens in our State and disabled individuals are not going to be able to get the care they need. It is not going to be a choice for them between a brand-name and a generic drug; they are not going to be able to see a physician in their community to get any kind of prescription. So I plead with you to give this your personal attention before you leave, and I hope we can talk further about it.

Thank you, Mr. Chairman, for your indulgence on this issue.

Dr. MCCLELLAN. If you don't mind, could I have a couple of minutes?

Senator KOHL. Yes.

Dr. MCCLELLAN. This is a very important issue and, Senator, one of the things I have come to appreciate in this job is that no matter how hard my staff works, how well-meaning they are out of Baltimore and our offices around the country to get the program right and make sure it works for people, unless we listen to those who are on the ground actually delivering services, we aren't going to do an effective job in running this program and we aren't going to serve all of our beneficiaries as well as we should.

One of the things that I have truly appreciated in my time working with you here at CMS is your input to us on those issues in Maine. Maine, like many States, has very distinctive kinds of provider arrangements that involve serving a lot of beneficiaries who don't have great access to health care to begin with and need all the help they can get to maintain and improve quality of care.

I remember one of our first meetings when I came into this job. You brought up this issue of the need for residency training programs that work and the need for getting primary care doctors out into parts of rural Maine that otherwise would have no access to medical services at all and how important the programs that Southern Maine Medical Center and Maine General Medical Center are to achieving that critical public health goal for the State of Maine.

You have been with us every step of the way over the last couple of years that we have tried to work through this issue. No one has put as much time and effort into identifying this problem and trying to find constructive ways to address it as you have. While we haven't connected over the past week, that doesn't mean my staff hasn't been working on this.

What I would like to tell you right now is that as a result of your actions and your involvement in this issue, we are going to suspend the notice of program reimbursement. It is not going to end up being many millions of dollars. We are going to have to address this a little bit further and I intend to do that over the next few weeks while I am still at the agency. So you will hear from me about this first as we take further steps to resolve this issue. I am not sure we are going to be able to do every single thing that the medical centers would like, but you have raised some valid and important and critical issues all along in this process, and as a result of that we are suspending the NPR while we work this out over the next few weeks, and I will be giving that my personal attention before I leave the agency.

Senator COLLINS. Thank you very much. I really appreciate that answer. Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Collins.

Senator Blanche Lincoln from Arkansas.

Senator LINCOLN. Well, thank you, Senator Kohl and Chairman Smith. Thank you both for the incredible work you all do in this Committee. We appreciate so much Co-Chairman Kohl bringing up such a great issue here on generic drugs. It is so vitally important to getting it right in this program of providing the kind of needed prescription needs that our seniors need.

Just a couple of quick comments, if I may, and I do want to compliment my colleague from Maine, Senator Collins. I work with her on many things and am proud to do so, and she does bring up very critical issues for Maine and for those specific residency programs she has. But I would like to also broaden that issue, Dr. McClellan, to simply say she is exactly right; without the physicians out there, there are no prescriptions that are going to be written that will help our seniors get either a brand name or a generic.

A couple of issues that I think we could certainly address there are the physician reimbursements, which we time and time again here have tried to address in terms of the cuts that they are going to see in January 2007. I was doing a seniors meeting in northwest Arkansas and visited with several constituents who said, you know, we have just now hit 65, but we can't find doctors that are taking new Medicare patients. Physicians are waiting to see what it is we are going to do in terms of the priorities and the values we place on this program and the importance of seniors getting that kind of health care and being able to see the medical professionals they need to see.

One of the other things that we have written to you about, or we actually wrote the President about and many of us are concerned about was that the funding for the geriatric education centers was eliminated in the budget. Just bringing it back to 2005 levels would provide the medical professionals, the physicians and others the ability to access training and to get those services out to the seniors particularly in rural areas, but all across the country.

So I hope that we will take a very serious look at the whole package of health care delivery to our seniors, not just, as Senator Collins mentioned, in the major medical areas and teaching hospitals, but also how we get that information out. I know your group saw it firsthand because they traveled across the State of Arkansas

with me last fall as we had those seniors meetings and talked to seniors out there.

Being able to access information over the Internet about what drugs are available in a generic form is just not sufficient; it is not enough. I have way too many seniors that don't access the Internet, don't have a way to access the Internet. So I hope is that we can certainly look at some of these delivery programs that have been successful that are being cut out of the budget that could be very helpful in that education.

I know my colleague from Florida mentioned what one of our constituents in Arkansas is doing. Wal-Mart has piloted a program in Florida, in the Tampa Bay area, making generics available to the insured and the uninsured for a co-pay, which I think is a wonderful start to test and see how it is that we can get delivery and confidence among consumers about generics. I think that is great, so we are looking forward to seeing how that gets expanded.

I would like to also just follow up a meeting we had with you in the Finance Committee about the premium refunds. I know you have been working extra hard with Kentucky. When we were in that meeting, we knew we had some constituent problems; we didn't know how many. I would like to see if I can't get the same kind of attention Kentucky is getting on those premium refunds.

Dr. MCCLELLAN. Absolutely. We will follow up with you.

Senator LINCOLN. We are starting to hear an awful lot about that from our constituency, so we appreciate that.

I guess the last thing I would just like to add is I know you are not representing FDA here today, but I would like to know the steps you are taking at CMS in the encouragement of moving the generics through FDA. There was a front-page story, I guess, on Monday in USA Today talking about some of the issues of FDA, not necessarily with generics, but just getting through those processes and a lot of drugs that have not been approved that are out there on the market and being used.

What are we doing to encourage FDA to step up to the plate and deal with the backlog that they have in terms of generics and really get the process going of making sure that our drug industry is being properly regulated and put out into the marketplace?

Dr. MCCLELLAN. Well, on this last issue I know that the FDA is very concerned about that. When I was there, faster access to generic drugs was an important priority. We were able to increase the budget for the staff that reviewed the generic drug applications, and we also took some steps to help the generic manufacturers get their applications right the first time so you could reduce the time it takes to determine that a generic is equivalent to the brand-name drug and it is just as safe and effective, which is the FDA standard.

Senator LINCOLN. Did they stop doing that when you left?

Dr. MCCLELLAN. Well, I know the agency is very concerned about continuing this priority. I think one thing that they really need, frankly, is confirmation of their commissioner. Andy von Eschenbach is very passionate about these issues of affordable access to innovative medicines, and getting him as a fully confirmed commissioner would definitely help the FDA move on in important——

Senator LINCOLN. He is acting now, correct?

Dr. MCCLELLAN. Right, and as a fully confirmed commissioner it would definitely help him undertake initiatives like that this that I know are very important to him and to the agency.

There are a couple of constraints. One is how good the applications are coming in. If they are not acceptable, if they don't meet the safety standards, they are not going to get approved and it is going to take another round of going back and filling in the additional safety data and evidence that is needed to approve the generic drug.

Second is just the resources that FDA has available to deal with the applications. With tight resources, that is a challenge, and I know that, frankly, additional resources for reviewing the generic drugs could help with that, too.

Senator LINCOLN. So resources is something we should be pushing for. Will you help us do that? It certainly benefits your program.

Dr. MCCLELLAN. It certainly does, and I mean working with the generic industry on getting those applications right the first time is another step that could really help.

Senator LINCOLN. What is the difference between being acting and confirmed? Can't he still do the same job?

Dr. MCCLELLAN. Well, he is still acting in the job, but, you know, speaking as someone who had the privilege of being a confirmed FDA Commissioner, it is just different. I mean, people look to you to lead the agency in new directions and to undertake major new initiatives. When you are acting without the support, the endorsement of the Senate, it is a little bit harder to do that.

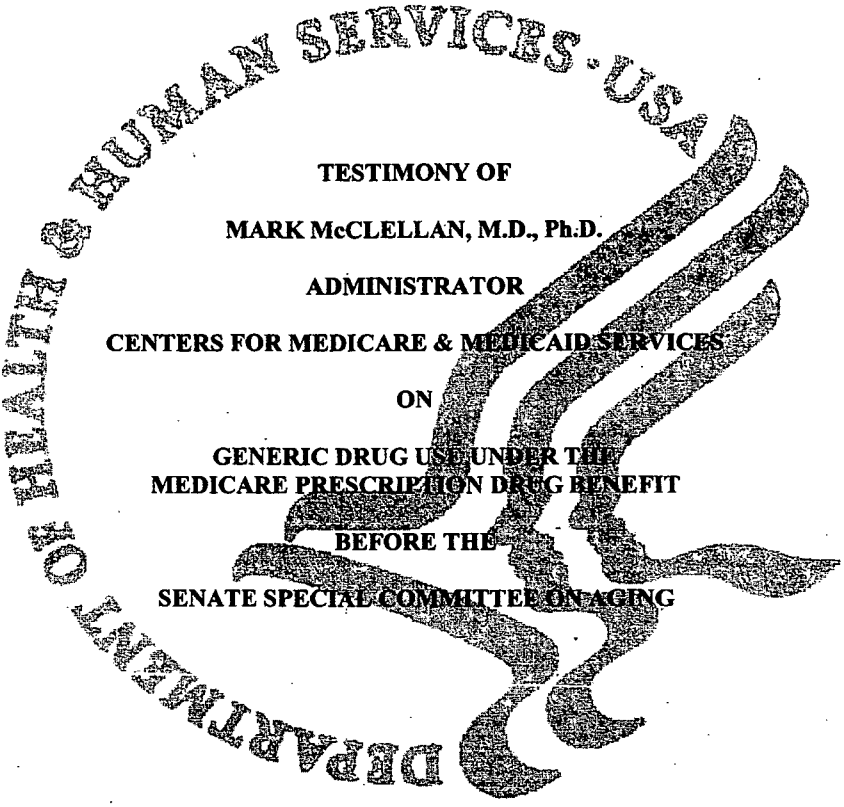
Senator LINCOLN. Thank you.

Senator KOHL. Thank you, Senator Lincoln.

We thank you again, Dr. McClellan. You have been great this morning, you have been wonderful to work with, and we wish you well.

Dr. MCCLELLAN. Thank you so much, Senator.

[The prepared statement of Dr. McClellan follows:]



TESTIMONY OF

MARK McCLELLAN, M.D., Ph.D.

ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

GENERIC DRUG USE UNDER THE MEDICARE PRESCRIPTION DRUG BENEFIT

BEFORE THE

SENATE SPECIAL COMMITTEE ON AGING

September 22, 2006

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Testimony of
Mark B. McClellan, MD, Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Before the Senate Special Committee on Aging
Hearing on Generic Drug Utilization in the Medicare Prescription Drug Benefit
September 21, 2006

Chairman Smith, Senator Kohl, distinguished committee members, thank you for the opportunity to provide you with information on how the new Medicare prescription drug benefit (Part D) is helping to encourage generic drug utilization and lower the cost of prescription drugs for people with Medicare, the Medicare program, and taxpayers. I appreciate your interest in this topic, but more importantly, Members of Congress from both parties have been a key part of this massive grassroots education effort put in place to help Medicare beneficiaries select a plan that best fits their needs. Members of Congress have supported and participated in enrollment events sponsored by CMS and our thousands of partners throughout the country, sent flyers to their constituents, and spoken extensively to the public about the value of this new benefit. With the recent launch of this fall's *My Health. My Medicare.* campaign, I expect that this partnership will continue as we begin to drive greater awareness and use of the enhanced preventive benefits and coverage options for 2007.

Improvements made to the drug benefit in 2007 will continue to help beneficiaries save money, in part by increasing awareness about the value of generic drugs. There are a number of tools available to consumers to help them evaluate their options for the new plan year, including enhancements for the Drug Plan Finder, the *Medicare & You Handbook*, and personalized assistance through our 1-800-Medicare call centers and the State Health Insurance Assistance Programs (SHIP). As we change our focus from that of a payer of health benefits to one that

promotes steps to stay well and reduce health care costs, we will be educating beneficiaries and partners about the preventive benefits offered in Medicare.

The Part D benefit is the most important new coverage to be added to the Medicare program in its more than 40-year history. It is critical to preventing and managing chronic disease, treating illness, preserving quality of life, and delivering modern medical care in the 21st century. Comprehensive prescription drug coverage is also a key element of our ongoing efforts to transform the emphasis in Medicare from simply paying bills when people get sick to paying for high quality, prevention-oriented care that allows people with Medicare to live healthier lives while avoiding preventable healthcare costs.

Thanks to the enactment of the new Medicare prescription drug benefit, tens of millions of Americans are now getting better benefits from Medicare than ever before and at a cost significantly lower cost than originally projected. Strong competition in 2006 and well-informed beneficiary choices have resulted significant savings over what had been previously estimated. Current estimates of the cost of the drug benefit indicate that beneficiaries and the Federal government will be saving tens of billions of dollars more, over the next five years, than had been anticipated just a year ago. Notably, the average Part D premium for 2006, now estimated to be less than $24, is about 35 percent lower than had been projected a year ago. Beneficiaries, the Federal government and the states are all benefiting from lower costs and will continue doing so next year. And even greater savings are ahead in 2007. Based in part on the strong competitive bids for 2007, average premiums will again be around $24 for beneficiaries, and the vast majority of beneficiaries will have access to Medicare drug plans that have lower premiums

than those in 2006. In addition, costs to taxpayers may be even lower in 2007 than 2006 because lower bid amounts mean that the Federal government's costs will be commensurately lower.

The utilization of generic drugs has played an important role in the low costs and expected further cost reductions in the drug benefit. Due in part to increasing generic drug availability, strong competition in the prescription drug marketplace has led to slower rates of growth in overall prescription drug spending. Also, the availability of excellent coverage of generic drugs in the Part D drug benefit, as well as personalized information and support to help beneficiaries find out about how they can save using generics, have been important contributors to costs that are much lower than expected. Continuing to promote greater reliance on generics when available among Medicare beneficiaries is an important strategy to keep the new drug benefit affordable over the long term.

Generics Are Widely Available at Low Cost

With ever-increasing generic drug availability, more and more Americans are seeing the value of generics and using them to help save money on their prescription drug costs. Roughly three-quarters of the drugs currently listed in the Food and Drug Administration's Orange Book currently have generic counterparts. According to the Generic Pharmaceutical Association (GPhA), U.S. generic pharmaceutical sales increased 10 percent between 2003 and 2004 and amounted to $22.3 billion in 2005; the generic share of the pharmaceutical market is expected to grow by roughly 13 percent in 2006. This growing availability of generics is well accounted for in Medicare Part D, with all stand-alone prescription drug plans and Medicare Advantage Prescription Drug plans (MA-PDs) offering comprehensive, low-cost access to generic

pharmaceuticals in 2006. In addition, all Medicare beneficiaries eligible for Medicare Part D had access to at least one prescription drug plan with some coverage in the gap in 2006, including coverage of generics during the gap. And in 2007, even more plans will offer coverage of generics in the gap.

Equally important, and again as a result of strong competition, the cost of generic drugs in the United States is very low and they are relatively widely used. The FDA notes that generic drugs typically cost 50-70 percent less than their brand-name counterparts. Further, prices for generic drugs in the U.S. are much lower than in many other countries. For example, a study by the National Opinion Research Center at the University of Chicago reported that people living in Canada pay 37 percent more for generic drugs than people in the U.S.[1] In addition, generic drugs are more widely used in the U.S. than in other countries, providing further drug cost savings. For example, during 2005, in terms of value, generic drugs accounted for less than 10 percent of the market in Austria, Belgium, Finland, France, Ireland, Italy, Portugal and Spain.[2]

The Medicare prescription drug benefit is reinforcing these trends. Generic drug prices for people with Medicare can be even lower due to the excellent coverage available through Part D. Medicare plans encourage the use of generics with tiered formularies, under which generic drug co-pays are typically far lower than co-pays for brand alternatives. Some Part D plans even offer generics for a $0 copay. As a result of very low prices and information and support for beneficiaries on how they personally can save by using generic versions of their medicines, Medicare Part D has resulted in increased use of generic drugs by Medicare beneficiaries.

[1] Understanding Variations in International Drug Prices. National Opinion Research Center (NORC) at the University of Chicago and Georgetown University. July 2006.
[2] See: http://www.egagenerics.com/doc/PharmaMkts2005.pdf

The benefits of generic drug use by the Medicare population is clear, and generic drug availability for Medicare beneficiaries will be increasing further, leading to additional savings. The GPhA has indicated that "blockbuster" name-brand pharmaceuticals coming off patent are valued at $22 billion in 2006, $27 billion in 2007, and $29 billion in 2008. For example, Zocor, a cholesterol lowering drug and one of the nation's top sellers, just recently came off patent. An anti-depressant, Zoloft, recently came off patent as well. The patent for a high blood pressure medicine, Norvasc, expires next year, and Advair, an asthma fighter, loses its patent protection in 2008. All told, between 2006 and 2009, there will be a significant number of patent expirations, opening the way for cheaper, generic alternatives.

Under the Medicare Part D program, prescription drug plans are able to add to their formularies at any time, making it simple to pass along to beneficiaries and taxpayers the savings offered by new generics as they become available. CMS takes its role as public health educator seriously, and we are committed to helping health care providers and people with Medicare to understand the value of generics.

Generic Utilization on the Rise

As more widely used branded prescription drugs go off patent and more generics become available, we expect to continue to see generic utilization rise. This will help provide additional savings on prescriptions for beneficiaries, as well as for the Medicare program. In fact, early evidence shows that CMS and its partners' efforts to promote generic utilization are paying off. There are early indications Medicare beneficiaries enrolled in Part D are relying on generics to a

greater extent than the U.S. population as a whole. We would expect this utilization trend to continue, as more and more beneficiaries realize the significant savings available by switching to generic drugs.

Nationwide, among all payers, the proportion of generic usage by prescriptions dispensed stands at 51.9 percent. Data recently gathered by CMS show that generic usage among all types of Part D plans was 60.1 percent during the first two quarters of 2006. Notably, Medicare Advantage plans offering drug coverage have achieved an even higher generic utilization rate. We attribute this to their longer experience with providing low-cost drug coverage to the Medicare beneficiaries they serve, and greater experience and ability to help provide well-coordinated, low-cost care for beneficiaries. In addition, many Part D plans are increasing the growth rate of generic utilization at a faster rate than the overall market. One large plan sponsor's generic utilization rate has grown at three times that of the national market.

This is very good news for beneficiaries and for the program. It means that beneficiaries have access to and are using lower-cost alternatives offered by their plans. It also means that our efforts to educate beneficiaries about the cost-saving potential of therapeutic alternatives have been successful and that pharmacists and physicians have the information they need to help beneficiaries make choices about their medications.

The benefit of greater reliance on generics or, in many cases, less expensive brand-name drugs that are equally effective for the same condition and appropriate for the beneficiary is well documented. According to an ongoing CMS analysis of negotiated price discounts available to

illustrative beneficiaries under Medicare Part D, when compared to retail prices, such beneficiaries would see savings of up to 74 percent if they joined one of a broad range of lower-cost Part D plans and then switched to generics.[3] When such beneficiaries, who are taking a brand name drug for which there are cheaper brand name drugs that treat the same condition and are clinically appropriate, switch to those cheaper alternatives, their savings increase to 82 percent for the lowest-cost plan and up to 75 percent for a range of low-cost plans. A number of external reports have comparable findings. For example, Consumers Union found that beneficiaries with common chronic conditions who switch to generic or other therapeutically equivalent medications can save between $2,300 and $5,300 a year.[4] These individual savings can add up to billions of dollars in savings across the beneficiary population as a whole

Similarly, the Pharmaceutical Care Management Association (PCMA) released a study earlier this year indicating that Medicare drug plans offer significant price discounts compared to what beneficiaries would pay without coverage.[5] A recent follow-up PCMA study found that beneficiaries can maximize the already-significant savings noted above by switching to lower-cost medications, such as generics.[6]

Education Helps Beneficiaries Save

Beneficiary and partner education has been an essential component of our strategy to increase the utilization of generic drugs among Medicare beneficiaries, to help them get the most out of their

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[3] CMS Office of Policy, Analysis of Savings Available Under Medicare Prescription Drug Plans, June 20, 2006

[4] "Helping Medicare Beneficiaries Lower Their Out-of-Pocket Costs Under the New Prescription Drug Benefit," Consumer's Union, December 14, 2005. As CMS has noted, beneficiaries should discuss any therapeutic changes with their physician and pharmacist, and the personalized information we provide can help inform those discussions.

[5] "Medicare Drug Discounts Real & Holding Steady", Pharmaceutical Care Management Association, February 7, 2006.

[6] "Potential Beneficiary Savings Associated with Generics & Mail-Service Pharmacies for Five Conditions Chronic to Seniors," Pharmaceutical Care Management Association, September 7, 2006.

prescription drug coverage. The personalized attention that people found so helpful in making decisions about the new drug benefit has become part of routine business for CMS, and we are going to continue to build on it to ensure that beneficiaries have what they need to make informed choices.

Immediately after the MMA was signed into law in 2003, CMS devised a comprehensive strategy for successful implementation of the Part D benefit by its January 1, 2006 effective date. Educating people with Medicare about the design and availability of the new drug benefit, and developing information and resources to assist them in evaluating numerous plan options were and continue to be among CMS' highest priorities.

Beginning in the fall of 2005, CMS launched a major initiative to educate beneficiaries about Part D, putting into place an outreach and education partnership comprised of more than 20,000 local and national organizations. Forty thousand volunteers staffed more than 50,000 Part D enrollment events across the country. Today, more than 38 million Medicare beneficiaries -- over 90 percent of people with Medicare -- have prescription drug coverage either through Part D directly, an employer plan that is supported through Part D, or another equivalent source, and satisfaction rates with the Part D prescription drug plans' coverage are very high – over 80 percent.

Improvements for 2007

CMS has a new and more comprehensive approach to beneficiary outreach called *My Health. My Medicare.*, which exemplifies the transformation of CMS from an entity which simply pays the bills, to one the promotes quality health care, that provides personalized support to help each of

our beneficiaries stay well and lower their health care costs. We have been working to transform our approach at the agency to assisting beneficiaries in achieving this goal over the past few years. As a part of this approach, CMS has developed and enhanced many tools available to provide beneficiaries enrolled in Part D the information they need to achieve maximum savings on their prescription drugs. One of these key tools is the *Medicare & You Handbook* that beneficiaries will receive in October. This year, the Handbook will highlight the preventive services available to people with Medicare, including a wide range of screening services. It has also been revised to enhance information on the benefits of using generic drugs, and to address potential beneficiary concerns about switching from brand name drugs to generics. Additionally, during our outreach events and through our extensive partner network, we are advising beneficiaries that asking their doctor or pharmacist about the generics or lower cost brand name alternatives available for their prescription drug needs can help them delay reaching the coverage gap. This strategy is supported by a recent PCMA study, which found that beneficiaries who use more generic drugs may be able to delay by an average of 74 days or even avoid the coverage gap[7].

In addition to outreach through partners and special events, CMS developed and maintains a comprehensive resource that beneficiaries can use to find lower-cost drugs covered by their plan: the "Drug Plan Finder" available at www.MyMedicare.gov. Beneficiaries can use the Plan Finder to search for lower cost alternatives available under a specific plan. When beneficiaries enter their drug regimen in the Plan Finder, the system defaults to provide them information about lower cost generic drugs when they are available, including personalized information on

[7] Pharmaceutical Care Management Association, "Potential Beneficiary Savings Associated with Generics & Mail-Service Pharmacies For Five Conditions Common to Seniors," September 7, 2006.

the specific additional estimated savings. In addition, the Plan Finder provides a link to a page that highlights the benefits of generic alternatives. Millions of people have already accessed this site to find information on their options and to help make important choices about their drug coverage based on their preferences. Even beneficiaries who choose a plan with no coverage in the gap can use the Plan Finder to access and compare prices negotiated by their plan on both generics and branded drugs.

In an effort to improve our many resources for beneficiaries, we have made enhancements to the Medicare Drug Plan Finder for 2007. In addition to including call center performance, complaint information and other plan performance information, it will be tightly integrated with the updated Medicare Coverage Options tool, making it easy for people to get personalized comparisons of their health plan choices along with their drug plan options. Users will be able to get estimates for their total annual health costs, and month to month estimated costs, incorporating the latest information on discounted drugs.

Plans, Pharmacists and Physicians Help Beneficiaries Save

In a competitive Part D market with proactive consumers who receive the support they need, Medicare drug plans have shown that competition leads to attractive plan options at competitive prices. Promoting generic utilization through education or by offering coverage for generics through the coverage gap helps plans stay competitive and saves beneficiaries and taxpayers money. This increased availability of plans with some coverage in the gap is good news for beneficiaries, who in 2006 overwhelmingly opted for benefit packages offering predictable coverage this year through features such as gap coverage, fixed co-pays and zero deductibles.

Physicians and pharmacists are important partners in helping beneficiaries get the most from their prescription drug coverage, and CMS truly appreciates their leadership in assisting so many beneficiaries to use their coverage effectively. CMS, Part D plans, pharmacists and physicians are all helping beneficiaries achieve even greater cost savings by educating them about lower-cost alternatives and their money saving potential. CMS has worked closely with physicians to ensure they have the tools and knowledge they need to help their Medicare patients. Among these key tools is a feature on www.medicare.gov called the Formulary Finder that allows doctors to link directly to a plan's formulary through the Web. Additionally, it is possible for physicians to use handheld and web based clinical reference tools, to access all Medicare Part D formularies, which are being made available for free. This means that any physicians using this approach will have quick access to formulary information, enabling them to make a decision about the potential of a lower-cost prescription while a beneficiary is in their office.

As an important element of Part D implementation, CMS supported the launch of the Pharmacy Quality Alliance (PQA), in partnership with pharmacy organizations, health plans, employers, consumers and many others. This strong and extensive alliance will focus primarily on developing strategies for defining and measuring pharmacy performance. A key step that PQA has taken is to develop an initial set of metrics to measure quality based on available pharmacy claims data. Included in these metrics is an evaluation of generic efficiency and formulary management. More specifics on the results of these evaluations will be available in the fall, and will help CMS promote best practices in pharmacy care – including generic utilization – for the Medicare population and more broadly.

Looking Ahead

Notwithstanding the many successes and high satisfaction with the Part D benefit in 2006, we are confident that even better things are coming in 2007 as a result of strong competition and enhanced benefit choices. More plans will be offering coverage in the gap, and lower-cost options will be available for most beneficiaries everywhere. Additional enhanced plan options enable beneficiaries to obtain more stable monthly costs throughout the year. And, with the average bids for 2007 almost 10 percent lower than in 2006, Part D will have lower Federal costs , making the program more stable and affordable over time. These cost savings are due in no small part to tough plan negotiation for lower drug prices and effective use of generics that cost much less than the drugs seniors may have used in the past.

Conclusion

Chairman Smith and Senator Kohl, thank you again for inviting me to speak with you today about generic drug utilization and how we can work to continue providing a high quality, low cost prescription drug benefit for Medicare beneficiaries. The drug benefit provides important new coverage for people with Medicare, and generic alternatives serve as an important and safe way to save a lot of money for both beneficiaries and the Medicare program.

CMS is working hard to make sure that everyone with Medicare has the tools and knowledge to make the most of their Medicare coverage. This means receiving high quality benefits at the lowest possible cost. We will continue to work to meet the health needs of beneficiaries by building on the strong partnerships that are helping to make the Medicare prescription drug program a success.

Senator KOHL. On our second panel, the first witness will be Bill Vaughan, who is a senior policy analyst in the Health Sector for Consumers Union. Consumers Union is the non-profit, independent publisher of Consumer Reports. Since 1965, Bill has worked for various members of the House of Representatives on the Ways and Means Committee and has served as director of Government Relations for Families USA. He is here today to describe Consumers Union's national drug project to help consumers and doctors use the most effective, safest and lowest-cost drugs.

The second witness will be Tim Antonelli. Mr. Antonelli serves as Pharmacy Services Clinical program manager at Blue Cross Blue Shield of Michigan. He is responsible for developing programs to encourage efficient prescription drug utilization. He will explain the success of the Blue Cross Blue Shield of Michigan program; the Unadvertised Brand, it is called, which is a program to promote generic drug use.

Our third witness will be Dr. William Shrank. Dr. Shrank is an internal medicine physician at the Brigham and Women's Hospital and an instructor at the Harvard Medical School. His research focuses on improving the efficiency and effectiveness of drug coverage policies. Dr. Shrank will discuss physician prescribing behaviors and a project that he is working on with the State of Pennsylvania to educate physicians on low-cost drug alternatives, including generic drugs.

We thank you, gentlemen, for being here. Mr. Vaughan, we will take your testimony.

STATEMENT OF WILLIAM VAUGHAN, SENIOR POLICY ANALYST, CONSUMERS UNION, WASHINGTON, DC

Mr. VAUGHAN. Thank you all very much for inviting us to testify. Consumers Union do publish Consumer Reports, and we don't just test cars and toasters; we try to help people with better drugs and with good health insurance policies. I would like to take just a second and say we at Consumers Union's Washington office strongly second your very kind comments about Dr. McClellan's very excellent public service.

We strongly encourage the use of generics as a way for consumers to save money, while obtaining quality health care. We also try to help consumers use the most effective drugs through our Best Buy Drugs program, a free service to everyone. I have attached in the testimony several examples of these projects by class of drugs. Basically what it comes down to is, don't believe all the hype you hear in the TV ads. There is a lot more to what is a good drug than what you see on television.

Briefly, we take the scientific work that the Chairman mentioned, the work of the Oregon Health and Science University's Drug Effectiveness Review Project, DERP, and translate their very technical reports into plain English. Then we match the findings of drug safety and effectiveness with recent average prices for the various drugs to come up with recommended best buy drugs. This is not cookbook medicine. We really stress you have got to talk to your doctor, one-by-one. But this best buy drugs list is a starting point to have the discussion. We clearly recognize that different people may need different drugs, and that is why we strongly sup-

port effective exceptions and appeals processes in private insurance and public insurance programs.

But where safety and effectiveness is similar, usually the best buy drug is a generic. As you see, Dr. McClellan often cites the studies we have done. I would just say they also apply to folks under age 65. But if a senior switched from brands to generics, they could save so much that in many cases they would not fall into the donut hole.

In my testimony there is an attached press release. We have done these in December and in March and just yesterday, showing that on five drugs that a senior often uses, switching to a generic you could save somewhere between $2,300 and over $5,000. I might say we are also doing some of the academic detailing work that Dr. Shrank will describe in his testimony.

But having said all that, I want to make it clear we would like to see the donut hole eliminated. But until such legislation is enacted, using the free tools of the Best Buy Drug program can help many seniors safely and effectively avoid the gap.

We hope Congress can do more to help consumers and doctors increase the use of generics.

As for this autumn, there is great news today that CMS will make Part D plan specific generic dispense rates public so that enrollees can pick the plans that are really good for the pocketbook. We all need to publicize that list. I suspect that that decision was speeded up by the scheduling of this hearing, so congratulations to you all.

Second, this fall when Congress deals with the physician payment problem or considers pay for performance, we hope you could put in as one of the performance items how much a doctor cares about finding the generic drug to help his patients so they can actually fill the prescription and take it.

In the 110th Congress, we hope that Congress will do more to promote generics in the FDA. As Senator Lincoln has mentioned clearly next year there has to be major FDA legislation that will involve, we hope, increased resources to that agency that could end this huge backlog they have in generics. As Senator Kohl said, that legislation could begin to get us to deal with the biogeneric issue that the Europeans are dealing with—we are just not dealing with it and close the loopholes, the bill that you are sponsoring, sir, S. 2306, that lets the PhRMA big drug companies delay the entry of generics into the market.

We also hope that people might take a look at all the drugs out there and say, gee, could some of these move to over-the-counter, where they would be a lot cheaper, if they are safe. Claritin moved a few years ago and the price came way down. I am not sure what the difference is with, say, Allegra. It would be a good review.

As for the long run, someone has said that the whole Medicare prescription drug debate is silly. The real debate should be why the cost of drugs is so high. We believe that the high cost of drugs could be moderated by better funding and aggressive use of the MMA's. Section 1013 where the AHRQ agency does comparative studies on what works and doesn't work, and we need to quit paying for things that don't work well.

We also hope that you might consider a hearing on whether there are more effective ways than patent monopoly and high consumer prices to encourage the research on really breakthrough, life-saving drugs. For example, there is the prize idea that is out there, or using Medicare's buying power—I describe this in our statement—to encourage research.

Thank you very much for your time. I would like permission to enter the full statement in the record, if I may. Thank you, sir.

[The prepared statement of Mr. Vaughan follows:]

Senate Special Committee on Aging
Hearing on Generic Drugs
September 21, 2006

Testimony of
William Vaughan, Senior Policy Analyst
Consumers Union, independent non-profit publisher of Consumer Reports

Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify today. Consumers Union is the independent non-profit publisher of Consumer Reports, and does extensive work on health insurance and costs, quality, and prescription drug issues.[1]

We strongly encourage the use of generics as a way for consumers to save money while obtaining quality health care. We have made a major organizational commitment to educating consumers better about generics and helping consumers obtain reliable, easy-to-understand advice about the safest, most effective, and lowest cost prescription drugs available.

For the past three years, Consumers Union/Consumer Reports has been developing its CRBestBuyDrugs.org program, a public information project and free service to everyone. I've attached several sample BestBuyDrug reports. We currently have provided information for 15 different classes of medicine, and will expand that to 20 in the near future. As you can see, it is useful information for all age groups, but especially for seniors who take more prescriptions.

The goals of our project are to:

--improve the quality of care by ensuring people get the safest, effective drugs with the least side effects;

--improve access by helping consumers choose drugs that are most affordable (taking into account effectiveness, side effects, safety, and price); and

--help consumers and taxpayers by reducing the long-range cost burdens of

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of Consumer Reports and ConsumerReports.org, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports and ConsumerReports.org, with approximately 6.5 million combined paid circulation, regularly carry articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

health insurance, Medicare, and Medicaid.

Briefly, we take the objective, unbiased, scientific, publicly-transparent work of the Oregon Health and Science University's Drug Effectiveness Review Project (DERP) and translate their technical reports into plain English. (Mr. Chairman, July 20, 2005 you had an excellent hearing with one of the leaders of that Oregon project that is still the best explanation of the DERP process that I know of.) We then match their findings of safety and effectiveness with recent average prices for the various drugs and come up with recommended Best Buy Drugs. Outside experts (doctors and pharmacists) peer review each of our reports. We update the reports as new science becomes available and prices change.

The Best Buy recommendations are the drugs in a class that would probably be the safest[2] and most effective at the lowest cost generally for most consumers. But we stress in all our publications that you should consult with your doctor on a case by case basis. This is not cookbook medicine. It is guidance on a conversation-starting place for consumers, doctors, and pharmacists, based on the best science and evidence currently available. While our Best Buy recommendations work for most people, we clearly recognize that different people may on occasion need different drugs that are not Best Buys—and this is particularly true in the mental health sector where many of the drugs do not work consistently well or without serious side effects. That is why Consumers Union has fought for decades to ensure that all HMOs, insurance plans, and Medicare and Medicaid should have effective exceptions and appeals processes. Effective, easy-to-use exceptions policies are a policy priority for Consumers Union.

Sometimes the recommended Best Buy is a brand name drug (like Lipitor as you can see on our Statin enclosure where Lipitor is important for those with certain conditions). Sometimes the Best Buy drug is a much cheaper generic or over-the-counter (as you can see in our comparison of Nexium versus the OTC Prilosec in the Proton Pump Inhibitor pamphlet, where the overwhelming number of people could save about $150 by switching to the OTC). In certain cases, e.g., drugs to treat overactive bladder, we passed over the most effective and lowest cost drug due to concerns about side effects. Usually Best Buy Drugs are the lowest cost drugs, but not always.

But obviously, in cases where safety and effectiveness issues are very similar, the Best Buy drug is usually a generic. CMS Administrator McClellan has frequently cited some studies we've done on how, if a senior in consultation with their doctor and pharmacist switched from brand drugs to generics, they could save so much they would not fall into the Part D doughnut. I've attached a press release describing one of our studies in this area. (I note again, the savings can apply to all age brackets, not just seniors.) In this example of 5 drugs that a real senior might easily be taking, they can save $2300 to $5000 by switching to generics that are just as safe and effective as the brand drugs.

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[2] It is interesting to note that among the 15 States that use DERP as an aid to the development of their Medicaid preferred drug lists (PDLs), almost all of them avoided the costly mistake of including Vioxx on their PDLs, thus savings thousands of lives and millions of dollars in medical expenses.

The doughnut hole is tremendously controversial and we would like to see it eliminated. But until legislation is enacted, using the free tools of the Best Buy Drug program can help many seniors and people with disabilities safely and effectively avoid the gap in coverage.

Congress needs to do more to make safe generics available

While consumers can do a lot to save money on prescription drugs, most seniors still are not Internet users and are not comfortable with the latest shopping tools. Our nation's level of health literacy is abysmal, and it is hard to get the generic 'word' to people. Even many physicians are suspicious of generics or cannot be bothered with them—a problem that hopefully e-prescribing can help erase. Therefore, we hope Congress can do more to help consumers and doctors have increased understanding and access to generics.

This autumn

We urge you to take a number of steps this fall to promote generics.

First, we hope you will urge CMS to make Part D plans' generic dispense rate (data that is **already** being reported to CMS each quarter) **public** so that enrollees—and groups like Consumer Reports that could rate plans--can see which plans have been best at generally helping people find the better deals while also saving dollars for Medicare.

Second, when the Congress deals with Medicare Part B physician payment problems and/or begins to legislate Pay for Performance (P4P), please include as one performance goal the generic dispense rate. While this is not commonly considered a quality issue, we believe making drugs affordable so people actually can buy them and take them is a quality issue. Once e-prescribing is in place, this will be easy to encourage and monitor electronically, and we urge that the groundwork for this consumer service be laid as soon as possible. In general, we hope some prescribing information and best practices will be part of P4P. As just one example, in early January, the FDA issued a press release to consumers, saying that when you see your doctor for a head cold, don't accept a prescription for an antibiotic, because it doesn't work! Why should it be the patient's job, when they are seeing someone they trust and feeling utterly miserable, to resist a doctor's offer of a shot? A good P4P system would not pay for anti-biotics that accompany visits coded for the common head cold.

Also, while we have no reports of problems, it might be a useful oversight function to ask how well the MMA provision 1860D-10(k) is working. This is the provision that requires a PDP to make sure its pharmacy network tells a patient when there is a lower cost generic available under the plan.

In the 110th Congress

We strongly hope that Congress will do more to promote generics, either in the FDA budget or as part of the Prescription Drug User Fee Act #IV (PDUFA) or in the key Chairman Enzi-Senator Kennedy reform bill (S. 3807). Because PDUFA expires September 30, 2007, it is almost certain that there will be major FDA legislation in the 110th. This will be a golden opportunity to:

--institutionalize a system that prevents backlogs in generic approvals from developing;

--ensure that the FDA starts to deal with the backlog of biogeneric approvals (as the Europeans are already doing) and that they continue to resist industry efforts to make biogenerics more difficult to substitute because of name changes; Attached is our previous letter to the Committee on this subject.

--close loopholes in the law that continue to allow brand companies to delay and subvert generic competition. For example, there is the legislation by Senators Stabenow and Lott and Ranking Member Kohl (S.2300) that we hope will be adopted. Among other things, this bill would stop petition-delaying abuses, make sure pediatric exclusivity is only granted for drugs that might actually ever be used by a child, and allow the FDA to override dilatory tactics. Almost daily there are news reports about legalistic abuse of the generic approval process. It seems like some companies are still putting more creative energy into their legal departments to delay generics than they are their drug research departments, and this whole area needs to be tightened up.

--systemize the review of drugs that could be safely moved from prescription status (and the accompanying cost of a doctor's visit) to cheaper, over-the-counter status. For example, if Claritin is okay OTC, why not Allegra (if there are no safety concerns)?

If you revisit the Medicaid program, either as part of the budget process or in reviewing the work of the Leavitt Commission, we hope you can do more to encourage all States to consult with the Oregon Health and Science University's Drug Effectiveness Review Project in the development of their Preferred Drug Lists (PDLs). Currently, 15 States consult the DERP work in establishing their PDLs. All should. It makes no sense for individual states to try to replicate the tremendous work of DERP. We believe that by using the evidence from the DERP work, more States will have better PDLs, ensuring that Medicaid beneficiaries get the best, safest value for the dollar.

In the long run

Someone has said that the 'the whole Medicare prescription drug debate is silly; the real debate should be why the cost of drugs is so high.'

In the long run, we believe that the high cost of drugs could be moderated by better funding and aggressive use of the MMA's Section 1013. This section provides for AHRQ research on outcomes of health care items and services—and would let us pay for those things that work the best. For example, there are many classes of drugs to treat heart disease and high blood pressure, and we spend a lot of time debating the merits of drugs within each class. But which class is best in which circumstances? Today, we look at all drugs and devices like people look at the children of Lake Wobegon—and say they are all above average. But of course, in reality some are not above average, and we need to identify what works best, when, and for whom. Another way to help this process is to encourage FDA and CMS's cooperation and coordination in CMS's Coverage with Evidence Development (CED) initiatives.

The brand and bio industries resist generics because they end the period of monopoly patent profits. The industries say that promoting generics makes it harder to finance research on breakthrough drugs that will cure mankind's most dreaded diseases. But are there better ways to encourage breakthrough research? We hope you will consider a hearing on innovative ideas that do not rely on patent monopolies/high consumer prices to provide the dollars for truly breakthrough research. While Consumers Union has no position on the following ideas, they are the kind of proposals that could be explored and developed in Congressional hearings. For example,

--some have proposed a prize or rewards system to encourage breakthrough (not me-too) research on key sectors, such as the prevention or cure of Alzheimer's disease. Clearly, it would be worth tens of billions of dollars upfront to Medicare/Medicaid and the public to find a cure for Alzheimer's disease that was also affordable.

--why not use Medicare's buying power to control costs while promoting innovation? One could set up a system where future growth of Part D would be budgeted to grow with population growth, GDP, etc. But if costs exceeded the budgeted amount (perhaps due to relentless direct-to-consumer advertising) companies with products covered by Medicare would owe a rebate to Medicare of the budget overrun amount, but on old product only. If a company had a product certified by the FDA as a new molecular entity or life-saving breakthrough, they would be exempt from the rebate for a number of years. Drug companies would quickly know that the way to grow would be to concentrate on breakthrough products (not just me-toos).

Thank you for your time and your continuing excellent work on these key consumer issues.

Consumer Reports
BEST BUY DRUGS
www.CRBestBuyDrugs.org

Consumers Union
NONPROFIT
PUBLISHER OF
CONSUMER REPORTS

FOR IMMEDIATE RELEASE
Thursday, March 2, 2006

Contact: Susan Herold, CU, 202-462-6262

Many Medicare Beneficiaries Could Cover Premiums by Switching to Cost-Effective Drugs; Taxpayers Also Could Save

***Best Buy Drugs* identifies affordable medicines; Alzheimer's meds latest category**

(Washington, D.C.) – Many seniors could save enough money to cover the cost of their Medicare drug benefit premiums if they consider switching to equally effective, lower-cost medicines identified by *Consumer Reports Best Buy Drugs*, according to the latest analysis by Consumers Union.

The report – released today at a symposium on using scientific evidence to identify effective and affordable drugs for consumers – also found that Medicare beneficiaries who take five common drugs could save between $2,300 and $5,000 a year by switching to lower-cost alternatives. Those savings could prevent seniors from falling into the 'doughnut hole' coverage gap, which requires beneficiaries to pay for drugs out-of-pocket once their total drug costs reach $2,250. The report looked at Medicare drug coverage in six markets throughout the country.

"Some seniors may not be signing up for Medicare drug coverage because they are uncertain about saving money," said Gail Shearer, director of the *Consumer Reports Best Buy Drugs* program. "It's important seniors know that they can significantly stretch their prescription drug dollars under Medicare if they first consider cost-effective medicines."

Those savings also translate to taxpayers. For example, if all Medicare beneficiaries taking statin drugs to lower cholesterol switched to generics, the savings to taxpayers and consumers could be about $8 billion a year starting in 2007, or up to 10 percent of the Medicare drug plan's estimated overall expenditures over the next decade.

"There are real savings for both patients and taxpayers if medicines are prescribed based on their effectiveness and track record, not on advertising campaigns and marketing," Shearer said.

Consumer Reports Best Buy Drugs is a free, public education project that uses the available scientific evidence to identify effective and affordable medications. It was created in part to counter pharmaceutical industry marketing that promotes the newest – but not necessarily most effective – drugs. It identifies Best Buys to help consumers consult with their doctors about lowering their drug costs. Drug reports, as well as the Medicare drug analysis, can be found at www.CRBestBuyDrugs.org.

Twelve drug categories have been analyzed to date, including medicines to treat high cholesterol, arthritis pain, menopause, and migraines. The latest report on Alzheimer's medications, released today, identifies three *Best Buys* based on evidence of their effectiveness, side effects, tolerability, flexibility of use, and cost.

The Alzheimer's disease *Best Buy Drugs* are:

- *Donepezil (Aricept) and Galantamine (Razadyne) – for people with early-stage Alzheimer's disease*

- *Memantine (Namenda) – for people with middle-stage and late-stage Alzheimer's disease*

The new analysis found that medicines used to slow mental decline in people with Alzheimer's disease are not particularly effective. When compared to a placebo, only 10 percent to 20 percent more people taking an Alzheimer's drug seem to benefit. And it is the rare person who has a significant delay in the worsening of their symptoms over time.

The report concludes there is no way as yet to predict who will respond and who will get little or no benefit from one of the five drugs approved to treat Alzheimer's disease. Thus, the decision to try one is a judgment based on whether the treatment is worth the cost and the risk of side effects. Alzheimer's disease drugs cost an average $148 to $195 a month.

The Medicare savings analysis looked at five commonly used categories of medicines – those to treat high cholesterol, high blood pressure, post-heart attack care, arthritis pain, and depression. Those switching to *Best Buys* for these drugs could save from $2,300 to $5,000 a year, depending on what Medicare drug plan they buy and where they live. The report looked at plans in Arizona, California, Georgia, Maryland, Minnesota and Pennsylvania.

Even if a Medicare beneficiary enrolled in a drug program switched just one higher-priced medication to a *Best Buy*, the savings could equal $350 to $800 a year, enough to cover the cost of the premium in most cases.

Consumers Union sponsored a day-long event Thursday in Washington D.C., on using evidence-based medicine to help consumers, Medicare beneficiaries and others identify effective, affordable medications. A morning news conference was also to be attended by Dr. Mark McClellan, administrator of the Centers for Medicare/Medicaid Services.

An afternoon symposium, which is to include Sen. Hillary Clinton, Dr. Michael McGinnis of the Institute of Medicine and Dr. C. Bernie Good of the Department of Veterans Affairs and others, can be viewed after 5 p.m EST at
http://www.kaisernetwork.org/healthcast/consumersunion/02mar06

Consumer Reports Best Buy Drugs is a grant-funded public information project administered by Consumers Union. The reports are based on an independent, scientific review of available medical evidence by the Drug Effectiveness Review Project, a 15-state initiative based at the Oregon Health & Science University. The initiative compares drugs on effectiveness and safety for state Medicaid programs. *Consumer Reports Best Buy Drugs* combines those reviews with available medical and pricing information to identify *Best Buys* in each category.

Consumer Reports Best Buy Drugs is designed to help patients – in consultation with their doctors – find effective, safe, and affordable medicines. The project is supported by the Engelberg Foundation, a private philanthropy, and the National Library of Medicine of the National Institutes of Health.

July 19, 2006

The Honorable Gordon Smith
Chairman, Committee on Aging
United States Senate
Washington, DC 20510

Dear Chairman Smith:

As the Senate Committee on Aging studies the issue of generic drugs, Consumers Union, the independent, non-profit publisher of *Consumer Reports*, hopes you will consider the topic of generic biologics, otherwise known as biogenerics or follow-on protein products. In particular, we urge you to guide the FDA to promptly establish a pathway for the approval of safe biogenerics.

As the last twenty-five years have shown, biologics are amazing drugs. These medicines, which are molecules derived from living organisms and not just chemicals, provide treatments for conditions ranging from growth abnormalities to cancer. They are revolutionary and their contribution to medicine will only continue to increase.

Nevertheless, the financial burden that biologics pose to the American consumer and the federal government through its Medicare Part D prescription drug benefit and the Medicaid program cannot be underestimated. Biologics routinely cost upwards of $10,000 for a year's treatment.[3] Less common treatments, such as Avastin, a colon cancer therapy, cost as much as $49,000 for a ten month course.[4] These financial costs may be moderated, though, through biogenerics. With an estimated $10 billion worth of these drugs coming off patent by 2011, there is a great opportunity to use generics to reduce the cost of biologics for the consumer and the government.[5]

Much of the delay on biogenerics is attributed to safety concerns. Given their highly specific allergic profiles, biologics pose a greater danger for adverse reactions in patients than do standard chemical drugs. These concerns can be addressed if biogenerics are subject to extensive non-clinical and limited clinical trials. Indeed, such an approach has been adopted in Europe, where, just this year, the European Medicines' agency (EMEA) released comprehensive guidelines for the approval and regulation of biogenerics. The European approach has been simple. First, they released a general, overarching guideline that specifies the kinds of non-clinical and clinical trials that all protein products would

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[3] Statement of Senator Orrin Hatch on June 23, 2004. Hearing entitled, "The Law of Biologic Medicine."
[4] "The Growth of Generic Drugs." 31 Jan. 2006. *Red Herring*. 5 July 2006. < http://www.redherring.com/.>
[5] "FDA Looks at Biogeneric Issue, but Action Unlikely in Near Term." 10 Nov. 2004. *Specialty Pharmacy News*. 10 July 2006. <http://www.aishealth.com/DrugCosts/specialty/SPNFDABiogeneric.html.>

need to undergo to demonstrate efficacy and safety.[6] Second, they have been progressively releasing additional product-specific amendments that give detailed criteria for testing and approval. For example, in February of this year, the agency adopted an annex guideline on human growth hormone[7] and a month later, one on epoetin.[8] The agency plans to release additional guidelines about other classes of drugs.

In contrast, no abbreviated biogenerics' approval pathway has been put in place in the United States. While the FDA has conceded that the simple biologics regulated under the Federal Food, Drug, and Cosmetic act (FDCA), such as growth hormone and epoetin, can be approved, it has offered no guidance about how generic versions of such drugs should be manufactured and tested. Additionally, the agency has argued that it has no legal authority to create a similar pathway for the majority of biologic drugs, which are regulated under the Public Health Service (PHS) Act. As the FDA will not act on the topic of biogenerics without Congressional guidance, it is imperative that Congress provide direction on this issue.[9]

Consumers Union is deeply committed to protecting the consumers' health, well-being, and finances. The European Medicines' Agency's example offers compelling evidence that safe, cost-saving biogenerics can be made. We hope that you and the Committee on Aging will take timely action and prompt the FDA to establish a timeline for releasing guidelines for the approval and regulation of biogenerics.

Thank you for your consideration of this point.

Sincerely,

William Vaughan
Senior Policy Analyst

Anuradha Phadke
Staff Assistant

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[6] EMEA/CHMP/42832/05 Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins As Active Substances: Non-clinical and Clinical Issues. (CHMP adopted February 2006).
[7] EMEA/CHMP/94528/05 Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guidance on Similar Medicinal Products containing Somatropin (CHMP adopted February 2006).
[8] EMEA/CHMP/94526/05 Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guidance on Similar Medicinal Products containing Recombinant Erythropoietins (CHMP adopted March 2006).
[9] "Omnitrope (somatropin [rDNA origin]): Questions and Answers." 30 May 2006. *US Food and Drug Administration*. 6 July 2006. <http://www.fda.gov/cder/drug/infopage/somatropin/qa.htm.>

Senator KOHL. Thank you, Mr. Vaughan.
Mr. Antonelli.

STATEMENT OF TIMOTHY ANTONELLI, R.Ph., CLINICAL PROGRAM MANAGER, BLUE CROSS BLUE SHIELD OF MICHIGAN, SOUTHFIELD, MI

Mr. ANTONELLI. Good morning, Chairman Smith, Ranking Member Kohl, members of the Committee. I am Tim Antonelli, a pharmacist and clinical program manager at Blue Cross Blue Shield of Michigan. We are a non-profit health care corporation that provides or administers pharmacy benefits to more than 2.7 million members, including 183,000 Medicare Part D beneficiaries. I am pleased to be here to share our efforts to educate our members, professional providers and the public about the safety, effectiveness and value of generic drugs.

Generic drugs provide considerable value to consumers, especially those over age 65 who have the highest average per capita prescription use compared to all other age groups. In 2001, we began the Unadvertised Brand Campaign, a comprehensive effort to provide useful, authoritative information on generic drugs and to encourage their use. Since that time, our members' use of generic prescriptions has increased from 37.7 percent of total prescriptions to over 52 percent.

Of course, we do recognize that various market forces, including access to first-time generics, are important pieces of the puzzle here. Nonetheless, what we have learned through our experience is that it takes concerted, ongoing efforts to provide practical information and to ensure that effective incentives are in place to promote the use of generic drugs when appropriate.

Today, our campaign continues to evolve and to date has included a pharmacy competition, a consumer awareness campaign, a health care professional conference, a website dedicated just to generic drugs, a shift in benefit design and a move to value partnerships with physicians, all of which I will talk about briefly in the next few minutes.

In the fourth quarter of 2001, we launched our campaign with a pharmacy competition. It was designed to enlist pharmacists as contacts to educate consumers about generics and increase their use. As a result, we saw the first uptick in generic use in 4 years. Following our competition, we launched a $1 million, five-part series of consumer awareness ads. The ads appeared in many Michigan newspapers and business journals, and helped to promote generics as safe, effective, low-cost alternatives to expensive brand-name drugs. We then used our brand marketing survey to measure the impact and found that after the advertising, 6 percent more respondents agreed that generic drugs produced the same effects as their brand-name counterparts.

Also, in response to our marketing efforts, we garnered early interest from many within the managed care industry which resulted in our hosting a full-day generic drug marketing conference for health care professionals. This conference was attended by more than 100 representatives of 50 different organizations, including representatives from the U.S. Department of Defense.

We also created a consumer generic drug website, *www.theunadvertisedbrand.com*, which provides consumers with generic drug facts, cost comparisons, and more. As well, because member cost-sharing can play such a vital role in engaging members in the choice between brand and generic medications, there has also been a shift in benefit design offerings from flat co-payment designs into benefit offerings that encourage the use of generics, such as dual-tier, triple-tier and percentage co-payment options. Our Medicare Part D program is included in this segment of tiered benefits and currently has a generic dispensing rate around 60 percent.

In addition, we also work closely with 4,500 Michigan physicians through our Value Partnerships program. This program focuses on generic drug opportunities, as well as a wide range of health care quality, safety and cost initiatives, and rewards performance and best practices. Through the efforts of these physicians, in 2005 alone they have helped save $7 million through increased generic use.

Last, in addition to all the efforts previously mentioned, we also continue to explore and use new opportunities to encourage generic use with co-pay waiver programs, e-prescribing initiatives and other clinical programs.

In summary, we have found that it takes concerted, ongoing efforts to educate and create incentives that encourage generic drug use and we remain committed to this effort because generic drugs provide considerable value to consumers, especially those over age 65. Furthermore, we applaud Congress for its continuing efforts to address issues affecting timely availability of generic drugs. Chief among those efforts is ensuring adequate FDA funding and addressing loopholes in the law that can delay the entry of generic drugs into the market.

We are pleased to have had the opportunity to testify here today and I would be happy to answer any questions for the Committee.

[The prepared statement of Mr. Antonelli follows:]

Statement of

Timothy Antonelli, R.Ph.

Clinical Program Manager
Blue Cross Blue Shield of Michigan

Before the

UNITED STATES SENATE

SPECIAL COMMITTEE ON AGING

Washington, D.C.

September 21, 2006

Good Morning Chairman Smith, Ranking Member Kohl and members of the Senate Special Committee on Aging.

I am Timothy Antonelli, a registered pharmacist and clinical program manager at Blue Cross Blue Shield of Michigan. BCBSM is a nonprofit corporation that provides or administers prescription drug benefits to more than 2.7 million members, including 183,000 Medicare Part D beneficiaries.

I am pleased to be here today to discuss our efforts to educate BCBSM members, professional providers and the public about the safety, effectiveness and value of generic drugs. Generic drugs provide considerable value to consumers, especially those over age 65. Americans over age 65 have the highest average per-capita prescription use: 26.5 prescriptions per year, compared to those under 65, who use an average of 10.5 prescriptions per year.[1] Today, the average cost of a brand-name prescription is $96.01, while the average generic prescription cost is $28.74. Tapping this savings potential for consumers deserves our best efforts.

In fourth quarter 2001, BCBSM began "The Unadvertised Brand Campaign," a comprehensive effort to provide useful, authoritative information on generic drugs and encourage their use. As a result, for the first time in four years, we saw an up-tick in generic use. Since that time, our members' use of generic prescriptions has increased from 37.7 percent of total prescriptions to more than 52 percent. As a result of this increase over the past five years, we estimate that BCBSM members have saved more than $45 million in out-of-pocket costs, due to lower co-payments. Of course, continued access to generics, and timely availability of new generic drugs, are equally important pieces of the puzzle as well.

To the point, it takes concerted, ongoing efforts to provide practical information and ensure that effective incentives are in place to promote the use of generics, when appropriate. And, as I stated earlier, timely availability of new generic drugs is also vitally important ... and the potential upside is huge. Since 2001, our members have increased their generic drug use more than 14 percent, on average, and saved themselves – and other stakeholders – more than $345 million in prescription drug benefit payments. Furthermore, the fact that more than half of our members' prescriptions are now filled with generics translates into even higher total savings.

The findings of our 2001 brand marketing survey, and others cited in independently published reports at that time, agreed that only between 40 and 60 percent of consumers then had a favorable view of generic drugs, or believed that generic medications produce the same positive effects as their brand-name counterparts.[2,3] We also found that some physicians had concerns about the safety and effectiveness of generic medications at that time.

Educating the public about the safety, effectiveness and value of generic drugs provides significant opportunities to help moderate the cost burden on the health care system in Michigan and far beyond our borders. The easiest to achieve are opportunities for collaboration among organizations with common interests. This is why BCBSM freely shares information and materials with anyone interested in encouraging the public to use generic medications, even if they replace references to BCBSM with their own branding. Today, The Unadvertised Brand Campaign continues to evolve and each of its many components work together to educate the public and encourage them to use generic medications whenever possible.

To date, "The Unadvertised Brand Campaign" has included:

- Pharmacy Competition
- Consumer Awareness Campaign
- Benefit Design Selection
- Generic Drug Web Site
- Health Care Professional Conference
- Physician Value Partnerships

Pharmacy Competition

The Unadvertised Brand Campaign was launched with a fourth quarter 2001 contest designed to enlist pharmacists as vital contacts with customers and increase their generic dispensing rates. The lively competition provided an effective springboard for the campaign. To help ensure participants' enthusiasm, first prize was a high-profile featured role in a $1 million BCBSM media campaign. Overall, 50 percent (1,100) of our Michigan pharmacies participated, and BCBSM's generic dispensing rate for retail pharmacies increased 0.9 percent, resulting in an extrapolated annual savings of about $13 million. Today, a similar result would deliver roughly $30 million in savings.

Consumer Awareness Campaign

In the spring of 2002, BCBSM launched a $1 million five-part series of consumer awareness advertisements designed to dispel myths about generic prescription drugs. The ads appeared in many Michigan newspapers and business journals and helped promote generics as safe, effective, low-cost alternatives to expensive brand-name drugs.

To command the public's attention, four of the full-page ads challenged consumers with the headline, "Want the truth about generic drugs?" Each ad provided answers to the challenge. Authorities cited in the ads included the FDA and representatives of pharmacies that were among Michigan's top performers in improving their generic dispensing rates.

BCBSM also invested in simple, to-the-point, billboard ads strategically placed around the state, then used a brand marketing survey to measure their impact. Here's a summary of our findings:

- In August 2001, before our campaign began, 58 percent of the roughly 1,000 Michigan residents who participated agreed, or strongly agreed, that "FDA-approved unadvertised drugs produce the same effects as nationally advertised brand drugs."
- Our July 2002 survey, conducted at the conclusion of the campaign, confirmed that the percentage of participants who agreed or strongly agreed had jumped to 64 percent.

Health Care Professional Conference

In September 2002, having garnered early interest and favorable responses from many within the managed care industry, BCBSM hosted a full-day generic drug marketing strategy conference that was attended by more than 100 representatives of 50 companies and professional organizations, as well as representatives from the U.S. Department of Defense.

Since that conference, we have distributed more than 200 kits containing tips and inspiration on "How to Promote Generic Drugs: The Unadvertised Brand." As a result, the number of health plans introducing generic drug marketing and communications initiatives continues to grow, firmly establishing BCBSM's campaign as a national model for generic medication advocacy efforts.

Generic Drug Web site

BCBSM also created a consumer Web site: www.theunadvertisedbrand.com, which provides consumers:

- **A cost and quality calculator** – Users can enter the names of the 100 most-used brand-name drugs that have generic counterparts and compare the costs.
- **Generic drug facts** – These provide information about the FDA's strict generic drug approval standards.
- **A generics pledge card** – Visitors can download and present the cards to their physicians as a reminder that they prefer generics whenever appropriate.
- **"Top 25" pricing chart** - This pocket-size chart has become the most-sought-after tool of our generic drug campaign. Small wonder; this handy resource lists the 25 most-used brand-name prescription drugs that have generic equivalents, along with their respective prices ... and the savings for each. This one resource alone has triggered articles about the savings potential of generic drugs in prominent newspapers across the country, including *The Washington Post*. The card is available on the Unadvertised Brand Web site (www.theunadvertisedbrand.com/pdfs/top25drugs.pdf) and is updated quarterly.

With BCBSM's permission, 13 other insurers have copied our special generic drug Web site. And to date, more than a million pages have been viewed, with the Cost Calculator feature being the most popular by far.

Benefit Design Selection

Back in 2001, our drug benefit programs typically had flat co-payment designs. Because member cost-sharing can play such a vital role in engaging members in the choice between brand-name and generic medications, there has been a shift away from these flat copayment designs into benefit offerings that encourage use of generic medications: dual-tier, triple-tier and percentage copayment options. Our Medicare Part D program is included in this segment of tiered benefits and currently has a generic dispensing rate around 60 percent.

Physician Value Partnerships

In 2000, BCBSM began offering physicians incentives to reduce overall prescription drug costs. During the initial phase of the effort, BCBSM worked directly with six physician groups, representing a total of approximately 1,000 Michigan primary care physicians. The initiative provided detailed prescribing information and highlighted potential opportunities to prescribe cost-effective generic alternatives. In addition to mailing information directly to physicians, BCBSM assigned four pharmacists to make face-to-face visits and work directly with the physician groups. It's also important to note that although the program was largely focused on increasing generic drug prescribing rates, BCBSM established effective safeguards to ensure that physicians focused on best practices in prescribing first, and on our incentives second.

Since 2000, the program has continued to evolve and is now part of BCBSM's Value Partnerships program, which facilitates close collaboration with approximately 4,500 Michigan physicians on a wide range of health care quality, safety and cost initiatives, and rewards performance and best practices in the delivery of care. Physician groups in the program are highly motivated and their efforts helped save $7 million through increased generic use last year alone.

Summary

Generic drugs provide considerable value to consumers, especially those over age 65. That's why BCBSM remains committed to educating consumers and health care professionals, and aligning benefits and physician incentives to promote generic drug use wherever appropriate. Looking ahead to the next three years, we anticipate that several expensive blockbuster brand-name medications will lose patent protection, which will present great savings opportunities through increased use of generic medications nationally.

Blue Cross Blue Shield of Michigan applauds Congress for its continuing efforts to address issues affecting timely availability of generic drugs. Chief among those efforts is ensuring adequate FDA funding and addressing loopholes in the law that can delay the entry of generic drugs into the marketplace. BCBSM is pleased to have had the opportunity to testify here today. I would be happy to answer any questions members may have.

[1] The Henry J. Kaiser Family Foundation, State Facts Online, [cited August 29, 2006] available online @ www.statehealthfacts.kff.org.

[2] Gaither CA, Kirking DM, Ascione FJ, Welage LS. Consumers' Views on Generic Medications: J AM Pharm Assoc. 2001; 41:729-736

[3] Blue Cross Blue Cross Blue Shield of Michigan, 2001 Brand Marketing Survey.

Senator KOHL. Thank you very much, Mr. Antonelli.
Dr. Shrank.

STATEMENT OF WILLIAM H. SHRANK, M.D., MSHS, DIVISION OF PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS, BRIGHAM AND WOMEN'S HOSPITAL, HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. SHRANK. Good morning, Chairman Smith, Ranking Member Kohl, members of the Committee. My name is William Shrank. I am an internal medicine physician at the Brigham and Women's Hospital and a drug policy researcher at Harvard Medical School. I spend most of my time researching how to improve efficiency and effectiveness of drug coverage policies. It is an honor to testify before you today.

There is a tension at the heart of all prescription drug policies in this country. On the one hand, we need to stem the rising costs of prescription drugs. We spend well over $200 billion annually on prescription drugs, the fastest growing sector of our health care economy. On the other hand, we have a quality problem. There is substantial under-use of effective medications, especially for chronic diseases, and we need to make sure that more patients with chronic diseases get the drugs they need.

So how do we reconcile this tension? By steering patients toward less expensive, equally effective medications. Greater use of generic drugs can do just that. A number of studies have shown that greater use of generic drugs can lead to a substantial savings, frequently estimated at over $20 billion annually in this country, as noted by Senator Kohl.

In my research, I have also looked at how greater use of generic drugs may improve the under-use problem. Most patients who have drug coverage are enrolled in tiered plans that charge them greater co-payments when they receive branded drugs and smaller co-payments when they receive generic drugs. Virtually all patients in Part D are enrolled in such plans. The idea is that cost-conscious doctors and patients would make thoughtful cost/benefit decisions about drugs and that market forces would lead to efficiency.

I surveyed patients and physicians to explore their knowledge and communication about patients' costs for drugs. I found that doctors are rarely aware of patients' formularies and costs, and they don't think it is their job to be aware. Patients also are frequently unaware of their costs until they reach the pharmacy and rarely communicate with their doctors about medication costs. Overall, the basic market assumptions are not being met.

My next study evaluated how the decision to prescribe a generic versus a branded drug affects patients' adherence to chronic medications. I studied patients in a large health plan—all were enrolled in tiered drug coverage—and found that when patients were started on generic drugs, they were substantially more likely to adhere to chronic therapy, to take the medications that they were prescribed. Patients had over 60-percent greater odds of adequate adherence when they received generic drugs as compared to the most expensive branded drugs. So steering patients toward more generic drugs not only saves money for the system and for patients, it increases the chances that patients will take important medication.

That is not to say that generics are appropriate for everyone. Branded drugs that do not have a generic equivalent may offer clinical benefits not possible with generics, and for some patients effectively treated with a branded medication it may not be appropriate to switch to a generic. The best opportunity to stimulate generic use occurs when new medications are prescribed. For most conditions, patients should be started on a generic and, if ineffective, can be switched to a more expensive branded drug.

This leads to the first of three suggestions I would propose to the Committee. First, we need better prescribing systems that provide doctors and patients with information about drug costs and formularies at the point of prescribing to steer patients toward generic drugs when they are available. Broader use of electronic prescribing could greatly assist in providing this information.

Second, we must simplify coverage. In Part D alone, doctors and patients are overwhelmed with the complexity of the dozens of formularies they must navigate. Now that the Government is the biggest purchaser of drugs in this country, the Government should take steps to simplify prescribing decisions by reducing the number of formularies that doctors must prescribe from. Additionally, Medicare should develop and require coverage standards for Part D plans, requiring all participating plans to include highly cost-effective drugs for very low co-payments or no co-payments at all.

Third, we need to educate doctors and patients about generic drugs and drug costs. Branded manufacturers are winning the education war, spending tens of billions of dollars to provide free samples to physicians, to detail doctors, and to educate patients through direct consumer advertising. Consumer Reports' Best Buy Drugs and Blue Cross in Michigan should be commended for providing information to patients, offering objective resources about costs and benefits for drugs. But many patients are not engaged enough or are incapable of participating in these decisions.

Our division has developed a counter-detailing strategy known as academic detailing to educate physicians. We train nurses and pharmacists to visit doctors in their offices and educate them about evidence-based, cost-effective prescribing. The PACE program in the State of Pennsylvania has contracted with our group to implement a statewide academic detailing program. Such programs have been shown to reduce costs and improve the quality of prescribing.

Considering that Medicare alone now spends well over $40 billion a year on prescription drugs, if they were to spend just one-tenth of a percent of that budget to create academic detailing programs to educate doctors, they would likely find they could save resources for the Government, reduce health care costs in general, and help create a culture of cost-effective prescribing.

Thank you very much, and I would be happy to answer any questions.

[The prepared statement of Dr. Shrank follows:]

Testimony of:

William H. Shrank M.D. MSHS

Division of Pharmacoepidemiology and Pharmacoeconoimics

Brigham and Women's Hospital

Harvard Medical School

Boston, MA.

Generic Drug Utilization in Medicare Part D

United States Senate

Special Committee on Aging

September, 21, 2006

Washington, D.C.

I. Introduction

Good Morning Chairman Smith, Ranking Member Kohl and Members of the Committee. My name is William Shrank. I am an Internal Medicine physician at the Brigham & Women's Hospital in Boston where I am an Instructor in the Division of Pharmacoepidemiology and Pharmacoeconomics and at the Harvard Medical School. I spend most of my time researching how to improve efficiency and effectiveness of drug coverage policies. It is an honor to have the opportunity to share my thoughts with you today about the costs of prescription drug care in the United States, the role that generic drugs can play in reducing those costs, and policy implications for Medicare Part D.

II. Background

Tensions exist regarding appropriate spending for prescription drugs. On the one hand, we spend a staggering amount, over $200 billion annually, on prescription drugs in the U.S.[1] Growth in spending for drugs has outpaced spending growth in all other sectors of the healthcare system in the last decade,[2] and is predicted to continue to do so.[3] The federal government's exposure to those costs has increased with passage of the Medicare Modernization Act which allows seniors to voluntarily enroll in federally-funded, private prescription drug coverage plans.[4] Even the most conservative estimates suggest that the federal Government will spend over $40 billion annually for this benefit.[5] Efforts to stem the rising costs of prescription drugs are needed.

On the other hand, the quality of care in the United States is disappointingly poor,[6] and highly effective, evidence-based medication therapy is often underused.[7] Patients with chronic disease frequently do not receive or do not take necessary

medications.[8] Patients, even those with drug coverage, frequently do not fill or refill their medications due to excessive out-of-pocket costs. [9,10] Policy-makers often struggle to reconcile the need to increase medication use for patients with chronic disease without adding to the unsustainable rise in prescription drug costs.

III. Potential Role of Generics in Reducing Overall Prescription Drug Costs

Numerous studies document the potential cost-savings that could be realized by greater use of generic medications. According to one study based on a nationally representative sample, switching prescriptions from branded medications to molecularly-identical generics could lead to an 11% reduction in overall drugs costs.[11] Another study of treatment for hypertension found that prescribing in accordance with established national guidelines (JNC-VII) can lead to greater generic drug use and substantial prescription drug cost savings (approximately 25% of total drug costs for hypertension medications) while providing higher quality, evidence-based care.[12] The potential cost-savings in the United States associated with switching generic medications for molecularly identical branded drugs typically is estimated at over $20 billion annually in this country.[13]

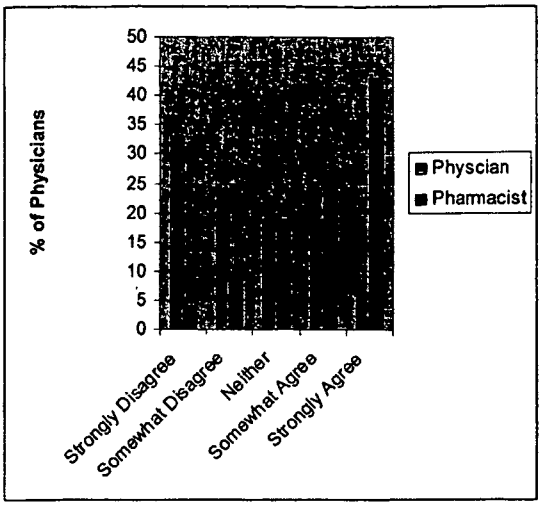
IV. Current Challenges for Doctors and Patients in our Market-Based System

Many policy makers have touted a market-based approach as the solution to inefficiency in health care. They predict that an "ownership society," in which educated consumers will be sensitive to medical care costs and communicate their preferences to their physicians, will lead to greater efficiency and cost management.[14] As a result, approximately three quarters of Americans with prescription drug coverage were enrolled

in pharmacy benefit designs with at least three tiers of copayments by 2004.[15] These plans require patients to pay lowest copayments for generic drugs, middle copayments for preferred branded mediations and highest copayments for non-preferred branded drugs. These plans utilize financial incentives to steer patients towards drugs they consider more cost-effective. The Medicare Modernization Act (MMA) has endorsed the creation of market-based prescription drug coverage for seniors,[16] and most seniors in Part D are enrolled in tiered plans.

Through both my clinical experience and my academic research, I have found that the critical assumptions of an efficient market are not met when it comes to prescription drugs. First of all, physicians face challenges when prescribing due to the substantial variability between formularies offered by different insurers in the community.[17] They also encounter challenges in identifying preferred formulary options for seniors enrolled in hundreds of different Medicare Part D plans, each with a unique formulary and set of benefits.[18] As a result, physicians frequently lack knowledge about patients' out-of-pocket costs. I performed a survey of California physician leaders and found that physicians are frequently unaware of patients' formularies and out-of-pocket costs and, furthermore, they do not feel responsible for managing patients' out-of-pocket costs.[19] Rather, physicians believe it is the responsibility of the pharmacist to be aware of patients' formularies and to help steer patients towards generic or less expensive medications.[19] (Figure 1.) In a statewide survey of California physicians, I confirmed these findings and found that physicians who prescribe electronically and who practice in large organizations were most likely to be aware of patients' out-of-pocket costs.[20]

Figure 1. Physicians' Responses When Asked if They Agree that it is the Physician's or the Pharmacist's Responsibility to Identify "Preferred" Formulary Medications (N = 129)

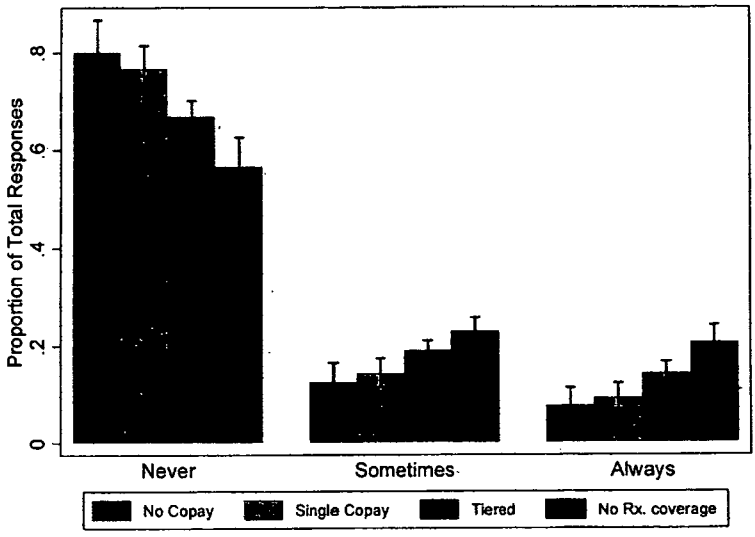


Adapted from Shrank WH, et al. American Journal of Managed Care, 2005.

In a follow-up study, I examined whether patients are aware of their cost requirements at the clinical encounter with their physicians and whether the use of market forces influences rates that patients communicate with their physicians about costs.[21] I performed a telephone survey of patients in California to assess their knowledge of out-of-pocket costs at the time of prescribing, the frequency that patients communicate with their doctors about medication costs, and the association between enrollment in tiered pharmacy benefit plans and the likelihood that patients and physicians communicate about costs. In a paper published in the *Journal of General Internal Medicine*, I found that patients are frequently unaware of the out-of-pocket costs of their medications when prescriptions are written, and they rarely talk to their physicians about costs. In addition, enrollment in a tiered or incentive-based formulary was associated with only a small increase in the likelihood that physicians and patients communicate about costs of

prescription drugs; the majority of patients reported that they never talk to their doctors about medication costs regardless of their pharmacy benefit design.[21] (Figure 2.)

Figure 2. Rates at which Patients Report they Discuss Out-of-Pocket Costs with their Physicians- By Pharmaceutical Benefit System



Adapted from Shrank WH, et al. Journal of General Internal Medicine, 2006.

In sum, in our current system, doctors and patients are unaware of patients' costs and do not communicate about these costs. Doctors rely on pharmacists or patients to intervene beyond the clinical encounter, when discussions about costs and benefits are less likely. However, it is the physician that must change the prescription to a less expensive medication. We have adopted a convoluted and inefficient system in which none of the parties involved have the both the necessary information and authorization to make a reasoned and cost-effective decision before the prescription is filled.

V. Generic Drug Use Can Improve Patient Adherence to Chronic Medications

Considering the challenges patients and physicians face when trying to identify medications that require lower out-of-pocket costs, I next studied how prescription choice influenced whether or not patients took their medication as prescribed. Specifically, I sought to understand whether patients were more or less likely to adhere to lower cost generic medications than branded medications. I collaborated with a large health plan to evaluate medication utilization in over 7,000 patients enrolled in three-tier benefit plans who were prescribed a chronic medication. I studied the relationship between receiving a generic medication, a preferred branded medication or a non-preferred branded medication from a patients' formulary and the odds that the patient adequately adhered to therapy. Adequate adherence was defined as filling 80% or more of prescriptions in the year subsequent to initiation of an important chronic medication.[9]

I found that when patients were prescribed generics, they were more adherent to chronic medications. When patients received generics they filled, on average, 12.6% more prescriptions in the subsequent year as compared to patients who were prescribed third tier, non-preferred branded medications. Patients prescribed preferred branded drugs filled 8.8% more prescriptions than those who received non-preferred branded drugs. Patients who received generics had 62% greater odds of adequate adherence than those who received non-preferred branded medications.[9] (Appendix 1.)

These findings suggest that greater generic drug use can increase adherence to important chronic medications, and can offer assistance in addressing the problem of underuse of appropriate medications in the United States.

VI. Value of Generic Drugs for Patients and the Health Care System

Greater generic drug use can address both aspects of the key tension we face when creating policies to reduce prescription drug costs and improve the quality of care that patients receive. By substituting less expensive generics for branded medications, we could reduce spending on prescription by tens of billions of dollars a year in this country. Additionally, by helping patients to receive generic medications that require lower out-of-pocket cost requirements, we could see increased rates that patients adhere to important chronic medications, which could avert hospitalizations and other adverse health outcomes.

VII. Limitations of Generic Drug Use

It is important to note that not all branded drugs have a generic alternative and that generic drugs are not appropriate for all patients. Some patients are better served by newer branded drugs, and for many patients who are treated effectively with branded drugs for which no generic exists, it may be unwise to try to switch to generic medications. For example, in patients stably treated for mental health disorders on newer anti-depressant or anti-psychotic medications, a switch to an older generic alternative may be clinically unwise. No policy to increase generic drug use should place any patients at risk of receiving worse quality of care. Thus, policies to increase generic drug use must be flexible enough to allow the use of branded drugs when deemed appropriate by the prescribing physician.

VIII. Interventions to Increase Generic Drug Use

Financial Barriers to Branded Medications: Insurers, pharmacy benefit managers, and state and national governments have implemented interventions using financial barriers to increase generic drug use. Insurers have overwhelmingly adopted tiered pharmacy benefit designs which use out-of-pocket cost incentives to steer patients towards generic medications. Tiered benefit designs have been shown to increase generic drug utilization in several settings.[10,22,23] In Canada, an intervention known as reference-pricing has been implemented. In such a benefit design, patients who are prescribed medications that cost more than a government selected reference drug (one drug for each drug class) are personally responsible for paying the difference in cost. Reference pricing has also been shown to increase generic medication utilization.[24]

Administrative Barriers to Branded Medications: Administrative barriers, such as prior authorization requirements, have also been implemented to stimulate greater generic drug utilization. In general, these requirements mandate that physicians who choose to prescribe an expensive medication must justify the decision prior to the patient's receipt of the medication. Studies indicate that prior authorization requirements can decrease prescribing of expensive branded medications. A nationwide evaluation of the effects of prior authorization requirements for COX-II non-steroidal anti-inflammatory medications was performed for patients enrolled in Medicaid. The study demonstrated that implementing a prior authorization program led to a 15% decrease in branded COX-II prescribing.[25]

Throughout the United States, mandatory generic substitution has also been widely adopted to substitute generic alternatives for the molecular entity at the point of

the pharmacy. This policy allows pharmacists to switch branded prescriptions to molecularly-identical generic prescriptions as long as the prescriber does not specifically indicate that the brand is to be filled. Mandatory generic substitution has been shown to reduce overall prescription drug costs as well as patient out-of-pocket costs.[26,27]

Educational Interventions: Jerry Avorn MD, the chief of my Division, and colleagues have developed an educational intervention known as ***academic detailing***. This intervention may be familiar to Senator Santorum; we have implemented an academic detailing program titled the Independent Drug Information Service (iDiS) for Pennsylvania's Pharmaceutical Assistance Contract for the Elderly (PACE) enrollees.[28]

Academic detailing is a method by which university-based outreach educators ("detailers") conduct educational sessions with physicians in the physicians' offices to deliver focused, evidence-based, non-commercial clinical messages about appropriate drug choices. The enhancements in the quality of prescribing due to academic detailing are well documented,[29,30] with opportunities for great cost savings (benefit-to-cost ratio of approximately 2).[31] In general, the key components of academic detailing include: (1) conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns, (2) focusing programs on specific categories of physicians as well as on their opinion leaders, (3) defining clear educational and behavioral objectives, (4) establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues, (5) stimulating active physician participation in educational interactions, (6) using concise graphic educational materials, (7) highlighting and repeating the essential messages, and (8) providing positive reinforcement of improved

practices in follow-up visits.[32] Studies consistently demonstrate that academic detailing is an efficacious means to improve appropriate prescribing in a variety of drug categories and in various settings, often through the proper prescribing of generic alternatives.[27,28]

In 2005, our division teamed up with the state of Pennsylvania to create the iDiS program to educate the state's doctors about improving the cost-effectiveness and quality of prescribing in the state. While we are in the process of measuring the effects of this intervention on the quality and costs of prescription drug care, early surveys of physicians suggest that they overwhelmingly appreciate the educational experience and they have requested that the program continues.

In addition, a number of resources have recently become available to educate patients about the costs and benefits of medication options for their conditions. Consumer Reports Best Buy Drugs is one such resource. While studies to evaluate the effects of these resources on prescription drug choices are currently unavailable, the makers of these resources should be commended for their efforts to stimulate demand for lower-cost, highly effective medications. The limitations of patient education must also be recognized. Educators rely on activated and engaged patients to participate in the decision-making process, but many patients may not have the desire or ability to participate. Nonetheless, arming patients with better information about the costs and benefits of medications will be critical in creating an environment in which patients are activated consumers who play an educated, meaningful role in their health care decision-making.

IX. Recommendations to the Committee

A) IMPROVE PRESCRIBING SYSTEMS:

We need better prescribing systems to provide doctors and patients with information about drug costs and formularies. Currently, most doctors write their prescriptions by hand, and efforts to gather knowledge about a patient's formulary requires the physician to take the time to look up that information in a handbook, on software available for handheld computers, or on insurer's web sites. Better systems to provide doctors with real-time information about patients' costs would enhance the likelihood that doctors would consider and discuss medication costs when prescribing.

Broader use of electronic prescribing could greatly assist in providing this information. E-prescribing could provide doctors with real-time information about costs and decision-support to help steer doctors towards equally effective generic medications when they are available. Greater generic prescribing and cost-effective prescribing could be some of the many beneficial effects of electronic prescribing.

b) SIMPLIFY COVERAGE: Missed Opportunity in Part D

Simplifying coverage could help streamline prescribing decisions. In Part D alone, doctors and patients are overwhelmed by the complexity of the multiple formularies they must navigate. Outside of Medicare, doctors manage patients from, on average, over a dozen different insurers, each with it's own set of pharmacy benefits and unique formulary. This complexity has led doctors to abdicate the role of financial agent for their patients, and hope that patients or pharmacists can help

identify less expensive options, leading patients to take unnecessarily expensive medications.

Now that the government is the biggest purchaser of drugs in this country, the government should take steps to simplify prescribing decisions in Medicare by reducing the number of formularies from which doctors must prescribe. Additionally, the government could identify certain first-line medications that are highly cost-effective and require that they are offered at the lowest tier copayments or no copayments at all in all Part D plans. Such policies could simplify the prescribing process for physicians and could help to insure that patients will be directed to clinically effective and cost-effective medications. Such policies could increase the likelihood that initial prescriptions for chronic conditions are filled with generic drugs – the best opportunity to influence prescribing decisions and stimulate long-term generic drug use.

c) EDUCATE DOCTORS AND PATIENTS ABOUT PRESCRIBING: Academic Detailing

Third, we need to educate doctors and patients more about generic drugs and drug costs. Branded manufacturers are winning the education war, spending tens of billions of dollars annually in the U.S. to provide free samples to physicians, to detail physicians in their offices, and to educate patients through direct-to-consumer advertising. Consumer Reports Best Buy Drugs should be commended for providing better information to patients – offering them an objective resource to learn more

about the costs and benefits of their medications. But many patients are incapable of accessing this information or effectively participating in these decisions.

Development of broader academic detailing programs to educate physicians, as have been done in many other countries such as Canada and Australia, could substantially improve the quality and cost-effectiveness of prescribing in the U.S. Medicare's massive investment in providing prescription drugs to seniors should inspire the federal government to play a more active role in improving the quality and cost-effectiveness of care and strive to get the most benefit from their investment. If Medicare were to invest just 1 tenth of a percent of their $40 billion annual budget on Part D to create academic detailing programs to educate doctors, they could save resources for the government, reduce health care costs in general, and help patients receive more affordable medications. Such an investment could also help to foster a culture of cost and efficacy awareness about medications.

X. Conclusion

Thank you for this opportunity to appear before you today to testify on my findings and recommendations. By creating better systems and policies I believe we can design coverage that helps Americans receive the right drug for their diagnosis at a fair price.

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Senator KOHL. Thank you, Dr. Shrank. How much has been invested in the academic detailing program that you have been working on in Pennsylvania?

Dr. SHRANK. It is about $1 million a year.

Senator KOHL. What is the potential of it in terms of dollars?

Dr. SHRANK. The potential is great. Previous studies have demonstrated that there is generally about a two-to-one benefit-to-cost ratio, that these plans tend to save money.

Senator KOHL. When you surveyed physicians in California, you found that most are not only unaware of patients' out-of-pocket drug costs, but they also don't believe it is their responsibility to consider that when writing prescriptions. So what can we do to change this and change the conversation and make them more aware of it and more concerned about it?

Dr. SHRANK. Well, I don't think it is a lack of concern. I think it is a lack of time and easily accessible resources. We have done some other studies that have shown that doctors do really care about helping patients manage their out-of-pocket costs, and they know that it is critically important to helping patients access appropriate medications.

But it is not really feasible on a very busy schedule to go look on the Internet or find a handbook or try to figure out what any particular patient's costs are going to be for any particular drug. Better systems can answer this, and there is a lot of attention that has been given here in this Committee about improving electronic prescribing. Electronic prescribing with very specific standards that require that with electronic prescribing comes some sort of information about the patient's formulary and the comparative costs of medications that are within the class that the patient could be prescribed could be very, very useful for doctors.

Senator KOHL. For the panel—and, Mr. Vaughan, maybe you want to respond first—Dr. McClellan made it clear that in most every case the generic drug is just as effective and, without any question, just as safe as the brand-name drug. That being the case, if we don't want to challenge his statement, which I think is for the most part accurate and true, what is the responsibility of those of us who work here in the public sector to see to it that every physician understands this and knows what the alternative is to the high-cost brand-name drug when or he she prescribes to the patient? Mr. Vaughan?

Mr. VAUGHAN. Well, again, I think we are moving toward pay for performance. We hope so, and once the e-prescribing is in place and the kinks are worked out on these hand-held devices—doctors are busy and the formularies and all the complexity is overwhelming for an individual doctor to just keep thinking, gee, what generic will this person be covered for and is it on their formulary. But once the electronics are there, let's have that as a rating that people can either see or it is part of, P4P, we will pay you extra for doing it or we will pay you less if you don't. But Congress, as it amends Medicare and Medicaid, in the future can reward the doctors who really say, gee, I am going to be aggressive in helping my patients meet these costs. It is not there today, but it will be there soon, and we ought to plan for it and lay the groundwork.

Senator KOHL. Mr. Antonelli.

Mr. ANTONELLI. I would have to agree with the statements of both my colleagues here. At Blue Cross Blue Shield of Michigan, we have been involved in programs such as academic detailing. In fact, that is what I started doing at Blue Cross Blue Shield of Michigan in 1999 when I hired on board, and we continue to do that today. It has been rolled into our Value Partnerships program and we have found that it has been very, very motivating for physicians because they now have a pay-for-performance program which will allow them to get services from pharmacists which provide information on their prescribing, as well as new information about what drugs might be available as generics, as well as cost information.

In addition, we also are pursuing e-prescribing efforts. We have secured some work with the Southeastern Michigan E-Prescribing Initiative and it is very exciting. We have about 600 physicians that have signed on to the program and we are currently awaiting some study results from them; we expect it this fall. It was actually a grant study by CMS which will provide the answers to our questions of how much did e-prescribing affect generic dispensing rates.

So at Blue Cross Blue Shield, we see this, too, as being very important, both e-prescribing, academic detailing, as well as all the other things I talked about because it is a very comprehensive package that we have to think about. There is no silver bullet to this.

Senator KOHL. To what extent are the pharmaceutical companies involved in this whole thing? I don't want to call them a villain because they are not, but they are the opposition, in a sense, at least at this hearing. What is their influence and what do you perceive their influence to be here in Washington at the political levels as we try to move from what it is now?

You know, 60 percent of all the prescriptions that are sold are generic prescriptions, which is not at all bad, but we understand for every one percent, you can save as much as $4 billion. So if you get from 60 to 80, well, you know, that is a fortune; that is $80 billion in savings if you can get from 60 to 80.

How are the brand-name pharmaceutical companies involved in this, and what do you perceive their influence to be here in Washington and what do you think we should and can do about it?

Mr. Vaughan:

Mr. VAUGHAN. I think it is an enormous influence. If you look at these Best Buy Drug examples, for example, the purple pill that you see all the time is a tiny bit better for heavy upper esophagal bleeders. But the difference in price is like $171 a month compared to an over-the-counter that does just as good for $24. Yet, Americans see it on TV and they say, my gosh, I saw it on TV, I want the thing I saw on TV. There are good peer-reviewed journals, studies showing where patients come in to the doctor and the doctor wants to keep the patient happy, so he writes a script for something he knows is way over-priced and not particularly better.

When it comes to all the pressure on our social programs, advertising is driving costs and you ought to consider a user fee. Let's just say your advertising works; that is why they do it. You are driving Medicare and Medicaid expenses up. Therefore excuse us, we are going to have a user fee and we will use it to make sure

we check every ad for accuracy. Many of the ads admit relevant adverse effects, but some fail to. This user fee will help fund Medicare and Medicaid because you are making the cost higher because of your ads.

We are the only country in the world that allows this kind of direct-to-consumer advertising. I think the New Zealanders still do it, but they are getting out of that business; they are saying no thanks, this is crazy. The rest of the industrialized world says no.

I am sorry. I get excited on this one.

Senator KOHL. Dr. Shrank.

Dr. SHRANK. We have a very lopsided competition for how we get information out about medications, and the drug companies do this very, very well. They give $15 billion a year in free samples to doctors, and that is incredibly effective at stimulating that first prescription to be filled for the branded drug. Certainly, in many cases that is not the right drug or not the most cost-effective drug for that patient, but that works. Once the patient is started on that free sample and it worked and they feel comfortable with it, it is pretty hard to switch.

The effect of direct-to-consumer advertising may be waning a little bit in the setting of a lot of recent Vioxx problems and things like that, but it is still very, very popular and it is very common and it is very powerful. As a practicing physician, many of my patients come into my office and say I saw a commercial for the purple pill. There is nothing wrong with the purple pill; it works just fine, but it is a lot more expensive than an identical medication that would be able to provide an equal amount of results.

So from the payer side, there are some very innovative, smaller-scale programs that are happening, but there is nothing that can compete with the massive educational approach that the pharmaceutical manufacturers have undertaken. The great opportunity here is that Medicare is a huge player in purchasing prescription drugs. It is very hard for a single insurer in a fragmented health care system to do much because a big investment from a single insurer actually helps all of their competitors as much as it helps the single insurer.

Medicare now is the big gorilla. It is a huge player and it has an opportunity to really influence this debate. If Medicare wanted to educate doctors or educate patients, they would have the ability to do that.

Senator KOHL. A very good point.

Mr. Antonelli.

Mr. ANTONELLI. I would just like to add that when you see products like Lunesta and Nexium having advertising campaigns that are over $200 million direct to consumer and we have a $1 million advertising campaign for generics, it is quite lopsided.

One thing that we have learned over time is that this direct-to-consumer advertising is new and can be improved. The FDA has been holding hearings over the last few years to collect information from different resources to find out what are the best means for making changes to this. One researcher in particular from Duke University—her name is Ruth Day, a very bright woman—has done some research on the advertising and looked at these ads and

found that most of the risk information is functionally absent from these ads.

People watching these ads very easily understand what the benefits are, but cannot figure out what the risks are. So they are going to their physicians asking for the purple pill and the physician feels obliged to actually take the purple pill and write for it. It is kind of a conflict of interest and I think the FDA does need to take a look at these guidelines and really update what they have done in 1999 so that we do have better quality advertising.

Senator KOHL. As you know—and I think you referenced it, Mr. Vaughan—we have legislation here that we are trying to move now that would it illegal for the pharmaceutical companies to pay off generic companies when it comes to introducing new products, either to delay or to go away entirely. I assume you all would support this legislation.

Mr. Vaughan.

Mr. VAUGHAN. Absolutely, and congratulations. A bill that has Senator Lott and yourself and Senator Stabenow on it should have some legs.

Senator KOHL. Senator Grassley, too.

Mr. VAUGHAN. Grassley. That is great.

Senator KOHL. Hopefully Senator Smith. I get the sense here that it really is important for an opposing force to confront the pharmaceutical companies, and that takes a lot of money, as we have all indicated. To the extent that it is legal and possible, the Government ought to be doing this, ought to be doing a better job on behalf of the people we represent all across this country in seeing to it that the pharmaceutical companies, with all of the financial resources they have, do not succeed in overwhelming the system and getting their way with consumers all across the country when it comes to prescription drugs.

Would you agree with that, Dr. Shrank?

Dr. SHRANK. I would certainly agree with that.

Senator KOHL. Any other comments you guys wish to make before we conclude?

Mr. VAUGHAN. I think it is news today that Medicare will be making those generic-specific data available on the plans. I don't know if the Committee does prints or something on plan quality, but this is something we will all want to publicize, because it is a great advance for consumers to get that kind of data.

Senator KOHL. To know which plan is doing a better job or a worse job in getting generics in front of the people who are with that plan.

Mr. VAUGHAN. Yes, sir.

Senator KOHL. That is very important.

Well, we thank you fellows for coming. You have been very useful. I think this has been a really good hearing and we will adjourn at this time.

[Whereupon, at 11:38 a.m., the Committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR SUSAN COLLINS

Mr. Chairman, thank you for calling this hearing to examine current efforts to encourage broader use of generic drugs as a means of keeping drug costs down for our nation's seniors.

The United States currently spends a staggering amount—over $200 billion a year—on prescription drugs. Rising drug costs are a particularly heavy burden for Americans who don't have drug coverage. They are also putting the squeeze on our nation's employers who are struggling in the face of double-digit premium increases to provide health care coverage for their workers. And they are putting increasing pressure on public programs like Medicare, which will spend over $40 billion a year on the new Part D prescription drug benefit.

Today the average cost of a brand-name drug is $96, while the average cost of a generic is less than $30. Generic drugs therefore have the potential to greatly reduce the health care cost burden for all consumers, but particularly for our nation's seniors.

Earlier this year, the Consumers Union did a study the found that Medicare beneficiaries who take five common drugs could save between $2,300 and $5,000 a year by switching to equally-effective, but lower-cost alternatives. Lower-cost generics therefore have the potential to help seniors significantly stretch their drug coverage under Medicare, and can even help them to avoid falling into the coverage gap known as the "doughnut hole."

There do, however, appear to be barriers that have prevented more widespread use of generics. Physicians may not be attuned to limitations in their patients' drug coverage and they also may not feel it is their responsibility to help steer them to lower-cost medications. The patients themselves may not be aware of these limitations, and they may also be hesitant to talk to their doctor about costs. Generic manufacturers also don't tend to employ fleets of salespeople marketing their products directly to physicians, and there also is far less "direct-to-consumer" advertising for generics. Many consumers may simply not be aware that there is a lower-cost alternative to "that little purple pill."

I do want to make it clear that I do not believe that generic drugs are always the right choice for everyone. Many patients are better served by the newer, branded drugs, and efforts to increase the use of generics should not come at the price of diminished patient care. Programs should be flexible enough to enable the physician to prescribe the drug that he or she thinks is most appropriate for the patient.

That said, I do think that we can do a better job of making sure that consumers, pharmacists and physicians have all of the information and incentives that they need to choose the safest, most effective and lowest cost prescription drugs available. This morning's hearing will give us an opportunity to learn about some innovative programs that are working to do just that, and once again, I want to thank the Chairman.

PREPARED STATEMENT OF SENATOR KEN SALAZAR

Thank you, Chairman Smith and Ranking Member Kohl for organizing this hearing and for inviting this panel of experts to discuss the importance of improving seniors' access to generic prescription drugs. I also want to thank the Centers for Medicare and Medicaid Administrator, Dr. Mark McClellan, for joining the Committee today to discuss this important issue. And thank you to the entire panel for your time, as well as your work.

I look forward to hearing expert testimony on how the federal government, the states, drug providers, drug representatives, pharmacists and physicians can help our seniors in gaining access to information on lower-cost and generic drugs. I believe increased information for beneficiaries about their drug choices is necessary to

lower their personal costs, and serves to educate them to become better advocates for their own health care.

Medicare provides the majority of our seniors their health care services. Colorado has an estimated 515,000 Medicare beneficiaries. Over 38 percent of these beneficiaries are low-income. Today America's seniors are living on tighter budgets and paying the increased costs of living in this country. It costs more today to heat homes, get transportation, purchase food, and as we are discussing here today—pay for health care.

The costs of prescription drugs have increased dramatically over the past two decades. According to the Kaiser Family Foundation, U.S. spending for prescription drugs has more than quadrupled since 1990. And prices continue to rise. Even the cost of drugs being covered by the Medicare Prescription Drug Plan have risen in the short time since it was implemented. According to a report done by Families USA, "virtually all Part D plans raised their prices for most of the top 20 [medications] prescribed to seniors." The report estimates the prices have increased by 4% since the program's implementation in January.

Meanwhile, as our graying population grows, the need for prescription drugs grows. We need to talk about solutions that actually help in lowering the costs of drugs for Americans. One such solution to lowering costs for Americans is the use of more generic drugs.

This hearings casts light on the fact that there are drug options other than brand names for our seniors. But seniors need to know about these options. The major challenge to this is the lack of information available to individuals about their drug options. The providers of this information are not doing enough. They include physicians, pharmacists, and government agencies. However, there are groups and states that have started to take action on this.

The state of Pennsylvania, with the assistance of Harvard researchers, has created an innovative program to reach out to physicians to help them in becoming a conduit of this information for their patients. The Pennsylvania "Unsales Team" program hires staff to reach out to physicians—educating them about generic and alternate drug options to brand-name drugs. This program is unique because these "drug" representatives are working on behalf of patients, rather than the bottomline of a pharmaceutical company. They want to help doctors in providing better advice on how seniors can get the best prices for their drugs. This program deserves our attention.

I also look forward to hearing more about the relationship between physicians and pharmacists. According to a survey of physicians done by the American Journal of Managed Care, physicians said they receive phone calls from pharmacists concerning formulary issues after 18.6 percent of the prescriptions they write. More communication between these health care professionals could make a difference for patients. Physicians should be utilizing pharmacists' information on the costs of drugs as part of the care-management of a patient. In turn, pharmacists should be providing this information to physicians. I hope to hear more from these groups on how we can provide better drug management assistance to seniors in dealing with their drug costs.

I appreciate the work of the Chairman and Ranking Member, who are responsible for this discussion of the increased costs of prescription drugs for seniors and the options seniors have in controlling these costs through increased use of generic or low-cost drugs. I will use the comments and ideas presented here today in my discussions with the health care community, as well as with my fellow legislators. I believe we can come up with solutions to help our seniors in accessing information on their health care needs and lowering their health care costs.