PATIENT ACCESS TO SELF-INJECTABLE PRESCRIPTION DRUGS IN THE MEDICARE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

MARCH 23, 2000

Serial No. 106–122

Printed for the use of the Committee on Commerce

U.S. GOVERNMENT PRINTING OFFICE
64–029CC WASHINGTON : 2000

COMMITTEE ON COMMERCE

TOM BLILEY, Virginia, *Chairman*

W.J. "BILLY" TAUZIN, Louisiana
MICHAEL G. OXLEY, Ohio
MICHAEL BILIRAKIS, Florida
JOE BARTON, Texas
FRED UPTON, Michigan
CLIFF STEARNS, Florida
PAUL E. GILLMOR, Ohio
Vice Chairman
JAMES C. GREENWOOD, Pennsylvania
CHRISTOPHER COX, California
NATHAN DEAL, Georgia
STEVE LARGENT, Oklahoma
RICHARD BURR, North Carolina
BRIAN P. BILBRAY, California
ED WHITFIELD, Kentucky
GREG GANSKE, Iowa
CHARLIE NORWOOD, Georgia
TOM A. COBURN, Oklahoma
RICK LAZIO, New York
BARBARA CUBIN, Wyoming
JAMES E. ROGAN, California
JOHN SHIMKUS, Illinois
HEATHER WILSON, New Mexico
JOHN B. SHADEGG, Arizona
CHARLES W. "CHIP" PICKERING,
Mississippi
VITO FOSSELLA, New York
ROY BLUNT, Missouri
ED BRYANT, Tennessee
ROBERT L. EHRLICH, Jr., Maryland

JOHN D. DINGELL, Michigan
HENRY A. WAXMAN, California
EDWARD J. MARKEY, Massachusetts
RALPH M. HALL, Texas
RICK BOUCHER, Virginia
EDOLPHUS TOWNS, New York
FRANK PALLONE, Jr., New Jersey
SHERROD BROWN, Ohio
BART GORDON, Tennessee
PETER DEUTSCH, Florida
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
RON KLINK, Pennsylvania
BART STUPAK, Michigan
ELIOT L. ENGEL, New York
TOM SAWYER, Ohio
ALBERT R. WYNN, Maryland
GENE GREEN, Texas
KAREN MCCARTHY, Missouri
TED STRICKLAND, Ohio
DIANA DEGETTE, Colorado
THOMAS M. BARRETT, Wisconsin
BILL LUTHER, Minnesota
LOIS CAPPS, California

JAMES E. DERDERIAN, *Chief of Staff*
JAMES D. BARNETTE, *General Counsel*
REID P.F. STUNTZ, *Minority Staff Director and Chief Counsel*

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

MICHAEL BILIRAKIS, Florida, *Chairman*

FRED UPTON, Michigan
CLIFF STEARNS, Florida
JAMES C. GREENWOOD, Pennsylvania
NATHAN DEAL, Georgia
RICHARD BURR, North Carolina
BRIAN P. BILBRAY, California
ED WHITFIELD, Kentucky
GREG GANSKE, Iowa
CHARLIE NORWOOD, Georgia
TOM A. COBURN, Oklahoma
Vice Chairman
RICK LAZIO, New York
BARBARA CUBIN, Wyoming
JOHN B. SHADEGG, Arizona
CHARLES W. "CHIP" PICKERING,
Mississippi
ED BRYANT, Tennessee
TOM BLILEY, Virginia,
(Ex Officio)

SHERROD BROWN, Ohio
HENRY A. WAXMAN, California
FRANK PALLONE, Jr., New Jersey
PETER DEUTSCH, Florida
BART STUPAK, Michigan
GENE GREEN, Texas
TED STRICKLAND, Ohio
DIANA DEGETTE, Colorado
THOMAS M. BARRETT, Wisconsin
LOIS CAPPS, California
RALPH M. HALL, Texas
EDOLPHUS TOWNS, New York
ANNA G. ESHOO, California
JOHN D. DINGELL, Michigan,
(Ex Officio)

CONTENTS

PATIENT ACCESS TO SELF-INJECTABLE PRESCRIPTION DRUGS IN THE MEDICARE PROGRAM

THURSDAY, MARCH 23, 2000

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Upton, Burr, Bilbray, Lazio, Norwood, Pickering, Bryant, Brown, Deutsch, Strickland, Barrett, and Capps.

Staff present: Tom Giles, majority counsel; Robert Simison, legislative clerk, Bridgett Taylor, professional staff; and Amy Droskoski, professional staff.

Mr. BILIRAKIS. Good morning.

The hearing will now come to order.

Today, as you know, the subcommittee is holding a hearing to review the Health Care Financing Administration's policy of coverage, or lack thereof, of self-administrable drugs under the Medicare program.

Since Medicare was created, the program has covered physician services and supplies, and I quote, "including drugs and biologicals which cannot, in accordance with the regulations, be self-administered."

The manual for carriers states that the determination of whether a drug or biological can be self-administered is based on the usual underlying method of administration. This policy has resulted in payment by Medicare for lifesaving drugs needed by patients who are incapable of self-injecting their medications.

On August 13, 1997, however, HCFA issued a program memoranda which significantly narrowed coverage for injectable drugs. In response, carriers began basing their coverage decisions on whether the drug could possibly, be self-administered, without regard to the unique needs of each patient. This action resulted in a loss of coverage for patients whose medications were previously covered by Medicare.

Beneficiaries in my home State of Florida were particularly hard hit by this payment change. After the new policy took effect, Blue Cross and Blue Shield of Florida attempted to deny coverage for Neupogen based on the fact that it could be self-administered, even

though it is usually administered by a physician, in conjunction with chemotherapy.

Congress became increasingly concerned as more and more claims were denied as a result of HCFA's actions. In response, Section 219 of the Consolidated Appropriations Act was enacted into law last year to prohibit the Agency from carrying out the program memorandum or from restricting coverage of self-injectable drugs in any way beyond the policy effective prior to August 13, 1997.

Unfortunately, and I say this, with our good friend, Mr. Hash, here, I don't know if he takes this personally, or not, but maybe in a way he should. The point is that, unfortunately, it took HCFA over 4 months to inform carriers that the pre-August 1997 policy should be reinstated. By law, that communication should have been made last November.

Ironically, the administration has proposed dropping coverage for these lifesaving drugs at the same time that Congress is considering ways to expand, as you know, access to affordable prescription drugs for all Medicare beneficiaries.

Not surprisingly, there has been bipartisan, bicameral opposition to the proposed changes. Along with several of my colleagues, I wrote Secretary Shalala last October, to request information regarding the rationale for the administration's policy. We did not receive the courtesy of any reply until late yesterday evening.

Those Members who signed the letter were trying to get answers for constituents who are being denied coverage for critical medications. However, the administration simply ignored the congressional request for over 5 months until this hearing was scheduled. Actually, I should say, that it ignored the congressional requests.

In my opinion, this inaction demonstrates an utter lack of concern for the patients affected by these proposed changes.

I would note that the President's budget proposal includes a provision to allow HCFA to move forward for the development of a proposed rulemaking process on injectable drugs. I am interested to learn why the administration believes such a rule is needed now, over three decades after the Medicare statute was enacted.

The impact of this policy change by HCFA is not limited to Medicare beneficiaries. Decisions about Medicare policy often set precedent for policy in the private health care market and our Nation's entire health care system. That is why today's hearing is so important.

I do want to thank all of our witnesses for appearing before the subcommittee to discuss this important issue, and I particularly appreciate the time and effort of the patients and patient advocates who will share their experiences with us. For them, the outcome of this debate will have significant personal consequences. I am sure we all look forward to hearing their testimony.

I yield to Mr. Brown for his opening statement.

Mr. BROWN. Thank you, Mr. Chairman.

We have choices today about what this hearing will be about. We can make use of this hearing to blame HCFA. We could somehow try to pin blame on the administration, rather than on Congress, for ambiguous language written into the Social Security Act of 1965 regarding self-administered medicines. The press loves it when we point fingers.

We could chastise HCFA for reiterating in a 1997 memorandum required to address the specific coverage issue an interpretation of the law that actually dates back to the 1980's. It is a misplaced criticism, but that has never stopped us before.

We could scold HCFA for allowing several months to pass before issuing a statutorily required clarification memo. I am not sure Congress has room to talk when it comes to creating or getting mired in red tape, and I'm sure HCFA has an explanation for the delay, but we should not let the facts get in the way of a good story.

We could question HCFA's plans to issue a proposed rule on the meaning of the statutory term "self-administered", even though it made perfect sense for Administrator DeParle to recommend this step.

Why anyone in their right minds would believe HCFA for some reason has it out for certain individuals who use self-administratable prescription drugs is beyond me. Nonetheless, we could take all our frustrations out on the agency. It would not be the first time.

Or we could get to what really matters: Should individuals who require a doctor's assistance to administer an otherwise self-injectable drug receive coverage under Medicare for that drug? From a policy perspective, I firmly believe Medicare should cover these individuals' costs, regardless of the reasons behind their inability to self-administer a needed medication.

A major goal of this hearing should be to clarify what, if any, actions are necessary to ensure that any Medicare beneficiary who needs but cannot self-administer one of these drugs have the same access as those who require drugs that are not self-administratable.

Speaking of equitable access, it would be irresponsible to assert that certain Medicare beneficiaries should receive coverage for certain medically necessary prescription drugs without mentioning that all Medicare beneficiaries should receive coverage for all medically necessary prescription drugs.

I am sure most of you have seen the Committee on Ways and Means press release in which Chairman Thomas, surprisingly enough, takes credit for convincing the Clinton administration to reverse its position on access to self-injectable drugs, no matter that HCFA had already determined it would solicit comments, or that this hearing was already scheduled when Chairman Thomas sent his letter to HCFA.

What I found most ironic was that Chairman Thomas chastised HCFA for, in his words, "carelessly limiting seniors' prescription drug coverage."

Let us talk about "careless." Careless is abiding a Medicare program that covers some of the prescription drugs required by a small subset of patients, but ignores the prescription drug needs of the rest of the Medicare population. Careless is ignoring the prescription drug issue until forced by politics in an election year to pay attention. Careless is promoting a stopgap solution to a broad-scale and growing problem. Careless is lashing out at HCFA for dragging its feet on a single policy while Congress drags its feet on an issue that has thrown millions of seniors into crisis.

A third of all seniors have no drug coverage. Millions more are underinsured. Employers are dropping retiree coverage. Private health insurers are cutting back the prescription drug benefits.

This is not an isolated or static problem that could be solved in a piecemeal fashion. It is broadbased, and it is getting worse. Ideally we would leave this meeting today not only confident that Medicare will cover injectables, which it should when a doctor must administer them to the patient, but also confident that the self-injectable issue will soon be moot.

The Medicare program covers hospitalization, it covers doctor's visits, and it should cover prescription drugs, period. I expect this hearing to resolve potential problems for individuals who should be eligible for coverage of self-injectable medications. I hope this hearing also takes us a step closer to Medicare prescription drug coverage for all senior citizens.

Mr. BILIRAKIS. Maybe you would not know it, but we are very close friends.

Mr. BROWN. That is true.

Mr. BILIRAKIS. I would remind the gentleman, though, that the problem of lack of prescription drugs for Medicare beneficiaries has been a longstanding problem. It is only recently when any Congress—certainly not during 40 years when the gentleman's party controlled the Congress—and he was not here for much of that time—had any concern for prescription drugs for Medicare.

I would now yield to the gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman, for your comments, and also for holding this hearing. I was very carefully watching the doors as my time came, because I am going to have to leave and be in and out today with other commitments. I very much am interested in what is said today. I think these are very good, very complex issues we have to deal with.

I certainly want to hear from people who are experts by virtue of their experience, whether it is a life experience or having to go through this type of medical situation, or whether they are experts educationally, from HCFA and all around.

But I was going to be brief in my remarks because I was the last one and we can get to the panels quicker, but we have had two members come in since that time, so I can take 10 or 15 minutes, I guess, now.

Mr. BILIRAKIS. Take your full 5 minutes, Mr. Bryant.

Mr. BRYANT. I am concerned about this. I do want to hear the testimony. I am in the process of reading the testimony of the witnesses. This is an important issue. It is one that—I might just reiterate what our chairman said, that this issue has been around since the beginning of Medicare. It did not cover drugs, and I think everybody in Washington over the years that this program has been in existence has had the opportunity to change that.

We are now, in this Congress, attempting to I think fix a very valid problem there for those people, especially 35 percent of the people, senior citizens, who do not have drug coverage.

We do not want to rush to judgment, so to speak. We do not want to go through this process of discharge petitions and things just so we can get something out quickly that might not be right, or that

we might try to embarrass somebody politically. We want to do it right.

I think through hearings like this—and I realize it is a limited hearing, it is not going to be focused on the bigger problem, but I think this adds to that. I think one quick step from this hearing is what are we going to do about those new drugs that are being or have been discovered since 1997 that would fit into this category that are very good drugs, but probably are going to be quite expensive. That is going to have to be considered when we write our drug bill.

I continue to hope the best in Congress; that we can keep politics, even though this is an election year—that we can keep politics out of this issue as much as possible. There is no Republican way, there is no Democrat way on this. I think there is an American way. I think there is a right way for the American people, particularly our senior citizens.

Again, I am rambling on now. I am going to stop, because I still have hope that I can hear some of the testimony before I have to leave at 11 o'clock. I yield back the balance of my time.

Mr. BILIRAKIS. Mrs. Capps?

Mrs. CAPPS. Good morning, Mr. Chairman. Thank you for holding this hearing. I send a welcome to all of the witnesses testifying before us today.

Today's hearing addresses one of the most critical needs of our Nation's seniors, drug coverage. I am glad we are looking at one aspect of this issue today. I would urge the Chairman that we do more. It is not a partisan issue.

Mr. Chairman, my district has a large senior citizen population. Many of these seniors rely on lifesaving therapies like the injectable drugs in issue at today's hearing to treat cancer, organ transplants, kidney failure, the side effects of chemotherapy, and other serious conditions. Many certainly cannot afford to pay for these self-injectable medications, which can cost up to $10,000 per year. Even if they could afford to pay for them, many of these seniors are often so elderly or sick that they cannot safely administer the drugs themselves.

I am glad to hear of HCFA's recent action, but I urge them to take action to extend that ruling permanently. I have to call to mind a dear friend of mine, an elderly man who was our church organist for many years.

He became very ill and was in critical care in a hospital for a while. He was able to be discharged, and was thrilled to go home. Then he discovered that the injectable that he needed to sustain him, which could be given at home, would not be covered by Medicare. It was so expensive he had to return to the acute care facility for a period of extended time, many weeks, solely to get this treatment. It is not a good use of our resources.

Recently I cosponsored H.R. 2892, introduced by my colleagues, Jay Inslee and Jennifer Dunn. This bill would require Medicare to cover self-injected biologics prescribed in lieu of a drug already covered by Part B. It would provide a patient with a choice between the intravenous in-office therapy or the self-injected therapy, depending on what is best for the patient.

Because of the savings from eliminated costs associated with in-office administration, this bill is basically budget-neutral. Some have even speculated that covering some self-injected products will actually save the Medicare program substantial dollars. I would hope that the committee would move this legislation soon.

As a nurse, I am particularly concerned that lack of access to drugs, to prescribed drugs, could be compromising seniors' health. In fact, I fear that it actually does. I believe this is one of the most critical issues facing our country's health care today.

I happen to represent a district where Medicare HMOs have been pulling out because of ridiculously low reimbursement rates. Of course, seniors are the ones who are truly hurt by all of this. They are the ones that have their lives disrupted when an HMO drops them. They are the ones who lose their prescription drug coverage and are forced to pay the full price for their medications out of their own pocket.

Many seniors simply cannot afford the high prices, so instead they take half the prescribed dose, or they just do not even buy these lifesaving medications because they cost too much.

We all know that today's prescription drugs are literally miracle drugs, and we cannot imagine quality health care without them. So while I am glad that we are holding this hearing today, I am very disappointed that this Congress has yet to address the issue of a Medicare drug benefit in any meaningful way.

Thank you, Mr. Chairman. I yield back my time.

Mr. BILIRAKIS. I thank the gentlewoman.

Mr. Upton from Michigan.

Mr. UPTON. Thank you, Mr. Chairman. I know we are going to have a vote on the Journal in just a few minutes, so I am going to put my statement into the record.

I just want to welcome our witnesses today, particularly Mr. Hash, who has done, I think, a pretty remarkable job in his role at HCFA.

One of the things that I intend to focus on is on the differences between States in reimbursing individuals, both under Medicare and Medicaid. I look forward to the testimony, and I yield back.

[The prepared statement of Hon. Fred Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding today's hearing on Medicare patients' access to self-injectable drugs. As a fellow member of the Chairman's task force on prescription drug coverage, I know that we share a deep concern about the burden that prescription drug costs place on the millions of Medicare beneficiaries who do not have any insurance coverage for prescriptions. No senior citizen should be forced to forego needed medication, take less than the prescribed dose, or go without other necessities in order to afford life-saving medications. Our nation leads the world in the development of new drugs and medical devices that enable us to effectively treat diseases and conditions. But if people cannot afford to buy these drugs, their benefits are lost to many in our population.

Until we can get a plan in place, it is important that we permit seniors who are getting a little assistance now under the Medicare program with their prescription needs to keep that assistance. I want to know what prompted the Health Care Financing Administration to issue a program memorandum to its Medicare carriers substantially tightening a long-standing policy that permitted Medicare carriers to cover some self-injectable drugs.

I want to raise a related issue, too. Last year, I was contacted by a constituent suffering from carcinoid cancer. Her physicians at the Mayo Clinic prescribed a drug

that can be a self-injectable. They told her that if she lived in Minnesota, Medicare would cover the drug, but that the Medicare carrier for Michigan, Wisconsin, and Illinois had elected not to cover it. I investigated this situation and found that was in fact the case and that Medicare carriers apparently have a lot of latitude in making these determinations.

Michigan later decided to cover this drug, and I believe that there may now be a national coverage policy in place on it. But this case is still very troubling to me. My Michigan constituents pay the same premiums as beneficiaries in Minnesota and other states whose carriers elected to cover this drug. I can see state by state variations 'in coverage policies in the Medicaid program, but not in the Medicare program, which is fully federally financed and national in scope. I'm going to try to get some answers today.

Mr. BILIRAKIS. I thank the gentleman.

The opening statements of all members of the subcommittee are made part of the record.

Mr. Norwood.

Mr. NORWOOD. Mr. Chairman, thank you for holding the hearing. We do thank our witnesses. As might be a little unusual, I will simply submit my opening statement for the record this morning, and give you a break.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

I want to thank the Chairman of the Health and Environment Subcommittee, Mr. Bilirakis for convening this hearing today. The issue of providing Medicare beneficiaries with access to prescription drugs is an issue this Committee is committed to addressing.

This is the fourth hearing this Subcommittee has conducted to focus on Medicare beneficiary access to prescription drugs. The Committee has invited the Health Care Financing Administration to testify three times on this topic. While I mean no disrespect to Mr. Hash, who formerly served on the staff of this Committee, I am disturbed that the HCFA Administrator, Nancy Ann Min DeParle, has been unavailable to attend any of the prescription drug hearings to which she has been invited. She is the head of HCFA, and it is her signature on the letters I have here explaining why Medicare will no longer cover certain life-saving drugs that it had previously provided coverage for.

We can all agree that no one would design a health care benefit today that did not include access to prescription drugs. This is just one significant area where the Medicare program doesn't measure up—particularly when compared to the health benefits we all enjoy working here in the Congress. I've been spending a lot of time studying this issue, and I agree with all my colleagues that we should do something to help seniors access affordable prescription drug coverage.

As I've already said, we've had three hearings on the larger issue of outpatient prescription drugs and we are working on addressing that issue. But that is not the topic of today's hearing.

We are here today to address the concerns of those patients who have had coverage for certain medications in the past, but due to a policy change by HCFA, no longer have that coverage. Since the Medicare program's inception 35 years ago, certain injectable drugs and biologicals have been covered when those drugs were administered by a physician in his or her office. Up until 1997, patients in need of these life-saving therapies had some comfort in knowing that, in almost all cases, they would have access to them. On August 13, 1997, HCFA effectively reversed this long-standing policy by issuing a Program Memorandum which caused Medicare carriers to discontinue coverage for these drugs and biologicals.

Not only did Medicare beneficiaries see their coverage curtailed, but some private health insurers began to follow suit and started denying coverage as well.

Recognizing that HCFA's Program Memorandum was resulting in a change in coverage policy that was having a devastating impact on patients in need of these drugs, Congress directed HCFA to reinstate the coverage policy that had existed prior to the August 13 Program Memorandum. Subsequently, President Clinton in his FY 2001 Budget request, proposed that the action taken by Congress last November and approved by the President be repealed.

I was pleased that last Friday, on St. Patrick's day, HCFA finally complied with the law that Congress passed to ensure that people with Cancer, Multiple Sclerosis,

AIDS and other diseases will once again have access to the lifesaving drugs they need.

For as long as Medicare has been on the books it has paid for these drugs. For reasons unbeknownst to me and many of my colleagues, HCFA began restricting coverage in August of 1997. I am further baffled as to why it has taken the Administration four months to comply with the law, and restore coverage for these life saving drugs. As we will hear from today's brave witnesses, this policy has had a direct impact on patient care. I believe this is unacceptable. The American people deserve better. The patients we will hear from today deserve better.

I have some specific questions for Mr. Hash today that I'd like to just highlight now. I'd like to know why HCFA decided to change a 33 year old policy in favor of one that denied patients treatment that Medicare had previously paid for. I'd like to know why it took HCFA four months to comply with a law passed last November instructing them to return to the previous coverage policy. And I'd like to know what the Agency intends to do next October when current law expires. I welcome Mr. Hash here today, and hope he can provide this Committee with some answers to these questions.

Finally, I particularly want to thank the witnesses on our second panel for making the trip here to the Nation's Capitol to tell us their stories. I welcome you and appreciate how important this issue is to you and your families.

Mr. BILIRAKIS. It is somewhat unusual.

Mr. Hash, if you will come forward, sir.

Mr. Hash, as we all know, is Deputy Administrator of Health Care Financing Administration, based here in Washington. Michael, it is always great to have you here. Hopefully you can help us out on some of these things that concern us.

Please proceed. We set it at 10 minutes. Obviously, do the best job you can.

STATEMENT OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Mr. HASH. Thank you, Mr. Chairman.

Chairman Bilirakis, Mr. Brown, and other distinguished members of the subcommittee, I want to thank you for inviting us here today to discuss Medicare's coverage for self-administered drugs.

The current situation, as all of you recognize, presents a really compelling example of why we must modernize the Medicare program with an affordable, comprehensive outpatient prescription drug benefit.

Medicare coverage for pharmaceuticals is now severely restricted outside of hospitals and nursing facilities. Congress has created only a limited number of exceptions outside of those settings in the law. One exception is for drugs that cannot be self-administered. The statute says Medicare must pay for drugs that cannot be self-administered when furnished as part of a physician's professional services.

Medicare's longstanding policy for coverage under this exception has addressed only whether a drug can be self-administered, not whether an individual patient can self-administer the drug. Congress has not provided an explicit exception for those who cannot self-administer drugs that generally are self-injectable.

The shortcomings of such a policy become clearer every day as we witness the new advances in drug therapies that are so important to patients' lives. Medicaid, and of course most private insurers, pay for all prescription drugs, regardless of whether they are self-administered. The current policy in Medicare is most troubling for conditions such as multiple sclerosis, where some patients can administer their drugs and others cannot. It is enough of a burden

to cope with the effects of such a debilitating disease without having in addition the worry of how to pay for expensive drugs.

Mr. Chairman, I think we all agree that the current limitations on Medicare coverage for self-administered drugs leave some beneficiaries without the medications they need. However, we are scheduling town hall meetings now, as directed by Congress, to allow all interested parties to air their concerns about the current situation, and to discuss available options, such as regulatory action to expand coverage for those who cannot self-administer drugs. Our first town meeting has been scheduled in Baltimore on May 18.

However, regulatory action to create another narrow exception allowing coverage for only some beneficiaries may not be the best solution to this problem. This approach could compound the current inequities that exist in our coverage policy.

Our clinicians at HCFA are concerned that such a narrow exception could create ethical dilemmas for compassionate physicians treating patients who can self-administer but who cannot afford the drug. This issue is in fact, as all of you know, a very small part of a larger problem for which patchwork solutions simply will not suffice.

As many Medicare beneficiaries lack prescription drug benefit coverage today as senior citizens lacked hospital coverage when Medicare was created in 1965. The program's current coverage restrictions leave many beneficiaries without coverage they need, not just those who are unable to self-administer drugs. We need to expand coverage to all beneficiaries. Patchwork solutions and limited exceptions cannot address a problem of this magnitude.

All beneficiaries, regardless of their health, their income, need access to an affordable, comprehensive outpatient drug benefit, as has been proposed by the President. Mr. Chairman, we look forward to working with you on this critical issue.

I do want to say, in response to your opening statement, Mr. Chairman, that we always try to be very responsive to any inquiry that you might make. I did write you myself, in response to your October letter, on November 3rd, where I attempted to lay out what Medicare's coverage policy was for self-injectable drugs, and I also indicated that we were working on a regulation to review the options that might be available for us to address this problem more adequately.

Thank you for your invitation for us to be here. I would be happy to answer any questions that you or other members of the subcommittee may have.

[The prepared statement of Michael Hash follows:]

PREPARED STATEMENT OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Chairman Bilirakis, Congressman Brown, distinguished Subcommittee members, thank you for inviting us to discuss Medicare coverage for self-administered drugs. The current situation provides a compelling example of why we must modernize Medicare with an affordable, comprehensive, outpatient prescription drug benefit available to all beneficiaries.

Medicare coverage for pharmaceuticals is now severely restricted outside of hospitals and nursing facilities. Congress has created only a limited number of exceptions, each spelled out in the law. One exception is for drugs that cannot be self-administered. Section 1861 (s)(2)(A) of the statute says Medicare may pay for drugs

"which cannot, as determined in accordance with regulations, be self-administered" when furnished "as an incident to a physician's professional services, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills."

Medicare's longstanding policy for coverage under this exception has addressed only whether a drug can be self -administered, not whether an individual patient can self-administer the drug. And Congress has not provided an explicit exception for those who cannot self-administer drugs that generally are self-administered.

The shortcomings of such a policy become clearer every day with dramatic new advances in drug therapies. Medicaid and most private insurers pay for all prescription drugs, regardless of whether they are self-administered. The current policy is most troubling for conditions such as multiple sclerosis, where some patients sometimes can administer their drugs and others cannot. It is enough of a burden to cope with the effects of such a disease without the worry of paying for expensive drugs.

We all agree that the current limitations on Medicare coverage for self-administered drugs leave beneficiaries without the medications they need. However, regulatory action to create limited exceptions allowing coverage for only some beneficiaries may not be the best solution to this problem.

Our clinicians at HCFA are concerned that creating such a narrow exception to the ban on Medicare coverage for outpatient drugs could create an ethical dilemma for compassionate physicians when caring for patients who can self-administer drugs but cannot afford the drugs they need. This approach could compound the current inequities in coverage, and may also create program integrity problems.

This issue is, in fact, a small part of a much larger problem for which patchwork solutions will not suffice. As many Medicare beneficiaries lack drug coverage today as senior citizens lacked hospital coverage when Medicare was created. All beneficiaries, regardless of health or income, need access to an affordable, comprehensive outpatient drug benefit, as has been proposed by the President.

BACKGROUND

Like many specific coverage policies in Medicare's history, determination of whether a specific drug could be self-administered has been left up to the medical directors of each claims processing contractor. Instructions to Medicare claims processing contractors on this issue have been provided through the Medicare Carrier Manual and were updated in 1995. Those instructions state that drugs may be covered only if they "are of the type that cannot be self-administered."

The question of whether a drug could be "self-administered" was self-evident when Medicare was created in 1965. A pill was self-administered, most injections except for insulin were not, so regulations defining "self-administered" were not promulgated. But now, dramatic advances in drug therapies have changed the medical landscape. Cancer drugs, for example, that had been available only as injections have become available in pill form.

Congress recognized some of these changes in technology in the Omnibus Budget Reconciliation Act of 1993 by authorizing Medicare coverage for certain oral anticancer drugs that contain the same active ingredient as an injectable drug that would be administered by a physician. The law also allowed for coverage of self-administered anti-emetic agents necessary for proper absorption of oral anticancer drugs covered under this provision. And it provided for coverage of clotting factors that hemophiliacs self-administer to control their condition.

Congress, however, has not created exceptions in the law to accommodate other compelling situations. Pharmaceutical advances are allowing more types of patients with different types of diseases to be successfully taught to administer drugs they need themselves. But some of these new agents are for conditions, such as multiple sclerosis, that create an unfortunate dilemma. Many of these patients can self-administer drugs. But others, especially those in later stages of the disease, are so debilitated that they cannot administer the drugs themselves.

We issued a memorandum in August 1997 clarifying the guidance in our carrier manual to emphasize that Medicare claims processing contractors may cover generally self-administered drugs when a provider is administering the drug in order to teach a patient how to self-administer. We did this to encourage more coverage in these situations. The memorandum also reiterated the long-standing policy that an "individual patient's mental or physical ability to administer any drug" may not be taken into consideration.

Because of continuing concern over this issue, we had planned to publish a proposal in the *Federal Register* exploring options and requesting public comments on ways to define "self-administered" through regulation. One option would have been to possibly expand coverage by taking individual patient conditions into account.

Unfortunately, some observers misinterpreted our plans for a proposal in the *Federal Register* as an effort to further restrict coverage.

This series of events led to inclusion of language in the Appropriations Act of 2000 in which Congress barred use of HCFA funds to carry out the transmittal of the August 1997 memo. The appropriations language also prohibited us from promulgating "any regulation or other transmittal or policy directive that has the effect of imposing (or clarifying the imposition of) a restriction on the coverage of injectable drugs under section 1861(s)(2) of the Social Security Act beyond the restrictions applied before the date of such transmittal."

We therefore postponed our proposal to solicit public comments on options in the *Federal Register* to avoid the appearance that we are attempting to restrict coverage in violation of the appropriations language. We have also suspended our 1997 memorandum and, as required by the law, alerted our contractors that current guidance on this matter is limited to instructions issued to them before the 1997 memorandum. We also are scheduling town hall meetings, as directed by Congress, to allow all interested parties to air concerns about the current situation and discuss available options. The first is set for May 18 in Baltimore.

We all agree that the current situation is not acceptable. The best solution is to provide all beneficiaries with access to affordable and comprehensive coverage for outpatient prescription drugs.

Need for Comprehensive Drug Benefit

Prescription drugs are as essential to modern medicine today as hospital care was when Medicare was created. Yet as many beneficiaries lack drug coverage today as senior citizens lacked hospital coverage then. Three out of five lack dependable coverage. Only half of beneficiaries have year-round coverage, and one third have no coverage at all.

Beneficiaries without drug coverage must pay for essential medicines fully out of their own pockets, and are forced to pay full retail prices because they do not get the generous discounts offered to insurers and other large purchasers. The result is that many go without the medicines they need to keep them healthy and out of the hospital.

This year more than half of Medicare beneficiaries will use prescription drugs costing $500 or more, and 38 percent will spend more than $1000. Each year, about 85 percent of Medicare beneficiaries fill at least one prescription. About half of the beneficiaries without coverage have incomes above 150 percent of poverty (above $17,000 for an elderly couple). Analysis by the National Economic Council shows that middle-income beneficiaries without prescription drug coverage purchase 20 percent fewer drugs but pay about 75 percent more out-of-pocket than those with drug coverage.

This situation is worse for the 10 million Medicare beneficiaries who live in rural areas. Nearly half of these beneficiaries have absolutely no drug coverage. They have less access to employer-based retiree health insurance because of the job structure in rural areas. And three-quarters of rural beneficiaries do not have access to Medicare+Choice plans and the drug coverage that many of these plans provide.

No one would design Medicare today without including broad coverage for prescription drugs. The private sector now includes outpatient drug coverage as a standard benefit in almost all policies. Further, all plans in the Federal Employees Health Benefits Program are required to offer a prescription drug benefit. And prescription drugs are particularly important for seniors and disabled Americans, who often take several drugs to treat multiple conditions. All across the country, Medicare beneficiaries are suffering physical and financial harm because they lack substantive prescription drug coverage.

The President has proposed a comprehensive Medicare reform plan that includes a voluntary, affordable, accessible, competitive, efficient, quality drug benefit that will be available to all beneficiaries. The President's plan dedicates over half of the on-budget surplus to Medicare and extends the life of the Medicare Trust Fund to at least 2025. It also improves preventive benefits, enhances competition and use of private sector purchasing tools, and strengthens program management and accountability.

Key Principles

The President has identified key principles that a Medicare drug benefit must meet.

- **It must be a voluntary benefit accessible to all beneficiaries.** Since access is a problem for beneficiaries of all incomes, ages, and areas, we must not limit a Medicare benefit to a targeted group.

- **It must be affordable to beneficiaries and the program.** We must provide assistance so almost all beneficiaries participate. Otherwise, primarily those with high drug costs would enroll and the benefit would become unaffordable. And beneficiaries must have meaningful protection against excessive out-of-pocket costs.
- **It must be competitive and have efficient administration.** Beneficiaries must have bargaining power in the market place. And we must integrate the benefit into Medicare but use the private sector to deliver it.
- **It must ensure access to needed medications and encourage high-quality care.** Beneficiaries must have a defined benefit providing access to the medications that their physicians deem to be medically necessary, and they must have the assurance of minimum quality standards, including protections against medication errors.
- **It must be consistent with broader reform.** The drug benefit should be a consistent part of a larger plan to strengthen and modernize Medicare.

The President's plan meets these principles.

- Beneficiaries will have access to an optional drug benefit through either traditional Medicare or Medicare managed care plans. Those with retiree coverage can keep it.
- Premiums will be affordable, with extra assistance for those with low-incomes.
- There will be no price controls or new bureaucracy; instead, the new benefit will be offered through private pharmacy benefit managers who can efficiently negotiate fair prices. All qualified pharmacies will be allowed to participate.
- Beneficiaries can get all drugs prescribed by their physicians from private benefit managers who meet minimum quality standards.

CONCLUSION

The need for an affordable, comprehensive, outpatient prescription drug benefit in Medicare is clear. The program's current coverage restrictions leave many beneficiaries without the coverage they need.

We want to expand coverage to all beneficiaries, not further restrict coverage. Patchwork solutions and limited exceptions cannot address a problem of this magnitude. There is broad consensus that the Medicare program must cover prescription drugs. Mr. Chairman, the opportunity is before us. The time to act is now.

We look forward to working with you further on this critical issue. I thank you for holding this hearing, and I am happy to answer your questions.

Mr. BILIRAKIS. Thank you, Michael. We will try to continue for another few minutes.

You made the statement, and we hear an awful lot of this, that legislative intent and the language in an appropriations bill may not be as clear as it should be.

But the thing that frustrates me is that we do not hear from you to that effect. We do not hear you tell us that "you were not clear enough in the way you drafted it. Therefore, this is what we recommend," or whatever the case may be. That is what is so really very frustrating. Of course, that was the intent of our October letter, and to date, we still have not heard anything.

We all know that—when I say we have not heard anything, we have not heard anything in terms of making recommendations, telling us basically that it is really the fault of the Congress, and this is what needs to be done, or something of that nature.

You refer to your town meetings. Had it been your intent to hold these all along? Yes, we did in fact require town meetings, but 4 months have gone by. Has it been your intent all along that you not do anything until after you have held your town meetings?

Mr. HASH. No, sir. We were trying to follow the language in the appropriations act faithfully, Mr. Chairman. Under that direction, we were told to do three things. One was to suspend the memorandum that we issued in August 1997, as you know. The second was to suspend any work on a regulation that would have any ef-

fect in limiting the coverage of self-injectable drugs. The third issue was that we should—in the conference report on the appropriations bill, it was suggested that we should hold town hall meetings to make sure stakeholders had an opportunity to comment on these issues.

Mr. BILIRAKIS. In the order in which you have stated them? Is that the way you interpreted them?

Mr. HASH. Yes, sir. And also, I would like to say that in my letter to you of November 3, in response to your October letter, Mr. Chairman, I did lay out that we were working on a regulation to address these issues.

We had recognized that, as all of us have, there have been tremendously important advancements in prescription drugs, many of which now can be administered in ways that do not require administration by a physician, and that part of our intent of doing a regulation was in fact to lay out alternatives and to get public comment, as we normally do in the rulemaking process, because we joined you in a concern about the limitations under the statute with respect to this coverage.

Mr. BILIRAKIS. Mr. Brown was at least partially right, certainly not completely right, but we should not be up here throwing stones. They are throwing stones because they say we have to do something overall on prescription drugs, and we have never disagreed with that.

As a matter of fact, I will repeat, we are the ones who are really working hard at that, unlike the past 40 years prior to when we took over—I hate to say that, because it is part of the statement. So we should not be throwing stones at one another, we should be working together on these things. I guess that is politics, and you do that.

The reasons, I suppose, why the prior majority, when they were the majority, did not address this issue was because of the difficulty of it, the expenses, trying to get it right. I don't know. Frankly, I don't remember that there were any efforts being made up here during all of those years, and I have been here for a good bit of them.

The AARP recently testified before this subcommittee that they would oppose any solution that is rushed, because they feel it is a very complex issue. It is something that is on a fast path, we feel.

I like to think that some of the comments that I have read in CQ made by some of the minority leader's chief staffers are not true when they say they would rather see nothing done unless there is a complete Republican capitulation, to use their words. I have been carrying that around with me, but I changed suits this morning and I did not bring it with me. But I intended to read it for my friend, Mr. Brown. So I hope that that is a wrong interpretation on my part.

I guess what I am saying, it is going to take a while. It may not take too long. Hopefully we will get it done this year. But in the meantime, there are some people out there hurting, and they are not—we are not talking about adding them to the Medicare program, which is what you are saying when you say solve the overall picture with prescription drugs.

We are saying, do what Congress intended back in the 1997 act and keep those people covered, because they were covered in the past. So it seems to me that if in fact HCFA is waiting until we can do something for the overall problem, we are really gambling with the lives of patients who depend on these medications. You would agree on that, wouldn't you?

Mr. HASH. We want to do whatever we can to address this problem as quickly as possible. That is true, Mr. Chairman.

I would also say, Mr. Chairman, that there have been some attempts during the long history of the Medicare program to address prescription drugs. Congress, actually, in a bipartisan fashion, passed something called the Catastrophic Act of 1988 in which we included——

Mr. BILIRAKIS. Don't remind us.

Mr. HASH. I understand why you might say that, Mr. Chairman. It did include coverage for outpatient prescription drugs.

Mr. BILIRAKIS. I supported it, and suffered along with so many others as a result of it.

Just very quickly, Section 219 of the fiscal year 2000 appropriations act that we have been referring to directed HCFA to cover injectable drugs and biologicals as it did before the August 1997 program memorandum.

It is my understanding that this coverage was intended to apply to all drugs and biologicals that had been reimbursed based on the "usual method of administration," and not just the drugs and biologicals that had been approved before August 13, 1997.

Has this been HCFA's practice?

Mr. HASH. Our practice, we have had a longstanding policy with regard to the coverage of drugs that can be self-administered. The August 13, 1997 memorandum to our regional offices was intended, Mr. Chairman, to actually modestly expand our historic coverage by recognizing that with the advent of many of these new drugs that could be self-administered, that we needed to encourage that by offering some limited coverage to individuals in physicians' offices at the time they began administration of this, so they could be taught how to self-administer drugs.

The 1997 memorandum was largely an attempt to say we were expanding what was otherwise our longstanding policy regarding self-administered drugs to allow some limited coverage in the case of individuals who were learning how to self-administer drugs under the supervision of their physician.

Mr. BILIRAKIS. But in any case, never any intent to just limit them to—limit this coverage to those drugs approved prior to the August, 1997 date?

Mr. HASH. No, no, sir, not to my knowledge.

Mr. BILIRAKIS. Thank you.

Mr. Brown.

Mr. BROWN. Mr. Chairman, I appreciate you and the majority working so hard on prescription drugs. We have legislation, the Allen bill, the Sanders bill, the Stark bill, my bill, and we could save you a lot of work by just adopting one of those, Mr. Chairman, if you would choose one.

Mr. Hash, we have injectable drugs that are self-administratable, we have injectable drugs that are not self-administratable but can

be given by a nontrained person, we have injectable drugs that are not self-administratable but can only be given by trained medical personnel.

Which of these three, just so we understand again, which of these three does HCFA cover?

Mr. HASH. Mr. Brown, generally speaking, Medicare does not cover drugs that are labeled self-injectables. There are a number of exceptions that are laid out in the law with respect to certain drugs that are self-injectable that are covered under Medicare relating to cancer drugs, certain renal failure drugs, hemophilia, clotting factors. Those are all self-administered drugs that by statute are carved out and in fact covered for Medicare beneficiaries.

As it stands now, we are trying to implement that in the fairest and fullest way possible, but generally speaking, the program has followed the label indications by the FDA about whether a drug is self-administratable or not.

Mr. BROWN. Does HCFA make the distinction of a patient's individual medical circumstances?

Mr. HASH. We do not. We do not believe—our longstanding policy on this was that we reviewed the literature and the FDA labeling to determine whether something could be self-administered, not the capacity of the individual patient to administer the drug themselves.

Mr. BROWN. Does this make sense, this incredibly complex way we are doing this?

Mr. HASH. It is clearly not in the best interests, I think, of patients who need access to these drugs. There is no question about that. But we believe that the statute and our longstanding policy has been an exclusion for coverage in the Medicare benefit package of drugs that can be self-administered. That is what the law says, and that is what we have been doing.

We would like to find a way to expand coverage in this way. That is why we were poised to put out a regulation that included a number of options that would take a look at this and involve stakeholders in it, and of course we believe, as I said in my opening statement, that patchwork solutions are really not what is going to address this problem, that we do in fact need a comprehensive outpatient drug benefit.

Mr. BROWN. I appreciate that. I do want to work bipartisanly with the chairman. In this subcommittee we have been able to do this. Sometimes the full committee has fallen short, sometimes all of us have. I think this subcommittee has been able to put partisanship aside better than most because of the Chairman's leadership.

I do hope that in two ways we can do something in conference. One is Medicare coverage, and second, a way really beyond the President's plan to deal with the exploding price of prescription drugs also, where we pay two and three times in this country what people in other countries pay; where individuals pay out of pocket twice as much as the VA pays and insurance companies and large hospitals pay.

I yield back, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. I know he sincerely means it when he says he wishes we would work together to provide access to these drugs.

We will recess for 5 minutes for a vote and we will be right back.

[Brief recess.]

Mr. BILIRAKIS. Thank you for your patience. The Chair now recognizes the gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman.

Mr. Hash, in your written testimony as well as your statement today you indicate that current limitations on Medicare coverage for self-administered drugs leaves beneficiaries without the medications they need. You go on to state further that, "The current situation is not acceptable."

But in reality, is it not true that for 30 years, HCFA had a policy that appropriately provided for coverage of certain injectable drugs, and that in fact it was not until HCFA's PM of August 1997 that caused this effect of denying coverage for those injectable drugs?

Mr. Chairman, I ask unanimous consent to put into the record two letters from Senators from the other body, one from Senator Kennedy, which, just extracting from that, it is directed to the Administrator at HCFA, your boss, Ms. DeParle, saying "As you know, Avonex, which is produced by Biogen, a leading Massachusetts biotechnology company, which was covered by Medicare until 1997"——

Mr. BILIRAKIS. Without objection, that will be the case.

I might add, if I may, that the letter that I initiated, signed along with me by 3 or 4 other members of October 18 to Ms. Shalala will be made part of the record, without objection.

[The information referred to follows:]

UNITED STATES SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
February 16, 2000

NANCY ANN MIN DEPARLE
Administrator
Health Care Financing Administration
Room S14G, Hubert H. Humphrey Building
200 Independence Avenue
Washington, D.C. 20201

DEAR MS. DEPARLE: I'm writing to urge the Health Care Financing Administration to take additional steps to make clear that Medicare coverage is available for Avonex, an injectable drug used to treat multiple sclerosis. As you know, Avonex, which is produced by Biogen, a leading Massachusetts biotechnology company, was covered by Medicare until 1997, when HCFA issued a memorandum to its regional offices on self-administered drugs. Avonex was determined to be self-administerable, and coverage was stopped for all Medicare patients.

In the wake of this decision, Congress acted last fall to restore the coverage. Section 219 of the "Department of Health and Human Services Appropriations Act 2000" (Public Law 106-113, Appendix D, 113 Stat. 15001A-241; November 29, 1999) provides that HCFA may not give any operative effect to its August 13, 1997 memorandum on self-administered drugs, or to any restrictions on coverage of such drugs imposed after the memorandum was issued.

I understand that many carriers responsible for Medicare reimbursement are unaware of the action by Congress on this coverage. I urge you to take all appropriate steps to see that this restoration of Medicare coverage for Avonex is clearly communicated to those administering Medicare, so that access by patients to this important treatment is available again as soon as possible.

With respect and appreciation,

Sincerely,

EDWARD M. KENNEDY

UNITED STATES SENATE
WASHINGTON, DC
October 27, 1999

The Honorable DONNA SHALALA
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

DEAR SECRETARY SHALALA: I am concerned about HCFA's intention to change the regulation regarding coverage for injectable drugs. The current policy that reimburses for drugs biologicals when provided incident to a physician's services is important for Medicare beneficiaries, especially those with cancer. Patients depend on us to ensure that they get the best cancer-care available. Restricting this policy at a time when the President and Congress are considering ways to expand drug coverage for seniors seems contradictory.

Cancer patients rely on supportive care drugs to help treat the symptoms and side effects of cancer and chemotherapy. These drugs that include colony stimulating factors, hematopoietic growth factors and low molecular weight heparins are an integral part of their chemotherapy regimen. These drugs can help patients tolerate their cancer treatment and improve their quality of life. Without coverage for these vital drugs, Medicare cancer patients may experience more infections and hospitalizations. The result may be increased costs to the health care system.

As I understand the situation, HCFA has covered injectable drugs that are given incident to a physician's services, if the drug is usually not self-administered. However, based on an August 1997 HCFA program memorandum to its regional office, some Medicare carriers are basing coverage decisions on whether they think some hypothetical patient could self-administer the drug, regardless of the standard method of administering a particular drug or a physician's judgment about the individual patient's ability to self-administer a necessary injection safely. The result has been narrowing coverage and, in some cases, denying coverage for medically necessary and clinically appropriate injectable drugs.

Many or most elderly cancer patients are not capable of injecting themselves, and often rely on health care professionals to help them. It is inaccurate to think that these drugs are usually self-administered, especially in this patient population.

I oppose any action on HCFA's part to restrict coverage of injectable drugs that are usually not self-administered. These drugs are a vital part of our Medicare beneficiaries' cancer regimen. Furthermore, the rule-making process is not necessary for HCFA to clarify its longstanding and broadly-supported policy to reimburse for injectable drugs that are usually administered incident to physicians' services. I suggest that HCFA notify the carriers through an official communication that carriers should continue to reimburse for these products, as they have since the inception of the Medicare program. I appreciate your careful examination of this issue, and request a status of HCFA's progress on clarifying this rule with your carriers.

With best personal regards, I am

Sincerely,

MAX BAUCUS

CONGRESS OF THE UNITED STATES
WASHINGTON, DC
October 18, 1999

The Honorable DONNA SHALALA
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

DEAR SECRETARY SHALALA: We understand that the Health Care Financing Administration (HCFA) is reviewing a policy that would effectively limit the access of Medicare beneficiaries to injectable drugs that are covered "incident to a physician's service." We are writing to express our serious concern about the impact of this policy on patients' ability to obtain necessary medications.

In the past, the administration of chemotherapeutic agents and life-saving injectable drugs in a physician's office to treat degenerative diseases was routinely covered by Medicare, if the drug was not usually self-administered by the patient. In August 1997, HCFA issued a memorandum to its regional offices "to clarify pro-

gram policy with respect to drugs that are usually self-administered, but may not always be self-administered."

It has come to our attention that under this guidance, some Medicare carriers are making coverage determinations based on a hypothetical analysis of a patient's ability to self-administer the drug—irrespective of the standard method of administering a particular drug or a physician's judgment about the individual patient's ability to self-administer a necessary injection safely.

This policy could seriously limit the access of Medicare beneficiaries to important injectable pharmaceuticals. It is also likely to create confusion among beneficiaries and providers regarding coverage of medications administered in a physician's office.

We would like to fully understand the rationale for this new policy. To that end, we are requesting your responses to the following questions:

1. What are HCFA's objectives with regard to coverage for injectable drugs provided incident to a physician's visit? What is the purpose of issuing a notice of proposed rulemaking? Is the Administration attempting to restrict coverage, to limit budget expenditures for currently covered products, or to limit coverage of future products?

Over the past two years, HCFA's policy regarding injectable drugs covered incident to a physician's visit has been interpreted in different ways. What is the current HCFA policy? Are the carriers aware of this policy, and are they implementing it accordingly?

3. What therapeutic categories of drugs will be addressed in any proposed rule? Are those categories currently covered?
4. What would be the impact of any change in policy for patient access, patient quality of care, and patient financial contributions?
5. Is HCFA's intent to continue coverage for products that are currently covered?
6. What other methods does HCFA have to clarify its policy without disrupting beneficiary services?

Considering the very serious nature of this issue, we respectfully ask that you respond to us with the requested information no later than October 22, 1999. Most importantly, we request that HCFA take no action with regard to changes in this policy, including publication of a proposed rule, until we have had a chance to examine all the relevant information and work with HCFA to address our concerns.

Thank you for your prompt attention to this matter.

Sincerely,

REP. MIKE BILIRAKIS
REP. ERNIE FLETCHER
REP. DEBORAH PRYCE
REP. JAMES GREENWOOD
REP. NANCY JOHNSON

cc: Nancy-Ann DeParle, HCFA Administrator

Mr. BRYANT. Senator Kennedy continues, "When HCFA issued this program memorandum, its regional offices at Avonex was determined to be self-administratable, and coverage was stopped for all Medicare patients."

The second letter is from Senator Baucus that says, and that is October, 1999; it says, "Restricting this policy at a time when the President and Congress are considering ways to expand drug coverage for seniors seems contradictory." He has other things to say about that. They will be placed in the record.

Don't you agree that this program memorandum of August, 1997, has created this unacceptable problem?

Mr. HASH. Mr. Bryant, with all due respect, I do not agree. I believe that the intention of the August 13, 1997 memorandum to our regional offices was a restatement and clarification of our longstanding policy, and further, that it provided in fact some small expansion of our coverage with respect to the teaching of individuals who were commencing self-injectable drug therapy.

Mr. BRYANT. In terms of what you believe and what actually happened, I think the reality is evidenced by letters from our chair-

man and the Senators' letters, that this PM had the effect of substantially restricting, as opposed to expanding.

Mr. HASH. Mr. Bryant, I know that the Administrator met on several occasions with representatives of the company that manufactures Avonex, the drug that you referred to in those letters, and that we sought diligently to find a way as to whether or not it could be covered under our drug policy, consistent with the law and our longstanding policy.

We were unable to do so. That is one of the experiences that led us to the decision to commence a rulemaking process to try to put out some additional options about how this might be handled, given the statutory limitations regarding self-administratable drugs.

Mr. BRYANT. We appreciate that. But I think the bottom line, the net effect, is that the folks that were able to take this and be reimbursed before 1997 no longer have that, as well as others. I think that is what we are here about.

The fiscal year 2000 appropriations bill prohibited HCFA from implementing any such policy that would have imposed new restrictions. I want to stress the word, we did not prevent you from expanding; we simply, in that bill, opposed new restrictions of Medicare coverage of injectable drugs.

The report language accompanying this provision directed HCFA to issue a program memorandum to all carriers clarifying this policy. It is my understanding that you issued—the one you issued on March 17, which was, I guess, Friday—that you did finally issue one.

Mr. HASH. Yes, sir.

Mr. BRYANT. We appreciate that.

Again, I, like a lot of people—we can point fingers all we want to, but we really need to get to the bottom of this. Certainly, I think the cause of the problem has been back with this August 1997 memorandum that was issued. I suppose it is up to us to now correct it. I think we thought we had corrected it, but it is slower than we expected.

Let me ask you one other question about I guess the broader scope of this on the issue I raised in my opening statement about the expense, the anticipated higher expenses for these new drugs.

As I understand it, the President's drug benefit proposal, when fully phased in, would provide only $2,500 in total Federal drug assistance to each senior each year. Would this be enough to cover a year's worth of disease treatments within general therapies? I don't think it would, but I would like your opinion. If you agree with me that it would not, would such a proposal then represent a reduction in Medicare coverage of many of the lifesaving drugs on which our ailing senior citizens rely?

Mr. HASH. One of the reasons that this year the President in his Medicare reform proposal modified the drug proposal that was released last summer was to include the recommendation of setting aside coverage for catastrophic costs above the $5,000 cap that was in the original proposal.

As you may know, there is a $35 billion set-aside that would be dedicated to providing increased coverage for individuals who have higher drug costs, because we, like you, recognize that some of these therapies, are extraordinarily expensive and need to be cov-

ered. That is the purpose of that extra provision in the President's proposal.

Mr. BRYANT. Again, as I originally stated, it would not have helped. In actuality, it would have probably hurt seniors in terms of trying to use this new medication. I know we added money later, and only recently have we seen language in a bill.

Mr. BILIRAKIS. The gentleman's time has expired, but please respond to that.

Mr. HASH. The other thing I wanted to say, Mr. Bryant, is I don't believe it would have harmed beneficiaries. One of the benefits of the President's original proposal was to make available to all Medicare beneficiaries the discounts that would be experienced as a result of relying on pharmacy benefit managers. That would continue, regardless of the caps on the coverage. It is estimated that those discounts would result in a 12.5 percent, on average, discount from current prices.

So it is clear that even without the catastrophic benefit, there would have been some important financial benefits to beneficiaries from having access to discounted drug prices.

Mr. BRYANT. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mrs. Capps?

Mrs. CAPPS. Thank you.

Mr. Hash, thank you for your testimony. If I could talk with you or if you could talk with us about the legislative changes or changes in general necessary to have the Medicare program cover self-injected drugs or biologics, does HCFA have the authority to do this, by your own decisions, administratively? What parts can you take care of and what parts need to be legislatively covered?

Mr. HASH. Mrs. Capps, the reason we were moving down the road toward a regulation is that there are some interpretations of existing statutory language that might have allowed some expansion with respect to coverage of self-administered drugs. That is why we wanted to put out some options to get public comment on and to assess that.

The reality, though, is the limitation is still or would still, even with options that might be available, be a piecemeal response to a much broader problem, as you recognized in your opening statement. That is why, of course, we are strongly supporting a broader outpatient prescription drug benefit. But we did want to explore some possibilities.

I should also say that in thinking about options to expand coverage for self-administrable drugs, a host of ethical issues come up; for example, where to draw the lines with regard to capability for self-administration, not just with injectables, but when you consider we have such a significant population of beneficiaries with dementia or Alzheimer's who may not be able to know and follow a pill regimen, which is clearly, by anyone's definition, a self-administrable drug, but on the other hand, is that someplace that the statute would allow us to go?

More importantly, as I mentioned in my opening statement, some of our own clinicians at HCFA are worried about the ethical dilemmas that would be posed for a health care professional who is treating a patient who clearly cannot—who clearly can self-administer, is capable of doing so, but cannot afford the drug.

Mrs. CAPPS. Yes. This is exactly the real world that our constituents and the people who are affected by this whole arena—this is where they live. These are ethical decisions they are making every day.

So I want to acknowledge that I commend the administration for entering into this world. I understand there are pitfalls. I guess in the same conversation, if we could discuss, then—and I don't want you to have to declare one way or the other about the particular bill that I referenced—access to Innovation for Medicare Patients Act of 1999.

Given, though, that it would provide coverage to biologicals that would be used in lieu of already covered products, is there some precedent for that kind of change? Is this the direction that legislation would be useful for your administration?

Mr. HASH. Legislation would, I think, be useful. I have not had a chance to review your bill in detail, but I think—I know you are trying to address the problem of access here, and I think we want to work with you on that.

I think the other part of this is, in the coverage of drugs, absent a more comprehensive approach, we need to be concerned about the payment policies. Under current law, the program is required to pay a set amount that is 95 percent of the price that virtually no one pays for drugs in this country today.

So when you are thinking about crafting legislative solutions that involve more expansive coverage of self-administered drugs, I would recommend that Congress consider the pricing strategy, a pricing strategy for such an expansion. Because at the present time, we have very little leverage with respect to purchasing at a price that is reasonable, given the purchasing power that Medicare would otherwise have.

Mrs. CAPPS. I know I don't have much more time, but just finishing up, you said something about—in your forums, that you have had meetings with people. Have you gotten the kind of feedback that would give you a set of boundaries?

Mr. HASH. Actually we have not had those meetings yet. The conference report on the appropriations bill requested or directed that we hold at least two town hall meetings, and to invite stakeholders to talk about a possible model for expanding the coverage of self-administered drugs.

The first one is scheduled in Baltimore for May 18.

Mr. BILIRAKIS. Is there a second one scheduled?

Mr. HASH. Not yet, Mr. Chairman.

Mr. BILIRAKIS. I'm sorry. Please proceed.

Mrs. CAPPS. I yield back the rest of my time.

Mr. BILIRAKIS. Mr. Burr, to inquire.

Mr. BURR. Thank you, Mr. Chairman. My apologies for my tardiness.

Mike, it is good to see you.

Mr. HASH. Thank you, Mr. Burr.

Mr. BURR. Let me go to a couple of areas, if I can. If what I am told is true, I am gratified to hear you say that HCFA never intended to reduce Medicare coverage of injectable drugs, but I have to tell you that I am confused. If that is the case, why was a provision stuck in the very last page of the President's budget proposal

for HHS that would have repealed the action just taken which prohibited such a cut?

Mr. HASH. Mr. Burr, what we typically do when we send up the President's budget, in response to provisions that were added to an annual appropriations bill, is to make recommendations to the Congress regarding those appropriation riders.

In this case, that recommendation on the President's behalf recognizes that what we would like to do is to do what we were in the progress of doing when the appropriations rider passed. That is, we would like to return to the rulemaking process, where we were prepared to lay out a series of scenarios to get public comment on for possible expansions of the coverage of self-administered drugs.

Mr. BURR. You said in your statement, and I will refer to your testimony a couple of times, you suggested HCFA cannot create an exception for patients who are unable to self-administer the drugs they need because Congress has not provided you, HCFA, explicit authority to do so. I will refer to page one of your testimony, the third paragraph, the last sentence, "And Congress has not provided an explicit exception for those who cannot self-administer drugs that generally are self-administered."

I guess you are telling us there that HCFA does not have policymaking authority, except when explicitly specified by legislation by Congress, is that right?

Mr. HASH. No, sir. In a number of cases the law is subject to interpretation, and there is administrative discretion associated with provisions in the law.

Mr. BURR. Okay. I am further confused, then.

Mr. HASH. Let me give you an example of how we, I think, got to where we are, if I may.

Back in 1990, I think it was OBRA 1990, the Congress passed in the Medicare statute a provision relating to the coverage of a drug that was used for women, postmenopausal women who had fractures related to osteoporosis. The drug, I believe, is called Calcetonin.

In the statutory language that is associated with that coverage, Congress went to great lengths to describe the fact that you needed to cover these injections by taking into account either the mental or physical capacity of the individual to administer that drug.

I think what that—the inference one takes from that is, but for that language in the statute, that drug would have been subject—as I think members knew at the time that matter was being considered, that drug would have been subject to the exclusion of the self-administered drugs.

But the fact that Congress specifically in the statute said, in covering this drug for fractures by women who have osteoporosis, you should take into account whether the individual beneficiary either mentally or physically has the capacity to self-administer this drug——

Mr. BURR. So only when there is a congressional reference to a specific area does HCFA feel that they have the authority to in fact propose a new rule?

Mr. HASH. Not only, but in this case of self-administered drugs, the Congress—the Calcetonin is but one example. Congress carved out a specific exception related to oral cancer drugs.

Mr. BURR. Whose interpretation of what Congress wrote are you referring to, Congress', HCFA's, or some third party?

Mr. HASH. I'm sorry, I don't know if I understand this.

Mr. BURR. The legislation, and I hate to be specific, but we have had those instances in the past, you and I know, where our interpretation or intent, our language, was interpreted in a totally different way. I am just trying to find out what the basis is.

Is it exactly what we say?

Mr. HASH. If the plain reading of the language of the statute leads to a reasonable conclusion, then I think the people who are executing the laws have no choice but to follow the plain reading of the statute.

If the plain reading of the statute leads to some alternative possibilities, rational possibilities, then I think one turns to the legislative history, to look at the conference reports, to look at the committee reports, to see if there was amplification of the provision that was included in the statute.

That is kind of the tree of logic I think that is applied to determine whether administration discretion resides.

Mr. BURR. If we added report language to a bill that suggested the scope of where HCFA had authority to propose rules, you would see that as congressional intent to allow you to make rulemaking?

Mr. HASH. I would definitely see anything in the committee report or conference report as an expression of congressional intent. I want to quickly add, if there is a conflict between the plain reading of the statute and the legislative history, the plain reading of the statute would be the guide we would follow.

Mr. BILIRAKIS. Would the gentleman yield? His time has expired.

Mr. BURR. I would happy to yield if the chairman would allow me one last follow-up question. But he can certainly go first.

Mr. BILIRAKIS. All right. Just to follow up on your questioning, pre-August 1997, the policy of paying for injectable drugs and biologicals was based on the usual method of administration, which the carriers used in making their coverage decision until that date.

What possessed HCFA to come up with a program memorandum in August 1997 in effect clearly changing that? Mr. Kennedy in his letter basically says stopping payment, and I'm not going to be that drastic, but in effect, changing the policy by adding in the phrase "The individual patient's mental or physical ability to administer any drug is not a consideration for this purpose?" .

I'm sure we all would like to know, why HCFA would do that? It came out of the woodwork, did it not?

Mr. HASH. I believe it is a reflection, Mr. Chairman—and I was not there in 1997, as you know—but I believe and I have been informed that the reason for the issuance of that memorandum was, as we have been talking about here this morning, there have been a lot of advancements in drug administration, including many drugs that started out as intravenous or intramuscular drugs that had moved into the arena of subcutaneous or self-administered drugs. There has been an evolution. Many questions were raised.

The purpose of the memorandum to our regional offices was to help respond to a series of questions about the clarification of our policy on self-administered drugs. It was not intended, and I want to say this in the strongest terms, it was never intended to restrict coverage.

In fact, as I have said several times this morning, it modestly expands coverage.

Mr. BILIRAKIS. Not according to the letter signed by Mr. Kennedy.

Without objection, the gentleman's time is extended for an additional 30 seconds.

Mr. BURR. I appreciate the extension, Mr. Chairman. I just want to make sure that we are clear.

HCFA's understanding is that if they cannot point to an area of legislation or report language that allows HCFA to propose a rule, than you don't have the authority to do it? If there is not legislation that leads one to see that the Congress wanted you to have some flexibility, wanted you to be involved in rulemaking, then you have none?

Mr. HASH. No, sir, I wouldn't say that. I think each case has to be judged—whatever we might be talking about specifically needs to be judged specifically.

Mr. BURR. Based on what?

Mr. HASH. Generally speaking, regulations are rooted in the statute. Regulations are to follow the statutory provisions.

Mr. BURR. Clearly you said there must be some tie to what Congress wrote that allows you the authority. If not, you don't have the authority?

Mr. HASH. I think we have the authority to write regulations. The substance of those regulations is covered by what is in the law, what is in the legislative history surrounding it.

Mr. BURR. My biggest concern is that we cannot have it both ways. We need to get an understanding.

I would only make this statement, Mr. Chairman, that as we talk about comprehensive drug coverage for seniors, if we have this much trouble understanding self-injectables, I hope every member will take that into consideration as we look at HCFA as a component of an overall comprehensive drug plan, and certainly make sure that it is part of their decisionmaking process.

I thank Mr. Hash. Mr. BILIRAKIS. Mr. Barrett?

Mr. BARRETT. Thank you, Mr. Chairman. Just to follow up on that in just a very generic sense, how would a comprehensive drug benefit change the way the current benefit works?

Mr. HASH. I believe, at least speaking of the President's comprehensive drug benefit, the coverage of drugs that are now covered either in a hospital or a nursing facility or covered as incident to a physician's service, which is what is covered now, that coverage would remain intact.

What the comprehensive new drug benefit would cover is all of the non-covered, in effect self-administered, outpatient drugs which are currently not covered under the Medicare statute.

Mr. BARRETT. Would you consider that a more equitable fashion to deal with this?

Mr. HASH. Absolutely. You were not here earlier, but what I was trying to say earlier was that while all of us would like to be dealing with the problems of self-administered drugs that we are here to talk about this morning, it does represent sort of a patchwork approach to this problem.

I think the reality for all of us is the most appropriate way of dealing with these problems is through a comprehensive outpatient drug benefit.

Mr. BARRETT. I am confused by some of the discrepancies, and I feel them floating around the room, too. We are talking about self-injected drugs, and the pharmaceutical companies want those covered by Medicare?

Mr. HASH. Definitely.

Mr. BARRETT. These are the same pharmaceutical companies that run these Flo commercials that say we don't want government in our medicine cabinets?

Mr. HASH. I think you see some inconsistencies.

Mr. BARRETT. The other concern I have with the self-injected, would we be creating some sort of market incentive to create these drugs as self-injectable drugs if they are not already so they could be covered by Medicare?

Mr. HASH. Yes, sir. I think your point is well taken. We don't want to have a public policy that influences the form in which drugs are manufactured. What ought to be influencing the form in which drugs are manufactured and made available to beneficiaries or to the American people ought to be on the basis of the form that works best for the drug itself, not on the question of whether it could be self-administered or administered through intravenous applications or not.

That is what should not determine it. What should determine it is what form of administration will make the drug work most effectively for the patient.

Mr. BARRETT. Okay. I yield back the balance of my time, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Pickering, the gentleman from Mississippi, to inquire.

Mr. PICKERING. Thank you, Mr. Chairman. I apologize for being late. If I go over some ground that has already been covered, please excuse me.

I am concerned, just the little bit that I have heard, that we are losing our focus of what today is about. That is simply, what is the status of self-injectables and HCFA's policy toward that, and then consequently, is that resulting in the denial of such benefits to Medicare recipients?

I would like to keep or regain our focus. We are all, on this committee, supportive of trying to find a way on the broader issue of prescription drug benefits, but that is not what this hearing is about. So let us keep our focus as we go forward.

Let me ask Mr. Hash, the program memorandum that came out in 1997, as a result of that, did it create a situation where the private market insurers began denying coverage for drugs and biologicals that they covered prior to 1997?

Mr. HASH. When you say private market insurers, do you mean private health plans and policies or do you mean the Medicare program?

Mr. PICKERING. Both. Both the Medicare carriers, as well as health insurers in the private market.

Mr. HASH. In general?

Mr. PICKERING. Yes.

Mr. HASH. I don't know about the policies of private insurers, so I am not prepared to answer that question. I would be happy to get you an answer if we have any data on that.

With respect to the Medicare program, as I said earlier, the August 13, 1997, memorandum we sent to our regional offices was intended to clarify our longstanding policy, and it actually provided a slight expansion of that policy to cover the instruction of individuals who were commencing a program of self-administration of drugs.

That is what was—and by the removal or suspension of that August 13 memorandum of 1997, the carriers who administer this program for us are to follow the carrier manual, which was last updated in 1995, and basically restates Medicare's longstanding position on the noncoverage of drugs that can be self-administered.

Mr. PICKERING. In practical terms, does that mean that the practice prior to 1997 of physicians being able to prescribe self-injectables was discontinued at that point by your carriers?

Mr. HASH. We have never had a policy of covering self-administered drugs.

Mr. PICKERING. But the practice—let us separate policy and practice, pre and post. The practice before was I think commonly used that we would have self-injectables——

Mr. HASH. I think the practice in reality varied quite widely, because carrier medical directors who actually oversee the application of the carrier manual instructions have some discretion to apply the findings in the manual to the real life claims that they get.

The manual actually says that drugs that can be self-administered in the form that they are usually provided cannot be covered. If the drug is generally administered by a physician in their office or in their clinic, and that is the form in which it is generally administered, then it would be covered under the Medicare program, and has been since the inception of the program.

Mr. PICKERING. Again, if I can, staying away from the manuals and the policy and just going back to the practice, pre-1997, you say the practice had disparities. In some cases that was followed and in some cases, maybe not?

Mr. HASH. I believe that to be the case.

Mr. PICKERING. Post-1997, did the policy memorandum, programmatic memorandum, have the effect of discontinuing that practice altogether?

Mr. HASH. I don't know that for a fact. I think it clearly has had some effects, because you and others and we are aware that it has had some effect. But what it was doing was restating the longstanding policy of Medicare.

If carrier medical directors had not been paying attention to that and saw the August 13 memorandum, then presumably they would

want to make sure that their decisions were consistent with the guidance that we had provided them.

Mr. PICKERING. Just for clarity, I will try to restate what I believe you just said. That is, after the memorandum in 1997, the practice discontinued?

Mr. HASH. No, sir, I did not say that. I said it varied before and after.

Mr. PICKERING. So it still varies before and after?

Mr. HASH. Yes, sir.

Mr. PICKERING. If the practice varies with your policy, what do you want to see? What is the practice that you want to see by your carriers?

Mr. HASH. What we have been trying to do before the appropriations language passed last year was to engage in a rulemaking process to put out a series of options that we thought would be consonant with the statute as it exists now in order to explore ways of expanding coverage. That is the direction we were headed.

Mr. PICKERING. Mr. Hash, if we can stay away from memorandums and statutes and all the gobbledegook, what practice do you want to see by your Medicare carriers for those who could benefit from self-injectables?

Mr. BILIRAKIS. The gentleman's time has expired, but you may proceed.

Mr. HASH. The practice we would like to see is to put out a rule to solicit comments with regard to options we think are consistent with the statute. We, like you, are just as frustrated with the limitations of the statute, particularly for people who suffer from the serious diseases like multiple sclerosis, and who in fact cannot physically self-inject.

There is no one who is disagreeing over the need to address that problem. That is something we want to do, just as much as you want to do it. We would like to work with you toward that end.

Mr. PICKERING. Mr. Chairman, can I just try one more time?

Mr. BILIRAKIS. Only if there is no objection to that effect.

Mr. BROWN. Mr. Chairman, I won't object, but there has sort of been a trend in this hearing that the majority goes over with one or two more questions and continues this.

Mr. BILIRAKIS. They have more questions.

Mr. BROWN. Perhaps they do have more questions, but I also understand that HCFA's administrative budget has been cut, HCFA does not have the power to hire and fire carriers, and I am not sure this is really a fair kind of approach that has been taken.

I certainly don't mind Chip continuing his questions, but I just think if people on our side want to go over the same way——

Mr. BILIRAKIS. Keep it short if there is no objection, please.

Mr. BROWN. I have no objection.

Mr. PICKERING. I just want to understand Mr. Hash's position and HCFA's position.

In practice, do you want to see those capable and those who pre-1997 were able to self-administer these drugs, which that did provide, from all accounts, a benefit to people, and as we talk about the broader issue of prescription drugs—we are trying to help people as they receive treatment to have that option—do you now want to see self-injectables through Medicare practiced?

Are you saying that you are limited and cannot do that?

Mr. HASH. What we said is we would like to expand in this area to the fullest extent of the law. We believe in order to do that we need to publish a rule.

Mr. PICKERING. Thank you, Mr. Chairman.

Mr. BILIRAKIS. It still goes back to statute. There is no change in the statute. The statute was in existence prior to August 1997. It was done a certain way. The program memorandum came out of the woodwork in August 1997 changing things.

Mr. Deutsch, to inquire.

Mr. DEUTSCH. Thank you, Mr. Chairman.

Mr. Hash, Ms. Story, who is on the second panel, notes in her testimony that Medicare would just cover the cancer drugs to prevent countless inpatient hospitalizations and infection and would reduce morbidity and mortality for people who currently cannot get them.

Does it not seem to you that this statement is true for coverage of all drugs? If Medicare provided a comprehensive drug benefit, do you not think we would do a lot more to reduce morbidity and mortality, promote health, prevent hospitalizations and make improvements in medical outcomes?

Mr. HASH. Absolutely, Mr. Deutsch.

Mr. DEUTSCH. I guess the emphasis on this side really has continually been that there is no question that the situation now is a horrendous situation, but is there anything really to point out the unique nature of the drugs that we are dealing with, these injectables, versus drugs across-the-board?

Mr. HASH. I think anyone who cannot get access to drugs that are lifesaving or life enhancing is in a situation that we should be remedying. That is the whole point of this effort to get a prescription drug benefit for Medicare. Whether it is an injectable drug or an oral drug or an IV drug, Medicare beneficiaries ought to be covered for outpatient drugs or inpatient drugs, for that matter. Drugs are key to managing and improving the health of our beneficiaries.

Mr. DEUTSCH. Right. I guess that is really where the emphasis is. I appreciate the fact that we are having this hearing, but I think the hearing emphasis really is about lack of access of prescription drugs.

Again, in some ways we are highlighting the situation, this anomaly that exists today really enforces that highlight and makes it clearer in terms of the situation that occurs.

Can we maybe talk a little bit about the actual dollar savings that either we have been able to come up with or drug companies can come up with in terms of savings that would occur if these drugs were available?

Mr. HASH. I think there is a lot of literature on certain drugs and what occurs as a result of their availability in terms of reduced need for hospitalization, reduced need for other kinds of services that would be required if the person did not have access to the drug.

I don't have the data right here handy, but I think drug companies themselves frequently, when they are introducing a drug to the market, have done some research about its effect on the utilization of other services if the drug is made available.

Mr. DEUTSCH. Again, there are different studies I know both of us have seen. There is at least an argument that could be made with empirical data to support that in fact there is a positive savings in terms of providing this type of coverage?

Mr. HASH. I believe for many drugs that is the case, Mr. Deutsch.

Mr. DEUTSCH. I have just a follow-up regarding that question.

When Medicare was instituted, can we have just both a ballpark and an empirical data sense—a way to quantify the dramatic increase prescription drugs have taken as part of the health care delivery system in America from when Medicare was instituted?

Mr. HASH. I don't have any exact figures for you, but I would be happy to try to quantify the sales of drugs in 1965 versus today.

Obviously, we all know, without knowing what the exact figures are, there has been a quantum change in that, no question about it.

Maybe another way of looking at it and answering your question is to say the failure of the Medicare program to have included prescription drugs in 1965 more than anything else suggests that it was not viewed as a significant part of the health care armamentarium of that period, because nobody would think about designing Medicare today from the ground up and leave out outpatient prescription drugs.

Mr. DEUTSCH. Which again I think is tied into the fact of what percentage of out-of-pocket costs are spent today by Medicare beneficiaries versus 1965 for prescription drugs.

Mr. HASH. Right. There are huge differences. In fact, even today, and one of your later panelists, Dr. Steinberg—I happened to review his testimony—he recently published an article in Health Affairs that shows pretty dramatically what the costs of drugs are for the Medicare population.

There are other articles that have recently come out showing that people without drug coverage actually pay more out of pocket for drugs, not surprisingly, but they get fewer prescriptions because they are unable to afford them.

So there is a real consequence with the absence of drug coverage in terms of both costs to beneficiaries and lack of access.

Mr. DEUTSCH. I want to give you a chance to answer this question, because I know this has come up, as well.

It is my understanding that the President's original prescription drug proposal would not have provided catastrophic coverage, and thus would not have provided any help for the people who need these expensive injectable drugs.

But the proposal in this year's budget does include a catastrophic element which would help with costs of these drugs. Could you comment on this?

Mr. HASH. Yes, sir. I said two things earlier. One is that obviously the President's proposal includes a set-aside of $35 billion for that purpose. That is in recognition of the need to provide this—what we now believe would be about 10 percent of the Medicare population by 2009 who would need more than $5,000 a year in drug expenditures.

The other point I made earlier was the fact that even under the original proposal, when the cap was reached, Medicare bene-

ficiaries would continue to enjoy the discounts that were made available to them through the contracting with pharmacy benefit managers above and beyond.

Those savings on an average basis were estimated at about 12.5 percent off the retail prices, which for Medicare beneficiaries means Medicare beneficiaries pay the very highest prices today for drugs of any other citizens in the United States.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Bilbray, to inquire.

Mr. BILBRAY. Thank you, Mr. Chairman. I want to sort of just follow up on what my colleague, the gentleman from Florida, was taking about.

We have had hearing after hearing about the issue on this challenge of the cost effectiveness of providing prescription drugs and different types of treatments that may not be available now. In Southern California we have some great programs. In fact, AARP has finally said that they would agree with co-pays and a lot of other stuff, so that is not the issue here.

I am sort of just flashing back to my days of administering health programs for $2.8 million. I have an administrator in front of me that tells me that there was no intention of reducing services or eliminating certain medication to the clientele, quote-unquote.

My question is, why was the memorandum—why was the restriction at not reducing those services eliminated if there was not some kind of intention of reducing those services?

Mr. HASH. As I said before, Mr. Bilbray, what we were doing there, as I understand it, is as drugs have moved from the category of injectable through IV and intramuscular into individual self-administered drugs, subcutaneous injections and so forth, we have had a series of questions that have come up to our carrier medical directors and to the HCFA as well, and as a result of that, periodically what we do when we encounter those kinds of questions is we put out any clarifying and, if possible, any expanding information we can so that we can properly administer the benefit.

Mr. BILBRAY. Are you saying that in Mr. Deutsch's State, for every product that was dropped, there was a comparable treatment that was exactly the type of program that a physician could be able to choose as an alternative to that program that had been reduced?

Mr. HASH. No, sir, I am not saying that.

Mr. BILBRAY. When you say that the technology moved away from a product, it means it moved to something.

Mr. HASH. Yes, sir.

Mr. BILBRAY. If it moved to something, my question was, did it move to a comparable treatment that basically made the original treatment obsolete? They had a better, different mousetrap, but it was still catching the same mouse?

Mr. HASH. That is possible, yes, sir.

Mr. BILBRAY. My question is, the way you are saying it is that it did it every time. I don't have that data that it did it every time.

Mr. HASH. No, sir, I didn't mean to imply that. I misspoke.

Mr. BILBRAY. So there was an abandonment of historical service, then?

Mr. HASH. No, sir.

Mr. BILBRAY. Either you covered every base with the new technology, or you abandoned one base, or some bases were left out. You cannot say I didn't cover every base, but I

didn't—but there wasn't any uncovered bases out there. It is conflicting testimony.

Mr. HASH. Let me try, if I may, to sort this out.

Historically, the Medicare policy for the coverage of outpatient drugs is limited to drugs that cannot be self-administered. Earlier on, most drugs that fell into this category were drugs that were administered under the supervision of a physician or a health care professional, usually intravenously or intramuscularly.

Now these products have either evolved, or in some cases they are brand new products that never have been administered that way, that are administered through subcutaneous injections.

The way we have interpreted the statute historically, all the way up until now, has been that if a drug in its usual form to the patient was capable of being self-administered, then it was excluded under the Medicare statute as a self-administered drug.

Mr. BILBRAY. Even if it had been used—even though it had been covered in the past?

Mr. HASH. It could continue to be both, because in some cases the proper form, because of the patient's condition, would be to administer some drugs intravenously, even though there is a form of it that can be administered subcutaneously. The difference is the condition of the patient, where the drug will actually work best.

Let me give an example.

Mr. BILBRAY. I have to stop you a second. I just cannot believe that an administrator at your level—the detail you are talking about making these calls, that making those calls in between a physician and their patient—I mean, the challenge is there, and I can imagine trying to do it at county level, but trying to do it at national level—do you really believe that that is practical?

Mr. HASH. Those are not the decisions that I make. If it sounds like I am making them, then I have misspoken again.

It's our contractors who administer the Medicare program, in this case, the carriers who administer Part B, there are medical directors who actually make the kinds of judgments that I was just talking about. That is why there is discretion at the contractor level within the guidance that we have given them.

That is why in some cases if the label from the FDA indicates that a drug can be administered intravenously, and it describes a set of patient characteristics where, for that kind of a patient, this drug will only work effectively if it is administered intravenously, and for other kinds of patients with different diseases or different conditions the label may say this can be self-administered through a subcutaneous injection, those are the kinds of decisions that come before the carrier medical directors. There are 22 of them around the country. They make those kinds of decisions.

Mr. BILBRAY. This is a classic——

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Strickland.

Mr. STRICKLAND. Mr. Hash, do you think that medical policy should rest in the hands of the Members of the House of Rep-

resentatives and the Members of the Senate, rather than in the staff at HCFA?

Mr. HASH. I think Congress has certainly plenty of prerogatives to establish policies, including medical policies, in the context of a program like Medicare. They do sometimes. Other times they leave those decisions to the marketplace or in fact to clinicians to make those decisions.

Mr. STRICKLAND. In all due respect to you, my experience with HCFA has been that oftentimes there seem to be individuals there who think they know better than those of us who have been elected by the people. That is one of the things that troubles me about this agency.

Having said that, I have a couple of questions. In your judgment, are there people who have very, very serious health conditions who still will not get the needed drugs, even after the August 1997 policy changes?

I would like for you, if you could, to think of this. Are there examples of the kinds of illnesses or costs of drugs that still are not covered; for example, the so-called triple cocktail that is used for individuals with HIV-AIDS—isn't this medication very expensive, and is it not administered orally? I would like your response, please.

Mr. HASH. That is my understanding, Mr. Strickland. It would not be covered.

Mr. STRICKLAND. It is very expensive, is it not?

Mr. HASH. Yes, I understand. Maybe as high as $20,000 to $30,000 a year for an individual.

Mr. STRICKLAND. Is this drug ever covered under Medicare?

Mr. HASH. No, sir, not in the outpatient setting.

Mr. STRICKLAND. My point is this: Would you not say that it would make more sense for us to have a policy that covers all prescriptions that people need, rather than to pick and choose among illnesses, among degrees of illnesses, among drugs, and among the way drugs are administered?

Would it not make sense for us, as compassionate people, just to have a comprehensive prescription benefit that would leave no one out?

Mr. HASH. Absolutely. I agree with that.

Mr. BURR. Would the gentleman yield for one question?

Mr. STRICKLAND. I would, quickly, please. I don't have much time.

Mr. BURR. At the heart of the example that Mr. Strickland used, in HCFA's mind, would the extension of that benefit for HCFA, the triple cocktail, actually be a net savings to the health care system because we have eliminated the hospitalization that that individual would have utilized if they had the opportunity for the prescription drug?

Mr. HASH. I think it would. I think there is no argument.

In fact, we have just launched a demonstration to that effect, to demonstrate that effect in the Medicaid program in the State of Maine where we are covering individuals who are HIV positive, not yet symptomatic, for these drugs in order to slow or retard the progression of the disease to show that that kind of early coverage for

people who otherwise would not have been covered shows benefits in terms of cost savings.

Mr. BURR. It is not the case in every case, but it is certainly something we should consider.

Mr. STRICKLAND. I thank my colleague for that very helpful observation. Thank you.

Mr. Hash, the second question. The second panel is going to be talking about drugs that are very costly, in some cases. Do you have any knowledge of who is experiencing hardship in accessing these drugs? Is it just the low-income, or are people who are of modest income also having difficulty affording these expensive drugs?

Mr. HASH. The problem of the cost of drugs for the low-income is a very serious problem, but it is not limited to low-income people. Over half of the people without any coverage under Medicare for drugs who have incomes above 150 percent of the poverty level—there are over half of them who do not have any coverage for drugs. For them the costs are very significant.

Across incomes, income spectrums, the cost of drugs are very serious problems for Medicare beneficiaries.

Mr. STRICKLAND. So a program tailored only for low-income people would leave out a host of others who would be unable to afford these medications, perhaps?

Mr. HASH. It would definitely do that.

Mr. STRICKLAND. Thank you very much.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Lazio, would you like to inquire?

Mr. LAZIO. Thank you, Mr. Chairman.

Mr. Chairman, I just note, Mr. Hash—thank you very much for being here, but I also want to note the bipartisan—almost universal concern about where HCFA is right now, and the people that are left behind.

I do a lot of work, as many people do in this committee, with the cancer community. I know they are acutely sensitive to the fact that this change is expected to have a detrimental effect on people that desperately need self-injected prescriptions.

I just want to try and follow up, if I can, for a moment, because I am struggling to understand exactly how this change came to be, as well, on where Mr. Bilbray left off.

I am reading, and I will be happy to provide you with a copy, if you would like, and it is probably fair for me to do that.

"Standard policy for 35 years." Section 2049 says in part, "Where, however, a physician injects a drug which is not usually self-injected, this drug is not subject to the self-administrable drug exclusion, regardless of whether the drug may also be available in oral forms, since it is not self-administrable in the form in which it was furnished to the patient."

But in a letter dated July 1 of last year from Nancy-Ann DeParle, and I want to quote from that, she says, "Medicare covers only those Food and Drug Administration approved drugs that are furnished incident to a physician's services and cannot be administered," as opposed to "not usually be self-administered."

"For example, as we discussed," a certain thing "is not covered by the program, even when it is necessary for the patient to have the drug administered in a physician's office. This is because the drug can be self-administered".

I am just wondering if you can try and square for me how we went from a standard policy that was in existence for so long to this change. How you can square the discrepancy in these two directives?

Mr. HASH. There is an explanation to that. I will take another stab at that.

I believe that what both the letter and the carrier manual site for our longstanding policy are trying to say is that if in fact the administration of a drug by a physician is appropriate because there is a standard of practice, there is a medical protocol, that says that in order for this drug to be effective it needs to be administered in a form that is supervised by a physician or someone trained in the physician's office, that is what I believe that statement in the record and this means.

That does not mean that if a drug also occurs in a pill form or in a self-injectable form, that that would disqualify for that given patient, because there is a medical need for the patient to be treated in that form in order to get the full benefit of the drug.

Mr. LAZIO. Isn't this letter fairly categorical, fairly conclusive? "incident to a physician's services and cannot be self-administered?" .

Mr. HASH. It is categorical in that sense. Also elsewhere in the carrier manual it says the same thing. That letter actually is excerpting from another section of the same carrier manual language that has been in there since the beginning of the program.

Mr. LAZIO. Let me, if I can, Mr. Chairman, introduce into the record a letter dated May 23 from HHS.

Mr. BILIRAKIS. Without objection.

[The information referred to follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
OFFICE OF CLINICAL STANDARDS & QUALITY
May 23, 1998

MS. ISABEL P. DUNST
Columbia Square
555 Thirteenth St. NW
Washington, D.C. 20004

DEAR MS. DUNST: I am writing as follow-up to your recent visit to discuss coverage of interferon beta-1a (trade name: Avonex) under the Medicare Program. Thank you for taking the time to describe the use of Avonex in treating relapsing forms of multiple sclerosis, and for bringing your perceptions of the issues involved concerning Medicare's coverage policy to our attention.

We have reviewed these issues and carefully evaluated the current policy on self-administered drugs. Although we are cognizant of your concerns, and have taken these into account in our evaluation and reconsideration, our position remains unchanged. That is, interferon beta-1a has been labeled as a drug capable of self-administration by the Food and Drug Administration (FDA) and this is common medical practice. As such, it is noncovered under the Medicare program, with very limited exceptions. As stated in previous communications, drugs that are self-administered are not covered by Medicare Part B unless the Social Security Act (the statute that governs the Medicare program) specifically provides such coverage, for example, in the case of immunosuppressive drugs. In those circumstances when certain drugs that are generally self-administered may not be, coverage is at the discretion of the Medicare Carrier. Thus, when the patient first learns how to administer a drug, the

carrier may determine whether it is medically necessary for the physician or staff to administer the drug. The patient's condition; i.e., the patient's mental or physical capacity to administer any drug, is not a consideration for coverage. The decision is based on the appropriate medical protocol that applies generally to patients that qualify for the drug in question. This Medicare policy reflects the statutory provision that excludes self-administered drugs from coverage. Any modification to this policy will require a statutory revision.

Thank you again for taking the time to meet with us and to explain your position on the coverage of Avonex. I hope this clarifies the Medicare policy and the process necessary to revise existing statutory requirements. If you have any questions, please contact Dorothy Colbert, 410-786-9671, of my staff.

Sincerely,

GRANT BAGLEY, M.D., *Director, Coverage and Analysis*
Office of Clinical Standards and Quality

DEPARTMENT OF HEALTH & HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION
THE ADMINISTRATOR
July 1, 1999

Mr. MICHAEL J. ASTRUE
Vice President and General Counsel
Biogen
14 Cambridge Center
Cambridge, Massachusetts 02142

DEAR MR. ASTRUE: Thank you for your letter concerning the Medicare program's coverage policy for Avonex, which is used to treat patients with multiple sclerosis (MS). I also wanted to say how much I appreciated meeting with you to discuss this important topic. Since our meeting, we have spent substantial time carefully considering the issues you raised.

I understand that Avonex is generally not administered incident to a physician's services and that no Medicare benefit payment currently exists for these instances. And, as our discussion reflected I fully appreciate the toll this debilitating disease takes on its victims. It is enough of a burden to cope with the effects of the disease without the worry of paying for an expensive drug like Avonex.

Unfortunately, we find ourselves in a dilemma. As you know, while the President has proposed a prescription drug benefit under Medicare, there currently is no benefit. Payment for drugs provided in the inpatient setting is included within the appropriate diagnosis related group. However, for outpatient drugs, by law, Medicare covers only those Food and Drug Administration approved drugs that are furnished incident to a physician's services and cannot be self-administered (with a few exceptions explicitly provided in the statute.

Historically, the Health Care Financing Administration (HCFA) has interpreted this coverage restriction as pertaining to the characteristics of the drug itself and not to the capacity of the particular beneficiary to self-administer any drug. For example, as we discussed, Betaseron (another drug used to treat MS) is not covered by the program, even when it is necessary for the patient to have the drug administered in a physician's office. This is because the drug can be self-administered. Another example is that eye drops used in connection with outpatient cataract surgery are not covered by the program when they are administered in the outpatient hospital setting. While the situation you described for MS patients is very compelling, these other situations are troublesome as well. Therefore, we are planning to publish a proposal in the *Federal Register* that will explore several alternative interpretations of this statutory provision. We will be soliciting public comments on those alternatives and any other interpretations that are legally supportable. We look forward to your comments in response to that proposal. In the meantime, local carriers will be able to make payment policy decisions concerning Avonex.

I want to again commend the Biogen company on its efforts to develop product that are able to ameliorate the suffering MS patients must endure. I wish that my response could have been more favorable.

Sincerely,

NANCY-ANN MIN DEPARLE
Administrator

Mr. LAZIO. I just want to follow up, if I can. Mr. Chairman, the 2000 fiscal year appropriations bill prohibited HCFA from implementing any policy, as you know, that would impose any new re-

strictions on Medicare coverage on injectables, and report language that accompanied the statutory language directed HCFA to issue a program memorandum to all the carriers that are supposed to be taking direction from HCFA.

I don't know how they get direction based on the discrepancy between these documents. But HCFA issued the program memorandum on March 17. In the PM HCFA notes that this program memorandum may be destroyed after September 30 of this year.

So you have indicated to the carriers that they can disregard what is written in the program memorandum that was issued by HCFA, and I would like to know if you can give us some sense of what assurances you can give and therefore we can give to the patients that may be testifying at this hearing, people who are listening and looking for direction and are relying on this, that injectable drugs that would be covered today would be covered, say, after October 1 when this memorandum is said to no longer be in effect.

Mr. HASH. I think the best way for me to answer that, Mr. Lazio, is to say that in our view, the memorandum of August 13, 1997, did not change existing longstanding Medicare policy.

Second, I would say that after the expiration of the appropriations provision that is in the law now, it would be our intention to return to the activity that we had underway before the rider passed, which was to put out a notice of proposed rulemaking where we lay out a number of options that explore how we could expand coverage of self-injectables under certain circumstances that would be consistent with the law.

Mr. BILIRAKIS. The gentleman's time has long expired.

Mr. LAZIO. Mr. Chairman, could I just ask the witness, I would like to submit a couple of questions in writing, if I could.

Mr. BILIRAKIS. I think Mr. Hash is accustomed to that.

Mr. HASH. Yes, sir. I will be happy to.

Mr. BILIRAKIS. Let me ask you very quickly. You referred to having read Dr. Steinberg's testimony.

Mr. HASH. Yes, sir.

Mr. BILIRAKIS. On page 4 of his testimony—and we really thought that one of the other panel members would have asked you this—in talking about the definitions he said, "I believe it is not possible to develop a definition that makes sense from a clinical perspective, other than leaving the judgment"—and Mr. Lazio really went into this—"other than leaving the judgment regarding the best means of administering a drug to the patient's physician."

Comment?

Mr. HASH. Yes, sir. I actually think that he is right about that, in the sense that this ought to be a matter that ought to be subject to physician judgment and application. That is why, under a broad prescription drug benefit, that would be what would be the physician's option in this case.

Mr. BILIRAKIS. But you have taken away their option of determining where an individual patient's mental or physical ability to administer any drug should be a consideration for this purpose?

Mr. HASH. As I said earlier, that was one of the issues that we wanted to address in our proposed rulemaking to get comment on that.

I said, Mr. Chairman, earlier that expanding this coverage is fraught with lots of ethical challenges. There are issues about how to draw the line here, what conditions to take into consideration. There are clearly equity questions about people who fall inside the line and people who fall outside of the line.

Our desire is not to have to make those kinds of decisions, but rather, to have a broad policy that does not force us to parse it in this way, and to do a sort of patchwork solution to what is really a comprehensive problem.

Mr. BILIRAKIS. I know, you keep referring to broad Medicare reform. I am not belittling it, it is very significant.

When you plan to make a change, is it not best to leave things be if they have been functioning all right, and then, if you are going to go through the process of developing a new regulation, let that determine when the change will be, rather than make the change through a program memorandum, and then decide to go through the process afterwards?

In the meantime an awful lot of people out there who have been depending upon this service have lost it. It may turn out—as a result of your town meetings that were required and as a result of the entire process, it may turn out that you will go back to what it was for so many years before HCFA came out with its program memorandum.

I am not really asking a question. I appreciate your patience, and I appreciate you being here.

Mr. HASH. I appreciate the opportunity. I know there is confusion out there. I know this affects real people with very serious diseases and illnesses.

I am encouraged by your willingness to continue to work with us and try to find a way to move forward with us; do what we can do now and also work for the larger solution as well.

Mr. BILIRAKIS. That is right. We cannot say we want a comprehensive solution and let people basically suffer in the meantime.

Thank you very much, sir.

The next panel consists of Ms. Nancy Davenport-Ennis, Founding Executive Director of the Patient Advocate Foundation out of Newport News, Virginia, Ms. Rosalie Lohrman from Pasadena, Maryland, Ms. Mary Ellen Rybicki from Reston, Virginia, Ms. Julie Sizemore from Simpsonville, South Carolina, Dr. Earl Steinberg, Chevy Chase, Maryland, and Ms. Jane Story of the Cancer Center of the Carolinas in Greenville, South Carolina.

Thank you, ladies and gentlemen, for being here. We are grateful for your patience.

Your written statement is made part of the record. We will set the clock at 5 minutes, and hopefully you can keep your oral testimony within that period of time.

Mr. BURR [presiding]. The Chair would also like to take this opportunity to recognize our distinguished colleague who served for over 100 years, Congressman Rose.

The Chair would recognize Mrs. Story for the purposes of her opening testimony for 5 minutes, and also welcome both our South Carolina witnesses from our sister State to the south of North Carolina.

Ms. Story.

STATEMENTS OF JANE A. STORY; EARL P. STEINBERG; JULIE SIZEMORE; MARIELLEN RYBICKI; ROSALIE LOHRMAN; AND NANCY DAVENPORT-ENNIS, FOUNDING EXECUTIVE DIRECTOR, PATIENT ADVOCATE FOUNDATION

Ms. STORY. I would like to say that I appreciate the opportunity to testify today. As you mention, I am a cancer nurse from Greenville, South Carolina, and part of my charge as a nurse is to treat the human response to a disease process.

Because my testimony today will focus on the face of the patients that perhaps this committee does not otherwise see, I would like to ask you to humor me and ask everyone in the room to please take out a pen and paper and jot down something for me. It would take just a moment.

If you would write down ten things that are important to you, please. Perhaps it would be your family—it might not be in any particular order—perhaps some faith that you have. If you would jot those things down for me. You might need to leave blanks.

Now if you would take a moment to look at that list, you might have some blanks there. You might not have gotten to ten yet. I would ask you to cross out four of those things that are most important to you in your life. Then take away another two. Now you may have four things that are important to you, but I need you to take away another two, please.

When I did this exercise yesterday, the person that I did it with said, but I can't take away those things, because you see, what is left is maybe family, maybe God, and that is about it. That is what every cancer patient that we treat faces. They lose their health. As soon as they are diagnosed they lose their health. They lose their financial security. They lose maybe their home. They lose their job. They lose their ability to take care of others.

These patients face quite a bit of loss. I see that devastation firsthand, and the impact on families. Then of course, the reason I do all of this is because I do have an opportunity to see the triumphs of the human spirit.

I think, in that context, it is important to look at these drugs. I am specifically speaking about cancer drugs. These drugs, including Procrit, Leukine, Neupogen, as well as actual chemotherapy drugs, Interferon and Interleukin, really do increase the quality of life for our patients. They make it possible for them to do things. I know Julie Sizemore will be addressing that for you. They make chemo tolerable, and they make chemo possible. They can allow patients to have a longer and routine treatment without the increased discomfort that a patient might have.

I would contend that these medications, even though they are subcu, they are not, by virtue of that fact, self-injectable.

Let me tell you why I believe that. The loss of coverage that this policy that we are talking about today would cause really brings up a lot of safety issues. We have patients who are physically frail. They have lost their dexterity. The chemotherapy can make their hands numb or tingle. There are issues of dosing, that the patient could possibly get a wrong dose.

We have finally gotten to the point in this country where we have continually, over the last 2 years, decreased the number of deaths that we have had because of cancer. We expect to do that

in the year 2000, so we are turning the corner on the war against cancer, mostly due to the National Cancer Act. We have more funding for research, so we know what the new drugs are. We know how they work. We have education for doctors and nurses that allows them to fight the war. This proposal of so-called self-injectable drugs and changing the coverage for them would threaten all that we work for and fight for.

You may not know what those people look like, but I do, because I see those people every day. I see them cry, and I did it before I left. I cried with a patient that was going to lose her life. She has progressed. I would ask you not to allow the coverage to be lost, because those people need it.

[The prepared statement of Jane A. Story follows:]

PREPARED STATEMENT OF JANE A. STORY

Thank you for the opportunity to share my experiences with you. I am head nurse in outpatient cancer setting. In that capacity, I care for cancer patients and their families physically, emotionally, and spiritually. When cancer patients come to an outpatient setting for their treatments, they often find in their nurses not only capable caregivers but also people who are willing to talk and laugh with them; sometimes those around them can manage to talk or laugh because life isn't "normal" anymore. These patients see us frequently and we become part of their family. Fortunately, we oncology nurses are the "expert" family members who have the specialized training to know when a patient is in trouble and needs intervention versus needing a compassionate ear and warm response.

Families frequently come into the challenge of cancer treatment unprepared for the rigors they face. They are not sure what the expected results of chemotherapy are, so they don't know whether the symptoms and problems they see are "normal" for a cancer patient in treatment or not. Cancer nurses guide and educate the family in these situations. For instance, we counsel patients and families about the threat of plummeting blood counts and work to address that problem whenever it arises. When a chemotherapy patient gets exposed to an infection and they do not have white blood cells to fight infection, they are at risk for a more serious illness than you or I might get. If a family member is not taught to call us when the temperature goes above 100.5 degrees (Fahrenheit), the infection could go into the patient's blood stream, necessitating hospitalization, sometimes in an intensive care unit. If the infection goes into the blood stream (sepsis) and remains untreated, death is possible. Without the skilled teaching of an oncology nurse, the patient and family members might not call for a temperature under 102 degrees.

Injectable drugs comprise an important facet of the sophisticated drug care that fights cancer. Several different classes exist, but the most frequently given drugs are those that either stimulate the bone marrow to make more blood cells (like Procrit, Neupogen, Leukine, and Neumega) or those that stimulate the immune system to fight the cancer (like Interferon or interleukin).

Chemotherapy affects quickly growing cells in the body. The chemotherapy doesn't know which cells are normal and which are cancerous, so it hits all quickly growing cells, including hair cells, cells in the throat, intestines, and bowels, the cancer cells, and blood cells. The types of cells that are affected (hair, gastrointestinal, and blood) generally represent the major adverse responses to chemotherapy.

The most important quickly growing cells to our discussion are the blood cells. There are three basic kinds of blood cells: white blood cells, which fight infections; red blood cells, which carry oxygen; and platelets, which clot the blood. Neupogen and Leukine increase the white blood cell count. If the white blood count or the mature white cells are too low, patients cannot get their chemotherapy since the chemo would further decrease the white blood count, potentially leaving the patient without any defense against infection.

Without Neupogen and Leukine, patients must wait until their body naturally regenerates the white blood cells. During this period, patients can be exposed to infection. Increased hospitalization will be needed if a patient gets an infection or becomes septic. The cancer cells also have an opportunity to grow (since the chemo is not killing the cancer), negating the positive effects of continuing chemotherapy.

Procrit increases the red blood cell count; a low red blood cell count increases the fatigue a chemo patient experiences and can cause increased shortness of breath. These increased side effects often debilitate chemo patients who are already phys-

ically and emotionally stressed. Procrit enables them to manage these side effects, often so that they can function at a more "normal" level. In other words, the Procrit allows them to cope better with their cancer treatments. One of our patients, for instance, is a Medicare beneficiary who lost an arm to cancer and is thrilled to have the strength to leave her home to do simple things like food shopping. If Procrit is not given, patients must receive transfusions of packed red blood cells in a hospital setting. In addition to the cost, the transfusions expose them to blood-borne diseases like Hepatitis-A or AIDS. The suppressed immune system of a cancer patient on chemotherapy will not be able to fight these diseases.

Neumega increases the platelet count. Patients usually have decreased platelets once they have received several rounds of chemotherapy. Without Neumega, patients typically must receive several platelet transfusions, which involve being admitted to the hospital (thus increasing hospital costs). Also, the patient is at increased risk of bleeding spontaneously. Obviously, the possible results of spontaneous, uncontrolled bleeding are hospitalization or death. Generally, Neumega is used after a patient has both had their platelet count drop into a dangerous range and needed transfusions of platelets. The Neumega prevents further drops in platelets. A decreased platelet count will also make a patient ineligible for chemotherapy.

Interferon and Interleukin are classes of drugs that stimulate the patient's own immune system to attack cancer cells. Interferon is used to treat melanoma, leukemia, lymphoma, Kaposi's sarcoma, and hepatitis. This drug can be a very effective and simple answer to these complex and deadly diseases. Interleukin, particularly Interleukin-2, treats renal cell cancer; no other chemotherapy has been found to be effective on this form of cancer. Without Interferon and Interleukin, the patient with a disease listed above faces either more extensive chemotherapy with less effectiveness or a much quicker death.

If the Medicare program were to classify the injectables discussed above as self-injectable drugs, the implications are profound. Foremost, these medications cannot be safely given and monitored by the patient. Medicare patients with cancer are generally frail; chemotherapy intensifies this effect. The patients may have tremors or numbness and tingling in their hands due to the effects of chemotherapy. Cancer fatigue, one of the most prevalent and least treatable side effects of chemo, creates a lack of energy, making any activity feel impossible. Thinking about giving themselves an injection—an unfamiliar and complex task—will also feel impossible to the elderly chemo patient.

Many Medicare patients cannot see clearly and have decreased manual dexterity (both partially due to advanced age, but increased by the effects of chemo). These drugs must be given in an exact dose via a needle with minute gradations. Of the six medications discussed above, three must be mixed with a dilutant at the time of injection. Only two of the medications come in individual dose vials. Thus, the possibility of mixing the drug improperly or getting too large or too small a dose is increased.

Additionally, in South Carolina, the majority of our Medicare patients have little or no other source of income to pay for injectables. In the past as a home health nurse, I entered Medicare patient homes with little or no heat, minimal food, and bugs. Some patients barely have the resources to pay for their bills and food. The medications in question cost anywhere from $500 to $5,000 per injection; the drugs are given from once a week to once a day. For the typical South Carolina Medicare patient and their families, the choice would either be surviving (eating, a roof over their heads, etc.) or paying for the drug. At the Cancer Centers of the Carolinas, we work with our patients and families to find a way to pay for their care (25% of our patients are indigent). Over the seven years I have been a nurse, however, I have seen patients and families, already stretched to their limit by the physical and emotional demands of cancer, frantically seeking funds to pay for their own or their loved one's care. The treatment that Medicare makes possible for cancer should not be taken away. Doing so would only add to the enormous burden the patients and families face.

While the physical and cost facets of administering the injection play a large role in my concern for Medicare coverage of these drugs, the possible adverse events are chilling to me as a nurse. As mentioned above, these drugs require exact doses and exact mixing. They also require trained observers (oncology nurses, with the support and guidance of doctors) to manage and deal with the side effects. Just as chemotherapy can have life-threatening effects, so can Neupogen, Leukine, Procrit, Neumega, Interferon, and Interleukin. For instance, Neupogen normally causes skeletal pain, frequently in the sternal (breast bone) area. This needs to be assessed by a nurse to discern whether the pain relates to cardiac problems or to the administration of the drug. Leukine can cause shortness of breath and fluid retention, as well as rashes and flu-like symptoms. The shortness of breath and fluid retention

could be related to cardiac problems or the drug, and both might require intervention, including teaching by the nurse or the doctor seeing the patient and providing medications. Procrit can cause hypertension, nausea, vomiting, and ankle swelling. Again, an experienced, highly trained cancer nurse can determine whether these side effects are a response to another drug (like chemotherapy), another disease process, or the injectable drug. Neumega can cause fluid retention, shortness of breath, and chest pain. These serious side effects may need the immediate medical action that a cancer nurse in an office setting can secure. Interferon and interleukin both have serious side effects that can limit the amount of the medication that the patient can receive. The dose limiting factors for interferon include fatigue and severe weight loss, although non-dose-limiting side effects range from chills and fever to liver, kidney, and heart changes. The patient may also have their potassium level drop to an unsafe level, requiring oral or intravenous replacement. For interleukin, dose-limiting adverse effects are mental status changes (confusion, agitation, and disorientation); decreased platelet and red blood cell counts; and decreased blood pressure. Patients receiving medications that have dose-limiting toxicities need a trained observer to determine when the dose needs to be modified. An elderly patient at home would not be able to fulfill this role.

Every medication listed has the possibility of an allergic reaction with the first dose. A patient taking the drug at home as a prescription might not have the medical resources available to survive such a situation. Office-based nurses can easily manage this task.

All of these injectable medications require regular review of blood values (labs) by a nurse for several reasons. First, if the patient takes the drug to increase their white cells, red cells, or platelets, these blood levels can go too high if they are not monitored. In the case of the white blood cells, this will cause aches and pains. Platelets running too high can cause the blood to clot unnecessarily, perhaps causing a stroke or other adverse event. Second, a particular dose of a medication may not guarantee the effect that is desired. Procrit, intended to increase the red blood count, may increase the counts too much at one dose and not enough at another dose. When a nurse assesses the patient regularly, this issue can be managed for the appropriate outcome. Take our patient, Lucy W., as an example. On 40,000 units of Procrit per week, the patient's counts went up too high. When the nurse reported this to the doctor, the dose was decreased to 20,000 units per week. Subsequently, the patient came in with increased weakness and shortness of breath, so the nurse requested blood counts be run. The results showed a drop in the counts, so the Procrit dose was increased to 30,000 units per week and the patient's counts are being maintained. This intervention could only have happened via the intervention of a nurse attuned to the patient's symptoms and knowledgeable about the meaning and implications of blood test results as they relate to the medication.

In summary, making drugs used for cancer treatment self-injectable would undermine the war on cancer we are fighting. Out there on the front lines of that battle, we have the tools to provide patients with optimal cancer care: drugs, which can cure the cancer; supportive medications like these injectables, which allow patients to tolerate their chemotherapy at higher doses with less side effects; and cancer nurses, who treat the human response to the disease of cancer. Without any of the three, the battle will be harder and the patients could lose the care and medications they need. We will go backwards in time, losing the ground we have gained in this battle and the resources we have invested in that fight through the National Cancer Institute. The result will be increases: increases in inpatient hospital admissions (and the associated costs) to deal with infections that could have been prevented; increases in morbidity and mortality of patients who cannot afford the care they need without the Medicare coverage they now receive; and an increased sense of helplessness and hopelessness because patients and their families will lose the psychosocial and spiritual support oncology nurses provide.

I an thankful to Chairman Bliley and all the members of this committee for the excellent job you have done in urging the Medicare program to do the right thing, at least through September 30th. However, I urge you to keep the problem from reoccurring in the future. Our patients—who have become my friends and family—and I thank you for your consideration as we fight the War on Cancer together.

Mr. BURR. Thank you very much, Ms. Story, for that very compelling and emotional testimony.

Dr. Steinberg, you are recognized for an opening statement.

STATEMENT OF EARL P. STEINBERG

Mr. STEINBERG. Thank you very much for the opportunity to present to you this morning.

In the few minutes that I have available to me, I would like to try to make five points related to the issue before you. First is that outpatient prescription drugs, whether they are self-administered or administered by a health care professional, are an absolutely essential part of the high quality or even a minimum standard of appropriate health care today.

This is particularly true with regard to treatment of chronic diseases. As Mr. Hash said, if the Medicare program were being designed today, I cannot imagine that prescription drugs would not be a covered benefit, any more than I could imagine that either surgery or radiology services would be excluded from coverage.

It is not unusual for elderly individuals with common chronic diseases, common chronic diseases, to require between $5,000 and $10,000 worth of prescription medications in a given year. Without insurance coverage for outpatient prescription medications, many Medicare beneficiaries are not able to buy them.

I want to point out that this is not only high cost outlier patients, or those who are poor who have difficulty affording their medications. Many of my former patients at Johns Hopkins who had incomes in the range of $25,000 per year did not fill the prescriptions that I gave them because they could not afford to do so.

To the extent that Medicare beneficiaries do not have access to these treatments, the Medicare program fails to accomplish its goal of ensuring that the elderly and the disabled have access to necessary health care.

Second, as has been mentioned several times today, not all patients are the same. They vary greatly in the severity of their disease as well as the types and severity of morbidities that they have. Consequently, the fact that one patient can self-administer a drug does not mean that all patients can self-administer the same drug.

In fact, given the progress that has been made in the development of drugs and in injection devices, it would be a rare instance in which a physician or nurse could not train at least one patient to administer a drug safely.

The third point I would like to make is that over the past 35 years incredible progress has been made in medical science, computer and electronic technology, and the development of lightweighting and improved solid materials. As a result, pharmaceutical products, as well as techniques for administering them, are available today that likely could not have even been imagined 35 years ago.

This progress has enabled patients who used to require prolonged hospitalization to be treated safely, more conveniently, and less expensively at home. In other instances, the availability of new routes of administration for drugs can result in the increased effectiveness of treatment due to faster or more thorough absorption.

I believe it is a mistake to have a coverage policy that actively discourages rather than encourages such innovation.

Fourth, I would like to make a point that the status quo with regard to coverage of self-administratable drugs unfortunately per-

turbs pharmaceutical manufacturers' behavior in a perverse way. Under the policy in place today, manufacturers sometimes are induced to formulate or reformulate drugs as injectables that could be better administered orally.

A case in point is the drug Lupron, which is used to treat prostate cancer. Lupron was first developed in a formulation in which it could be self-administered by subcutaneous injection. As a result, it was not covered by Medicare. It was a failure commercially, and the manufacturer then reformulated the drug so that it had to be administered intermuscularly by a health care professional. That reformulated drug was then covered by Medicare and is now used commonly today.

Finally, the current situation with regard to coverage also perturbs physician behavior in a perverse way. If the optimal drug for a patient is self-administratable but the patient cannot afford to buy the drug, it does no good for a physician to prescribe it.

As a result, under current policy, when the best therapy can be administered by a patient, this physician sometimes will resort to prescribing an alternative, albeit suboptimal drug that must be administered by a health care professional.

In summary, given the high cost of prescription drugs, especially among the elderly with chronic disease, many elderly cannot afford to buy the drugs they need. Given the central role of these drugs in health care today, Congress should add a prescription drug benefit to Medicare.

If, however, a politically viable approach for providing such a benefit cannot be found, I urge you to modify the statutory language so as to maximize the number of Medicare beneficiaries who have access under existing benefits to drugs that are safe and effective in treatment of the diseases from which they suffer.

In closing, I might just add that it seems to me that part of the confusion about this issue results from the fact that there are multiple alternative definitions being made of what "self-administratable" means. On the one hand, the more expansive definition is based on the usual method of administration, whereas the more restrictive is based on a definition of whether the drug cannot be self-administered.

I think this is where the heart of the issue about the cutback has occurred.

Thank you very much.

[The prepared statement of Earl P. Steinberg follows:]

PREPARED STATEMENT OF EARL P. STEINBERG

Good morning. I appreciate the opportunity to testify today regarding Medicare coverage of drugs that can, in some cases, be self-administered by patients in the outpatient setting.

My name is Dr. Earl Steinberg. I am a general internist who practiced internal medicine full- or part-time from 1979-1990. For the past 18 years, I have devoted my career to 1) evaluation of the safety, effectiveness and cost-effectiveness of medical technologies, including prescription drugs; 2)—evaluation of health care providers' actual patterns of practice; and 3) design and implementation of interventions to improve the quality and/or efficiency of care. From 1982 to 1994, I was on the full-time faculty of The Johns Hopkins School of Medicine and School of Hygiene and Public Health. I also served as Director of The Johns Hopkins Program for Medical Technology and Practice Assessment.

From 1994 to February of this year, I was a Vice President at Covance Health Economics and Outcomes Services Inc., a consulting firm that helps to bring high

quality medical innovations to market, evaluate their performance once they are in actual use, and improve the quality and efficiency of provider practice. During my tenure at Covance, I served as Director of its Division of Quality Assessment and Improvement Systems and Co-Director of its Outcomes Studies Group.

I currently am an independent health care services consultant, and an Adjunct Professor of Medicine and of Health Policy and Management at The Johns Hopkins University. I also am a member of the Blue Cross and Blue Shield Association's National Medical Advisory Panel, on which I have served for the past 10 years. This Panel oversees what is widely considered to be the best and most rigorous technology assessment activity in this country.

My background enables me to bring multiple, complementary perspectives to bear on the issue you are considering today—an issue that I believe has become far more complicated and vexing because of 30 years of medical and technological progress, as well as two decades of changes in the Medicare payment system that provide a strong financial incentive to discharge patients from the hospital as early as possible.

In the brief time I have with you this morning, I would like to make five points that are central to the debate over how broadly or narrowly the concept of "self-administerable drugs" should be construed.

First, outpatient prescription drugs, whether they are self-administered or administered by a health care professional, are an essential part of high quality, or even a minimal standard of appropriate, health care today. This is particularly true with regard to treatment of chronic diseases. If the Medicare program were being designed today, I cannot imagine that prescription drugs would not be a covered benefit, any more than I could imagine that either surgery or radiology services would be excluded from coverage. Last year Medicare beneficiaries used between $30 and $40 billion worth of outpatient prescription drugs, many of which have become quite expensive. It is not unusual for elderly individuals with common chronic diseases to require between $5000 and $10,000 worth of prescription medication in a given year. In a study of actual prescription claims generated by over 375,000 elderly individuals that I recently conducted with collaborators at Merck Medco Managed Care and the Henry J. Kaiser Family Foundation (Steinberg EP, Gutierrez B, Momani A, Boscarino JA, Neuman P, and Deverka P; Beyond Survey Data: A Claims-Based Analysis of Drug Use and Spending by the Elderly; Health Affairs (March/April 2000): 198-211) , we found that 5 percent of people in our sample had more than $4000 in prescription drug expenditures and one percent had $6,600 or more in such expenditures during 1998. Total annual spending for elderly with chronic disease was 50% to 200% higher than for others. As a result, one percent of elderly with cancer or common combinations of chronic diseases,, such as diabetes and heart disease, had total annual spending greater than $9,000. Without insurance coverage for outpatient prescription medications, many Medicare beneficiaries are not able to buy them. I should point out that it is not only high cost outlier patients, or those who are poor, who have difficulty affording their medications. Many of my former patients at Johns Hopkins who had incomes in the range of $25,000 per year did not fill the prescriptions I gave them because they could not afford to do so. To the extent that Medicare beneficiaries do not have access to these treatments, the Medicare program fails to accomplish its goal of ensuring that the elderly and disabled have access to necessary health care.

Second, not all patients with a given disease are the same. Patients vary greatly in the severity of their disease, as well as the types, number and severity of the other diseases that they have. Some have poor vision. Some have cognitive disorders. Some are physically unable to perform simple tasks. Consequently, the fact that one patient can self-administer a drug does not mean that all patients can self-administer the same drug. Congress recognized this fact when it fashioned the Medicare benefit for Coverage of Osteoporosis Drugs. This provision states that injectable drugs approved for use in treatment of a woman who has suffered a bone fracture that is related to postmenopausal osteoporosis are covered if "the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug." To me, as a clinician, it makes little sense to apply these very relevant considerations ONLY to women with postmenopausal osteoporotic fractures.

For many reasons it is not surprising to me that there is confusion and controversy surrounding interpretation of the Social Security Act's provision regarding coverage for drugs and biologicals which cannot be self-administered. There are many other potential operational definitions of what constitutes a self-administerable drug. For example, judgments regarding the self-administerability of a drug could be based on the usual method of administration of the drug, on the basis of whether any patient can self-administer the drug, or on the basis of wheth-

er a given patient can self-administer the drug. Given the progress that has been made in development of injection devices, it would be a rare instance in which a physician or nurse could not train at least one patient to administer a given drug safely. Yet another potential definition would be one in which a drug would be considered to be self-administerable if the label for the drug indicates that the drug can be administered by a patient without the need for medical supervision. While many other such definitions could be fashioned, I believe it is not possible to develop a definition that makes sense from a clinical perspective other than leaving the judgment regarding the best means of administering a drug to the patient's physician.

The third point I would like to make is that over the 35 years since the Medicare program was enacted, incredible progress has been made in medical science, computer and electronic technologies, and the development of light-weight and improved solid materials. As a result, pharmaceutical products, and techniques for administering them, are available today that likely could not have been imagined 35 years ago. This progress has enabled patients who used to require prolonged hospitalization to be treated safely, more conveniently, and less expensively at home. In other instances, the availability of new routes of administration for drugs—for example, topically, intranasally, or via inhalation—can result in increased effectiveness of treatment as a result of faster or more thorough absorption. I believe it is a mistake to have a coverage policy that actively discourages, rather than encourages such innovation.

Fourth, the status quo with regard to coverage of self-administerable drugs perturbs pharmaceutical manufacturers' behavior in a perverse way. In circumstances in which only a small number of non-elderly are the target patient population for a drug, the commercial success of a product may depend on whether Medicare covers it. Consequently, under the policy in place today, manufacturers are induced to formulate drugs as injectables that could be better administered orally. A case in point is the drug Lupron ,which is now commonly used to treat prostate cancer, a disease that occurs most commonly in men over the age of 65. Lupron was first developed in a formulation in which it could be self-administered by subcutaneous injection. As a result, Lupron was not covered by Medicare. In order to make the drug commercially viable, the manufacturer of Lupron re-formulated the drug so that it had to be administered intramuscularly by a health care professional. The reformulated drug was covered by Medicare and now is used commonly. Many other companies have been forced to employ less than optimal formulations of their products in order for them to be covered by Medicare.

Finally, the current situation with regard to coverage of self-administerable drugs also perturbs physician behavior in a perverse way. If the optimal drug for a patient is self-administerable, but the patient cannot afford to buy the drug, it does no good for a physician to prescribe it. As a result, under current policy, when the best therapy can be administered by a patient, physicians often will prescribe an alternative, albeit sub-optimal, drug that must be administered by a health care professional. In some instances, such "second-best practice" from a clinical perspective can also be the most costly practice, either because the second best drug is more expensive or because administration of it can require the development of an office infrastructure that adds to the cost of therapy.

In summary, given the high cost of prescription drugs, especially among elderly individuals with chronic disease, many elderly cannot afford to buy the drugs they need without drug insurance. Given the central role prescription drugs play in health care today, Congress should add a prescription drug benefit to Medicare. If a politically viable approach for providing such a benefit cannot be found, I urge you to modify the statutory language so as to maximize the number of Medicare beneficiaries who have access to drugs that are safe and effective in treatment of diseases from which they suffer under existing benefits.

Mr. BURR. Thank you, Dr. Steinberg. I want to apologize to the rest of our panel, at least for the bell. It is our intent to take a break here. We have a series of votes on the House floor. We would like to recess until 12:45. Hopefully, that is enough time to get our series of votes out of the way and to allow you each to get a bite to eat downstairs if that is something that you choose to do, or to get just a little break.

The committee will reconvene at 12:45 for the rest of the testimony.

[Brief recess.]

Mr. BILIRAKIS. The hearing will come to order.

Ms. Sizemore, of course, you know your written testimony is part of the record. Would you like to proceed?

STATEMENT OF JULIE SIZEMORE

Ms. SIZEMORE. Yes.

First of all, I want to thank you for letting me speak today: I will try it my best to say what I need to say in the time allotted.

First of all, I need to show you a picture of my family. This is my husband and my son Jacob. My son Jacob was 15 months old when my husband was diagnosed with stage 4 adrenal cancer. Prior to June 7, 1998, David and I knew very little about cancer. No one in our family had had it, no close friends had had it, so our knowledge was very limited. After June 7, 1998, we would embark on a journey that would teach us more than we would ever want to know about this disease.

The first of our learning experiences began with injections. The chemotherapy that David was given broke down his blood, and in order for his blood and his body to be able to endure chemotherapy given in a timely fashion and in a dose that would kill the cancer, he had to have these injectables.

These injectables enhanced David's quality of life and extended his life. He lived 15 months with this disease. Fifteen months was 15 months longer that Jacob got to spend time with his father. The injectables, along with the chemotherapy, gave us time. Time to make memories, and time for David to take Jacob to the airport to watch the airplanes land for the first time. Time to put up a basketball goal for him. Time to take him to an amusement park. Time to take him out on the golf course for the first time. Things that we took pictures of and that now are my memories. Now when my son asks about his daddy, they are in a photo album that we pull out, and I will show him all the things his daddy did with him.

You may ask yourself, at 32 years old, what do I know about Medicare? It has come to my awareness in the last week that if Medicare no longer provides funding for these injections, that managed care, in my case Blue Cross-Blue Shield, would follow suit. Then not only are the elderly citizens of our country affected, but anyone is with a terminal illness that needs these injections.

Self-injectables are first of all dangerous. David was a 36-year-old very strong, healthy man with a very sharp mind when he was diagnosed with cancer. The chemo left him sick, left him fatigued, left him cloudy mentally, at times. He was in no way in a shape to inject himself.

He was 36. I can only imagine if he had been 40 years older, even if he did not have Alzheimer's at 76, even if he did not have dementia, just the mere fact as we age we forget things——

Mr. BILIRAKIS. Tell me about it.

Ms. SIZEMORE. He also had allergic reactions to these injections. For someone injecting themselves who may not have someone to care for them at home, to have an allergic reaction could be fatal.

The injectables are expensive. I have a list that I got from my pharmacy of all the drugs that David received in 15 months. These injections, if we had had to pay for them, as well as if an elderly citizen had to pay for them, in 15 months' time, which he was not

on these injections every day, it would have exceeded $40,000, which would have financially devastated us, and we are not poor. We are not in a poor income. But it would have financially devastated us.

Shortly after David was diagnosed with cancer, his 76-year-old father, who was a World War II veteran, was diagnosed with leukemia. His responsibility to my family, as I said, has changed at 76. He now can provide memories to my son of his son, of what David was like when he was a boy, a teenager, something that I was not around for.

So his existence is insurmountable in my family now. The thought of Leo not being covered for these injectables if he would need them, not being paid for, having to inject himself, would be detrimental. He would die, just as David would have died without these injections, he would have died earlier.

I want to back up, because this is real important for me to say. In terms of the safety involved in self-injecting, David had times after cis platinum where his hands were numb and he could not feel his fingers, let alone give himself an injection. Due to the high doses of morphine he received, he jerked. He would be lying still and he would jerk, because the doses of morphine were so high.

His side effects were unpredictable. The way he would feel was unpredictable. It would have to be something that a physician would have to examine him every single day if you are going to say someone can give themselves an injection, because it was unpredictable side effects.

I ask you to provide funding for older Americans, for everyone who needs these drugs, and to not let them self-inject out of safety. Do not put their families in a position of having to decide whether or not they die or live based on money.

You cannot put a price on the memories that I have of my husband, the time that we got, that we had with those 15 months, for him to fill out a journal for his son. You cannot put a price on that, and you cannot put a price on the memories that my father-in-law still has to share with Jacob about his son.

So I ask, for my son's sake and for my father-in-law's sake, that you not let this pass.

[The prepared statement of Julie Sizemore follows:]

PREPARED STATEMENT OF JULIE SIZEMORE

Before June 7, 1998, my husband David and I knew very little about cancer. In fact, all we knew is what we heard about other families' experiences or what we saw on television. Frankly, cancer was not anything we really paid any attention to because it had never touched our lives.

But then, on June 7, 1998, David and I embarked on a journey that would teach us more about cancer than we would have ever wanted to know. On that date, David was diagnosed with Stage IV adrenal cancer. David had a tumor the size of a grapefruit that had actually taken over his right adrenal gland. He also had 60-70 metastases in his lungs.

Even though adrenal cancer is often curable, it has to be caught early. The problem with adrenal cancer, though, is that its symptoms are often masked until the cancer has metastasized into other areas of the body. Because of the advanced state of David's cancer, we soon learned that his cancer was incurable.

David's treatment began on June 21, 1998, and it ended shortly before his death on September 14, 1999. At the time my husband was diagnosed, our son Jacob was 15 months old. When David left us, Jacob was 30 months old.

I am here today to honor David and, hopefully, to bring a human perspective to the issue you are addressing. If what I have learned along my family's journey with

cancer is helpful to you, then I pray that something good will come of the tragedy we experienced.

Among the things I learned during the last two years is how important cancer therapies are. David's treatment included chemotherapy and injectable drugs. The drugs enabled David to tolerate his chemo and extended David's life. The drugs gave us more time to make memories as a family, and they enhanced David's quality of life, giving him more energy to enjoy the time he had left.

In other words, the injections, along with the chemotherapy David received, bought us time. It bought time for David to take Jacob to the airport to watch airplanes land for the very first time. It bought time for David to take Jacob to a golf course and an amusement park, and to build him a bicycle. It bought time for Jacob to watch his daddy playing piano, and it bought time to establish for Jacob a favorite song—"Great Balls of Fire"—which he would ask David to play for him.

In short, David's treatment bought him the time he needed to leave Jacob not when he was only 15 months old, but when he was twice that age.

The treatment David received gave us the time to build memories and compile the pictures that Jacob and I often call on to help us through the days and nights without him. Those are memories of love that our extended time with David has given to Jacob and me. If David had only lived 6 months, Jacob would have missed so much. The injections and care David received gave him something priceless—time with his father. I don't know what the term "quality of life" means to you, but that is what it means to me.

Only months after David's diagnosis, David's 75 year old father—a WWII veteran—was diagnosed with leukemia. I know that the thought of a senior with cancer is not always as heart-wrenching as a child with the disease. I, too, found myself at times having a silent conversation with the elderly patients I saw at David's cancer center. "You've had your whole life to live," I would think. "My husband is only 36 and he's dying."

That terrible thought left me for good, though, after David died. At that time, I realized that I needed his father to live not only for his own sake but for my son's. With his wealth of memories of his son, my father-in-law is a connection to David that my son needs very, very much.

And so, at 76 years old, my father-in-law, Leo, has a new responsibility. You see, Leo needs to pass on to Jacob the memories he has of David as a child, a teen, and a young adult. And Leo needs to be there when my son is old enough to inquire about and understand who his father was.

As David's battle progressed, I learned that the tremendous value of the treatments he received and his father continues to receive do not come without cost. If David's injections had not been covered by his insurance, his treatment would have been financially devastating to us. Instead, David's coverage enabled him to receive the drugs he needed and to live as long as was possible. The same holds true today for Leo and the Medicare coverage he currently receives.

During David's battle, I also learned that these injections come with a great deal of risk. Although I understand that many of these therapies may be technically self-injectable, self-injection was out of the question for David as it is for so many other patients. How David felt was never something that could have been predicted; chemotherapy often left him extremely fatigued, weak, and nauseated. These side-effects not only made life difficult for David, they made consistently safe self-injection impossible.

It is because of these experiences that I approach the issue you are addressing today with quite a bit of fear. What David, Jacob, and I experienced is something that I would spare others, if only I could. It also makes me worry for those, like Leo, who would be impacted by the loss of Medicare coverage for the therapy that made such a difference in David's life.

I fear for Leo and other seniors with cancer, for whom the loss of the Medicare coverage they receive today would be financially devastating. Many of these patients would not be able to afford their therapy. And their families would be forced to deal with the painful choice of having to do whatever is necessary to find the resources they need—or to let their loved ones die.

I fear for those seniors for whom self-injection would mean a death sentence. Like many cancer patients, David had an adverse reaction to one of his injections. If a senior had a similar response, and was alone, who would help them? If they were unaware of the reaction until it was too late, would they be able to even pick up the phone and dial 911? Or would they have to rely on a spouse who may also be weak or disabled?

I fear for the seniors who may not be able to keep track, by themselves, of all that their care entails. Fortunately, David's mind was very sharp. But because there were so many medications to take, he would have forgotten which he had taken and

which he had yet to take were it not for the care of his doctor and nurse. Chemotherapy makes this even more difficult, since it often causes fatigue and, for many, disorientation. David was only 36 when he died—what would it be like for people 40 years older than him to have to tackle these challenges alone?

I also fear for people who, like David, are too young for Medicare. While cutting current Medicare coverage may not impact them directly, they will suffer as a result. That is because managed care plans often follow Medicare's lead when it comes to cutting reimbursement. We would not have made it without David's coverage. What would happen to all those patients and families whose insurers copy Medicare and drop coverage for the life-saving drugs they need?

Finally, I fear for my son, Jacob.

If my father-in-law, Leo, loses the coverage that gives him the care he depends upon to live, he might lose his battle with cancer too early to fulfill his mission. The difference of a few years in an elderly man's life may not seem like much to some, but they mean the difference between my son really knowing his father, or not.

For Jacob's sake. For Leo's sake. For the sake of the other old and young cancer patients who are out there. And for the sake of my husband's memory. Please do not allow anyone to take away the coverage that lets some win their war on cancer and helps others make the most of the time that they have left.

Thank you.

Mr. BILIRAKIS. Thanks, Ms. Sizemore.

Ms. Rybicki?

STATEMENT OF MARIELLEN RYBICKI

Ms. RYBICKI. Mr. Chairman and other members of the committee, my name is Mariellen Rybicki. I live in Reston, Virginia, and I have multiple sclerosis. On behalf of myself and the many others who have Medicare coverage but who cannot afford drug treatment, I wish to thank this committee for your efforts to restore Medicare coverage for MS treatment.

As a result of last week's announcement that Medicare has changed its policy, I will now be able to receive the treatment that I have not been able to afford. From 1997 to the present, Medicare has not covered any drug for the treatment of multiple sclerosis. However, 3 years ago my Medicare carrier in Virginia did reimburse for a multiple sclerosis drug which is given intramuscularly.

Then, in 1997, for reasons I do not understand, Medicare terminated coverage for this drug. Last week's announcement is the first good news I have had since my diagnosis.

I was not able to utilize drug therapy during the time Medicare provided coverage, that is, prior to 1997. The intramuscular drug therapy Medicare used to reimburse for only became available in May 1996. Later that year, my doctor made me aware of the availability of drug therapy. I was already enrolled in Medicare Part A, but I was not enrolled in Medicare Part B, the part of the Medicare program that reimburses for the type of drugs that we are talking about today. It was not until 1997 that I applied to become eligible for Medicare Part B, and then I had to satisfy a waiting period. When I did become eligible for Part B, I literally had a prescription in my hand, and then I was told that Medicare had already changed its policy and had stopped coverage.

I need to be in a course of extended drug treatment. The drug that will now be covered by Medicare has been shown to significantly retard the progression of multiple sclerosis. Presently, I take high doses of steroids to control my spasticity. However, no matter what I do to control my symptoms, my disease will continue to worsen without drug therapy.

Multiple sclerosis is a horrible disease. It causes the body's immune system to attack the nerve tissue in the brain and spinal column, forming patches called plaques. As the disease progresses, it destroys the myelin coating that surrounds the nerves and the nerves themselves. Intact nerves with a myelin coating are what enable the transmission of messages between the brain and other parts of the body. As the coating and nerves are progressively destroyed, the symptoms of multiple sclerosis get worse.

For some inexplicable reason, in the early stages of multiple sclerosis symptoms generally will come and go. Later, these symptoms usually become permanent. Presently, I have great difficulty walking. I wear a brace and use a cane because my foot falls when I try to put my heel on the ground. I have numbness in my right hand and weakness in my fingers. I also have difficulty swallowing. Still, without drug therapy, and allowing this disease to go unchecked, my symptoms will worsen.

Many people who suffer from MS have brain atrophy. Cognitive skills are lost, tremors, loss of balance, and control of bodily function can ensue. Because of the many difficulties multiple sclerosis patients face on a daily basis, many cannot physically self-inject.

This is especially true for the drug treatment that is given intramuscularly. The needle that is required for this injection is about one and a quarter inches, and requires some skill for the proper dilution of the drug. This obviously makes it nearly impossible to self-inject for a person who has tremors, loss of hand-eye coordination, weakness, and loss of sensation.

Now under the policy change, people with multiple sclerosis will be able to get reimbursement for intramuscular injections when done in a doctor's office.

I cannot overstate my appreciation for what Congress has done to restore drug coverage for multiple sclerosis patients. However, since this policy change expires in September, I am also concerned that this coverage for multiple sclerosis treatment will once again be taken away. Today I ask that Congress not allow this to happen.

I would be glad to answer any questions that any of the members of the committee might care to ask.

[The prepared statement of Mariellen Rybicki follows:]

PREPARED STATEMENT OF MARIELLEN RYBICKI

Mr. Chairman and other members of the committee, my name is Mariellen Rybicki. I live in Reston, Virginia and I have multiple sclerosis. On behalf of myself and the many others who have Medicare coverage but who cannot afford drug treatment, I wish to thank this committee for your efforts to restore Medicare coverage for MS drug treatment.

As a result of last week's announcement that Medicare has changed its policy, I will now be able receive the treatment that I have not been able to afford. From 1997 to the present, Medicare has not covered any drug for the treatment of multiple sclerosis. However, three years ago my Medicare insurance carrier in Virginia did reimburse for a multiple sclerosis drug which is given intramuscularly. Then in 1997, for reasons I do not understand, Medicare terminated coverage for this drug. Last week's announcement is the first good news I've had since my diagnosis.

I was not able to utilize drug therapy during the time that Medicare provided coverage (that is prior to 1997). The intramuscular drug therapy that Medicare used to reimburse for was only available in May, 1996. Later that year, my doctor made me aware of the availability of this drug therapy. While I was already enrolled in Medicare, Part A, I was not enrolled in Medicare Part B, the part of the Medicare program that reimburses for the type of drugs that we are taking about today. It was not until 1997 that I applied to become eligible for Medicare Part B, and then

I had to satisfy a waiting period. When I did become eligible for Part B, I literally had my prescription in hand when I was told that Medicare had already changed its policy and had stopped coverage.

I need to be on a course of extended drug treatment. The drug that will now be covered by Medicare has been shown to significantly retard the progression of multiple sclerosis. Presently, I take high doses of steroids to control my spasticity. However, no matter what I do to control my symptoms, my disease will continue to worsen without drug therapy.

Multiple sclerosis is a horrible disease. It causes the body's immune system to attack the nerve tissue in the brain and spinal column, forming patches called plaques. As the disease progresses, it destroys the myelin coating that surrounds the nerves and the nerves themselves. Intact nerves with a myelin coating are what enables the transmission of messages between the brain and other parts of the body. As the coating and nerves are progressively destroyed, the symptoms of multiple sclerosis get worse.

For some inexplicable reason, in the early stages of multiple sclerosis, symptoms generally will come and go. Later these symptoms usually become permanent. Presently, I have great difficultly walking. I wear a brace and use a cane because my foot falls when I try to put my heal on the ground. I have numbness in my right hand and weakness in my fingers. I also have difficulty swallowing.

Still, without drug therapy and allowing this disease to continue unchecked my symptoms will worsen. Many people who suffer from MS have brain atrophy. Cognitive skills are lost. Tremors, loss of balance, and control over bodily functions can ensue.

Because of the many difficulties multiple sclerosis patients face on a daily basis, they cannot physically self-inject. This is especially true for the drug treatment that is given intramuscularly. The needle that is required for this injection is about 1 and a quarter inches and requires some skill for the proper dilution of the drug. This obviously makes it is nearly impossible to self-inject for a person who has tremors, loss of hand-eye coordination, weakness, or loss of sensation. Now, under the policy change, people with multiple sclerosis will be able to get reimbursement for intramuscular injections when done in a doctor's office.

I cannot overstate my appreciation for what Congress has done to restore drug coverage for multiple sclerosis patients. However, since this policy change expires in September, I am also concerned that this coverage for multiple sclerosis treatment will once again be taken away. Today I ask that Congress not allow this to happen.

I would be glad to answer any questions that any of the members of the committee might care to ask.

Mr. BILIRAKIS. Thank you very much, Mrs. Rybicki.

Ms. Lohrman.

STATEMENT OF ROSALIE LOHRMAN

Ms. LOHRMAN. Your Honor, Mr. Chairman, my name is Rosalie Lohrman. I am 61 years of age. I have renal cell cancer. I had to retire at age 57, not because I wanted to, but because of my disease. I had to take an early disability. That put me into the system of social security, and after 2 years of being disabled I was put into the Medicare system. I had good insurance, but I had to go into the Medicare system.

In August 1999, my doctor, Dr. John Downs from Towson, he suggested that I go on Interferon and Interleukin because my cancer had advanced quite rapidly within a short period of time, so we went through with applying for it. Imagine my surprise when I was denied. I thought surely it must be a mistake. My government was not going to let me down now, after I had paid into the system for my whole entire working life. So I sent in and received a second denial. Medicare wouldn't pay for self-injectable drugs.

That was the time I really started getting mad about it. I started knocking on every door and ringing every telephone I could. The National Cancer Foundation, the Kidney Foundation, Patient Advo-

cates, my Congressperson, anybody and everybody I could, and mostly my insurance company, because I wanted them to know when they saw the name Rosalie Lohrman who I was. I didn't care whether I talked to the secretary, I didn't care whether I talked to the president of the association that I was in contact with, I just wanted somebody to hear my voice and say that self-injectable drugs do need to be approved for cancer, for Interferon and Interleukin.

At that point I felt like a nobody, because I felt like, well, Medicare is just seeing me as a name and Medicare number 2192063102. But I was somebody. I am a wife of 44 years, mother of three sons, 11 grandchildren, a sister, a friend, and I thought a good American citizen, but now the system was letting me down. But I continued to fight. But a lot of times people with cancer, they don't have the stamina to fight and knock on every door and ring every phone, so that is an added stress.

Then you think, well, how am I going to fight the U.S. Government? If they are saying no, they are saying no. So it was just a lot of stress, that is all I can say. It was a lot of stress, but it did give me the will to keep on going.

I guess what I am saying is I became depressed. I just was put under added stress that I did not need to be under at that point. I guess the point I want to make is when you have cancer, sometimes you do not have the strength or the state of mind to fight as hard as I did.

Some people would have gotten their first denial and said, well, I can't fight City Hall. I might as well just give up now. But you cannot have that outlook. Therefore, I must stress to you the need for a permanent change in Medicare to cover self-injectable drugs.

Thank you.

[The prepared statement of Rosalie Lohrman follows:]

PREPARED STATEMENT OF ROSALIE LOHRMAN

Your Honorable Mr. Chairman, my name is Rosalie Lohrman of Pasadena, Maryland. I'm 61 years of age, I have renal cell cancer, I retired at age 57 on disability due to my cancer. I worked for 30 years at Super Fresh. In August, Dr. John Downs prescribed interferon and interleukin 2—the only effective treatment for my type of cancer. Imagine my surprise when I got my first denial. I thought surely they had made a mistake. How could they deny me when I needed them? A system I had paid into my entire working life. I got my second denial reason being they would not cover self-injectable drugs. Now I was getting mad. Here I have advanced cancer and Medicare was denying the only hope for me. I felt like a nobody, just a name and a Medicare # 219263102. Here I am a wife for 44 years, a mother of 3 sons, a sister, a friend and a hard-working American citizen and paid into the system every week. Now they are denying me a cancer treatment because they won't cover self-injectable drugs. I went on to my third appeal and was denied, but they knew who Rosalie Lohrman was. I called and got in touch with anybody and everybody I could. National Kidney Foundation, PAF office, my congressperson, my state government, general attorney's office, and I called my insurance company almost every day. I didn't want to fall through the cracks, I wanted them to know who I was and what I needed. I became depressed and full of stress. Now I am not only fighting cancer, but I am fighting the system because Medicare won't cover self-injectable treatment. The point I want to make is, there needs to be changes to Medicare coverage. Cancer patients sometimes neither have the strength or the state of mind to fight as hard as I did, therefore, I must stress to you, there needs to be changes in Medicare to include coverage of self-injectable drugs.

Mr. BILIRAKIS. Thank you, Ms. Lohrman.

Ms. Nancy Davenport-Ennis. Please proceed, ma'am.

STATEMENT OF NANCY DAVENPORT-ENNIS

Ms. DAVENPORT-ENNIS. Thank you. I must say, Mr. Chairman and members of the committee, that I think without question the witnesses that you have heard have probably told a far more compelling story than I.

I would like to share with you that I am before you today as a cancer survivor, as a mother-in-law of a 25-year-old son-in-law who is a cancer survivor, as an aunt of a 34-year-old niece who was deceased with ovarian cancer in October of this year.

I sit before you as an American who is concerned about the health care delivery system of this country, in an effort to try to do something to improve it. I sit before you also as a founding executive director of the Patient Advocate Foundation, which supplies direct patient services to patients who are confronting access problems and insurance and job discrimination and debt crisis problems.

I also sit before you as a founding executive director of the National Patient Advocate Foundation, which is an organization that has worked really very hard and very deliberately to try to be able to have positive dialog with both parties in our Nation as we seek to effect policy reform.

I would like to thank members of the subcommittee for their leadership in ensuring that the issue of Medicare reimbursement for injectable drugs and biologicals was addressed in the Department of Health and Human Services funding bill. I am also pleased that the Health Care Financing Administration issued a program memoranda on March 17 that removes, for at least this fiscal year, the barriers to Medicare reimbursement for injectable drugs.

I would like to take this opportunity to explain the involvement of our organization in this issue. In 1999, the Patient Advocate Foundation handled 29,000 calls. Many of our calls came from cancer patients, but we also served individuals with AIDS, with other serious and life-threatening illnesses.

It is our mission to provide case managers and attorneys to individuals who are having difficulty gaining access to health care. When individuals are diagnosed with cancer or any other serious illness, we feel they need to devote themselves to fighting their disease, and not to be distracted by fighting for access to the care that their physicians have recommended. If there is a need to address access, we feel that it is our role as a voluntary health agency to do that for those patients that contact us.

The National Patient Advocate Foundation is an organization that seeks to create avenues of access through policy and legislative reform, that serves as a voice for those who are seeking access in the system. Our advocacy activities are informed and influenced by the information that we receive through the counseling and case management activities through the Patient Advocate Foundation.

When we observe trends in the cases that we handle, whether they are a pattern of denials or an apparent shift in public or private insurance coverage standards, we explore the reasons for the apparent pattern. If appropriate, we address the underlying policy behind a new or revised coverage decision, and we seek to ensure patient's continued access to quality care.

It is the work of public education that brings us to this committee today. In 1998 and in 1999, we observed an increased rate of Medicare denials for certain self-injectable drugs and biologicals. Individuals who had previously received Medicare coverage for injectable products were being denied this coverage.

Our calls regarding denials came from individuals with cancer, carcinoid syndrome, acromegaly, and AIDS, as well as those who had received organ transplants and renal dialysis.

When we investigated this matter, we discovered that it had been the consistent policy of Medicare to provide payment for injectable drugs and biologicals if they are administered in a physician's office, even though they may theoretically be self-administered in some settings. The question of whether they should be considered self-administrable and thus not covered by Medicare have been resolved based on, and I quote from the regulation, "the usual method of administration of the form of that drug or biological as furnished by the physician," according to the Medicare carriers' manual.

Under this provision, injectable drugs had long been reimbursed when administered incident to physician services. Unfortunately, in 1999, HCFA appeared to be considering changes in its policy of reimbursement for injectable drugs, and a number of carriers had begun to deny reimbursement for injectable drugs.

The result for our patients was disastrous. Medicare patients were left with the responsibility to pay for their own medications and then to self-inject them. This results in decreased quality of care. Injectable drugs cannot be easily self-administered by the elderly or disabled, as you have heard in earlier testimony. Our patients affirmed to us how these changes would adversely affect their health.

We joined with our colleagues in the Cancer Leadership Council to oppose efforts by HCFA to restrict reimbursement for injectable drugs and biologicals. In addition, we supported efforts to include a provision in Public Law 106-113, the Department of Health and Human Services.

We would like to express our thanks to the Congress for its action on this matter. Regrettably, enactment of Section 219 of Public Law 106-113 did not result in immediate action by HCFA to clarify with its carriers the policy for reimbursement of injectable drugs. This memorandum should temporarily eliminate the reimbursement difficulties that our clients have recently encountered.

However, we also note that the program memoranda "may be discarded after September 30, 2000." HCFA appears to be relying on the technicality that the provision related to injectable drugs was included in an appropriations bill to justify discarding the program memorandum at the end of the year. Although we believe the intent of Congress on this matter is clear, it may be necessary for Congress to revisit this issue before the end of the fiscal year to prevent disruption in services to Medicare beneficiaries.

In closing, I would like to state we believe the current policy in reimbursement of injectable drugs and biologicals, the policy announced in the March 17 program memorandum, is the correct one for Medicare beneficiaries and for the program. We urge that HCFA clarify that this policy is a permanent one. We will be joined

by the entire cancer community in opposing any policy that will limit access to injectable drugs and biologicals.

Thank you for indulging me.

[The prepared statement of Nancy Davenport-Ennis follows:]

PREPARED STATEMENT OF NANCY DAVENPORT-ENNIS, EXECUTIVE DIRECTOR, PATIENT ADVOCATE FOUNDATION AND THE NATIONAL PATIENT ADVOCATE FOUNDATION

Mr. Chairman and Members of the Subcommittee, I am Nancy Davenport-Ennis, Executive Director of the Patient Advocate Foundation and the National Patient Advocate Foundation. I would like to thank the members of the Subcommittee for their leadership in ensuring that the issue of Medicare reimbursement for injectable drugs and biologicals was addressed in the Department of Health and Human Services funding bill. I am also pleased that the Health Care Financing Administration (HCFA) issued a Program Memorandum on March 17 that removes, for at least this fiscal year, the barriers to Medicare reimbursement for injectable drugs.

I would like to take this opportunity to explain our involvement in this issue. The Patient Advocate Foundation is a national non-profit organization that serves as an active liaison between patients and their insurers, employers, and/or creditors to resolve insurance, job discrimination, and/or debt crisis matters relative to their diagnosis. The Patient Advocate Foundation seeks, through case managers and attorneys, to assure patients access to care, maintenance of employment, and preservation of their financial stability.

In 1999, the Patient Advocate Foundation handled 29,000 calls. Many of our calls came from cancer patients, but we also serve individuals with AIDS and other serious and life-threatening illnesses. It is our mission to provide case managers and/or attorneys to individuals who are having difficulty gaining access to health care. When individuals are diagnosed with cancer or any other serious illness, they need to devote themselves to fighting the disease and need not be distracted by fighting for access to the care recommended by their physician. If there is a need to address access, job discrimination, or debt crisis issues, we are prepared to help with those matters.

The National Patient Advocate Foundation is an organization that seeks to create avenues of access through policy and legislative reform that serves as a voice for those who are seeking access to high quality health care prescribed by treating physicians. Most of our activity is directly related to improving access to care for individuals with cancer. Our advocacy activities are informed and influenced by the information we receive through the counseling and case management activities in the Patient Advocate Foundation. When we observe trends in the cases we handle—whether a pattern of denials or an apparent shift in public or private insurance coverage standards—we explore the reasons for the apparent pattern. If appropriate, we address the underlying policy behind a new or revised coverage decision and seek to ensure patients continued access to quality care.

It is the work of the Patient Advocate Foundation that brings us here today. In 1998 and 1999, we observed an increased rate of Medicare denials for certain injectable drugs and biologicals. Individuals who had previously received Medicare coverage for injectable products were being denied this coverage. Our calls regarding denials came from individuals with cancer, carcinoid syndrome, acromegaly, and AIDS, as well as from those who had received organ transplants and those on renal dialysis.

When we investigated this matter, we discovered that it had been the consistent policy of Medicare to provide payment for injectable drugs and biologicals if they are administered in a physician's office even though they may theoretically be self-administered in some settings. The question of whether they should be considered self-administrable—and thus not covered by Medicare—had been resolved based on the "usual method of administration of the form of that drug or biological as furnished by the physician," according to the Medicare Carriers Manual. Under this provision, injectable drugs had long been reimbursed when administered incident to physician services.

Unfortunately, in 1999 HCFA appeared to be considering changes in its policy of reimbursement for injectable drugs, and a number of carriers had begun to deny reimbursement for injectable drugs. The result for our patients was disastrous. Medicare patients were left with the responsibility to pay for their own medications and to then self-inject them. This results in decreased quality of care. Injectable drugs cannot be easily self-administered by elderly or disabled Medicare patients, and feared their care and health would be adversely affected by a change in HCFA pol-

icy. Our patients affirmed to us how these changes would adversely affect their health.

We joined with our colleagues in the Cancer Leadership Council to oppose efforts by HCFA to restrict reimbursement for injectable drugs and biologicals. In addition, we supported efforts to include a provision in Pub. Law No. 106-113, the Department of Health and Human Services Appropriations Act, to prevent HCFA from restricting coverage for injectable drugs.

We would like to express our thanks to the Congress for its action on this matter. Regrettably, enactment of § 219 of Pub. L. No. 106-113 did not result in immediate action by HCFA to clarify with its carriers the policy for reimbursement of injectable drugs and biologicals, and we again sought the intervention of Congress on this issue. This Memorandum should temporarily eliminate the reimbursement difficulties our clients have recently encountered. However, we also note that the Program Memorandum "may be discarded after September 30, 2000." HCFA appears to be relying on the technicality that the provision related to injectable drugs was included in an appropriations bill to justify "discarding" the Program Memorandum at the end of the year. Although we believe the intent of Congress on this matter is clear, it may be necessary for Congress to revisit this issue before the end of the fiscal year to prevent disruption in services to Medicare beneficiaries.

We believe the current policy on reimbursement of injectable drugs and biologicals—the policy announced in the March 17 Program Memorandum—is the correct one for Medicare beneficiaries and for the program. We urge that HCFA clarify that this policy is a permanent one. We will be joined by the entire cancer community in opposing any change in the current policy for reimbursement of injectable drugs and biologicals.

Mr. BILIRAKIS. Thank you very much, Ms. Davenport-Ennis.

Let me ask you, do you have an opinion as to why you think HCFA all of a sudden issued the program memorandum in August 1997 changing its policy on self-administered drugs by virtue of adding the language "the individual patient's mental or physical ability to administer any drug is not a consideration for this purpose"? Why?

Virtually all of us raised that question with Mr. Hash. Was anybody satisfied with his response?

Ms. DAVENPORT-ENNIS. I think in response to your question, Mr. Chairman, certainly we have asked Mr. Hash that question. We took our entire policy committee in to meet with Mr. Hash shortly after that policy memorandum was issued. We do not understand why it was issued, nor why there was that change.

Mr. BILIRAKIS. What has changed, other than—well, I was going to say other than maybe pressure from Congress? But heck, back in October we sent that letter forward. What has changed between when they changed that policy and now all of a sudden on March 17 they decided to go back to that original policy?

The head of HCFA cares about the health of people and reimbursements as much as anyone. Mr. Hash certainly does. We all do up here. We throw stones at each other, which is very unfortunate, but I know we all believe that we all care.

I have been really scratching my head, wondering why in the world would they do this all of a sudden; just pull it out of the air? Then basically, in effect, they admitted their mistake by changing it all just last week.

Ms. Story or Ms. Davenport-Ennis, were any of you contacted, or do you know of any other patient groups who may have been contacted prior to their having issued that August, 1997, PM?

Ms. DAVENPORT-ENNIS. I am not aware that any other group within the Cancer Leadership Council that we work with actively were contacted. However, I certainly could not speak with absolute

assuredness that they were not. But I have no working knowledge or recollection.

Mr. BILIRAKIS. Ms. Story, you have no knowledge of that?

Ms. STORY. No.

Mr. BILIRAKIS. Dr. Steinberg, do you have any impression of that, any idea of any contact that you may have heard?

Mr. STEINBERG. No.

Mr. BILIRAKIS. Mr. Hash said over and over and over again that—is any representative of HCFA here? Are you taking notes? Please. I more often than not ask that they stay over to listen to the other panels, and I appreciate very much HCFA having done that.

Mr. Hash said that the 1997 memorandum would clarify and even expand, and he kept referring to expanding, expanding coverage. Does anybody agree with that?

Ms. Rybicki, you of course very painfully described for us how your physical and mental condition would have kept you from self-administering the drug, and Ms. Sizemore, with a hell of a lot of courage and guts, certainly described how her husband would not have been able to do it.

Frankly, and I say this with HCFA present and with my colleague to my left being here, the phrase that they have thrown in here regarding not taking into consideration the patient's mental or physical ability is what really troubles me I think probably more than anything else. Where did that come from? I just cannot imagine.

At this point I will defer to Mr. Strickland.

Mr. STRICKLAND. Mr. Chairman, I detected that Ms. Lohrman may have wanted to say something.

Mr. BILIRAKIS. I am sorry, did you? Please proceed, ma'am.

Ms. LOHRMAN. What they are saying is that they do not want the bill passed, or the law changed to include injectable drugs, is that what they are saying? That you don't want it to where other people can get this drug?

Ms. RYBICKI. No, that is not what I am saying at all. I am hopefully speaking on behalf of everybody who needs to have it.

Ms. LOHRMAN. I misunderstood her. I was going to say, that should be up to the doctor and the health care provider.

Mr. BILIRAKIS. Dr. Steinberg made that clear in his written testimony. I missed some of his oral because I had some community health center people out there who wanted to see me. We have so much up here in our place.

All right, back to Mr. Strickland.

Mr. STRICKLAND. Thank you, sir.

I was just sitting here listening to your testimony, and a lot of thoughts came to my mind. A thought, I guess, that was most troubling to me is that we are rationing health care in America today. I don't think there is any question about that. We need to face up to that fact. We need to ask ourselves if that is what we want to do or want to continue to do, but we are rationing health care.

There are people who need medications who cannot get them, cannot afford them. That is the state of affairs in America today.

I was also thinking of a quote by Hubert Humphrey who said, you judge a society by the way it treats those in the dawn of life,

the children; those in the twilight of life, the sick and the elderly; and those in the shadows of life, the disabled and those who are in most need. Your stories are gut-wrenching.

I say to myself, this is America. We are a rich country, and we do what we choose to do with our resources. We just simply have not chosen to provide health care to the people in this country who need it.

I strongly think we should do what we can to correct this problem that has been brought to us. I think that is a step that we can take and should take to guarantee you that in September you will not have to worry about your benefits being eliminated. But I have a question for Dr. Steinberg.

Dr. Steinberg, we have had some people suggest that we go back—that HCFA go back to the old rules to cover whatever injectable drugs HCFA covered before 1997. I wonder, though, if going back to the old rules is going to resolve the controversy about self-injectable drugs. Is it conceivable that drugs that are injected by a doctor today could become for self-injection in the future, or even in pill form?

Mr. STEINBERG. It is more than conceivable, it is likely. I think the point that you are making simply highlights the fact that even sitting around talking about how to define "self-injectable," it is sort of a micro issue which hopefully we can do something with, but it is not the issue, right?

The fact that certain drugs are self-injectable and therefore are not covered, you know, we are talking about whether this person can self-inject or that person can self-inject. The reality is that there are hundreds of other medicines that are oral that may have as big an impact on patient's survival or quality of life. We have not even talked about them today.

This is an anachronistic issue, this self-injectability. As I say, it is a rare drug that you could not train at least one patient to self-administer. So if the definition is could somebody do it, well, it would wipe out coverage for almost any injectable.

Mr. STRICKLAND. So what in your judgment, as a physician, is the best answer to this dilemma that we face? If you were us—if you had the power to make a decision to solve the problem, what would you suggest?

Mr. STEINBERG. I guess I would suggest the following; that if the Congress, through its legislation, has decided that, at least to date, drugs that are not self-injectable or drugs that are self-injectable will not be covered, as I indicated in my testimony, it is not possible for you or somebody at HCFA or anybody else other than the physician caring for a patient to make an informed judgment as to whether or not a patient can or cannot safely inject a drug.

So if we have to live within the box related to self-injectability, I would leave that decision to the physician. But at the same time, by the same token, I would encourage you to recognize that this is the micro issue, and the macro issue is that drugs have become an absolutely essential component of health care today.

It does not make a lot of sense to have a program that is supposed to enable people to get necessary health care and to deny them access to what may be for them the most critical component.

The reason I highlighted chronic disease is that the treatments for chronic disease tend to be medication. They are not surgery, they are not hospitalization. Those are treatments for acute disease. But Medicare is supposed to cover acute and chronic disease.

So I guess if I could wave a magic wand, I would make the definition of "self-administrable" up to the physician. If the physician deemed it self-administrable, then it would not be covered under this law. But I would urge you to revise the law to make all drugs available.

Mr. STRICKLAND. Thank you, sir.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. Thank you, Mr. Strickland. It bothers me that we—do any one of you out there doubt that the entire Congress of the United States wants to do and will make every possible, honest effort to include prescription drugs in Medicare?

Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman. I am not sure exactly where to start. I have a ton of notes I wrote, and probably half of which I will get to.

Julie, let me just say one thing, I don't know that I could have done what you just did. But for that I am very thankful. It sent me back to visions, Mr. Chairman, of the FDA Reform Act, the Modernization Act. People have since asked me how we had the passion to go 2½ years through two different Congresses to accomplish a bill that people said in the beginning could not be done, and my answer was, it was because of the individuals that came 1 year to lobby me about the sickness that they had that did not return the next year, because they had a sense of urgency that we never figured out then.

Clearly that is the human side, sometimes we forget that not only do we have policy decisions to make, we have human faces behind the issue to remember, and an urgency that goes along with it that affects lives, and affects families in ways that many of us don't know.

I want to highlight one thing Julie said in her comments. That was that there was a fear that the actions taken by HCFA, right or wrong, would be replicated in the private sector. That is a fact. There is significant history to prove that that is the case. I am not saying that it is always bad, but it is a statement that you can accept with a great degree of certainty.

If we produce a product that is good, the private sector will replicate a good product. If we produce a product that is bad, that does not take into consideration all of the things that it should, because it was the Health Care Financing Administration, the private sector will take the opportunity to replicate that.

I know there is somebody here from HCFA. I will not ask who they are. I hope they will carry that message back, and I hope they will also carry the message back that I have heard, and that is that regardless of how much I think of Mike Hash and Nancy-Ann, I think that we all agree that what we have heard so far does not give us a great deal of comfort that we have addressed the problem, whether short-term or long-term.

I would like to be specific on a few questions, if I can.

Dr. Steinberg, you said earlier that were we to design Medicare today, it would have included a drug benefit. I totally agree with you. I would also add a caveat to that. Were we to design Medicare today, it would not resemble in any way, shape, or form the model that we currently have.

Would you agree with that?

Mr. STEINBERG. I have a little more difficulty responding to the latter part. Clearly I agree with you that drugs would be included. I guess in order to answer the latter part of the question, I would have to know a little more specifically which aspects——

Mr. BURR. Let me just use the analogy that I see sort of behind this issue that we are here on today. Because of technology, we are trying to make a determination about whether we cover a drug that technology allows us to self-inject which before was something we did in a hospital or doctor's office. Is that a fair observation on my part?

Mr. STEINBERG. Yes. As I mentioned in my testimony, both oral and written, I think the current situation, whether it is due to the Social Security Act or whether it is due to how it has been interpreted, provides perverse incentives to both manufacturers and to physicians.

As I tried to describe, to have a situation where a manufacturer reformulates a product that could be administered much more simply one way but it is not covered that way, have them reformulate it so it can be only administered intramuscularly by a professional and therefore be covered, that should not be what the effect of a law is.

Similarly, to have a physician prescribe a second best product simply because they have to administer it, it is more expensive but it is covered, that also is a perverse incentive.

So I guess my view is that whatever policies we have should be policies that encourage innovation, that also encourage I will say appropriate high quality health care, and some accountability for that. Because otherwise we could spend every dollar in the country, but it does not mean it would be well spent.

Mr. BURR. How does the private sector delivery system adapt to the ever-changing availabilities in medicine, whether they are pharmaceuticals or devices or techniques?

Mr. STEINBERG. They do it as imperfectly as anybody else.

Mr. BURR. But they do it without congressional legislation forcing it to happen. Is that right?

Mr. STEINBERG. They sure do, but they do it under different types of constraints. They do it under contractual constraints, under policy constraints.

For the past 10 years, I have been a member of a national Blue Cross/Blue Shield medical advisory panel. That panel is the panel that makes determinations about whether or not drugs, devices, procedures are safe and effective.

I can tell you that it is a laborious process. It involves a considerable amount of work, and many of the decisions are difficult, oftentimes because the requisite information that one needs to make those judgments is not available.

The issue of making decisions about new technology is problematic everywhere, and I believe that no matter what system we

have, we are still going to have to wrestle with which new technologies are appropriate to use and which are not.

Mr. BILIRAKIS. The Chair would announce that we are now going into a second round, and the Chair yields to the gentleman from North Carolina, Mr. Burr.

Mr. BURR. The gentleman from North Carolina would thank the Chair for letting him lead off this series.

Ms. Story, let me just ask you a very simple question. Were there drugs and biologics that Medicare paid for in 1997 that after this memorandum are not reimbursable today?

Ms. STORY. Yes.

Mr. BURR. A lot?

Ms. STORY. A good number.

Mr. BURR. So for anybody that would stand up and say that nothing has changed, that is misinformed? Would that be an accurate statement?

Ms. STORY. Yes.

Mr. BURR. I tried to be very selective as to how I chose those words.

Mr. Chairman, I would like to enter into the record a letter dated February 29, 2000. It was a letter from the Health Care Financing Administration. It referenced the memorandum.

I think that it is important that—are you familiar with that, Ms. Story? I think it was from a South Carolina—staff can make that available.

Mr. BILIRAKIS. Without objection, that will be done.

[The information referred to follows:]

HCFA
Health Care Financing Administration

MEDICARE

Part A Intermediary
Part B Carrier
DME Regional Carrier

February 29, 2000

RE: Self-administration of Interferon

I am responding to your letter of February 17, 2000. As a Medicare contractor, we must adhere to instructions from the Atlanta Regional Office when questions of interpretation of the Medicare Carriers Manual arise. The primary instruction addressing this issue was printed on page 16 of the October, 1997, Medicare Advisory. In regards to the Consolidated Appropriations Act for Fiscal Year 2000, the Regional Office has indicated that no change will be made in the coverage policy until the public forums are held and the clarifying policy is implemented. Until that time, it is our responsibility to administer the existing policy.

In this particular case, many forms of interferon are potentially self-administered. Excluded from this policy are those agents that are administered intralesionally and those agents that do not have a form appropriate for subcutaneous administration. In addition, your assistance would be appreciated in determining guidelines for particular agents or dosage of an agent where there is a significant likelihood of acute toxicity that would require office monitoring and immediate physician intervention. Complications that do not require emergency intervention would not be considered as "reasonable and necessary" for coverage. If you would like additional clarification of this request, please feel free to contact me.

In the meantime, we will be instructing offices to provide additional notes with the claim of the agent, dosage, and rationale for coverage. If we determine that coverage is appropriate with a particular patient and agent, we will allow the EJ modifier to be used for subsequent claims without additional documentation. If, however, the agent or the dosage changes, providers must submit the service without the EJ modifier and provide the explanatory information.

I look forward to our further discussions.

Sincerely,

David P. Sheridan, MD, MS
Medical Director

c: Bill Crown, Director, Part B Medical Review
Ed Greenleaf, Director, Part B Customer Service
Janice Knudsen, RN, Medical Affairs Coordinator

Palmetto Government Benefits Administrators, LLC
Medical Affairs
Post Office Box 100190 • Columbia, South Carolina • 29202-3190 • (803) 735-1384 • Fax (803) 754-8540

A HCFA Contracted Intermediary and Carrier

[redacted]

Program payment for drugs covered under the "incident to a physician's service" provision depends on, 1) whether the physician/staff administered the drug (i.e., not the patient); and 2) whether it is medically necessary based on a medically appropriate protocol for the physician/staff to administer the drug to every patient. The individual patient's mental or physical ability to administer any drug is not a consideration for this purpose.

Drugs that are self-administered are not covered by Medicare Part B unless the statute includes a benefit that specifically provides for such coverage (e.g. immunosuppressive drugs and hemophilia clotting factors, EPO and certain oral cancer drugs). However, certain drugs that are generally self-administered, such as Betaseron or Avonex, may not be self-administered under certain limited circumstances such as when the patient first learns how to administer the drug.

Coverage decisions are based on an appropriate medical protocol that would apply to any patient with an illness or injury that is being treated by the drug in question. In these cases, the usual program rules for coverage and payment of drugs furnished "incident to a physician's service" apply. The patient's condition, such as mental or physical disability, may not be a factor in making coverage determinations.

When an office or other outpatient evaluation and management E/M procedure code is used, it is not clear if the patient or the office staff administered the drug. In these cases, the medical necessity determination for the drug is independent of the coverage of the E/M procedure. Generally, the E/M service will be covered but the drug will not because either the patient self-administered the drug *or* it was not medically necessary for the physician/staff to administer the drug.

If the procedure code billed is a special injection or minor procedure code (e.g., 54235, injection of corpora cavernosa with pharmacologic agents), coverage of the drug automatically follows coverage of the procedure. The procedure, by definition, means that the physician performed the injection. In other words, the physician may only report one of these procedure codes when he or she has performed the injections. There is no Medicare coverage when the patient has self-injected the drug.

The same policy applies to suppositories. Medicare has discretion to cover the drug itself only in those cases where it is medically necessary (i.e. that appropriate medical protocol dictates) for the physician or staff to administer the suppository.

Oral drugs are not covered under the "incident to a physician's service" provision.

[redacted]trix Electrical Stimulation Device

You may not report Matrix electrical stimulation services with CPT codes 64400-64530. Section 35-46 of the Medicare Coverage Issues Manual (MCIM) provides for coverage of electrical stimulation for pain control only to assess a patient's suitability for transcutaneous electrical nerve stimulator (TENS) or percutaneous electrical nerve stimulator (PENS). The covered services described in MCIM 35-46 are reported using CPT procedure codes 64550-64595. Procedure codes 64400-64530 are not the appropriate procedure codes for electrical stimulation services.

Use of this device in physical therapy should be coded only with 97014 when medically necessary for specific conditions.

Mr. BURR. What did that letter say?

Ms. STORY. Basically it said that with Interferon, Interferon that had been covered prior to 1997 was no longer being covered.

Mr. BURR. This is the letter dated February 29, 2000?

Ms. STORY. Yes. That would be correct.

Mr. BURR. What kind of impact does that have?

Ms. STORY. It really means, for a patient that has some form of cancer that requires treatment with Interferon, that they are not going to get it.

Mr. BURR. Is that a common drug for the treatment of cancer?

Ms. STORY. Certain kinds of cancer.

Mr. BURR. Certain types?

Ms. STORY. Yes.

Mr. BURR. How does that letter fit with Mr. Hash's testimony that nothing has changed?

Ms. STORY. It doesn't, because it has. After 1997 there were changes, and our patients are not having drugs covered. They don't have access to the drug. They don't have the money to pay for the drugs themselves. They don't have professional care or expertise that they might need, should it be self-injectable.

Interferon can be a dangerous drug for a patient home alone that does not know what to look for. They have lost all that, in addition to all the other losses that they face.

Mr. BURR. Mr. Chairman, I have a lot more, but I don't know that it necessarily would achieve any other answers than what I have heard so far.

My only hope, let me say this to all of the witnesses—I want to personally thank them for their willingness to come here and share with us. It is really the intent, I won't say of this committee but I will say of this Congress, to figure out, one, how to extend drug coverage to seniors, because in fact those who say if we designed it today, it would be part of it, they are right. But I think it is also time that we try to figure out what the delivery system for health care for our seniors and for ourselves will look like in the future.

As Julie pointed out, the actions taken by government entities have a significant influence on the policies of the private sector, of private sector entities at some point after that.

I am confident that we can get this closer to perfect than many give us odds on doing, Mr. Chairman, like the FDA. I am convinced it will not be easy, but I think there are some people who are also convinced that we are not going to go away until we finish. For your leadership on that, I am thankful.

I yield back.

Ms. SIZEMORE. May I say something, please? This knowledge that I learned just this last week of how Medicare decisions can affect the private sector is not something that a lot of people know. I shared this with my family, I shared it with a man on the plane flying here, and they were blown away. They could not believe that that is what would happen.

I hope you all realize that a lot of the American people do not know this. If they found out about this, I don't know what their reaction would be, but you would have, I am sure, at your private offices your phone lines ringing off the hook over this, because it would affect everyone.

But unfortunately, most of the American people do not know that this could happen. They do not realize it, because they are busy with their lives.

Mr. BURR. Mr. Chairman, let me just say to Julie, I hope she will give us a couple months before she tells the other 249 million people, because I think we can accomplish a lot in that period of time.

Mr. BILIRAKIS. If we truly want to, all of us, if we truly want to.

Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman. I think I can be brief.

I had an experience over the last weekend in Columbus, Ohio. I was eating in a senior citizens center, and an older gentleman told me that he had just been diagnosed about a year earlier with Parkinson's disease.

He says, I take six prescriptions. One of my prescriptions costs over $200 a month. My wife, the only way we can make it is for my wife to continue to work. I asked him how old his wife was, and she is 78 years old.

I listened to you talk about cancer and multiple sclerosis and various illnesses and diseases. I am thinking, we ought not to be making these kinds of choices. We ought not to be deciding who gets medicine and under what conditions.

It is true that, if not all of us in the Congress, most of us in the Congress want a prescription drug benefit under Medicare, but how we do that is very important, a very important question that needs to be resolved.

Dr. Steinberg, I just have a question for you that I think I know the answer to, but I am just wanting to get this on the record. You work with a lot of people, and some of the people you work with are poor people. Some of the people you work with are people with modest incomes, or even people with very healthy incomes.

As a physician, knowing what you know, will a prescription benefit that is targeted only toward low-income people solve the problem that we face in this country, or even the problems that many people who are represented here at this table face?

Mr. STEINBERG. Absolutely not. What you say is definitely the case. As I mentioned, I had many patients of modest means, they would not be considered poor, they would be considered working class, in East Baltimore who simply did not fill medications, prescription medications, because they didn't have enough means to do so. So it is not limited to the poor.

If I could, I would also like to say that, as you all realize, a prescription benefit is not a prescription benefit is not a prescription benefit.

To just say that we will add a prescription benefit will not necessarily solve any problem. It depends on how that benefit is designed, not just who it is targeted at.

So I would encourage you to understand that for those who are on chronic medications that they have to fill monthly, that they are, as we found in our study, spending $5,000, $10,000 a year. And to give $1,000 worth of coverage to someone who has a need for $10,000 worth of medication is like saying, we will give you enough to treat your diabetes, but we don't have enough to treat

your heart failure or angina. And I am not sure we have accomplished a lot in that sort of circumstance.

Mr. STRICKLAND. I represent a district in southern Ohio, an Appalachian district, where the median income for a family of four is less than $22,000. So you see the dilemma that many of the people I represent face.

I want to thank each of you for coming here. I want to thank our good chairman for his leadership. He is a wonderful person to work with, and I think all of us on this committee value him.

Mr. BILIRAKIS. Thank you very much for that, Ted.

Dr. Steinberg, what you are really saying is that there—anything we do should have a stop loss attached to it. We can use the term "catastrophic", although we don't like to use that term, for obvious reasons.

Is that what you are saying, basically, that there ought to be——

Mr. STEINBERG. I believe there is a need for the high end coverage. There are many ways it could be designed, but my point is to cap a benefit, as even many private policies currently do, at $1,000, it does not cut it for somebody who——

Mr. BILIRAKIS. That is something, frankly, and I think Mr. Strickland knows that, we have been working awfully hard on. Granted, the process here being what it is, you would like to think that you can get all of the people, both sides of the aisle, together in a room and get things worked out, but unfortunately, that just does not work. So you sort of have to first convince your colleagues on your side to come up with a position, and then try to share.

Mr. STRICKLAND. Mr. Chairman, most people are not as cooperative as we are.

Mr. BILIRAKIS. Getting back to Mr. Hash's written testimony, and he is not here and I hope he does not mind, I certainly don't mean to attack him, but it says here in the second page, at the top of the second paragraph, the top of page 2 of his written testimony, "Our clinicians at HCFA are concerned that creating such a narrow exception to the ban on Medicare coverage for outpatient drugs could create an ethical dilemma for compassionate physicians when caring for patients who can self-administer drugs but cannot afford the drugs they need. This approach could compound the current inequities in coverage, and may also create program integrity problems."

I don't disagree with that. But so what, I guess is the question I ask. On one hand we say we want all prescription drugs covered. We have had a history of covering some of them.

Are we helping the situation by taking away some of that coverage that has been there, in existence, for all these many years? I think not. We need to retain that partial coverage, expand upon it, and improve upon it.

Again, I am having problems—all of us here are having problems trying to understand the reason for that PM back in August 1997.

Ms. Davenport-Ennis, yesterday's edition of Health News Daily quotes a senior HCFA official about the agency's perspective on their report policy change. Are you familiar with what I am referring to?

Ms. DAVENPORT-ENNIS. Very.

Mr. BILIRAKIS. I will just go ahead and read it: "the guidance had clarified that although self-administered drugs are not covered under Part B, a carrier may choose to provide reimbursement if such a drug is administered by a physician in order to teach the patient the correct self-injection procedure."

I guess the question is, does HCFA's view of their program memorandum satisfy your concerns, or this more recent program memorandum, if you will, satisfy your concerns, or does it really raise a fear that they are trying to undermine, and I hate to put it this way, but to undermine Medicare coverage of injectable therapies?

I don't mean that as strictly as it sounds, undermine. But that is really what has been happening.

Ms. DAVENPORT-ENNIS. I would like to respond with some specificity. I do feel that my concern at reading that today is that once again it appears that HCFA is saying to their carriers, this is still a discretionary matter, that you may choose to interpret this the way you feel is appropriate.

We do not read the law that was passed as being discretionary. We read it as having very specific instruction for the carrier.

We find over and over again with both the physicians who refer their patients to us and the thousands of patients with whom we interact that there seems to be a global plea which is, simply, help us understand what the rules are, whether they are in the private health care sector or whether they are in the Medicare sector.

If you will help us understand what the rules are, then we will have confidence in that and we will feel reassured that if we follow those rules, then in fact the result will be that we have the coverage we think we have. We continue, since the memorandum of 1997, in all sincerity, to find that the reasonable expectations that we had as we interpreted the language evaporate from time to time. We find inconsistencies, depending upon which carrier memorandum we might be reading about which particular product in which particular State.

So when we read what the Health News Daily had to say yesterday we found it very troubling, because I can see in my office the phones beginning to ring again with carriers who may in good faith be trying to follow the direction that perhaps they think is being reflected in the Health News Daily, only again to maybe issue another memorandum, as the one that was just issued in South Carolina on February 29, that was so troubling and that once again caused those phones to start to ring.

So it is a huge concern for us. We also, in closing, must say that when the U.S. Congress looks at any issue that involves health care, and once you have had thorough hearings on the matter and you voted it out of committee and you voted it off the House floor and off the Senate floor, and it becomes a law of the land, within our organization, I can assure you, we view that law as stout. We view that law as one that deserves respect from every citizen, every entity that is being directed by that law.

We have great concern when it comes to a sense on any part that it is a discretionary matter when the U.S. Congress passes a law.

Mr. BILIRAKIS. That should tell us something.

Mr. STEINBERG. Mr. Chairman, can I comment on that?

Mr. BILIRAKIS. Without objection.

Mr. STRICKLAND. No objection.

Mr. BILIRAKIS. Please.

Mr. STEINBERG. It seems clear from listening today that the language in the statute, at least to a number of people, is ambiguous. I would just like to say that anything your committee can do to clarify what you think that language should mean would take on the effect of eliminating the problem with discretion or variability in interpretation.

So I guess I would ask for all the help you can provide to clarify this.

Mr. BILIRAKIS. And to turn it around, we need your help. We are an ivory tower. We have probably more physicians maybe in the Congress than we have ever had. But the truth of the matter is that we have some practical experience, but not really very much. Yet, we have to make these very tough decisions. We don't know how it is going to affect the patient out there and the medical provider. That is why it is so very important that we do get your inputs to help us out.

Dr. Steinberg and Ms. Davenport-Ennis, particularly you mentioned it, over the years, and you can imagine in my position, I just cannot even walk by a doctor back home without him stopping me and complaining about this or that; and Ted gets that, we all do.

But the biggest complaint that we have had is, look, I want to follow the law. I want to follow the law, but it is inconsistent. We need some clarification and some consistency on how to file the claims and the reimbursements.

When my son started his medical practice—he is also an internist—he could not afford any of the computer systems and all that equipment, and he had the pegboard system which you are probably familiar with. Maybe most doctors start out that way.

It was in January at the beginning of a new Congress, so I had a lot of time at home. I spent a lot of time in his office working with the pegboard system, and trying to understand the different classifications, the coding and things of that nature. My God, what you all go through, thanks to us.

Well, you are really all wonderful, and the courage, of course, of Ms. Sizemore, Ms. Rybicki, and Ms. Lohrman, have shown, and of course the knowledge that Dr. Steinberg and Ms. Story and Ms. Davenport communicated to us is very valuable.

I like to think that we will address prescription drugs, the overall picture, in time to keep what you are concerned about from happening. I don't know. But it takes two to tango, and that is a problem.

We might do something. If we don't, we certainly ought to shore up this area. I know with cooperation with people like Mr. Strickland and so many others, we are going to do it. Thank you very much for being here. God bless you.

Again, you are available for any written questions we may want to offer to you to respond?

Ms. DAVENPORT-ENNIS. Yes.

Ms. SIZEMORE. Yes.

Mr. BILIRAKIS. The hearing is concluded.

[Whereupon, at 2:06 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:

RESPONSES FOR THE RECORD OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Question 1. According to your testimony, it was never HCFA's intent for the August 13, 1997 directive to reduce or limit the Medicare program's longstanding coverage of professionally-administered injectable drugs. Is that an accurate reading of your testimony?

Answer: Yes. The August 13, 1997 memorandum was a clarification of the longstanding HCFA policy with respect to coverage for drugs and biologicals that cannot be self-administered. In fact, the memo emphasized that Medicare claims processing contractors may cover generally self-administered drugs when a provider is administering the drug in order to teach a patient how to self-administer. We did this to encourage more coverage in these situations.

Question 2. The Committee heard testimony, however, that a number of professionally-administered injectable drugs which were routinely reimbursed prior to August 13, 1997 were denied coverage after that date. Can you confirm or do you deny that such has been the case?

Answer: This is possible. Like many specific coverage policies in Medicare's history, determination of whether a specific drug can be self-administered has been left up to the medical directors of each claims processing contractor. Instructions to Medicare claims processing contractors on this issue have been provided through the Medicare Carrier Manual and were updated in 1995. Those instructions stated that drugs may be covered only if they "are of the type that cannot be self-administered." Some carriers expressed confusion over this policy, which may have led to improper reimbursements. In order to address carrier confusion, we issued a memorandum clarifying the national guidance in our carrier manual on August 13, 1997.

Question 3. From what the Committee has learned about these denials, the Medicare carriers involved are asserting that their actions to restrict Medicare are a result of the August 1997 transmittal. How do you respond?

Answer: Instructions to Medicare claims processing contractors on this issue have been provided through the Medicare Carrier Manual and were updated in 1995. Those instructions stated that drugs may be covered only if they "are of the type that cannot be self-administered." Rapid advancements in pharmacolgical and medical developments caused confusion in carriers' interpretation of Carrier Manual instructions, which may have led to improper reimbursements. The August 13, 1997 memorandum was a clarification of the longstanding HCFA policy in this area. This memorandum did not increase restrictions on beneficiary access to prescription drugs. It clarified for carriers the criteria for making drug coverage decisions as required by the Social Security Act.

Many of these types of coverage decisions are left to carriers' discretion, and we try to ensure their decisions are consistent with statute. The August 1997 memorandum reminded carriers that according to the way the statute is written, coverage decisions should be based on the nature of the drug or biological in question rather than on the capacity of any one individual.

Question 4. It has come to our attention that the Medicare carrier serving South Carolina—Palmetto Government Benefits Administrators (PGBA)—has informed cancer caregivers that injections of Interferon for cancer patients will not be covered unless the carrier is convinced that the injection incident to a physician's professional services is "medically necessary. This requirement is in direct contradiction to the reimbursement process that existed prior to August 1997, and appears to ignore the Program Memorandum issued by HCFA on March 17, 2000. Of even greater concern to the Committee, however, is the statement by a senior officer at PGBA that HCFA has recommended the carrier adopt and maintain this course of action. What is your response to this set of circumstances? What will you do to correct the course of action adopted by PGBA, and when will the Committee be informed of corrective action you will take?

Answer: Any items or services covered by Medicare by law must be medically necessary. Policy relating to medical necessity, as described in section 2049.4 of the Medicare Carriers Manual, remains unchanged, both before and after the August 1997 memo. Medical necessity determinations are made at carriers' discretion. Policy relating to the issue of injectable drug types is found in a separate section of the Medicare Carriers Manual, section 2049.2. The August 13, 1997 memo, as well as section 219 of the Appropriations Act, only refer to Carrier Manual section 2049.2, and not the section on medical necessity.

Question 5. As you know, the vast majority of my colleagues support the establishment of a broad Medicare drug benefit. However, the case of coverage of profes-

sionally-administered injectable drugs raises an important issue that must be addressed as we move forward on the broader reform effort. The President's proposal to establish a new Part D optional drug benefit specifically excludes the currently covered outpatient prescription drugs. The current confusion regarding injectable drugs has raised concerns that, if the President's proposal were enacted into law, these drugs would not be covered under either Part B (due to ongoing carrier actions and the time-limited nature of the March 17, 2000 Program Memorandum) or under Part D (due to the design of the President's plan). In the meantime, there are patients who used to have some important injectable drugs covered by Medicare and now find themselves in a bureaucratic snafu which is leading to denials of coverage. While Congress and the Administration are exploring the creation of a broad Medicare drug benefit, will HCFA take definitive steps to resolve the problem faced by these seniors and the apparent confusion of the carriers?

Answer: Under the President's proposal, prescription drugs would be covered either under Parts A and B or the new Part D. Those that are covered under A or B would retain such coverage to the extent that the benefit has not expired, at which point Part D would pick up the coverage. Those drugs that are not covered under Parts A or B would be covered under Part D.

We believe that all prescription drugs would be covered and no one would be "caught in the middle." We are holding a series of town hall meetings on the issue of injectable drugs. When the restrictions included in the FY 2000 Appropriations Act expire, we plan to publish a proposal in the Federal Register offering several different options for determining "self-administered," including options which take patient characteristics into account. When finalized, this definition would serve as a basis for determining coverage under Part B versus Part D.

Question 6. The March 17, 2000 Program Memorandum advises carriers to discard it after September 30, 2000. This statement suggests to many of us that it may be HCFA's intent to restrict Medicare program's longstanding coverage of professionally administered injectable therapies after that date. What do you think will happen to seniors and people with disabilities who depend upon Medicare coverage of these drugs after September 30, 2000? In light of the continuing action taken by Palmetto Government Benefits Administrators and other carriers, will HCFA amend the Program Memorandum to make permanent the current ban on the restriction of this coverage? If not, then why?

Answer: Rather than amend the Program Memorandum, we would like to pursue the issuance of a proposed rule to solicit public comment on the definition of the term "self-administered" to solicit input from the broadest possible range of stakeholders. We attempted this previously, but postponed the proposal out of concern that we not appear to violate the appropriations language, In lieu of a broader solicitation through the *Federal Register,* and as instructed in the Appropriations Act conference report, we are scheduling town hall meetings to allow interested parties to discuss this issue and available options. The first meeting is set for May 18th in Baltimore. The information collected during these town hall meetings will provide HCFA with guidance in considering future steps on this topic that was in effect before the August 1997 memorandum.

Question 7. Included in your final rule on Medicare's Prospective Payment System for Hospital Outpatient services (HCFA-1005-FC) issued on April 7, 2000, you state "Drugs that can be self-administered are not covered under Part B of Medicare." Yet in section 219 of the Consolidated Appropriations Act of 1999, Congress directed HCFA to continue Medicare's coverage policy that was in effect prior to August 13, 1997, which covers drugs usually administered incident-to a physician's services. Do you view your March 17 Program Memorandum issued to implement section 219 of the Consolidated Appropriations Act of 1999 as consistent with the statement in the April 7, 2000 final rule?

Answer: The Prospective Payment System for Hospital Outpatient services final rule states "Drugs that can be self-administered are not covered under Part B of Medicare (with specific exemptions for certain oral chemotherapeutic agents and antiemetics, blood-clotting factors, immunosuppressives, and erythropoietin for dialysis patients)." This statement is consistent with the current Medicare payment policy.

○