LESSON'S LEARNED: THE DEPARTMENT OF VETERANS AFFAIRS PRESCRIPTION DRUG PURCHASING PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

JULY 22, 2002

Serial No. 107–214

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpo.gov/congress/house
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

87–140 PDF WASHINGTON : 2003

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON GOVERNMENT REFORM

DAN BURTON, Indiana, *Chairman*

BENJAMIN A. GILMAN, New York
CONSTANCE A. MORELLA, Maryland
CHRISTOPHER SHAYS, Connecticut
ILEANA ROS-LEHTINEN, Florida
JOHN M. MCHUGH, New York
STEPHEN HORN, California
JOHN L. MICA, Florida
THOMAS M. DAVIS, Virginia
MARK E. SOUDER, Indiana
STEVEN C. LATOURETTE, Ohio
BOB BARR, Georgia
DAN MILLER, Florida
DOUG OSE, California
RON LEWIS, Kentucky
JO ANN DAVIS, Virginia
TODD RUSSELL PLATTS, Pennsylvania
DAVE WELDON, Florida
CHRIS CANNON, Utah
ADAM H. PUTNAM, Florida
C.L. "BUTCH" OTTER, Idaho
EDWARD L. SCHROCK, Virginia
JOHN J. DUNCAN, JR., Tennessee
JOHN SULLIVAN, Oklahoma

HENRY A. WAXMAN, California
TOM LANTOS, California
MAJOR R. OWENS, New York
EDOLPHUS TOWNS, New York
PAUL E. KANJORSKI, Pennsylvania
PATSY T. MINK, Hawaii
CAROLYN B. MALONEY, New York
ELEANOR HOLMES NORTON, Washington, DC
ELIJAH E. CUMMINGS, Maryland
DENNIS J. KUCINICH, Ohio
ROD R. BLAGOJEVICH, Illinois
DANNY K. DAVIS, Illinois
JOHN F. TIERNEY, Massachusetts
JIM TURNER, Texas
THOMAS H. ALLEN, Maine
JANICE D. SCHAKOWSKY, Illinois
WM. LACY CLAY, Missouri
DIANE E. WATSON, California
STEPHEN F. LYNCH, Massachusetts

BERNARD SANDERS, Vermont
(Independent)

KEVIN BINGER, *Staff Director*
DANIEL R. MOLL, *Deputy Staff Director*
JAMES C. WILSON, *Chief Counsel*
ROBERT A. BRIGGS, *Chief Clerk*
PHIL SCHILIRO, *Minority Staff Director*

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

CHRISTOPHER SHAYS, Connecticut, *Chairman*

ADAM H. PUTNAM, Florida
BENJAMIN A. GILMAN, New York
ILEANA ROS-LEHTINEN, Florida
JOHN M. MCHUGH, New York
STEVEN C. LATOURETTE, Ohio
RON LEWIS, Kentucky
TODD RUSSELL PLATTS, Pennsylvania
DAVE WELDON, Florida
C.L. "BUTCH" OTTER, Idaho
EDWARD L. SCHROCK, Virginia

DENNIS J. KUCINICH, Ohio
BERNARD SANDERS, Vermont
THOMAS H. ALLEN, Maine
TOM LANTOS, California
JOHN F. TIERNEY, Massachusetts
JANICE D. SCHAKOWSKY, Illinois
WM. LACY CLAY, Missouri
DIANE E. WATSON, California
STEPHEN F. LYNCH, Massachusetts

EX OFFICIO

DAN BURTON, Indiana

HENRY A. WAXMAN, California

LAWRENCE J. HALLORAN, *Staff Director and Counsel*
KRISTINE MCELROY, *Professional Staff Member*
JASON CHUNG, *Clerk*

CONTENTS

LESSON'S LEARNED: THE DEPARTMENT OF VETERANS AFFAIRS PRESCRIPTION DRUG PURCHASING PROGRAM

MONDAY, JULY 22, 2002

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Boston, MA.

The subcommittee met, pursuant to notice, at 9:30 a.m., in McCormack Courthouse, 1500 John W. McCormack Post Office and Courthouse, 90 Devonshire Street, Boston, MA, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Tierney, Allen and Lynch.

Staff present: Lawrence J. Halloran, staff director and counsel; Kristine McElroy, professional staff member; and Jason M. Chung, clerk.

Mr. SHAYS. The quorum being present, the Subcommittee on National Security, Veterans Affairs and International Relations, hearing entitled "Lessons Learned: The Department of Veterans Affairs Prescription Drug Purchasing Program" is called to order.

We welcome our witnesses. We welcome our guests. Good morning to everyone.

At the invitation of Congressman Tierney, the subcommittee has come to Boston today to discuss the Department of Veterans Affairs, VA, prescription drug benefit program and the impact of Federal pharmaceutical purchases on the national effort to made medicines more affordable. These are important issues to veterans, senior citizens and to all of us as health care consumers.

In the current debate on how best to structure a Medicare prescription drug benefit, VA and the Department of Defense programs offer important lessons and cautions about how to expand and access and control costs.

As the General Accounting Office [GAO] recently concluded, "Considerable leverage can be exerted when the departments commit to buy increased volumes of a particular drug when there are generic drugs or brand name drugs that are interchangeable in efficacy, safety and outcomes."

Bringing the benefit of that leverage to patients is a matter of fiscal discipline and effective medical management. Savings from national contracts and use of evidence-based formularies can work to make therapies more affordable in the context of a complete health care delivery system.

But VA cannot afford to become a mere prescription window. VA health facilities in many areas are already straining under the weight of increased demand by veterans who once had access to affordable care elsewhere.

To save costs, not just shift costs, strategies to reduce prescription drug expenditures must focus on health outcomes as well as a healthy bottom line.

In this area, and on other important issues, Mr. Tierney has been a thoughtful, hard working partner in our partnership oversight of Federal programs. The subcommittee is grateful for the opportunity to be here today and we look forward to the testimony of all of our witnesses.

[The prepared statement of Hon. Christopher Shays follows:]

Statement of Rep. Christopher Shays
July 22, 2002

Good morning and welcome.

At the invitation of Congressman Tierney, the Subcommittee has come to Boston today to discuss the Department of Veterans' Affairs (VA) prescription drug benefit program and the impact of federal pharmaceutical purchases on the national effort to make medicines more affordable. These are important issues to veterans, to senior citizens and to all of us as health care consumers.

In the current debate on how best to structure a Medicare prescription drug benefit, VA and Department of Defense programs offer important lessons and cautions about how to expand access and control costs.

As the General Accounting Office (GAO) recently concluded, "Considerable leverage can be exerted when the departments commit to buy increased volumes of a particular drug when there are generic drugs or brand name drugs that are interchangeable in efficacy, safety and outcomes."

Bringing the benefit of that leverage to patients is a matter of fiscal discipline and effective medical management. Savings from national contracts and use of evidence-based formularies can work to make therapies more affordable in the context of a complete health care delivery system.

But VA cannot afford to become a mere prescription window. VA health facilities in many areas are already straining under the weight of increased demand by veterans who once had access to affordable care elsewhere.

To save costs, not just shift costs, strategies to reduce prescription drug expenditures must focus on health outcomes as well as a healthy bottom line.

In this area, and on other important issues, Mr. Tierney has been a thoughtful, hard working partner in our bipartisan oversight of federal programs. The Subcommittee is grateful for the opportunity to be here today, and we look forward to the testimony of all our witnesses.

Mr. SHAYS. I would extend that by saving gratitude to Mr. Allen and I think Mr. Lynch will be joining us. I am fortunate to chair a committee of just outstanding members, any one of whom could take this gavel and make sure this committee served well.

At this time I would recognize Mr. Tierney, and again, thank you for asking us to be here.

Mr. TIERNEY. Thank you, Mr. Chairman. I want to extend my gratitude to you for having this hearing and bringing it up to the Boston area in Massachusetts. Like everywhere else in this country, this is a very significant issue in Massachusetts and in my District, as well as others.

I want to also thank Tom Allen, who has been a leader on this issue for some time, particularly with regard to the cost aspects of it. No matter what we do in terms of trying to make prescription drugs accessible to people, the cost is always going to be an issue and that's one thing we both are going to address here today.

The fact of the matter is that we're bankrupting many, many individuals, many of them seniors right now by the high cost charged to individuals for prescription drugs and if we were to put an end to Medicare or any other program, we'd run the risk of bankrupting that program if we didn't also attend to the issue of cost.

Once again, last year we saw double digit increases in prescription drug spending in this country, an increase of 17.1 percent in 2001. Once again, prescription drugs are one of the facet growing components of health care. Once again, seniors remain the hardest hit because they were the most in need of prescription drugs while remaining of the least likely groups to have prescription drug insurance. And Judy Waxman will testify to that, that 50 percent of Medicare beneficiaries were without prescription drug insurance at some point during the year and nearly 30 percent had no drug coverage at all. And once again, it remains my hope that this situation will change and that Congress will demonstrate the political will to protect its most vulnerable citizens by passing a comprehensive Medicare prescription drug benefit.

In the past, as a Nation, when we had the political will to protect and serve the most vulnerable, we have been up to the task. There are lessons to be learned from these efforts and today we'll focus on Department of Veteran Affairs' efforts to manage a pharmacy benefit that is both cost effective and able to provide a high quality benefit to its patients.

One of our charts paraphrases a GAO study that reported that the VA national contract prices were up to 70, 72 and 88 percent lower than the recommended retail price for cholesterol lowering drugs.

It's clear from VA's success at negotiating lower drug prices that drug manufacturers have the ability to make a profit without charging their highest prices. We can also see that there's room for negotiations in drug manufacturers' profit margins when, even in the most dire circumstances, the manufacturers can still make a profit.

Last October, when this country suffered from a terrorist attack in the form of anthrax sent through the mail, we needed affordable antibiotics. Health and Human Services Secretary Tommy Thompson convinced Bayer to provide Cipro to the United States at a dis-

count. Because of the size of the order placed by our government, Bayer still walked away with millions of dollars in profit.

We have a chart that shows that in 2001, the pharmaceutical industry was the most profitable industry in the United States with 18.5 percent of its revenues going to profits. The next most-profitable industry, commercial banking, had 13.5 percent of revenues going to profits. The median for the Fortune 500 companies was profits at 3.3 percent of revenue.

Some of our witnesses today will talk about how drug companies use that money. The companies claim that their high prices are necessary to support research and development, but we'll hear today about where the money really goes. We'll hear that the companies spend significantly more money on marketing, advertising, and administration than they do on research and development. And we will also hear that drug companies make more in profits than they spend on research and development.

I think it's also important to remember that a large portion of the dollars for pharmaceutical research and development comes from taxpayers. Pharmaceutical companies have benefited from the basic drug research conducted primarily through the National Institute of Health. Of the 21 most important drugs introduced between 1965 and 992, 15 were developed using knowledge and techniques from federally funded research. That research has contributed to the development of drugs to treat cancer, HIV, depression and other diseases—drugs that are now reaping billions of dollars in revenues for drug manufacturers.

We have to find a way to bring down the costs of drugs, especially for the elderly. As we'll hear today, we don't need to reinvent the wheel. Instead, we can learn from the VA's success at getting lower drug prices and adapt those lessons to other settings. And we'll see that there is room for negotiation in the drug manufacturers' profit margins.

I believe the time has come to put patients over profits, to learn from our successes and to protect our most vulnerable citizens with a cost effective and high quality drug benefit.

The fact of the matter is that we can do all of that while providing manufacturers with the resources for research and development and a decent profit. So I look forward to the testimony of all the witnesses that are here today. I thank them for coming and I welcome them to the hearing. And again, thank you, Mr. Chairman, for being so strong on this issue for letting us have this hearing here.

[The prepared statement of Hon. John F. Tierney follows:]

Opening Statement before Subcommittee on National Security, Veteran Affairs and International Relations
By Rep. John F. Tierney
July 22, 2002

Hearing on VA Prescription Drug Price Discounts

I'd like to start by expressing my gratitude to Chairman Shays for scheduling and conducting today's hearing. I'd also like to extend my appreciation for the panelists for their time, insight and testimony today.

Once again, last year we saw double digit increases in prescription drug spending in the United States – an increase of 17.1 percent in 2001. Once again, prescription drugs were the fastest growing component of healthcare.

Once again, seniors remained the hardest hit because they were the most in need of prescription drugs while remaining one of the least likely groups to have prescription drug insurance – as Judy Waxman will testify, 50 percent of Medicare beneficiaries were without prescription drug insurance at some point in time during the year and nearly 30 percent had no drug coverage at all. And once again, it remains my hope that this situation will change and that Congress will demonstrate the political will to protect its most vulnerable citizens by passing a comprehensive Medicare prescription drug benefit.

In the past, as a nation, when we have had the political will to protect and serve the most vulnerable, we have been up to the task. There are lessons to be learned from these efforts and today we'll focus on Department of Veteran Affairs' efforts to manage a pharmacy benefit that is both cost effective and able to provide a high quality benefit to its patients.

One of our charts paraphrases a GAO study that reported that the VA national contract prices were up to 70, 72 and 88 percent lower than the recommended retail price for cholesterol lowering drugs.

It's clear from VA's success at negotiating lower drug prices that drug manufacturers have the ability to make a profit without charging their highest prices. We can also see that there's room for negotiations in drug manufacturers' profit margins when, even in the most dire circumstances, the manufacturers can still make a profit. Last October, when this country suffered from a terrorist attack in the form of anthrax sent through the mail, we needed affordable antibiotics. Health and Human Services Secretary Tommy Thompson convinced Bayer to provide Cipro to the United States at a discount. Because of the size of the order placed by our government, Bayer still walked away with millions of dollars in profits.

We have a chart that shows that in 2001, the pharmaceutical industry was the most profitable industry in the U.S., with 18.5% of its revenues going to profits. The next most-profitable industry, commercial banking, had 13.5% of revenues going to profits. The median for the Fortune 500 companies was profits at 3.3% of revenue.

Some of our witnesses today will talk about how drug companies use that their money. The companies claim that their high prices are necessary to support research and development, but we'll hear today about where the money really goes. We'll hear that the companies spend significantly more money on marketing, advertising, and

administration than they do on research and development. And we will also hear that drug companies make more in profits than they spend on research and development.

I think it's also important to remember that a large portion of the dollars for pharmaceutical research and development comes from taxpayers. Pharmaceutical companies have benefited from the basic drug research conducted primarily through the National Institutes of Health. Of the 21 most important drugs introduced between 1965 and 1992, 15 of those drugs were developed using knowledge and techniques from federally funded research. That research has contributed to the development of drugs to treat cancer, HIV, depression,

and other diseases – drugs that are now reaping billions of dollars in revenues for drug manufacturers.

We have to find a way to bring down the costs of drugs, especially for the elderly. As we'll hear today, we don't need to reinvent the wheel. Instead, we can learn from VA's success at getting lower drug prices, and adapt those lessons to other settings. And we will see that there is room for negotiation in the drug manufacturers' profit margins.

I believe the time has come to put patients over profits, to learn from our successes and to protect our

most vulnerable citizens with a cost effective and high quality drug benefit.

I look forward to the testimony of the witnesses. Again, I welcome all of you to this hearing and thank you for being here.

Mr. SHAYS. I thank the gentleman. At this time I recognize Mr. Allen from Maine.

Mr. ALLEN. Thank you, Mr. Chairman. I want to thank you and Congressman Tierney for organizing this hearing. I came down from Maine this morning because I knew I would learn something from our panelists and from the interaction with our—as we go on through the hearing.

Congressman Tierney has been a tireless advocate, absolutely tireless advocate for our seniors and others in need of assistance with the high cost of their prescription drugs. And Chairman Shays, I have to say is my model chairman. We all should hope that if we ever do get the gavel, we handle it the way he does.

Congress has been working on legislation to provide Medicare beneficiaries with prescription drug coverage. Although the structure of the various plans we have considered have varied greatly in administration, benefit structure and cost sharing, the urgent need for a Medicare prescription drug benefit is clear. Seniors in Maine cannot wait any longer for prescription drug price relief.

Prescription drug expenditures have continued to rise almost 20 percent each year for the last 6 years or so. By comparison, spending for physician and clinical services grew by approximately one third and expenditures for hospitals increased by one fifth between 1995 and the year 2000. Escalating drug costs contribute to higher insurance premiums and higher out of pocket spending for everyone with insurance. According to a recent Families USA study, over one third of the increase in national prescription drug spending from 2000 to 2001 was directly attributable to increases in drug prices. And the other one third is basically related to increased use of prescription drugs and the substitution of newer, high cost prescription drugs for older, lower cost prescription drugs. Because of high premiums, fewer and fewer Medicare recipients in Maine can afford the Medicare supplements that have the prescription drug coverage.

These trends lead to more and more veterans seeking to enroll in the VA health care system in order to obtain the prescription drug benefit. The $7 co-payment for prescription drug is very enticing for those individuals with little or no prescription drug coverage. However, the increased number of veterans coming into the system leads to higher case loads and longer waiting lists. At Togus, Maine's only VA hospital, for example, there are over 4,000 veterans awaiting assignment to a primary care physician.

The average wait for an initial appointment is now back up to 1 year. It was better a while ago. I know one veteran who had to wait 9 months to get in to see a doctor. When it finally came time for his appointment, the veteran was diagnosed with prostate cancer. His doctor said if he had seen him 6 months earlier, his life could have been saved.

In Maine, over the last 2 years, the VA medical system has added over 500 veterans to its practice every month. Under the current compensation formulary, this should mean a commensurate increase in funding for those facilities. Unfortunately, the formula also contains a huge 2 year lead time in recognizing this increase. So we're getting paid for the number of veterans that we had 2 years ago.

I would like to this opportunity just to commend the staff at Togus. They're not here, but they do a terrific job. They're dedicated, hardworking. They do feel understaffed and underworked and I am convinced they work hard and do the best they can and with limited resources. The fundamental problem is the lack of affordable prescription drugs in the civilian market is resulting in a deluge of veterans forced to turn to the VA in order to afford the drugs their doctors prescribe.

If we fail to address the prescription drug pricing issue and don't add a prescription drug benefit to Medicare, the VA system will continue to be overwhelmed. The increasing backlog created by the influx of veterans seeking lower cost prescription drugs means that more and more patients with chronic illnesses will not receive timely and appropriate care.

I believe one lesson to be learned is that the VA system works. It provides affordable prescription drugs through bulk purchasing using the buying power of more than 90 million veterans. While the model works, the capacity of the VA health system is totally inadequate. We should be replicating the model in one way or another, the model of the VA, for the entire Medicare population so we can leverage the buying power of the 40 million Americans who are Medicare beneficiaries.

Thank you, Mr. Chairman, and thank you, Mr. Tierney. I'm very pleased to be with you today.

[The prepared statement of Hon. Thomas H. Allen follows:]

Opening Statement by Congressman Tom Allen
House Committee on Government Reform
Subcommittee on National Security, Veterans Affairs, and International Relations
"Lessons Learned: The Department of Veterans Affairs
Prescription Drug Purchasing Program"
July 22, 2002

Thank you, Mr. Chairman. I would like to thank you and Congressman ~~Kanjorski~~ for arranging this hearing.

Congress has been working on legislation to provide Medicare beneficiaries with prescription drug coverage. Although the structure of the various plans we have considered have varied greatly in administration, benefit structure, and cost sharing, the urgent need for a Medicare prescription benefit is clear. Seniors in Maine can't wait any longer for prescription drug price relief.

Prescription drug expenditures have continued to rise almost twenty percent each year. ~~In the United States, prescription drug spending doubled between 1995 and 2000 when expenditures reached $122 billion~~. By comparison, spending for physician and clinical services grew by approximately one-third, and expenditures for hospitals increased by one-fifth. Escalating drug costs contribute to higher insurance premiums and higher out-of-pocket spending for everyone with insurance. According to a recent Families USA study, over one-third of the increase in national prescription drug spending from 2000 to 2001 was directly attributable to increases in drug prices. Because of high premiums, fewer and fewer Medicare recipients in Maine can afford the Medicare supplements that have prescription drug coverage.

These trends lead to more and more veterans seeking to enroll in the VA health care system in order to obtain the prescription drug benefit. The $7 co-payment for prescription drugs is very enticing for those individuals with little or no prescription drug coverage. However, the increased number of veterans coming into the system leads to higher case loads and longer waiting lists. At Togus, Maine's only VA hospital, for example, there are over 4,000 veterans awaiting assignment to a primary care physician. The average wait for an initial appointment is one year. I ~~personally~~ know a veteran who had to wait nine months to get in to see a doctor. When it finally came time for his appointment, the veteran was diagnosed with prostate cancer. His doctor said if he had seen him six months earlier, his life could have been saved.

In Maine, over the last two years, the VA medical system has added over 500 veterans to its practice *every month*. Under the current compensation formula, this should mean a commensurate increase in funding for those facilities. Unfortunately, the formula also contains a huge two year lead time in recognizing this increase. That is, although Maine facilities are caring for these additional veterans now, Togus won't see the increase in allotment for a long time. This is completely unacceptable.

I would like to take this opportunity to commend the staff at Togus for their hard work

and dedication serving Maine's veteran population. The veterans I have talked to are supportive of Togus' staff, doctors, and nurses. They tell me that the staff is caring and truly want to do what is best for the patients. However, these same veterans also tell me that the facility is understaffed and overworked. I am convinced that Togus staff work hard and do the best they can with limited resources.

The lack of affordable prescription drugs in the civilian market is resulting in a deluge of veterans forced to turn to the VA in order to afford the drugs their doctors prescribe. If we fail to address the prescription drug pricing issue and don't add a prescription drug benefit to Medicare, the VA system will continue to be overwhelmed. The increasing backlog created by the influx of veterans seeking lower cost prescription drugs means that more and more patients with chronic illnesses will not receive timely and appropriate care.

The lesson to be learned here today is that the VA system works. It provides affordable prescription drugs through bulk purchasing, using the buying power of more than 90 million veterans. While the model works, the capacity of the VA health care system is totally inadequate. We should be replicating the model of the VA for the entire Medicare population, leveraging the buying power of 40 million Medicare beneficiaries.

Thank you Mr. Chairman.

Mr. SHAYS. Thank you. I'd like the record to note that Mr. Tierney will be chairing this entire hearing.

Mr. TIERNEY. Thank you, Mr. Shays. We're going to have our first panel testify today with Judy Waxman who is the deputy executive director of Families USA; Dr. Alan Sager who is professor of health services and director of the health reform program at Boston University School of Public Health; Ms. Cynthia Bascetta, who is the Director of Health Care for Veterans' Health and Benefits Issues at the General Accounting Office and with her is Jim Musselwhite who is the Assistant Director of the General Accounting Office, who I understand will not be testifying.

Those people who are going to testify, will you please rise.

[Witnesses sworn.]

Mr. SHAYS. Let the record reflect that the witnesses have testified in the affirmative.

Ms. Waxman, why don't we start with you.

STATEMENTS OF JUDY WAXMAN, DEPUTY EXECUTIVE DIRECTOR, FAMILIES USA; DR. ALAN SAGER, PROFESSOR OF HEALTH SERVICES, DIRECTOR, HEALTH REFORM PROGRAM, BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH; AND CYNTHIA BASCETTA, DIRECTOR, HEALTH CARE, VETERANS' HEALTH AND BENEFITS ISSUES, GENERAL ACCOUNTING OFFICE

Ms. WAXMAN. Thank you, Congressman. Mr. Chairman and other Members of Congress, thank you so much for asking me to testify today. Families USA is a national organization that represents consumers and I've been asked this morning to give an overview of what's happening with drug crisis.

Since 1995, national spending on prescription drugs has grown double the rate of growth of spending in other parts of the health care system, particularly hospital care, physician care and clinical services. Three trends have been driving this rapid sustained growth: the number of prescriptions per person is increasing, newer, higher cost prescriptions are replacing older, less costly drugs, and the prices of prescriptions keep rising. As already has been said this morning, more than a third of the increase in national prescription drug spending from 2000 to 2001 was directly attributable to increases in drug prices.

As you are all aware, older Americans are the population most likely to need drugs and they are the least likely to have insurance coverage. For a number of years now, Families USA has monitored the 50 prescription drugs that seniors are most likely to take. Last month, we issued a report called "Bitter Pill, the Rising Crisis of Prescription Drugs for Older Americans." And we found a number of interesting facts.

The prices of the 50 most-prescribed drugs for seniors rose, on average, by nearly three times the rate of inflation. This is not a 1-year phenomenon.

Forty-two of the 50 drugs were on the market for the 50-year period from 1997 to 2002 and they rose, on average, twice the rate of inflation during that 5 years.

Twenty of the 50 drugs had been on the market for 10 years. The prices for nine of those drugs increased at least three times the

rate of inflation and five of those drugs rose at least four times the rate of inflation.

Now why are the prices rising so much? There's a couple of reasons I'd like to highlight this morning, two of them being brand name monopolies and also advertising.

Generic drugs can offer seniors a lower cost alternative to higher cost brand names. Another fact, we found was that the yearly average for brand new drug for seniors was $1,106 compared to $375 for generics. Additionally, in the last year, the price of generic drugs rose only 1.8 percent as compared to 8.1 percent as an increase in brand name drugs. Not surprisingly, the brand name companies go to great lengths to prevent generic drugs from entering the market. This is a serious problem that Congress can address.

Not coincidentally, high price drugs, some of which are among the most commonly prescribed for seniors are the most heavily advertised. Direct consumer advertising plays a major role in increasing the demand for many high priced drugs. I want to give you one example. In 2000, AstraZeneca, the maker of Prilosec, spent $107.5 million in direct-to-consumer advertising for this drug. In 2001, that company had sales of $5.68 billion for that drug alone. That shows you that direct-to-consumer advertising works for the manufacturers.

As public concern mounts about the explosion of prescription drug costs, the pharmaceutical industry argues that the high drug prices are necessary in order to finance research and development. We've decided to look at how much profit the companies are actually making and where the money is going. So this month, just last week, we issued a report entitled "Profiting from Pain: Where Prescription Drug Dollars Go."

What we did was we examined the SEC filings of the companies that offered those 50 drugs I spoke about earlier and there were nine publicly traded companies we could examine. As has already been said, the pharmaceutical industry is the most profitable industry in the United States for each of the past 10 years. In 2001, their profits were 5.5 times as large as the median return for all Fortune 500 countries. Additionally, the nine companies we looked at generated $30.6 billion in profits last year which was more than 60 percent higher than expenditures on research and development.

Many of the companies report marketing, advertising and administration together, so what we did is we looked at those items as compared to their spending on research and development and we found that in the nine companies, spent a total of $45.4 billion on marketing, advertising and administration and only $19.1 billion on research and development. Eight of the nine companies actually spent twice as much on those items as they did on research and development.

We think it's fair to say that the gap between the cost of medications Americans and particularly seniors need, and what they can afford is growing wider and wider. And as also has been mentioned, there are 50 percent of seniors do not have drug coverage at some time during the year and 30 percent don't have it at all. Sixty-five million Americans in total do not have drug coverage, pardon me, do not have insurance coverage for prescription drugs.

So one obvious solution is to add a meaningful drug benefit for the Medicare program, but they must include systems to moderate the prices. One, for the seniors and two for the Medicare program itself, so the drug—so the program does not become unaffordable.

But I wouldn't finish my testimony without saying that drug price moderation is necessary for Medicare, for insurers, for employers and for all others because we're in a situation now with consumers, all consumers are in jeopardy of facing the time when more and more drugs will simply be unaffordable and out of reach.

Thank you.

[The prepared statement of Ms. Waxman follows:]

Testimony by

Judith Waxman, Deputy Executive Director
Families USA

At the Hearing

Lessons Learned:
The Department of Veterans Affairs' Prescription Drugs Purchasing Program

Before the
U.S. House of Representatives
Committee on Government Reform
Subcommittee on National Security, Veterans Affairs
and International Relations

Boston, Massachusetts

Monday, July 22, 2002

1334 G Street, NW + Washington, DC 20005 + 202-628-3030 + Fax 202-347-2417
E-mail: info@familiesusa.org + Web site: www.familiesusa.org

Mr. Chairman and Members of the Committee:

Thank you for inviting me to testify today. Families USA is the national organization for health care consumers. Our mission is to ensure that all Americans have access to high-quality, affordable health care, including prescription drugs.

Prescription drug expenditures are the fastest-growing component of health care spending. In my testimony today I will identify the some of the factors causing these rising costs, focusing on the effect of these increases on older Americans.

Since 1995, national spending on prescription drugs has grown by over 10 percent every year, more than double the rate of growth for spending on hospital care or physician and clinical services.[1] Three trends have been driving this rapid, sustained growth: The number of prescriptions per person is increasing; newer, higher-cost prescriptions are replacing older, less-costly medications; and the prices of prescription drugs are rising. The latter trend—rising prices—has become increasingly important. More than one-third of the increase in national prescription drug spending from 2000 to 2001 was directly attributable to increases in drug prices.

Rising prices affect all purchasers of prescription drugs—employers, insurers, states (as purchasers of drugs for Medicaid beneficiaries and state employees), and consumers. In recent years, many of these purchasers have taken steps to contain their prescription drug expenses.[2] These steps have included negotiating rebates or discounts from drug manufacturers, steering consumers away from higher-priced drugs, reducing drug coverage, and shifting more costs to consumers through higher copayments and deductibles. Individual consumers, by contrast, have little recourse. Those who have insurance covering prescription drugs face higher copayments and, possibly, limits on which (or how many) prescriptions will be covered. Individuals who have no coverage for prescription drugs, however, bear the brunt of these price increases. With no

employer or insurer to negotiate better prices on their behalf, they are left to pay the full cost of their rising prescription drug costs out-of-pocket.

The Effect on Seniors

Older Americans, in particular, are burdened by the increasing prices of prescription drugs. Seniors are the population most likely to need prescription drugs, yet they are the least likely of all insured groups to have prescription drug coverage. For several years, Families USA has monitored the prices of the 50 prescription drugs most commonly used by older Americans.

The latest in this series of reports on prescription drug prices, *Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans* (June 2002), has again found that the prices for the 50 prescription drugs most commonly used by seniors have increased considerably faster than inflation. This finding holds for last year (January 2001 to January 2002), for the past five years, and for the past 10 years. Senior citizens generally live on fixed incomes that are indexed to keep pace with inflation, but last year:

- The prices of the 50 most-prescribed drugs for senior citizens rose, on average, by nearly three times the rate of inflation.
- Nearly three quarters (36 out of 50) of these drugs rose at least one-and-one-half times the rate of inflation.
- 10 of the top 50 drugs are generics, and nine of these 10 did not rise in price at all. Among the 40 brand-name drugs, all but three rose in price.
- Forty-two of the 50 drugs were on the market for the five-year period from January 1997 to January 2002, and rose, on average, more than twice the rate of inflation during those five years.
- During that period of time, 32 of those drugs increased their prices on at least five occasions.

- 20 of the 50 drugs have been on the market for at least 10 years. The prices for nine of the 20 drugs increased at least three times the rate of inflation in the last decade, and one-quarter (five of 20) of them rose at least four times the rate of inflation.

Most of the drugs with the fastest-growing prices are drugs used to manage chronic health conditions. Older Americans with chronic conditions depend on these drugs to maintain their well-being. Seven million Americans age 65 and older have diabetes.[3] Millions more suffer from high blood pressure, heart disease, and high blood cholesterol.[4] Older people with chronic diseases like diabetes and hypertension frequently take more than one drug to treat just that one condition, and many older people are living with two or more of these conditions simultaneously. While a senior may be able to compensate for a dramatic increase in price for one medication by making adjustments to other areas of household spending, few can afford simultaneous increases for multiple drugs.

Brand-Name Monopolies and Advertising

Brand-name monopolies and advertising are two other factors that contribute to high drug prices.

The Effects of Brand-Name Monopolies

Generic drugs offer seniors a lower-cost alternative to higher-cost, brand-name drugs. The average yearly cost of the 50 drugs most commonly used by seniors was $1,070. For brand-name drugs, the average was $1,106, compared to $375 for generics. The most expensive generic drug on the list, APAP/propoxyphene, had an annual cost of $444; the lowest, the 20 mg strength of furosemide, cost $52 a year. Additionally, in the last year, the price of generic drugs rose only 1.8 percent, as compared to an 8.1 percent price increase in brand-name drugs. The lower cost of generics and the slower growth in their prices argue for a greater emphasis on getting more high-quality generics to the market.

When a generic drug enters a market where only a brand-name drug is available, price competition results, offering consumers the potential for great savings. According to the Congressional Budget Office, generic drugs are about half the price of brand-name drugs in the first year after the generic enters the market.[5] Not surprisingly, the brand-name companies go to great lengths to prevent generic drugs from entering the market. A drug company can extend its monopoly in a number of ways, including marketing what is essentially a "new and improved" version of an existing drug; claiming the generic company has infringed on a patent, halting the entry of the generic for up to 30 months; and by entering into deals with generic manufacturers to delay their marketing of the generic.

One example of what these delays mean for consumers is the case of Prilosec, the number one drug prescribed for seniors. The original patent for Prilosec expired in October 2001. However, the marketer, AstraZeneca, delayed market entry of a generic by filing nearly a dozen lawsuits and by claiming that Prilosec is unique when administered with applesauce. This forced the generic manufacturer to do time-consuming research on how the generic works when sprinkled on applesauce before it could receive approval to go to market.[6] Every day that brand-name manufacturers can avoid competition from generics, they stand to make millions of dollars. In 2001, AstraZeneca had Prilosec sales of more than $16 million a day; that year, the company raised the price of Prilosec by more than four times the rate of inflation. Based on 2001 sales, the eight-month delay since the expiration of the patent means an estimated $3.8 billion in sales for AstraZeneca from this one drug, depriving consumers of the savings from a generic alternative.

The Effects of Advertising

Not coincidentally, high-priced drugs, some of which are among the most commonly prescribed for seniors, are among the most heavily advertised. Direct-to-consumer advertising plays a major role in increasing the demand for many high-priced drugs, sometimes steering

consumers to higher-priced drugs when a lower-cost alternative may be equally appropriate. Marketing and advertising efforts of the drug companies have proven to be quite lucrative. In 2000, AstraZeneca, the maker of Prilosec, spent $107.5 million just in direct-to-consumer advertising of Prilosec (this figure does not include other promotional activities such as marketing efforts targeted to physicians and medical students). In 2001, AstraZeneca had sales of $5.68 billion for Prilosec alone. Direct-to-consumer advertising is common among other high-priced drugs as well. In 2000, Searle, the marketer of Celebrex, spent $78 million on direct-to-consumer advertising of Celebrex; the firm had $3.1 billion in sales of Celebrex in 2001.

Where Prescription Drug Dollars Go

As public concern mounts about the explosion in prescription drug costs, the pharmaceutical industry argues that high drug prices are necessary. High prices are needed, the industry repeatedly contends, to finance R&D so manufacturers can bring newer, better drugs to market. If steps are taken to rein in drug prices, so the industry argument goes, manufacturers will be forced to slash R&D.

Data gathered by the Families USA report, *Profiting from Pain: Where Prescription Drug Dollars Go* (July 2002), demonstrate that the major pharmaceutical companies spend significantly more on marketing, advertising, and administration than they spend on research and development (R&D).[7]

The report examined SEC filings of the companies that produce the top 50 drugs used by seniors. According to the report:

- The pharmaceutical industry has been the most profitable industry in the U.S. for each of the past 10 years. In 2001, their profits represented an 18.5 percent return on revenue—nearly five-and-one-half times as large as the median return (3.3 percent) for Fortune 500 companies.

- Over the same time period, the industry's profitability (as measured by return on revenue) was, on average, one-and-one-half times that of the next most profitable industry.[8, 9]
- Nine U.S. publicly traded companies spent a combined total of $45.4 billion on marketing, advertising, and administration and only $19.1 billion on R&D last year.
- Eight of the nine companies spent more than twice as much on marketing, advertising, and administration as they did on R&D.
- The nine companies generated $30.6 billion in profits last year—more than 60 percent higher than their expenditures on R&D.

While the SEC filings show that spending on marketing, advertising, and administration overshadows spending on R&D, those numbers do not tell the full story of the industry's research investments.

The drug industry benefits from several federal tax breaks; some of these encourage research by allowing companies to deduct qualified research expenses and receive research and experimentation tax credits.[10] Because research-related tax credits are reported along with other tax credits as "general business tax credits," there are no publicly available data showing the exact amount of tax relief that the industry receives for its investment in research.[11] However, the effect of tax credits is clear. In 1999, the Congressional Research Service (CRS) studied industry taxation for the years 1990 to 1996. CRS found that the drug industry was taxed relatively lightly; total tax credits, many related to research investments, lowered the industry's effective tax rate from 35.2 percent to 17.1 percent.[12] Given the favorable tax treatment of R&D, it is unlikely that the industry would turn to R&D first for spending reductions.

The drug industry has lobbied hard for the R&D tax credit, arguing that "the credit supports the development of new and innovative medicines, technologies, products, and services, which

benefit all Americans."[13] While favorable tax treatment does encourage industry investment in R&D, it is not clear that taxpayers receive adequate return for this investment.. As the industry demands high drug prices and special tax concessions to fund R&D, studies show that it is providing the public with fewer and fewer new drugs that offer significant clinical improvements over existing therapies.

The industry is focusing on developing reformulations of existing products, in part, because it is not discovering new drugs as quickly as it did in the 1990s—the "easy" compounds have been discovered.[14] With fewer new discoveries, the industry has focused resources on developing knock-offs of successful products and on aggressive marketing of existing products.

Why Price Moderation Is Necessary

Rising drug prices hurt everyone who pays for health care—especially the estimated 65 million Americans who lack insurance coverage for prescription drugs and must shoulder these price increases on their own.[15] Price increases are a particular hardship for Medicare beneficiaries. As a group, Medicare beneficiaries use more drugs than any other segment of the population, yet Medicare has no outpatient prescription drug coverage.[16] Although some have other sources of drug coverage, 50 percent of Medicare beneficiaries are without prescription drug insurance at some point in time during the year and nearly 30 percent have no drug coverage at all.[17] Those individuals, many of whom are on fixed incomes, must pay for increasingly expensive drugs themselves. All the research and drug development in the world means little if drugs are priced out of the reach of those who need them.

Rising drug prices also make a Medicare prescription drug benefit less affordable.[18] Continued double-digit increases in prescription drug spending raise the price tag for a prescription drug benefit in Medicare, which makes it more difficult to afford a benefit that will

provide Medicare beneficiaries with real relief from prescription drug costs. Price moderation would help reduce drug spending increases, making a real benefit in Medicare more attainable.

It is unlikely that the industry will moderate prices on its own. However, price moderation could be accomplished through greater competition in the industry. Real competition in the drug industry comes when generics enter the market. Generic drugs are about half the price of brand-name drugs in the first year after a generic enters the market.[19] Access to generics could be increased by removing existing legal loopholes that allow brand-name drug manufacturers to extend their monopolies through manipulation of the patent system.

Moderating drug prices might have another effect as well. The industry appears to be maintaining its high level of profitability in part by focusing resources on developing "knock-offs" of successful products and on marketing, reaping greater and greater revenues by simply increasing prices for drugs already on the market. Although expedient, these practices do not give the public real innovation, and they keep drugs priced out of the reach of millions. If some of these more expedient approaches to making money were tempered, the drug industry might be forced to compete through greater real innovation and, to do that, would devote more resources to R&D.

Conclusion

The gap between the cost of the medications Americans—and, in particular, seniors—need and what they can afford is growing wider as drug prices rise faster than inflation. Part of the solution to this mounting problem is the enactment of a meaningful drug benefit within the Medicare program. Without any moderation in prescription drug prices, however, the future of prescription drug coverage for Medicare beneficiaries (as well as Medicaid, insurers, employers, and all others) will be in jeopardy, and consumers will be forced to bear the brunt of continuing increases in prescription drug prices.

[1] The Kaiser Family Foundation and Sonderegger Research Center, *Prescription Drug Trends: A Chartbook Update* (Washington: Henry J. Kaiser Family Foundation, November 2001).
[2] National Institute for Health Care Management Research and Education Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* (Washington: National Institute for Health Care Management, May 2001).
[3] Centers for Disease Control and Prevention, *National Diabetes Fact Sheet: General Information and National Estimates on Diabetes in the United States, 2002* (Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2002).
[4] American Heart Association, *2002 Heart and Stroke Statistical Update* (Dallas: American Heart Association, 2001).
[5] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (Washington: Congressional Budget Office, July 1998).
[6] Rachel Zimmerman and Susannah Rodgers, "FDA Approves Generic Version of Prilosec," *The Wall Street Journal*, November 19, 2001.
[7] Companies consistently aggregated these items in their SEC filings. While a few companies reported money spent on advertising separately, advertising comprises only a small percent of total marketing spending; none reported spending on marketing separately from spending on administration. Although spending on "marketing, advertising, and administration" includes administrative costs that are not related to marketing, when contrasted with R&D spending, it provides some insight into corporate priorities.
8 America's Largest Corporations, *Fortune*, Annual Special Editions, 1992-2002.
[9] The industry has also been good to investors. For the last five years, shareholders have received an annual rate of return of 18.4 percent, twice the 9.2 percent median return to shareholders for the Fortune 500.
[10] Internal Revenue Service Code, section 174.
[11] The research and experimentation tax credit is reported under a general business tax credit, and there is no estimate of the amount of research expenses that the industry claims for deductions. Gary Guenther, "Federal Taxation of the Drug Industry from 1990 to 1996," Memorandum to the Joint Economic Committee, Congressional Research Service (Washington: Library of Congress, December 13, 1999).
[12] The effective tax rate is the amount that is actually paid in taxes after all deductions and credits. The drug industry realizes significant tax savings from five tax provisions: the deduction of qualified research expenses; the research and experimentation tax credit; the foreign tax credit, which is intended to prevent double-taxation of foreign-source income; the possessions tax credit, which encourages firms to locate manufacturing facilities in Puerto Rico and other U.S. territorial possessions and which is being phased out; and the orphan drug tax credit, which encourages development of drugs to treat rare diseases. Ibid.
[13] Pharmaceutical Research and Manufacturers of America , *Pharmaceutical Industry 2001 Profile* (Washington: PhRMA, 2001).
[14] Theresa Agovino, "Drug Makers: New Challenges Present Obstacles to Growth," *AP/Nando Times,* April 8, 2002.
[15] Steve Findlay, *Prescription Drug Expenditures in 2000: The Upward Trend Continues* (Washington: The National Institute for Health Care Management Research and Education Foundation, May 2001).
[16] Medicare beneficiaries comprise only 14 percent of the population yet account for 43 percent of the nation's expenditures on prescription drugs. *The Medicare Program: Medicare and Prescription Drugs* (Washington: The Henry J. Kaiser Family Foundation, May 2001).
[17] Ibid.
[18] U.S. spending on prescription drugs has risen 15 percent or more per year over the past several years and rose over 17 percent in 2001 alone. Over one-third of the spending increases in 2001 can be attributed to increasing drug prices, which rose over 10 percent last year. Steve Findlay, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* (Washington: National Institute for Health Care Management Research and Education Foundation, May 2002).
[19] *How Increased Competition for Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (Washington: Congressional Budget Office, July 1998).

Mr. TIERNEY. Thank you for your testimony.

Dr. Sager.

Mr. SAGER. Congressman Tierney, Congressman Shays, others. Good morning. Thank you very much for inviting me to appear before you. After distilling six lessons from the VA's recent experiences in paying for prescription drugs and from Congress' experiences in designing a Medicare medication benefit, I'll apply these lessons to crafting a new approach to a Medicare drug benefit.

The six lessons. 1. The VA has become one of the main lightning rods in the electrical storm caused by the collision of soaring drug prices and lack of adequate insurance. The number of 30-day equivalent prescriptions filled by the VA in fiscal year 2001 was more than 2½ times as much as 5 years earlier.

2. Owing to rising volumes and prices, the VA's drug costs are expected to double from $1.6 billion in fiscal year 1999 to a conservatively projected $3.3 billion in fiscal year 2003.

3. The VA has shown that winning lower drug prices is a far more effective way to contain costs than is restricting use of drugs. But costs are projected to soar despite the VA's efforts.

4. Unless we find a way to finance affordable drugs for all elderly, disabled and chronically ill Americans, the VA drug budget will explode or human suffering will magnify. Indeed, both are possible.

Most of the VA's future efforts to limit its own obligations can succeed only by adding to the obligations of others. There has been too much of this already. Congress has won lower drug prices for Federal programs while allowing drug makers to charge higher prices to ordinary citizens.

5. The VA's own problems would be eased by creating a strong Medicare prescription drug benefit. Building such a benefit has been stymied by the combination of one, high drug prices and two, the need to find new Federal dollars both to protect people who haven't been able to afford drugs in the past and to replace most of today's private spending by people who can somehow struggle to afford their medications. This dilemma appears to create a choice between continued suffering and much higher spending.

6. Fortunately, there is a third choice which is reform. We've spent $200 billion on medications a year, this year. That makes the prescription drug problem literally the easiest one to solve in the United States of America. There are some unique opportunities.

It's easy to design an inferior Medicare drug benefit with high premiums, co-pay and multi-thousand dollar donuts, holes, and other patient financial exposure. It's also easy to design a benefit that costs the Federal Government many new dollars. But low patient cost can and must be combined with low, new Federal costs and with comprehensive benefits.

What are the costs of a good Medicare prescription drug program? My colleague, Deborah Socolar and I estimate the gross cost of a good Medicare prescription drug benefit at $2.2 trillion for the full decade from 2002 to 2011 before factoring in opportunities for savings. Now this is for a full 10 years that needs to be compared carefully with other estimates that might be for 5 or 6 or 7 years.

The costs includes, they start with three quarters of the spending projected by the CBO for its baseline in the absence of a new drug program, how much people are expected, Medicare eligible patients

are expected to spend on drugs. An additional $440 billion, we estimate, would be necessary to buy drugs for previously uninsured Americans to pick up the higher volume of medications, if we pay retail price. We also budget $80 billion for a new center to measure which medications are effective, which are safe and who needs them and to disseminate that information to doctors and patients. Other minor costs for administration, building pharmacy capacity and the like.

How to cover those costs. Through modest patient payments, substantial cost cuts capturing existing revenue and new Federal dollars. Patient payments cover one tenth of the amount. Premiums would be set at between 2.5 and 3 percent on a sliding scale of Social Security checks, so this could be a progressive premium that would not impoverish people who are getting $200 and $300 amount Social Security checks.

Also, modest co-pays between $5 and $10 with substantial protections for low income patients. So that raises a tenth of the money.

Reducing costs will cover a third of this money, of the $2.1 trillion we need, $2.1 trillion we need to raise.

We would propose to cap the rise in total spending after this year at 8.5 percent a year instead of the 11.5 or 12 percent or 12.5 percent that CBO projects will happen in the absence of intervention.

This means that drug spending doubles only every 10 years instead of every 6 years as CBO projects. I think the drug makers can live with revenue that doubles every 10 years. Indeed, we would protect drug makers' profits as return on revenue, return on equity.

Also, to save $400 billion over the 10 years, we would pay for higher volume of medications that newly covered people would be able now to afford, not at retail price, but at the marginal cost of producing the pills, to cover the drug makers' actual costs. We estimate that at 7.5 percent of retail. Once the drug makers do the research and bill the factories, the added cost of making more pills is tiny.

We cover 40 percent of the cost by capturing existing revenue. $400 billion of that would be drug makers' own marketing and advertising costs, costs that they would no longer need to bear as part of a drug peace treaty, whereby information on which medications are needed would be disseminated by the new Public Refinance Center. We'd also capture $60 billion worth of State Medicaid spending, frozen at today's revenue levels, today's spending levels. $160 billion in Federal Medicaid spending and about $50 billion in VA spending. Also, about $175 billion in captured employer maintenance of effort, frozen at 20 percent of this year's level. These are obligations that employers take on to retirees and others.

So we raise—recover, $1.75 trillion in cost, leaving about $375 billion to be covered by new Federal dollars. That's 18 percent of the bill. And this $375 billion, 90 percent of that replaces existing private spending by Medicare patients as part of the new Medicare prescription drug program. Patients' financial exposure would be measured in the hundreds, not in the thousands, no donut, no hole. The pie chart included in the testimony itemizes the revenue sources.

I'd be happy to provide additional supplementary information, either now or in writing and thank you very much for the chance to speak today.

[The prepared statement of Mr. Sager follows:]

Embargoed – Not for release until Mon. 22 July 2002, 9:30 a.m.

Crafting an Affordable Medicare Prescription Drug Benefit:
Lessons from the Veterans Administration Experience

Alan Sager, Ph.D.
Professor of Health Services
Director, Health Reform Program
Boston University School of Public Health
715 Albany Street, T3W
Boston, Massachusetts 02118

phone (617) 638 - 4664
email asager@bu.edu
web www.healthreformprogram.org

Hearing on

The Department of Veterans Affairs Prescription Drug Purchasing Program:
Lessons Learned and
Remaining Challenges to Making Prescription Drugs Affordable

Subcommittee on National Security, Veterans Affairs, and International Relations
Government Reform Committee, United States House of Representatives,
Field Hearing

John W. McCormack United States Post Office and Court House
Courtroom 3, 12th Floor
Boston, Massachusetts
22 July 2002
9:30 A.M.

Disclaimer and acknowledgement:

As always, I testify only for myself, and not on behalf of Boston University or any of its components. I acknowledge with pleasure the contributions of my colleague, Deborah Socolar.

Congressman Shays, Congressman Tierney, and others: Good morning. Thank you for inviting me to appear before you. After distilling six lessons from the Veterans Administration's recent experiences in paying for prescription drugs, and from Congress's experiences in designing a Medicare prescription drug benefit, I will apply these lessons to crafting a different approach to a Medicare drug benefit.

A. Lessons from the V.A. Experience

1. The V.A. has become one of the main lightning rods in the electrical storm caused by the collision of soaring drug prices and lack of adequate insurance.

- More veterans have understandably sought V.A. outpatient prescription drugs.
- The number of 30-day-equivalent prescriptions filled by the V.A. FY 2001 was more than two and one-half times greater than in FY 1995.[1]
- The V.A. has shown that winning lower prices is a far more effective way to contain cost than is restricting use of drugs.

2. Owing to rising volumes and prices, the V.A.'s drug costs are expected to double from $1.6 billion in FY 1999 to a conservatively projected $3.3 billion in FY 2003.[2]

3. Costs are projected to soar despite the V.A.'s vigorous cost containment efforts. These include

- Purchasing almost one-quarter of its drugs through highly competitive national contract prices that can run "as low as 65 percent below AWP" (average wholesale price);
- Purchasing the remaining brand name drugs at prices averaging less than half of AWP; [3]
- Raising co-payments from $2.00 per prescription to $7.00; and
- Encouraging the use of less costly alternatives to expensive drugs like Zyprexa.[4]

4. Unless we develop a method of affordably financing medications for elderly, disabled, or chronically ill Americans, either the V.A. drug budget will continue to explode or human suffering will rise. In the worst case, both are possible. Therefore, most of the V.A.'s efforts to limit its own obligations can succeed only at the expense of adding to the obligations of others. There has been too much of this already. Congress has won lower drug prices for federal agencies and, to a lesser degree, Medicaid programs, while allowing drug makers to charge higher prices for ordinary citizens, especially those without insurance. This is wrong. Congress must look after all of us even-handedly.

5. The V.A.'s own problems would be alleviated by creation of a strong Medicare prescription drug benefit, one with affordable premiums and low out-of-pocket costs. Congressional progress toward such a benefit has been stymied by the combination of a) high drug prices and b) the need to find new federal dollars both to protect people who have not been able to afford drugs in the past and to replace private spending on drugs. This appears to create a choice between continued suffering and much higher spending.

6. Fortunately, there is a third choice: reform. We can design an affordable Medicare prescription drug benefit. **What follows is intended as a rough framework, one open to modification in light of emerging policy concerns and improving evidence.**

Information on other methods of winning affordable prescription drugs while enhancing drug makers' research is posted on the Health Reform Program's web site, www.healthreformprogram.org.

B. Designing a Medicare Drug Benefit—Part Rx

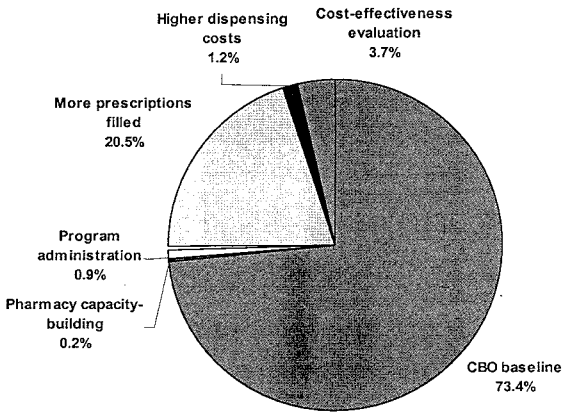
It is easy to design an inferior Medicare drug benefit with high premiums, co-payments, and multi-thousand-dollar patient financial exposure. And it is easy to design a Medicare drug benefit that costs the federal government a great deal of new dollars. The challenge is to design a drug benefit that protects all patients against high out-of-pocket costs and protects the federal treasury. ***I am convinced that low patient costs can be combined with holding net federal cost under $400 billion for the decade.***

1. Costs of a good Medicare prescription drug program. My colleague, Deborah Socolar, and I estimate the *gross* cost of a good Medicare prescription drug benefit at $2.2 trillion for the ten years from 2002 through 2011, before factoring in opportunities for savings.

This includes

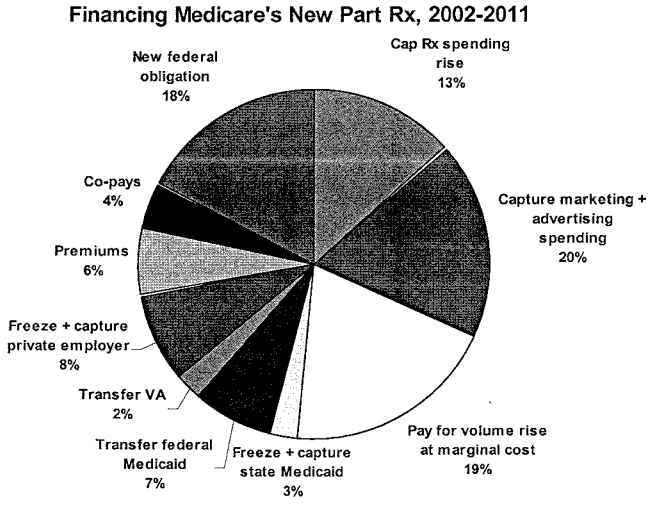
GROSS COST ELEMENTS, Medicare Part Rx, 2002 – 2011	**$ Billion**
A. CBO March 2002 baseline[5]	$1,580
B. Higher volume at retail price, with price rising 8% annually	$441
C. Higher dispensing costs at retail @$5.00 per prescription	$27
D. New drug cost-effectiveness evaluation/dissemination	$80
E. Program administration @ 1 % of baseline + higher volume	$20
F. One-time pharmacy/dispensing capacity-building	$5
Total gross costs, $ billion	**$2,153**

***GROSS* COSTS OF MEDICARE'S NEW PART Rx, 2002 - 2011**



2. Covering the costs of a good Medicare prescription drug program through modest patient payments, substantial cost cuts, capturing existing revenue, and new federal dollars. I believe that it is possible to design a very comprehensive program that limits out-of-pocket costs to affordable levels but still holds the net rise in new federal obligations under $400 billion over the decade from 2002 through 2011. The revenue sources are detailed in the text table and are displayed in the pie chart that follows.

COVERING THE GROSS COSTS, Medicare Part Rx, 2002 – 2011	**$ Billion**
Patient Payments	
premiums (2.5%-3.5% of Social Security checks, rising 2.5% yearly)	$140
co-pays ($5, $10,with 1/3 forgiven to low-income patients)	$87
Reductions in Cost	
cap annual rise in total spending after 2002 at 8.5 percent annually	$286
pay for higher volume at marginal cost, at 7.5 percent of retail	$408
Capture Existing Revenue	
capture offset marketing and advertising, growing at 12.5 % annually	$410
capture state Medicaid dollars, frozen at 2002 level	$59
Transfer federal Medicaid dollars, projected rise	$159
Transfer federal VA dollars, projected rise	$54
Capture employer maintenance of effort, frozen at 20% of 2002 level	$174
Total of above	$1,775
Gross costs (calculated on previous page)	$2,153
Net rise in federal obligation, $ billion	**$378**



Notes on gross costs

Almost three-quarters of the projected gross cost is attributable to baseline use of prescription drugs by Medicare recipients, in the absence of a Medicare prescription drug insurance program. This is as projected by the Congressional Budget Office.

One-fifth of the gross cost goes to buying the additional volumes of medications attributable to the new benefit by people previously uninsured or underinsured for prescription drugs. This additional volume is priced here at retail.

Four percent of spending finances new efforts to evaluate prescription drugs' cost-effectiveness, and to diffuse the evidence compiled. By facilitating better prescribing, these new efforts will enable Medicare to get more its money. Solid evidence on the value and limits of existing drugs will displace marketing-induced misperceptions. Solid evidence on new drugs will encourage quick adoption of genuine breakthroughs while discouraging adoption of costly drugs that lack added clinical value.

Minor sums cover the added costs of retail dispensing, program administration, and one-time payments to expand pharmacy capacity.

Notes on methods of covering the costs

My colleague and I have estimated methods of covering the costs in several ways. The figures reported here are the mid-point of high and low estimates.

First, patient premiums and co-payments cover about one-tenth of gross program cost. These are the only out-of-pocket costs. There is no financial donut and no financial hole. Patients are not forced to choose among costly and inadequate benefit packages. Instead, they pay little for one benefit package that offers freedom of choice of all medications.

- Premiums are scaled progressively with income, ranging from 2.5 percent to 3.5 percent of an individual's Social Security check. For example, individuals with monthly checks of $250 would pay a Part Rx premium of $6.25 monthly. Individuals with monthly checks of $1,300 would pay a monthly premium of $45.00. The median premium would be close to $20.00 monthly.
- Total annual co-payments would also rise and fall with income.
- Patients face no other financial exposure.

Second, the net rise in new federal obligations is less than one-fifth of gross program cost, averaging $38 billion yearly. This is made possible by employing an eclectic range of sources of containing costs and raising revenues.

Third, cost can be contained in two main ways.

- We would save almost $300 billion by capping the average annual rise in baseline spending (before considering higher volumes of medication use induced by improved coverage) at 8.5 percent yearly. This is somewhat below the Congressional Budget Office (CBO) baseline estimates, which average 12.3 percent yearly over the decade. We believe that this cut is essential to make medications affordable for all Americans, and that it can be accomplished in ways that both preclude cost-shifting and ***protect manufacturers' returns on equity and research.***

- More important, **paying for the increased volume of prescriptions at marginal cost saves over $400 billion**. This covers manufacturers' actual cost of producing higher volumes of medications. They do not earn additional profits—windfall profits—on the higher volume, but their profits do not fall, either. Paying marginal cost on the higher volume does mean a drop in average price paid, but this is offset by the rise in volume of medications sold, keeping drug makers financially whole.

Finally, five existing sources of spending can be captured and pooled to help finance the new benefit.

- The most important ($410 billion) is capturing drug makers' existing marketing and advertising spending. Since information would be disseminated by a new federal effort to compile evidence on efficacy, safety, and cost, and since drug makers' returns on equity on existing medications would be protected at current levels, they would not need to waste money on marketing and advertising. One approach would be to require that participants in the Medicare Rx program would need to sign over their projected marketing and advertising spending to the trust fund from which Part Rx would be financed.

- Dollars that would otherwise pay for current and future federal participation in purchase of prescription drugs by state Medicaid programs for Medicare patients would be channeled to the new Part Rx trust fund. This would garner almost $160 billion.

- Relieving states of a soaring cost, states' Medicaid spending on prescription drugs for Medicare patients would be frozen at 2002 levels, and this sum would also be paid into the new trust fund, harvesting about $60 billion. The Medicare prescription drug program would also relieve states of the huge administrative burdens and tough political decisions that they now face as they struggle to care for these needy patients while containing costs.

- Projected V.A. payments for prescription drugs for Medicare patients ($50 billion) would be transferred to the new trust fund. V.A. patients would be protected from any diminution in current benefits. I believe that transferring most of the burden of financing increasingly costly outpatient prescription drugs to Medicare will strengthen the V.A.'s long-term ability to finance its core hospital, physician, and other services.

- Finally, private employers who now provide retiree benefits for people on Medicare would make annual payments to the new trust fund. These would be frozen at the level of their 2002 expenditures, granting employers immediate financial relief from existing contractual obligations, and sparing them the pain and damage to reputations that would follow from reneging on promises to employees or retirees. This would raise almost $175 billion.

Conclusion

The nation faces two decisions.

The first is to choose among suffering, paying more, and reform. That should be easy.

The second is to choose between today's fragmented and weak attacks on high drug prices, and tomorrow's concerted efforts to negotiate a prescription drug peace treaty that protects the core needs of each stakeholder.

Too many efforts today are devoted to peripheral fights over re-importing drugs from Canada, patent duration, generics, formularies, PBMs, and the like. The more important core fights concern how much money drug makers shall earn, and what value they must create in order to earn it.

Some believe that the peripheral fights will be easier to win. This has not yet been demonstrated. Moreover, winning the peripheral fights will be a distraction, because the victory—if won—will be hollow. Drug makers would respond to a re-importation law, for example, by emptying their Canadian warehouses, leaving little to re-import.

The longer the drug makers paralyze durably affordable reform, the greater the chance that they will elect the world's angriest Congress—one that will gut their prices in ways that actually do disrupt breakthrough research.

That is why we must do more than protect ourselves from the drug makers. We must protect the drug makers from themselves.

NOTES

[1] 167.6 million prescriptions were filled in HFY 2001, compared with only 65.4 million in HFY 1995. Estimates prepared by John Ogden, Chief Consultant, Pharmacy Benefits Management, Veterans Administration, telephone communication with Deborah Socolar 2 April 2002.

[2] Data compiled by John Ogden, Chief Consultant, Pharmacy Benefits Management, Veterans Administration, telephone communication with Deborah Socolar 2 April 2002. Some consider that these projections may be under-estimates.

[3] William H. von Oehsen, III, *Pharmaceutical Discounts under Federal Law: State Program Opportunities,* Public Health Institute, Pharmaceuticals & Indigent Care Program, May 2001, pp. ii and 16.

[4] David Rogers, "Veterans Affairs' Bid to Trim Costs May Anger Pharmaceutical Firms," *Wall Street Journal,* 13 February 2002.

[5] Dan L. Crippen (Director, Congressional Budget Office), "Projections of Medicare and Prescription Drug Spending," testimony before the Committee on Finance, United States Senate, 7 March 2002, table 3.

Mr. TIERNEY. Thank you very much, doctor.

Ms. Bascetta.

Ms. BASCETTA. Good morning. I'm pleased to be here today. I've been asked to discuss the factors that have contributed to pharmacy costs, reductions in pharmacy costs in the VA and DOD as well as the continuing challenges that they face in procuring drugs jointly. Reflecting national trends, VA and DOD pharmacy expenditures have risen significantly, and they consume an increasing share of the Department's health care budgets. But pharmacy costs would have been even greater if not for the efforts taken by VA and DOD.

In my remarks today, I would like to highlight formularies, purchasing agreements, mail order dispensing and joint procurement, four ways that VA and DOD have been able to reduce their spending on drugs. My comments are based on work that we conducted last year for you, Chairman Shays, and other requesters.

First, VA and DOD have been able to control spending on drugs by establishing formularies. Through formularies, health care systems can control costs by effect physician-prescribing patterns. VA and DOD, for example, substitute lower or higher cost drugs on their formularies when they determine them to be therapeutically interchangeable, that is, essentially equivalent in terms of efficacy, safety and outcomes.

In these cases, VA and DOD may restrict provider choice in closed classes or they may encourage the use of lower cost drugs in preferred classes. The Institute of Medicine studied VA's formulary and found that it was well-managed and not overly restrictive. In addition, IOM recommended that VA use more contracts to carefully limit drug choices in more classes based on quality and cost considerations.

Second, VA and DO have reduced costs by using different purchasing arrangements to obtain substantial discounts on prescription drugs. For example, VA and DOD obtained favorable prices through the Federal Supply Schedule which accounted for the bulk more than 80 percent of their combined drug expenditures. These FSS prices are intended to be no more than the prices manufacturers charge their most favored, nonFederal customers under comparable terms and conditions. Also, by statute, they can purchase brand name drugs at a price at least 24 percent lower than the nonFederal average manufacturer price which may be lower than the FSS price.

VA and DOD have also been able to obtain even lower prices than FSS prices. For therapeutically equivalent drugs, they've used a competitively bidding process which has resulted in prices that average 33 percent below FSS prices.

Third, VA has been able to cut dispensing costs for prescription drugs through its consolidated mail outpatient pharmacy centers. These CMOPs reduce costs through economies of scale. Mail-in refills by using highly automated CMOP technology is several times more productive than refilling prescriptions at VA hospitals and clinic. VA and DOD are currently working on a pilot demonstration to test the feasibility of using CMOPs to lower the cost of refilling military pharmacy prescriptions.

Finally, VA and DOD have secured additional savings through joint procurement. In 2001, VA and DOD estimated savings of about $170 million per year from current and planned joint procurements. The Departments can exert considerable leverage when they commit to jointly buy increased volumes of particular generic drugs or therapeutically equivalent brand name drugs. Nevertheless, joint procurement remains one of their most important challenges. Significant differences between the VA and DOD health care systems make the joint purchasing of brand name drugs more difficult. According to Department officials, differences in their populations result in dissimilar patterns of drug use and demand. For example, VA serves mostly older men while DOD also serves younger men as well as their dependents, women and children. Also, finding overlap between their formularies has been complicated because VA's national formulary lists about 1,100 drugs in more than 250 classes, compared to DOD's much smaller basic core formulary of 175 drugs in only 70 classes.

Finally, DOD is concerned about its ability to persuade nonmilitary providers to prescribe drugs contracted for jointly. In 2000, private providers wrote about half of DOD's prescriptions. The Departments are continuing to pursue joint procurement of brand name drugs because they make up a far higher share of expenditures than generic drugs.

Consequently, jointly procuring them could yield much greater financial benefits. For example, VA's brand name drug purchases in fiscal year 2000 were 36 percent of the volume, but 91 percent of their expenditures.

Mr. Chairman, it would be crucial for VA and DOD initially and individual and together to stay focused on potential pharmacy cost savings to maintain control of their overall health care budgets.

This concludes my statement and we'd be happy to answer any questions you might have.

[The prepared statement of Ms. Bascetta follows:]

United States General Accounting Office

GAO

Testimony

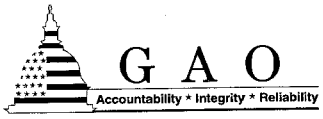
Before the Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 9:30 a.m.
in Boston, Massachusetts
Monday, July 22, 2002

VA AND DOD HEALTH CARE

Factors Contributing to Reduced Pharmacy Costs and Continuing Challenges

Statement of Cynthia A. Bascetta
Director, Health Care—Veterans' Health and Benefits Issues



GAO-02-969T

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss factors that have contributed to reduced pharmacy costs in the Department of Veterans Affairs (VA) and the Department of Defense (DOD) and continuing challenges the departments face. Since the early 1980s, the Congress has had a particular interest in having VA and DOD achieve greater efficiencies through increased collaboration. These two departments combined spent about $3.2 billion on pharmaceuticals for their beneficiaries in fiscal year 2000.[1] These pharmacy expenditures are primarily for prescription drugs and their dispensing but also include some supplies and over-the-counter drugs. Reflecting national trends, VA and DOD pharmacy expenditures have risen significantly, consuming an increasing percentage of the departments' health care budgets. The increase in pharmacy costs would have been even greater if not for the efforts taken by VA and DOD to avoid additional pharmacy costs.

In my remarks today, I will discuss factors that have contributed to reduced pharmacy spending in VA and DOD and the continuing challenges these departments face. My comments are based on work we have previously done for you and other congressional requesters.[2] As part of that work, we used VA and DOD's definition of cost avoidance to describe potential savings from their joint procurement or purchasing efforts to contract for drugs from manufacturers. The departments define cost avoidance as the difference between the theoretical cost that would have occurred if contracts were not awarded and the actual cost incurred for the drugs affected by each contract.

In summary, we identified four important factors that have contributed to reduced pharmacy spending in VA and DOD. First, the two departments have used formularies to encourage the substitution of a lower-cost drug that is determined to be just as effective as a higher-cost drug. Second, VA and DOD have been able to effectively employ different arrangements to pay for or purchase prescription drugs at substantial discounts. Third, VA has significantly reduced the cost of dispensing prescription refills by using highly automated and less expensive consolidated mail outpatient pharmacy (CMOP) centers to handle a majority of the pharmacy workload

[1]In addition, DOD's TRICARE health program spent $455 million on prescriptions filled for beneficiaries at retail pharmacies in fiscal year 2000.

[2]See related GAO products at the end of this statement.

instead of VA hospital and clinic pharmacies. Fourth, VA and DOD have reduced costs by leveraging their combined purchasing power by jointly buying prescription drugs. Nevertheless, VA and DOD face continuing challenges in reducing pharmacy costs. One of the most important challenges is the joint procurement of brand name drugs. Although brand name prescription drugs account for the bulk of prescription drug expenditures, most of VA/DOD joint contracts have been for generic drugs. Generic drugs are easier to contract for because these products are already known to be chemically and therapeutically alike. Contracting for brand name drugs is more difficult because of the scientific reviews needed to gain clinical agreement on therapeutic equivalence of competing drugs. Joint purchasing of brand name drugs also is more difficult due to the significant differences between the VA and DOD health care systems. These include differences between the systems in patient populations, national formularies, and prescribing patterns of providers, some of whom are private physicians.

Background

The Congress has urged VA and DOD to work together to maximize the efficiency and effectiveness of federal health care resources they use for pharmacy and other services.[3] In May 1982, the Congress passed the VA and DOD Health Resources Sharing and Emergency Operations Act (P.L. 97-174), which generally encouraged the two departments to enter into agreements to share health care services. Beginning in the mid-1990s, the Congress increasingly emphasized that the departments cooperate in the purchase and distribution of pharmaceuticals. A 1999 report by a congressional commission concluded that VA and DOD should combine their market power to get better pharmaceutical prices through joint contracts.[4] More recently, the Veterans Millennium Health Care and Benefits Act (P.L. 106-117) required VA and DOD to submit a report on how joint pharmaceutical procurement can be enhanced and cost

[3]In fiscal year 2000, VA purchased 86 million prescriptions for veterans. Also in that year, DOD purchased 54 million military pharmacy and mail-order prescriptions for active duty and retired military service members and their families. In addition, TRICARE's health program paid for 12 million prescriptions for beneficiaries at retail pharmacies.

[4]*Report of the Congressional Commission on Servicemembers and Veterans Transition Assistance*, Anthony J. Principi, Chairman (Arlington, Va. Congressional Commission on Servicemembers and Veterans Transition Assistance, Jan. 14, 1999).

reductions realized.[4] Finally, the Veterans Benefits and Health Care Improvement Act of 2000 (P.L. 106-419) included a provision encouraging VA and DOD to increase to the maximum extent consistent with their respective missions their level of cooperation in the procurement and management of prescription drugs.

Factors Contributing to Reduced Pharmacy Costs

We identified four factors that have contributed to VA's and DOD's success in reducing pharmacy costs:

- Formularies to substitute cost-effective drugs
- Different types of purchasing arrangements to secure lower prices
- Mail-order dispensing to refill prescriptions
- Joint purchasing of prescription drugs to leverage purchasing power

Drug Formularies Help to Reduce Drug Costs

VA and DOD have been able to reduce spending on drugs by establishing formularies. VA and DOD can increase their savings by using one or more of the lower cost drugs from their formularies in drug classes that they have determined are therapeutically interchangeable—that is, essentially equivalent in terms of efficacy, safety, and outcomes. In these cases, VA and DOD place restrictions on providers' choice of drug, by classifying a drug class as either closed or preferred. In the closed classes, VA providers must prescribe and pharmacies must dispense the selected drug, instead of therapeutic alternatives. Case-by-case exceptions for nonformulary prescriptions are allowed. VA has classified about 2 percent of the classes on VA's national formulary as closed or preferred. VA obtains more favorable prices for some drugs in the closed classes by competitively awarding contracts that guarantee companies a high volume of use.[5] In preferred classes, VA and DOD providers and pharmacies are encouraged to use the preferred drug but may prescribe or dispense other drugs in the same class without obtaining an exception.

VA has been able to control costs by encouraging their providers to use drugs on their formulary without having adverse effects on health care

[4] In January 2001, VA and DOD submitted this report, which detailed ongoing efforts to share information, work, ideas, and requirements toward maximizing efficiencies in their health care systems. See VA and DOD, *Report on Implementation of Section 210 of the "Veterans Millennium Health Care and Benefits Act" – P.L. 106-117* (Washington, D.C.: U.S. Government Printing Office, Jan. 4, 2001).

[5] VA and DOD refer to these as committed-use contracts.

quality, according to an Institute of Medicine (IOM) study.[7] The IOM study noted that formularies are a key part of modern health care systems and that VA's formulary was well managed and not overly restrictive. IOM recommended that VA continue to prudently establish closed and preferred classes of drugs on its formulary and to use more contracts to carefully limit drug choices in more classes, based on quality and cost considerations.

Departments Use Several Purchasing Arrangements to Obtain Lower Drug Prices

VA and DOD have been successful in using a number of purchasing arrangements to obtain substantial discounts on prescription drugs (see table 1). For the bulk of their pharmaceutical purchases, VA and DOD obtain favorable prices through the Federal Supply Schedule (FSS). By statute,[8] in order to be able to obtain reimbursement for drugs for Medicaid beneficiaries, manufacturers must offer their drugs on the FSS. The FSS schedule prices are intended to be no more than the prices manufacturers charge their most-favored nonfederal customers under comparable terms and conditions. In 1999, about 81 percent of VA and DOD's combined $2.4 billion in drug expenditures was for drugs bought through the FSS for pharmaceuticals.

[7]David Blumenthal and Roger Herdman, eds., *Description and Analysis of the VA National Formulary*, IOM, Division of Health Care Services, VA Pharmacy Formulary Analysis Committee (Washington, D.C.: National Academy Press, 2000).

[8]38 U.S.C. § 8126(a)(4).

Table 1: VA and DOD Pharmaceutical Purchasing Arrangements

Purchasing arrangements	Description	Discount
FSS for pharmaceuticals	VA negotiates contracts with drug companies to set prices available to all federal purchasers. FSS prices are intended to be no more than the prices manufacturers charge their most-favored nonfederal customers under comparable terms and conditions. Under federal law,[a] drug manufacturers must list their brand name drugs on the FSS to receive reimbursement for drugs covered by Medicaid.	About 50 to 58 percent lower than average wholesale price.[b]
Federal ceiling price for pharmaceuticals	VA, DOD, Public Health Service (PHS), and the Coast Guard can purchase at the Federal Ceiling Price (FCP), which must be at least 24 percent lower than the nonfederal average manufacturer price (NFAMP). The NFAMP is the average price paid to a manufacturer by wholesalers for drugs distributed to nonfederal purchasers.	FCP price is lower than the FSS price for many drugs.
FSS blanket purchase agreements (BPA)	FSS contracts with drug manufacturers contain BPA provisions so that VA and DOD can negotiate additional discounts. Sometimes the lower prices are dependent on specific volumes being purchased by particular facilities, such as one or more VA or military hospitals. VA and DOD have negotiated a few BPAs for preferred status on their respective national formularies.	Variable discounts below FSS prices.
Requirements contracts	VA and DOD brand name drug and generic drug requirements contracts differ as follows.	Average 33 percent lower than FSS prices.
	After performing drug class reviews, VA and DOD determine that some brand name drugs are therapeutic alternatives. This determination allows VA and DOD to conduct a competition among the equivalent drugs and to select one winner based on price alone. VA and DOD commit to use the selected drug on their respective national formularies and close the class to other therapeutic alternatives. Providers must prescribe and VA and DOD pharmacies must dispense the contract drug, instead of therapeutic alternatives, to guarantee drug companies a high volume of use. Case-by-case exceptions are allowed under certain circumstances, such as for medical necessity.	
	In some cases, brand name drug requirements contracts are also based on competitions among drugs that have been determined to be therapeutic alternatives. Here, however, VA and DOD list the contracted drugs as preferred agents on their respective national formularies, but do not close the class. Individual VA and military pharmacies may add and use other drugs in the same class on their local formularies.	
	For generic drugs, VA and DOD conduct a competition for an exclusive contract with one manufacturer. Contracted items are usually selected from among generic products approved by the Food and Drug Administration that are tested against a standard of bioequivalence to the original brand name version.	

[a]38 U.S.C. § 8126(a)(4).

[b]The average wholesale price (AWP) is a price assigned by the product's manufacturer and may be neither "average" nor "wholesale." Instead, the AWP is often described as a "list price," "sticker price," or "suggested retail price." The term AWP is not defined in law or regulation, so the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers.

Sources: U.S. General Accounting Office, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, GAC/HEHS-00-118 (Washington, D.C.: Aug. 7, 2000), U.S. General Accounting Office, *Medicare Part B Drugs: Program Payments Should Reflect Market Prices*, GA0-01-1142T (Washington D.C.: Sept. 21, 2000), and GAO analysis of VA and DOD information.

VA and DOD also buy some brand name drugs for prices less than those listed under the FSS schedule. For example, by statute VA and DOD can buy brand name drugs at a price at least 24 percent lower than the nonfederal average manufacturer price (NFAMP), which may be lower than the FSS price for many drugs.[9] In addition, VA and DOD have obtained some drugs at lower than FSS prices through national contracts with a single manufacturer based on a competitive-bid process. VA and DOD may solicit competitive bids for therapeutically equivalent drugs and may select one winner based on price alone for exclusive or preferred use on their formularies. These competitive processes for formulary drugs result in prices that average 33 percent lower than FSS prices.

Consolidated Mail Outpatient Pharmacies Reduce Drug Refill Costs

VA has used consolidated mail outpatient pharmacy (CMOP) centers to reduce dispensing costs. CMOPs reduce costs through economies of scale.[10] Specifically, CMOP automated technologies have enabled each full-time CMOP employee to dispense between 50,000 and 100,000 prescriptions annually, compared to about 15,000 prescriptions dispensed by VA pharmacy employees. According to VA, such productivity rates are several times greater than traditional hospital and clinic systems. As a result of these automated technologies, VA estimated that its dispensing cost per prescription for CMOPs was approximately $2.00 in fiscal year 2000. VA and DOD are currently working on a pilot demonstration to test the feasibility of DOD using VA's CMOPs to assume refill prescription workload from military pharmacies.

In addition to reducing dispensing costs, additional benefits could result because VA's CMOPs have reduced the pharmacy workload of VA hospital and clinic pharmacies. Between 1996 and 2000, the CMOPs have increased their prescription processing by 30 percent per year. Instead of patients

[9]The NFAMP is the weighted average price of each single form and dosage unit of a drug that is paid to a manufacturer by wholesalers for nonfederal purchasers, taking into account any cash discounts or similar price reductions.

[10]Since 1994, VA has established seven CMOPs. These are located in Bedford, Mass.; Charleston, S.C.; Dallas, Tex.; Hines, Ill.; Leavenworth, Kan.; Los Angeles, Calif.; and Murfreesboro, Tenn.

receiving prescriptions from VA hospitals or clinics, the CMOPs process and mail out the prescriptions. Patients generally receive their medications by mail within 4 days of their orders going from the VA medical facility to a CMOP. As a result of this reduction in pharmacy volume at VA hospital and clinic pharmacies, VA can potentially operate with fewer pharmacists and other staff, free-up more of pharmacists' time to counsel patients, and reduce waiting times for beneficiaries in VA hospital and clinic pharmacies.

VA and DOD Joint Purchasing Efforts Obtain Additional Savings

While VA and DOD have obtained prices that are better than the FSS through negotiating contracts, they have secured additional savings through joint procurement. In 2001, VA and DOD estimated substantial savings from current and planned joint procurements of pharmaceuticals—about $170 million per year. [11] The departments can exert considerable leverage when they commit to buy increased volumes of particular generic or brand name drugs that are interchangeable in efficacy, safety, and outcomes. For example, from October 1998 through April 2000, VA and DOD awarded joint contracts for 18 products, which accounted for about $62 million in combined drug expenditures in fiscal year 2000. Although these drugs accounted for just 1.9 percent of the departments' combined $3.2 billion drug spending in 2000, VA and DOD estimate these joint procurement discounts achieved sizeable cost avoidance—about $40 million in 2000.

Most VA and DOD joint procurements have been for low-cost generic drugs. VA and DOD have experienced difficulties in joint contracting for brand name drugs because limiting beneficiary choice requires gaining clinical agreement on therapeutic equivalence of competing drugs. Due to the complexity of the care issues and the need to garner clinical acceptance and support, VA and DOD can take as long as a year between the date their respective class reviews establish therapeutic equivalence of competing brand name drugs and the date a contract is awarded. Generic drug contracts do not require drug class reviews—since competing products are already known to be chemically and therapeutically alike—and, therefore, take less effort and time—about 120 days.

[11]The departments estimated the theoretical cost by multiplying the weighted average price per unit before the contract took effect, by the quantity purchased in fiscal year 2000. For example, the departments' estimated cost avoidance for cholesterol-lowering drugs takes account of expenditures for all six such brand name drugs, not just the two for which each department has contracted. In our view, this is a reasonable estimating methodology.

VA and DOD have demonstrated that in a few cases, with flexible arrangements, they can procure brand name drugs at maximum discounts while still allowing one or both departments to preserve drug choice. For example, DOD negotiated a blanket purchase agreement (BPA) to receive the same price as VA's contract price for Zoladex—a 33-percent discount off of old prices[12] for the leutinizing hormone–releasing hormone (LHRH) class of anticancer drugs.[13] In return, DOD has agreed to the preferential use of Zoladex to treat a subset of DOD's population—adult prostate cancer patients. However, the BPA does not limit providers' choice in prescribing LHRH drugs for women and children.[14]

Continuing Challenges for Reducing Pharmacy Costs

VA and DOD face continuing challenges to reduce future drug costs. One of the most important challenges is the joint procurement of brand name drugs. VA and DOD officials state that it is more difficult to restrict brand name drugs on their formularies than generic drugs. As discussed earlier, garnering clinical support and provider acceptance on certain brand name drugs is more difficult because of the scientific reviews needed to gain clinical agreement on therapeutic equivalence of competing drugs. As a result, most VA and DOD joint procurements have been for low-cost generic drugs. However, because brand name drugs make up a far higher share of expenditures than generic drugs, the financial benefit of more joint procurement of brand name drugs is much greater. For example, VA's brand name drug purchases are 36 percent of volume but 91 percent of expenditures.[15]

The joint purchase of brand name drugs is further complicated due to the significant differences between the VA and DOD health care systems. These include differences in patient populations. VA serves mostly older

[12]FSS contracts contain BPA provisions so that DOD can negotiate additional discounts in return for specific volumes being purchased by military hospitals. To retain the 33-percent discount below prior DOD prices, the Zoladex BPA calls for achieving an overall military pharmacy market share of 80 percent of prescriptions for adult prostate cancer patients (aged 18 years and older) by September 2001.

[13]The LHRH class includes goserelin (Zoladex) and leuprolide (Lupron).

[14]In addition to being used to treat prostate cancer, LHRH drugs may also be used to treat breast cancer, endometriosis, and precocious puberty.

[15]According to DOD, an estimated 40 percent of military pharmacists' prescription volume in 1999 and 2000 was for brand name drugs; however, data are unavailable on DOD brand name versus generic drug costs.

men, while DOD also serves younger men as well as women and children. VA and DOD officials state that different populations result in dissimilar patterns of drug use and demand among their respective beneficiaries, resulting in fewer opportunities to combine drug requirements and solicit joint contracts. However, increasing numbers of military retirees and expanded DOD benefits are lessening differences between VA and DOD drug needs. In fiscal year 2000, close to 70 percent of military pharmacies' drug costs was for retirees' prescriptions.

Another difference between the two systems that complicates joint procurement efforts is the scope of VA's and DOD's formularies. In 2001, VA's national formulary listed about 1,100 drugs for inpatient and outpatient care representing 254 classes, while DOD's basic core formulary listed 175 drugs for outpatient care in only 71 classes. VA's national formulary was supplemented by 22 regional formularies of its health care networks. In addition, DOD's hospitals, its national mail pharmacy, and its retail pharmacy networks maintain their own separate formularies. The different scope of the formularies complicates VA and DOD's efforts to find overlap between the formularies. In an effort to address differences in DOD's formularies, the Congress passed legislation in 1999 requiring DOD to establish a uniform drug formulary by October 2000, applicable to both military pharmacies and TRICARE retail and mail-order pharmacies.[16] DOD issued a proposed rule to establish a uniform formulary in April 2002, but this rule has not been finalized.

Finally, differences in prescribing patterns of providers further complicate joint procurement. DOD is concerned about its ability to control private-provider prescribing practices and persuade these providers to prescribe drugs contracted under joint procurements. Unlike VA beneficiary prescriptions, which are almost all written by VA providers and dispensed by VA pharmacies, DOD beneficiary prescriptions are written by both military and private providers and dispensed by both military and retail pharmacies. For example, about half of the 52 million prescriptions dispensed by military pharmacies in fiscal year 2000 were written by nonmilitary providers treating DOD beneficiaries.

[16]10 U.S.C. § 1074g.

Concluding Observations

VA and DOD have faced continuing pressure on their health care budgets from rapidly rising pharmacy costs. As in the private sector, these costs have risen faster than overall health care spending for the two departments. VA and DOD have taken a number of actions separately and jointly to attempt to restrain pharmacy costs. These actions include the establishment of formularies, use of different contract arrangements to purchase drugs, use of mail-order pharmacies, and use of joint procurement. Nonetheless, VA and DOD face continuing challenges as pharmacy cost pressures continue unabated. One of these challenges is to increase joint purchasing of brand name drugs, which account for most pharmacy costs. To do this, the two departments need to address how differences in their respective patient populations, national formularies, and practice patterns among prescribers, some of whom are private physicians, can be managed to facilitate joint purchasing. Effectively doing so will be crucial for both VA and DOD to maintain control of their overall health care budgets.

Mr. Chairman, this concludes my prepared remarks. I will be pleased to answer any questions you or other members of the Subcommittee may have.

Contacts and Acknowledgments

For further information please contact me at (202) 512-7101 or James Musselwhite at (202) 512-7259. Thomas Walke also contributed to this statement.

Related GAO Products

VA Health Care: Implementation of Prescribing Guideline for Atypical Antipsychotic Drugs Generally Sound. GAO-02-579. Washington D.C.: April 29, 2002.

VA Health Care: Continuing Oversight Needed to Achieve Formulary Goals. GAO-01-998T. Washington D.C.: July 24, 2001.

DOD and VA Pharmacy: Progress and Remaining Challenges in Jointly Buying and Mailing Out Drugs. GAO-01-588. Washington D.C.: May 25, 2001.

VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs. GAO-01-183. Washington D.C.: January 29, 2001.

Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes. GAO/HEHS-00-118. Washington D.C.: August 7, 2000.

DOD and VA Health Care: Jointly Buying and Mailing Out Pharmaceuticals Could Save Millions of Dollars. GAO/T-HEHS-00-121. Washington D.C.: May 25, 2000.

VA Health Care: VA's Management of Drugs on Its National Formulary. GAO/HEHS-00-34. Washington D.C.: December 14, 1999.

Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness. GAO/HEHS-98-176. Washington D.C.: June 12, 1998.

Mr. TIERNEY. Thank you. I want to thank all of you for your testimony. We are, in fact, going to have a round or maybe several rounds of questioning as we go forward.

First, let me do some housekeeping. I ask unanimous consent that all members of the subcommittee be permitted to place any opening statement in the record and let the record remain open for 3 days for that purpose. Without objection, so ordered.

[The prepared statement of Hon. Stephen F. Lynch follows:]

STEPHEN F. LYNCH
9TH DISTRICT, MASSACHUSETTS

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON NATIONAL SECURITY
VETERANS' AFFAIRS AND INTERNATIONAL RELATIONS
SUBCOMMITTEE ON THE DISTRICT OF COLUMBIA

COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON HEALTH

Congress of the United States
House of Representatives
Washington, DC 20515-2109

235 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-8273
(202) 225-3984 FAX

JOHN JOSEPH MOAKLEY FEDERAL COURTHOUSE
ONE COURTHOUSE WAY
SUITE 3110
BOSTON, MA 02210
617-428-2000
617-428-2011 FAX

BROCKTON FEDERAL BUILDING
166 MAIN STREET
BROCKTON, MA 02301
508-586-5555
508-580-4692 FAX

STEPHEN.LYNCH@MAIL.HOUSE.GOV
WWW.HOUSE.GOV/LYNCH

FOR IMMEDIATE RELEASE
July 22, 2002

CONTACT: Matt Ferraguto
(617) 428-2000

OPENING STATEMENT OF CONGRESSMAN STEPHEN F. LYNCH
COMMITTEE ON GOVERNMENT REFORM FIELD HEARING ON
LOWERING THE COST OF PRESCRIPTION DRUGS

Thank you Mr. Chairman for the opportunity to discuss what we can learn from the Veterans Administration prescription drug-purchasing program here in the City of Boston.

Thirty-six years ago, Congress enacted Medicare to provide doctor and hospital coverage to Americans 65 and over and those with certain disabilities. While there is no doubt that Medicare has proven to improve the quality of life for millions of people. Today, prescription drug coverage is the critical missing piece of Medicare. Millions of seniors struggle to pay for needed medication. And those who have some kind of drug coverage to fill Medicare's gap often find it inadequate or increasingly unaffordable.

Of the medical advances gained over the past three decades, few have had a greater impact than the many new medicines that provide an alternative to painful surgeries and uncomfortable hospital stays. Many Americans have seen their over-all quality of life improved because of these new prescription therapies. However, as the demand for breakthrough drugs has climbed, so have the prices.

As a result, many of our seniors are making health decisions based on economics rather than their best care. As we all know, prescription drug prices are astronomically high in this country. Because of these circumstances, we are told that it is cost prohibitive to offer a full prescription drug benefit under Medicare.

While cost is a definite issue that we must address as we look at implementing a full prescription drug benefit under Medicare, I believe the Veterans Administration has created a model of a large, public, national organization that offers its beneficiaries a prescription drug benefit that makes sense and does not force participants into a no-win situation.

Mr. Chairman, there is little argument that our country's health care system is in crisis. Our hospitals are in trouble, our nursing homes are closing, and our seniors are forced to make terrible choices between the prescription drugs they need and heating their homes or putting food on the table.

-more-

Amazingly, in this atmosphere we have a veterans health system that provides our veterans with comprehensive health care and prescription drugs at a reasonable cost. Our VA is not perfect, and with consolidation we are seeing problems of access. Yet, we have a model that is working.

As a member of the Committee on Veterans' Affairs, I have heard testimony from our veterans' advocates detailing the terrible waits that some of our veterans face when they want to see a Doctor. Today, there are over *300,000* veterans in this country who are wait-listed simply to get an appointment to see a Doctor. A majority of these veterans have been waiting for six months or more. This situation is unacceptable and needs to be improved.

The VA tells us all veterans who require emergency care are given a priority and receive the care they need. However, the VA also tells us that there are a "substantial, but unknown, number of reported veterans" who are receiving their primary health care through non-VA sources, but they come to the VA for the pharmaceutical benefits.

I would ask the VA if they have undertaken any studies that look at exactly how many of our veterans, especially those who are Category 7, who come to the VA strictly for the pharmaceutical benefit? Anecdotally, I hear stories from veterans who say that they have some sort of private insurance, or Medicare covers them, and the only reason they come to the VA is to access that pharmaceutical benefit.

This leads to unnecessary costs to the VA and possible duplicative tests and appointments for our veterans. If this is the case, then I think that we need to address the issue and establish some sort of process by which our veterans can access the pharmaceutical benefit without over-loading our VA healthcare system. I know that VA believes that a "continuum of care" must be maintained for our veterans. But, I wonder if we can look at this issue more closely and develop a creative approach. In Washington I am working on legislation that would create a pilot program in our region that would allow VA pharmacies to honor prescriptions written by non-VA doctors. My hope is this program would alleviate some of the wait list issues as well as maybe save the VA precious dollars. I would be interested to hear our witnesses' thoughts on this issue.

-30-

Mr. TIERNEY. I ask for further unanimous consent that all the witnesses be permitted to include their written statements in the record. Without objection, so ordered.

And what we're going to do is because we're all getting along so well up here, everybody is deferring to everybody else, I'm going to start the questioning just to take that issue off the table and we'll go for 5 minutes and then we'll allow each of the Members—we'll probably go around for a number of cycles here until we get satisfied that we've got all the information that we think we can get this morning. Because what you're saying is obviously very helpful to us.

Let me begin the question by asking Ms. Waxman, your testimony talked about a lot of places where the money goes once the pharmaceutical companies get their money in. We heard a lot of stock options, CEO pay, lately. I know that Families USA has done a report with respect to the CEO pay in the pharmaceutical industry.

What have you learned from that report?

Ms. WAXMAN. Yes, I actually have the report with me and I think it might be appropriate to enter it into the record as well.

Mr. TIERNEY. So ordered.

Ms. WAXMAN. I did not put in my testimony the exact numbers, but I do have it here. For example, what we looked at in the SEC report was not just the salary, but also the unexercised stock options as well. And so when you look at and I'm looking for my chart here, the total compensation for a number of the top executives, for instance, the total compensation for the top executive laboratories was over $10 million. This is last year. And others are $12—I'm sorry, that wasn't the highest one. That was just the A. The highest one was almost $75 million.

Mr. TIERNEY. $75 million?

Ms. WAXMAN. Yes, for 1 year. So the point really of that is just that—the point we were really trying to make with those numbers is that while the companies are screaming that they need high costs to cover R & D, when you look at some of the ways they spend their money such as many, many millions of dollars for their top executives' compensation and you look at all the money spent on advertising, administration and marketing, then some of their claims about the need for high prices to cover R & D just don't live up.

Mr. TIERNEY. Well, staying on that just for a second, one of the comments in here was that prices for prescription drugs have risen four times inflation, is that right?

Ms. WAXMAN. Yes, this past year was almost three times.

Mr. TIERNEY. Am I wrong in assuming that when a company gets the prescription drug ready to put on the market in the first place, no doubt sets the price at a level they think will give them a return on their investment?

Ms. WAXMAN. I assume that's true.

Mr. TIERNEY. And then I would think that the only adjustment after that would be necessary on that figure would be something that would account for inflation or increase in their costs?

Ms. WAXMAN. I would think so.

Mr. TIERNEY. Is it at all likely that the cost associated with marketing these pharmaceutical products are four times that of the cost of marketing any other product?

Ms. WAXMAN. I think the reason we looked at the SEC reports and looked at how much profit there was, was really to make the connection that those prices are going up so much higher than inflation, really has more to do with profit for the industry than it does for research and development.

Mr. TIERNEY. Thank you.

[Pause.]

Mr. ALLEN. Thank you all very much for being here. Ms. Bascetta, I wanted to ask you some questions about—I think you were saying that for therapeutically equivalent drugs you were able to enter into contracts and get reduced prices, but most of those are generic drugs as I recall.

Ms. BASCETTA. That's correct.

Mr. ALLEN. And when you try to deal with brand name drugs you run into the problem of proving they are therapeutically equivalent and there are lots of steps. I think I was looking for the number here, but I remember the number 91 percent, whether that was in your testimony or in the materials that 91 percent of your purchases are brand name drugs, not generic?

[Microphone interference.]

Ms. BASCETTA. Ninety-one percent of the expenditures are for brand name drugs.

Mr. ALLEN. OK, so 91 percent of the expenditures are for brand name drugs. Just by—do you know how much of the purchases are for brand name drugs, what percentage of the purchases? If you don't have it——

Ms. BASCETTA. We have that. We believe it's around 40 percent.

Mr. ALLEN. So 40 percent of the purchases are brand name. We'll correct that later, are brand name, but 91 percent of the cost.

Ms. BASCETTA. Thirty-six percent of the brand name and they account for 19 percent of the expenditures.

Mr. ALLEN. Now I've introduced legislation in the Congress that would allow one of the existing Federal agency to do studies independent studies of the pharmaceutical industry that would look at the cost effectiveness and the comparative effectiveness of different drugs. The reason for doing that, this is a way of offsetting the impact of direct-to-consumer advertising, but if we had some sanctioned studies looking at the comparative effectiveness of drugs, different drugs, let's assume two brand name drugs, the thought is that then we could tell what we can't find out from the advertising, then we know which of the two drugs works the best and that's the kind of information you can't get now very easily in an independent way.

Would that help or would you have to do something further than measuring comparative effectiveness in order to decide whether drugs were therapeutically equivalent?

Ms. BASCETTA. I can only tell you what I know the VA and DOD goes through and what similar large purchasers go through in making those decisions. And one of the first steps that they take is to look at their own populations and determine which drugs their populations need and then primarily to gain the support of

their clinicians they use their pharmacy and therapeutics committees to go through these scientific processes of determining whether, in fact, the drugs are interchangeable and then as you've pointed, once they make that determination, they can competitively bid for the—solely on cost. But as to whether or not a process like that for the country would work, I don't know. I don't know enough about what FDA does in determining therapeutic equivalence of interchangeability, for example. Perhaps the VA witness, John Ogden, would be able to comment on that.

Mr. ALLEN. Just to clarify some of your testimony, when you—you set up—the VA has a formulary. It operates its formulary. Does that—I just wasn't quite clear. Is that a formulary that operates with respect to both brand name drugs and generic drugs or do you run into the same kinds of problems you do with getting a contracted discount?

Ms. BASCETTA. No, they have both generic and brand name drugs on their formulary.

Mr. ALLEN. So they basically pick—they're doing enough studies to figure out which drugs are preferable in which classes, whether or not they are brand name or generic.

Ms. BASCETTA. That's right.

Mr. ALLEN. Thank you.

Mr. TIERNEY. Mr. Shays.

Mr. SHAYS. Thank you, let me—what I'm going to do is just tell you my attitude and then in the rounds of questions I have you can respond based on my general conception which may be true or not.

Theoretically, the system, as I saw the pharmaceutical program in the United States to work was that you had incentives to drug companies to spend colossal sums of money in research. They would have an exclusive ability to sell their product if they were successful, make a very general profit and then ultimately that would become a generic drug in which the price would drop significantly and what you would have is this constant feeding of new brand breakthroughs plus older drugs that had proved quite successful.

What I sense has happened is that the drug companies, particularly before the end of the cycle, if it's 17 years, mas o menos, they would trump that drug and convince the consuming public that the drug that they had just had the monopoly on is no longer the drug of choice. And in some cases that may be true. In other words, they may have come through with a significant break through or it may just be the difference between 98 percent and 100 percent.

There is a challenge though because people always want the best and then the issue for me is when does the government step in and say we'll fund the drug that does 85 percent of what this new drug does at 100 percent.

The other point that I would just bring to the table is I view the VA as being one of their greatest successes is that they have managed to buy drugs in large quantities, reduce the cost of those drugs 30 percent, give or take, and you then wonder why we don't do that for Medicare, in general, but in Medicare, we allow individuals to buy drugs as individuals, so there's no mass buying. So when I'm looking at the Department of Veterans Affairs, I'm also saying OK, we learn lessons how we can, under the Medicare pro-

gram be buying at those, at that mass volume. So that's kind of my view.

Ms. Waxman, you basically said that drug companies can extend their monopolies in a number of ways including marketing, what is essentially a new and improved version of an existing drug.

Ms. WAXMAN. Right.

Mr. SHAYS. That's one point. You say the claim the generic companies has infringed on patents holding the entry of the generic drug for up to 30 months. And then the last point was by entering into deals with generic manufacturers to delay their marketing of generic, that intrigues me first and that's the one I want to take up.

Anyone can make a generic drug basically, so how would a drug company be able to prevent the generics from coming in under that third scenario, could you respond? I'd like a nice, loud voice.

Ms. WAXMAN. What has happened is because the way the Federal law now is that governs generics, there is a Federal law now that governs the way generics can come into the market. There's a whole system. And so what happens is the generic would, the generic company would file a claim, let's put it that way, that the patent in existence is not infringed by this generic coming into the market and as to my third point, that one generic, if the company is successful gets 180 days exclusivity in the marketplace.

Mr. SHAYS. Let me ask you this. Do different generic companies have to race to see which one gets there first?

Ms. WAXMAN. Yes, they do have to race under current law, if they want that extra 180 days exclusivity; the theory being they did all the paperwork, they had to do other research, they did some work to be able to offer the generic, so they get this benefit of 180 days exclusivity. That is the theory.

So what has happened, unfortunately, is as you might imagine, the generic companies are usually not as profitable, not as big as the big brand name companies, so on occasion the brand name has gone to the generic company and say I'll make you a deal. You're going to make X money in your 180-days exclusivity. I'll give you this much money. You don't even have to put the product on the market. I get to keep my patent for a longer period of time and everybody is happy. Everybody but the American consumer——

Mr. SHAYS. Any company can jump into the marketplace?

Ms. WAXMAN. Well, after that 180 days, then other companies can——

Mr. SHAYS. Which company gets that first 180-day crack?

Ms. WAXMAN. The first generic company that's ready to go to market. They get 180 days exclusivity on their generic product and so does that make sense? So what happens is the grand name says to the generic company, I'll make a deal with you. You don't even have to go to market. Just don't go to market and I'll give you this money. I get to keep my patent which I can charge a lot more, and both companies come out ahead. The problem is, of course, the American consumer is the loser and that has happened on a number of occasions. The FTC is actually looking into that problem and indeed, there are certainly different bills coming out of Congress that would fix that.

Mr. SHAYS. Is there anyone else who wants to comment on this issue, the issue of the different ways the pharmaceuticals try to prevent the generics from coming in the marketplace, either adding a slight variation to their exclusive product or claiming the infringement. Do you basically accept all three of her points, Ms. Waxman's points, Dr. Sager?

Mr. SAGER. We might add pediatric exclusivity, if you test for pediatric use, you get an extension on your patent.

Mr. SHAYS. Is that because companies tend not to invest as much in pediatric drugs because there's not a bigger market?

Mr. SAGER. The theory was that it costs additional money to conduct the additional trials, although it seems that typically the extra revenue garnered far exceeds the cost of the testing for pediatric use.

Mr. SHAYS. I mean there's no question, if you make the generic, the cost of production can be quite small, so generic companies still can still make a very nice return.

Mr. SAGER. To which, of course, the brand name manufacturers would claim well, we need the high profits to finance their research. I think that's why——

Mr. SHAYS. Let me just tell you, I happen to accept that part. I mean I was out with a company in California that invested $1 billion in a drug to retard the deterioration that would cause Alzheimer's, and so far they're out $1 billion. If they didn't get some—if they had succeeded, they would have had a license to print money, but frankly, we all would have benefited. So I accept some bit of that concept.

Mr. SAGER. I think it's a matter of balance.

Mr. SHAYS. OK.

Mr. SAGER. We have some evidence recently that a massive effort to push generics would save only about 1.3 percent over a decade. I think we're skirmishing about unfortunately areas that are peripheral.

Mr. SHAYS. Do you think the generic issue is peripheral?

Mr. SAGER. I think today it's a big focus and it's a way that many people hope in the short term to save money. For the long haul, I don't think it takes us very far. If we look at Western Europe, for example, most nations very little on generics. That's because they negotiate and set fair prices on the brand name drugs.

Overall, what I think we need to do is design a package deal.

Mr. SHAYS. I'm sorry, who sets a fair price on exclusive drugs?

Mr. SAGER. The government does, Cigna funds do. It's really a matter of public regulation that set the prices on the brand name drugs. And the prices are low enough so that there's just not—they don't rely on the very high prices on the brand name drugs followed by lower prices.

Mr. SHAYS. I don't understand who they is. I'm sorry——

Mr. SAGER. I'm sorry, Western Europe governments.

Mr. SHAYS. Yes, but I'm not aware that Western European governments have seen great breakthroughs in pharmaceuticals.

Mr. SAGER. I think that issue is——

Mr. SHAYS. Canada controls prices. Are they having great breakthroughs as Western Europe?

Mr. SAGER. The new molecular entities, the new medications that come out of Western Europe pharmaceutical companies seem to be about proportionate. And their investment in research seems to be about proportionate to ours. I know Pharma denies that. But what's interesting is the world pharmaceutical companies earn a disproportionate share of profits in the United States because our prices are not regulated, but British, Swiss, Swedish, French, German and other pharmaceutical companies are quite innovative. They just don't make as much of their profit in their own companies.

You might think of this as equal opportunity, pillaging and plundering of the American patient.

Mr. SHAYS. I think that.

Mr. SAGER. And I don't think we can sustain that. I'm not saying that other countries need to pay more, but we need to pay less and I think that's part—a lower price for medications, but allow the drug companies to develop effective new breakthrough drugs to garner the higher profits they deserve through higher volume.

Mr. SHAYS. Ms. Bascetta, is there any comment you'd like to make in this area?

Ms. BASCETTA. Only to say that GAO hasn't done any work on research and development and profitability in the drug industry.

Mr. SHAYS. OK. Mr. Chairman, I'll do the next round, but I appreciate we're going to be doing 10-minute rounds?

Mr. TIERNEY. Yes, I think that helps a lot. Let me just followup on that. I know that one of the mechanisms that VA would allow them to get 24 percent lower than the average of nonFederal price, is that right? Anybody want to step up on that?

Mr. SAGER. A minimum effect.

Mr. TIERNEY. A minimum effect. And they do that how? Just by establishing that by Federal law that this is as much as you can charge? Is that a mandate? How does it come into play?

Mr. SAGER. My understanding is that they will get a price equal to the lowest price prevailing anywhere else, which is the way the Federal Government buys most things, not just medications.

Mr. TIERNEY. So Ms. Bascetta, in the report, you indicated GAO had some concern that if we were to take the Medicare population, combine that with the VA and Department of Defense and all that, that one of the problems would be that other prices would go for other populations?

Ms. BASCETTA. That's correct.

Mr. TIERNEY. So what we have here instead is that because other countries manage to find a way to negotiate a better price, the price in this country goes up. Wouldn't we be all better off if we also joined the fray and got some better prices and maybe it would even out a little bit as opposed to the people who just get whacked with higher prices all the time?

Ms. BASCETTA. It's certainly a vexing problem. The concern that we and others have raised is that as you pointed out, the more people have access to the FSS prices, the more that manufacturers would be inevitably driven to offset any decreases in revenue by increasing prices for those nonFederal purchasers.

Mr. TIERNEY. Or people in other countries?

Ms. BASCETTA. Yes, wherever else they would have their——

Mr. TIERNEY. Right now, every time they cut a deal with Canada or England or some other country, they just turn to the United States and say well, that's what we're going to get back. We'll just jack the prices up over there.

Ms. BASCETTA. I'm not familiar with the——

Mr. TIERNEY. We've done studies in this committee, this subcommittee, the minority side have done studies to show that cost shifting actually occurs in a significant way.

Ms. BASCETTA. I'm certain that it does. But the tail chasing that occurs, unfortunately, is that those FSS prices ultimately go up because——

Mr. TIERNEY. Well, they may go up, but they go up a little bit all across a much larger board instead of just going up over here. I guess I'm saying at some point people take advantage of the United States because we're the only country that seems to say these prescription drug companies just go out and treat us any way they want to treat us no matter no shabbily, but if we want to say that we're going to get in there and start negotiating for some better prices, then the prices everywhere in the world may have to shift a little bit as opposed to taking a lower price over Europe and decide we're going to make the profits in the United States and just take it on to them, right?

Ms. BASCETTA. I suppose that would be true.

Mr. TIERNEY. Dr. Sager, let me go over—I assume my colleagues and other people hopefully have your charts. You put a proposal out here as to what you might do and I suspect that one of the good parts of your proposal is that you deal with that issue that we always hear about, if you lower our prices, we're not going to do any research, we're all going to die. That's essentially the comeback we get from the companies. You do that by making sure that the companies get a decent profit and that they get money for research and development?

Mr. SAGER. That's right.

Mr. TIERNEY. Would that keep in place all the tax credits that they currently get for research and development which, as I understand it, reduces their taxable rate right now to something about 17 percent instead of 35 percent?

Mr. SAGER. I think it would be necessary top ut together a package deal, really sit back and negotiate all of the arrangements by which drug makers garner revenue to first of all sustain competition by protecting businesses, allow them to ride out the dry seasons. Competition requires competitors. Competition will prompt more breakthroughs. Mergers probably will reduce innovation.

I think that profits should be commensurate with risk and with the value of the drug they produce. Unfortunately, in today's market, where we lack a competitive marketplace, drug makers set prices to maximize revenue and they may be able to persuade doctors and patients to prescribe and buy drugs out of proportion to the value of the medications because we don't have a free market at work.

Mr. TIERNEY. I'm going to just for the sake of time here, I'm going to assume that your calculations on the gross constant elements of the medication prescription drug benefit are accurate and we have time later, we can go over that, but you basically come

down to the figure $2,153,000,000 for a 10-year period, 2002 to 2011. That's for everybody being able to get their prescription drugs, that's the veterans' population, the seniors' population, being able to get them at a reasonable program that you've described for very low co-pay and a very low deductible and then help them from then on in.

Mr. SAGER. For all Medicare eligibles.

Mr. TIERNEY. For all the Medicare eligibles. And whether or not they're veterans or anybody, right, you include them?

Mr. SAGER. Yes sir.

Mr. TIERNEY. Now I'll cover the gross cost, the way that you would expect to pay for this and maybe you can explain a little bit more so even I can understand. The patient payments you indicate, you would charge a premium of 2.5 to 3.5 percent of someone's Social Security check and that small amount would then rise by 2.5 percent a year.

Mr. SAGER. Yes.

Mr. TIERNEY. What do you suspect would be the lowest premium somebody would pay, what would be the highest somebody would pay under Social Security?

Mr. SAGER. Premiums would range from about $6.50 a month up into the $40 range.

Mr. TIERNEY. And that would be pretty much the extent of it. And you would have co-pays of $5 or $10 with one third that are given to low income patients?

Mr. SAGER. That's right. The one third of the total co-pay amount would be directed toward lower income people.

Mr. TIERNEY. And they would pay no co-pay or just a smaller co-pay?

Mr. SAGER. There might be a nominal $1 co-pay.

Mr. TIERNEY. All right, then you get back a sizable amount of money, almost $964 million by capping the annual rise in total spending after 2002 at 8.5 percent annually and you would just have this—this law would just mandate to the companies to make 8.5 percent per year increase and that's it.

Mr. SAGER. Increase in revenue, yes. And that would also be—actually, that would garner around, that would save around $300 billion and we'd save around $400 billion by paying for new prescriptions that Medicare patients were now able to afford, by virtue of the Medicare benefit at the cost of manufacture. So the manufacturers don't earn windfall profits on the higher volume, but their actual costs of making more pills are covered.

Mr. TIERNEY. So if I'm making Medicine A and I'm selling to one population now, I'll be able to make every year after this 8.5 percent annually, increase on that?

Mr. SAGER. In total revenue.

Mr. TIERNEY. In total revenue. And how do we check that? How do we police that?

Mr. SAGER. We check their financial reports year by year and if they generated too much money, next year's prices would be adjusted down. And so this would be reconciled year by year.

Mr. TIERNEY. And how do we keep track now, the second part of that, how do we keep track of the additional people coming on because we've now created this new benefit and separate them out

from the others so that we know that the manufacturers are going to get their marginal cost on that group? How do we logistically do that?

Mr. SAGER. We could translate this into an overall price discount on all drugs because that would be—it would make the record keeping far easier. This translate into a 22 percent effective price discount.

Mr. TIERNEY. And then you would capture your existing revenue in a number of different ways. the largest capture seems to capture offset marketing and advertising by growing at 12.5 percent annually. Explain to me what you mean by that, please?

Mr. SAGER. Well, the drug makers, if they accepted this arrangement, would no longer be marketing and advertising their own medications. Instead, a federally financed, publicly financed organization, maybe a separate nonprofit organization, would be evaluating the safety and efficacy of new medications and indicating which patients the medication would be useful for and provide that information to patients and to physicians. One source, objective information. In that case, we would say to the drug makers, you no longer need to market and advertise. Provide the dollars that you would have spent on marketing and advertising to help pay for the cost of this new benefit.

Mr. TIERNEY. I see some problems with that. One is you're only going to get people to compete through advertising and marketing and they say I won't play. I think I do a better job of effectively advertising than the guy next door and that's how I want to effectively get the market share, so that's going to have to be more of a mandate than a voluntary mode, I suspect.

Mr. SAGER. And that's tough because of first amendment issues. That's why it might be a contractual arrangement. If you'd like Medicare to pay for your medications, you need to sign on board.

Unfortunately, I think the prescription drug industry is thinking short-term bottom line next quarter, higher prices, profits, making more through marketing, through breakthroughs, through higher prices on existing medications as Judy Waxman testified.

Unfortunately, I don't think that's going to work forever. It's not going to work for them and it's not going to work for us and unless they're willing to consider alternative arrangements, we may suffer something like World War I, 4 years of blood and machine guns and gas and no progress. Better to have an armistice and a peace treaty in 1914. And I think we need new ways of thinking about medications and paying for them.

Mr. TIERNEY. Well, how do you stop a company from saying that arrangement, well, I wasn't going to advertise at all this year, so I'm not going to put any money in the pot.

Mr. SAGER. We would look at the historical record and extrapolate forward.

Mr. TIERNEY. And marry them for life on that. And what about new products coming on market? How do we determine how they would have advertised for that? Again, just use some extrapolation out of previous products?

Mr. SAGER. I think that would be right. Or we could take the historic average for that company, looking how it marketed new medications.

Mr. TIERNEY. And then you would capture the Medicaid dollars from States, whatever they were paying to Medicaid and now they're paying through this program?

Mr. SAGER. Right, and that would be frozen at today's levels. So they would have instant relief.

Mr. TIERNEY. And the same with the Federal dollars with the projected rise, you'd now apply them to that and the VA dollars the same way?

Mr. SAGER. Yes.

Mr. TIERNEY. And capture employer maintenance of effort. Explain to me what you mean by that last item there?

Mr. SAGER. Employers provide—employers still finance very substantial amounts of prescription drug for employees who are Medicare eligible, over 65 and especially for retirees. The employers are finding it very difficult to sustain, as you know, their retiree health benefits owing to the rising costs, principally of medications.

In many instances, these are contractual obligations or in other instances, moral obligations and employers suffered terrible black eyes in the public and in the relations with existing workers and retirees if they reneg on commitments. So we would engage employers that now have these obligations and say we'll buy you out, but you maintain your effort at 20 percent of today's level.

Mr. TIERNEY. So you're counting the fact that all of them are substantially would participate as opposed to turning down your offer?

Mr. SAGER. Those that now pay.

Mr. TIERNEY. Thank you. Mr. Allen.

Mr. ALLEN. Thank you, Mr. Tierney. Ms. Bascetta, I want to come back to you for a moment.

Mr. Tierney did a good job of laying out what I have always taken to be the GAO argument about what happens if you reduce prices for one group that is on the Federal Supply Schedule and again, we're getting the benefit of the Federal Supply Schedule.

Mr. Tierney said and he extended it to other countries, and this is common currency in the debate in Washington among Members in Congress too. And the suggestion is that if you give someone who is not getting a discount now, that the industry will be forced, this is sometimes a verb, encouraged, whatever, given an incentive, to raise prices to other groups.

I want to make an argument to you as to why that argument and it is an estimate about future behavior. It is, in its nature, it's not so much a matter of fact as a matter of opinion, but let me give you this argument. I spent some time talking a few years to someone who used to set prices, who used to work for a pharmaceutical company setting prices and basically, what the said they did was they charged what the market would bear in every market that they were dealing with.

The point I am making is this. I suggest that what they are doing now is maximizing their return from every group to whom they sell prescription drugs, whether that group is Aetna or Cigna or the Veterans Administration or France or Germany or anybody else. They're always trying to get as much as they can because their job, the CEO's job is to maximize revenues and income and keep the stock price up.

If that's the case, it is—they're getting as much out of Aetna now. If they lose—if there is pressure, if all Medicare beneficiaries got a discount now, there's still—it doesn't change the incentive to maximize the revenue from Aetna. This is not a case of—set of bottles of water where they all have to even out at the same level. So that's the conceptual argument. Here's the evidence to back it up. In January I was down at a conference in Florida with Mr. McConnell, the CEO of Pfizer. Pfizer has just announced its new discount program. They just said we will sell to every American senior under 200 percent of the poverty level all of our medication which averages $61, $62 per month, we will sell them those drugs for $15 a month. If you move away—that's a 75 percent discount. You move away from Pfizer and look to the discount cards, every company that's advertising a discount card is saying we will give you a discount of 25 to 40 percent. Well, that's the discount that all of us are talking about.

Now so the industry itself in the last year is really saying we can discount, provide substantial discounts to the Medicare population, but we certainly want Medicare to require that of us. That's one point.

Second point, there are 330 million people in Europe. There are 25 million in Canada. There are 127 million in Japan. There are 280 million in this country. The Medicare population that we're talking about when we get to a Medicare benefit, it's probably about half. Let's say 19 million Medicare beneficiaries that cannot—that have either no coverage or inadequate coverage. It's simply, I would argue, it simply cannot be true that these 19—charging the highest prices in the world to these 19 million Americans is what shores up an international multinational pharmaceutical industry. That's a long ramp in many ways. But the point I'm trying to get at is and I'm here asking for your response, let me pose a question. Why isn't it the case that if you give all Medicare beneficiaries the same kind of discount or benefit, let's say discount through the Federal supply schedule, why isn't it the case that the industry will sell more drugs than they are now? That's what Mr. McConnell said down in Florida. He said I'm now going to Wall Street and telling them that this will not reduce our revenues or our earnings. Even though we're giving a 75 percent discount to a significant number of seniors, it won't reduce our revenues or earnings. They'll sell more drugs and in any event, the market is expanding so fast that what's really going on, this is all about maximizing revenue and has almost nothing to do with the recovery of their costs. I'm sorry for doing that to you, but you see the conceptual challenge here that we face and I would like your reaction.

Ms. BASCETTA. I see the point that you're making and I have a few reactions.

Mr. ALLEN. Can you talk a little louder, please?

Ms. BASCETTA. Yes, certainly. One is that in some of the work that we've done, we've looked at what would happen, we've looked at how difficult it would be to predict exactly what would happen if the Medicare population, for example, were able to buy the FSS prices and there we're simply comparing the size of that population compared to essentially VA and DOD. And of course, it's much bigger. We haven't looked at all the other markets and drug pricing

is segmented by market, so we didn't look at the Medicare population compared to the world or all the other populations who would potentially be purchasing drugs at different prices. So that's one observation.

Another though is that in situations where Medicaid has obtained rebates, in fact, what did happen is that prices to HMOs and other purchasers did go up. So I guess the cautionary note is that much of this very complicated. There's been a proliferation of these complex relationships and financing arrangements. Much of the information is proprietary. It's very difficult to tell, in fact, what is actually going on with regard to pricing. That's one of the reasons that we didn't—we were careful to say that you couldn't predict exactly how much FSS prices might go up, for example. It would depend on the specific drug, the number of people who would have access, the competition in that particular market, the price sensitivity of other purchasers. It's very hard to figure it out and our concern would be that without much better, much, much better data, there could be some unintended consequences of picking a particular way to solve the problem.

Mr. ALLEN. And just for clarification, you said FSS prices could go up. And that's because, if I'm correct, and correct me if I'm wrong, that's because the FSS price is tied to something called the average manufacturer's price, is that right, in the statue?

Ms. BASCETTA. No. The FSS is based on the most favored price to a nonFederal customer.

Mr. ALLEN. Right.

Ms. BASCETTA. So what would happen would be as the number of people having access to the FSS price rises, the supposition is that the drug companies would face a decline in revenue which would cause them to raise the price for those nonFederal customers. And because the FSS is benchmarked for the nonFederal customer, you come around full circle and end up raising the FSS prices for everyone.

Mr. ALLEN. And no nonFederal customers, you're talking about Aetna or Cigna or Anthem Blue Cross or whomever?

Ms. BASCETTA. Right.

Mr. ALLEN. Kaiser?

Ms. BASCETTA. Correct.

Mr. ALLEN. And the foundation of that theory is that adding more people to FSS would actually reduce revenues for the industry. My point is it's a nonstatic world. There's an explosion in drug expenditures and pharmaceutical use?

Ms. BASCETTA. That's exactly right. It would reduce revenues for that segment of the market that the industry is dealing with and the belief is that they would—to make that up they would raise prices elsewhere.

Mr. ALLEN. All right, thank you.

Mr. TIERNEY. Mr. Shays.

Mr. SHAYS. Thank you, Mr. Chairman. One of the reasons we have this panel is to identify and then we'll have our second panel, to identify what is it that they do right that we can learn from and what other things in the process of their doing what they're doing with pharmaceutical drugs can we learn, in general, about the industry.

Ms. Bascetta, you identify four important factors that have contributed to reducing pharmaceutical spending by the VA and DOD. First, you say the two Departments have used formularies to encourage the substitution of a lower cost drug that is determined to be just as effective as a higher cost drug.

Now the challenge we have in Medicare is—first of all, it's being paid for by the individual. But the challenge we have there is that you will have customers, patients, who basically if they're sick and they take one drug does 95 percent of what another drug, they want 100 percent, even if it's three times as expensive. And they will clearly want that if someone else is paying for it.

So I happen to believe that particularly if the Federal Government is going to pay for it, they should have some right to say what it's willing to pay for it.

And I guess I would ask you, Dr. Sager or Ms. Waxman, will you be troubled if you were in our shoes and we designed a Medicare program that basically says we will pay for this drug at this price and we won't pay for this drug because we think this drug does almost as much and it's one third of the cost. Do you think that is the way that ultimately we might design a Medicare program, that we will pay for some drugs because we think they're almost as good and we'll pay a lot less and then let the consumer decide whether they want to pay all on their own or pay—or have the drug almost free? Comments, real short.

Ms. WAXMAN. I'll make one comment.

Mr. SHAYS. Keep your voice a little louder.

Ms. WAXMAN. Many private companies do that kind of thing. It's a practice that's used very widely.

What we have always said on behalf of the consumer is there has to be some way for the consumer to get that other drug if the doctor thinks it's really necessary.

Mr. SHAYS. I think you have a breakdown. You're not going to be able to take advantage of what the VA does. Because the VA basically decides they're going to get one drug over another——

Ms. WAXMAN. That's right.

Mr. SHAYS. They get it for a lot less. And you're saying we can't learn anything from that?

Ms. WAXMAN. I'm saying we can learn something and we can direct people to that lower cost structure, but I don't think it's tenable to say if in certain circumstances doctor thinks—you posed the example of 85 percent is good, just hypothetically. If the doctor says for this particular patient, that person really needs the 100 percent drug, there has to be some kind of mechanism or way to get that.

Mr. SHAYS. We know that doctors basically, just in terms of lawsuit, even if they thought one was 98 versus 100, they're going to go with the 100 because they're not taking any chance.

Ms. WAXMAN. There does need to be education of physicians. I think physicians need to be educated on looking at the drugs that can do just as well as relying on the manufacturers.

Mr. SHAYS. I get your point. In other words, it's not obvious here. Yes.

Mr. SAGER. There are several choices. One thing they could do as physicians, you've got $1 million worth of drugs you can pre-

scribe this year for your patients or half a million, whatever the appropriate amount would be. And you spend that money to do as much clinical good as possible for your patients because we have to balance it out somehow.

Mr. SHAYS. Fair enough.

Mr. SAGER. That would give the people with the greatest information the choice.

The other thing we could do is go to the person with the firm that's manufactured this valuable new medication that's much more expensive than saying what if we give you all the business, how far can you lower your price and recognizing that you will offset the lower price with much higher volume.

Mr. SHAYS. Would you agree that one of the challenges is basically you're going to have to decide how much better is one drug over another? The government would be stepping into that process and obviously a difference between 185 might be too big a gap, but I have a feeling that sometimes we're really talking about almost a horsehair's difference between one and another.

Mr. SAGER. There may be a tiny difference in value and there may actually in real world be a tiny difference in cost, once you talk with the drug makers about how much does it really cost to make that pill?

Mr. SHAYS. Ms. Bascetta, but bottom line, do you think we can learn a lesson from your Point 1?

Ms. BASCETTA. Yes, but I'd like to point out that in the VA one of the most significant differences is that the physicians work for the VA and so the VA has a distinct advantage of being able to influence their prescribing patterns from either restricting their choice for some of the drugs in the closed classes or for strongly encouraging and prescribing particular drugs in the preferred classes or in the formulary, whereas in the Medicare world——

Mr. SHAYS. When you say "preferred classes" is that the 100 percent versus the 85 percent? What do you mean by "preferred classes?"

Ms. BASCETTA. Preferred class, a closed class is one from which the VA has a committed use contract. In a preferred situation they don't have that committed use contract, but the drug is on their formulary and physicians are strongly encouraged to——

Mr. SHAYS. And the formularies, I view, as a laundry list of drugs that the VA buys?

Ms. BASCETTA. That's correct.

Mr. SHAYS. Let me ask you again, you said DOD had some difficulty getting private providers to adhere to a limited formulary, in other words, that's——

Ms. BASCETTA. Yes.

Mr. SHAYS. Explain what you mean by that?

Ms. BASCETTA. Thank you for asking me to explain that because that's where the analogy to Medicare comes in. In the Medicare situation in the DOD tri-care situation, you have private providers who are writing in the DOD case, about half of the prescriptions for the military beneficiaries. In the Medicare world, all of the providers would be private physicians and it's much harder in that situation for the DOD or potentially for CNS to exert influence over its providers to write for the drugs that are on the formularies. It

becomes much more complicated, particularly if the beneficiaries are asking for different products than happen to be on the formulary.

Mr. SHAYS. So that's an indication of trying to go to Medicare under this, then dealing with the private folks, that they seem less receptive to the formularies?

Ms. BASCETTA. That's right.

Mr. SHAYS. Let me get to your point 2. You say VA and DOD have been able to effect different arrangements to pay for or purchase prescription drugs at substantial discounts. I don't really how that's different from 1. How is that different from 1?

And by the way, Mr. Musselwhite, sometimes a person who says nothing has got more to say because they have been thinking about how they would answer it. I'm going to allow you to jump in with Ms. Bascetta's permission any time you want to. Fair enough?

Mr. MUSSLEWHITE. Sure.

Mr. SHAYS. So feel free to respond. Ms. Bascetta, explain to me Point 2 how it differs from Point 1?

Your Point 1 is formularies. Your Point 2 is are you saying are there other things besides formularies that they've been affecting employment, different arrangements to pay for it, purchase prescription drugs at substantial discounts. What are some of the other things you're talking about?

Mr. MUSSLEWHITE. They are related, the different contract arrangements and the formulary, but because VA buys the FSS schedule, any drug that buys is going to begin—it's going to be less expensive than what others have purchased. That if in addition to that VA is able to identify a class, a particular drug that is either to be used all the time or merely all the time or is preferred, then it's possible to compete a contract for that drug and get even better price than FSS.

Mr. SHAYS. The third one is you basically talk about the mail order process. And that seems like there would be significant savings. It would seem to me that would—one of the problems that we have been told is that the VA buy sin bulk, whereas Medicare is bought by individuals. But if you had a mail process, there would obviously be significant savings. The challenge, I guess, that some would suggest is that you're not sure who ultimately is using that drug that's mailed. You're also raising the question of whether the mail discontinues even when the person doesn't need the drug anymore. So maybe you could just tell me, do you believe, all four of you, do you believe that the mail order concept has a parallel to the Medicare program and does that illustrate a potential benefit for the Medicare program.

Ms. Waxman.

Ms. WAXMAN. I have to say quite frankly I don't exactly understand how the mail order saves money. It sounded to me like it was cheaper to send it out than have people come in and deal with a clerk and fill it that way. Is that correct or is there something else?

Mr. SHAYS. Dr. Sager, why don't you respond and then we'll have Ms. Bascetta.

Mr. SAGER. I don't think the savings are very substantial. And also, you reduce the availability of community pharmacies to provide the medications that you need stat, pain killers, antibiotics,

after hospitalization. They are covering their fixed costs on a smaller volume so they may have to raise their dispensing fees.

Mr. SHAYS. Thank you. Jim.

Mr. MUSSLEWHITE. The spending in VA is a dispensing cost and as we indicated in the testimony, the volume of prescriptions for pharmacists is much greater through the use of automation. These are refills for the most part. You get your first prescription at the clinic or at the hospital so that's where the efficiency or the cost savings——

Mr. SHAYS. I would think that would be quite significant under those terms. You don't have dialog. You don't have—it almost can be automated, it would strike me.

Mr. MUSSLEWHITE. In VA, it is automated. And it would have an effect on local retail pharmacies.

Mr. SHAYS. Is there any study that you've done that is shown and Mr. Chairman, I think I've run over a little bit, is there any study that you've done that's looked at the negative and that is drugs being sent out because it was refilled and the person may have passed away or the families get it and just chuck in the mail because the person——

Ms. BASCETTA. I'm not aware of any studies that we've done on that issue. I believe that VA will tell you that they have pretty strict controls over their mail order operation, but that would be a good question to pose to them.

Mr. SHAYS. Or to you all. Last point, last, you talk about the DOD joining forces and you mentioned VA has a much smaller list, over 1000 versus a much smaller number.

Ms. BASCETTA. 175.

Mr. SHAYS. What is it?

Ms. BASCETTA. 175.

Mr. SHAYS. 175, just basically quite a significant difference. But I would imagine that the DOD is using more of that 175, so it's pretty big volume stuff.

Ms. BASCETTA. That's correct.

Mr. SHAYS. And so they are working together to get the purchasing of that?

Ms. BASCETTA. Yes, we believe they're making good progress in their joint procurements. Also, I might point out that the Congress directed DOD to expand its national formulary and they are working on that. They have a draft regulation that was issued in April to do that.

In addition, with the expanded benefits to the retiree populations, there's more commonality now between the VA population and the DOD population.

Mr. SHAYS. I'm just going to comment on something Mr. Allen that you said. I'm struck by the fact that when we allow a monopoly pricing, a monopoly sets it at the highest amount they get, they look at their marginal costs and they set the highest price they can get before they reduce sales so significantly that they get revenue or profit. So when they're looking at the lowest market, I think they're saying that market isn't buying anything or very little and they're going to price it in a way that gets them above their marginal cost and they're going to get some benefit, but they don't want to do it, they don't want to price their product in a way that

others then start to argue that the market that is buying at the higher cost starts to say we want to pay less because there's a disincentive. So they're looking at both the economics, but they're also looking at the political issue of whether they start the price at less. Are they going to say that people can afford who are paying at that much higher price are going to demand that lower price and so they look at both the political—now they're beginning to see people that might want to set price and they're saying well, how can they take the air out of this movement so they're willing to take a little bit of a chance and show that they can sell to a lower income.

But I don't look at it as mercenary—if it's mercenary, maybe I could. It's very logical to me and we, in government have said you have this monopolistic price because we're saying you can go out and spend a lot of money in research which is to just have shared a view that I don't know where it leads, but I just would want a response from you.

I thank the chairman for his generosity of my time.

Mr. TIERNEY. Following along that line, I think part of the problem we have here is this whole corporate climate right now where people are recognizing that most people in industry are by and large fair and honest and know that they're doing a good job, but that a number of people are greedy and not as scrupulous as we would like them to be and then we look at an industry that is particularly important to people right now and it seems to be price gouging and there's a reason to be concerned.

Ms. Waxman, in your testimony, your written testimony, you talk about favorable tax refunds that the industry gets. And say that it does, in a sense, it encourages them to invest in R & D, research and development, but there's a question that the pharmaceutical company research dollars are funding. What are they funding that they demand high prices. They have a special tax exceptions for funding of research and development, but studies show that there are fewer and fewer new drugs that offer significant clinical improvements over existing therapies and we have a number of studies that recently show the industry has focused resources on developing knockoffs, so called "me too" drugs as opposed to significantly clinical improvements in drugs and instead use the money also to invest in marketing the existing products.

With that in mind, and the fact that, as I mentioned earlier, the studies also show that total tax credits, that these companies are getting are significant. It's lowered their Federal tax rate from 35.2 percent to 17.1 percent, but we can't really tell how much of that is for research and development because they're all lumped in to a general business tax credit category.

Ms. WAXMAN. Right.

Mr. TIERNEY. I think the problem is people think they're getting away with murder and wondering why they're not being fair about this and seeing that the plan will obfuscate things so nobody can sort of catch a bouncing ball.

Is there a way—do you think it would matter if we knew the exact amount of the tax credits that went to research and development, can we somehow separate that out on tax returns to give us an idea of how much of this tax credit is going into research and development?

Ms. WAXMAN. Yes, absolutely. I think it would be a good thing to know how much is going for what and also to look even deeper into the issue of what are the drugs that are coming out.

Mr. TIERNEY. That was my next question was going to be and would it also make sense to track just which of the drugs they're researching and developing are significant clinical improvements versus the knock offs and the so-called "me toos."

Ms. WAXMAN. Absolutely. Unfortunately, what we're seeing now, for example, on the case of Prilosec where the patent is almost up. I mean sure we've all seen those ads for the new purple pill. The new purple pill is an improvement in that it's a once a day as compared to Prilosec which you have to take a few times a day. And I assume for some populations that is a significant improvement, but it isn't necessarily for all of us and that's the kind of new research that's being done mostly, unfortunately.

Mr. TIERNEY. Mr. Shays raised an important point about somebody made a determination of which branded name, in this case, or generic in that case, which one should be prescribed if it isn't the 100 percent new one or to give the example you give, if it's the same thing, but it's given less times a day, who makes a decision that you go for the one that's less expensive as opposed to the other?

Couldn't we set up an independent group? It doesn't necessarily have to be a government group, but a quasi-public group of very qualified people to make those types of determinations?

Ms. WAXMAN. I assume that would be possible.

Mr. TIERNEY. Ms. Bascetta, does that sound beyond reach or does it?

Ms. BASCETTA. No.

Mr. SAGER. Our plan calls for that, Congressman Tierney. And also, I think the pricing of new drugs should be commensurate with their value and with the risks that drug makers undertake, incur to develop the drug.

Ms. WAXMAN. May I add one thing?

Mr. TIERNEY. Sure.

Ms. WAXMAN. There is a condition when a drug is—the research is done with Federal money, there is a condition in the statute that says the drug must be priced reasonable. No one has ever interpreted what reasonable means or ever enforced any particular definition of that term.

Mr. TIERNEY. And that's in which statute?

Ms. WAXMAN. In the tax credit statute.

Mr. TIERNEY. It's my throwaway question for a moment, is this, suppose we condition a drug manufacturer's eligibility for reimbursement and the tax credits and their use of National Institute of Health money for research and development, suppose we condition all of that on manufacturer offering their product at the most favorable price that they offer any non-U.S./Federal entity, including other countries.

Ms. BASCETTA. The consumer would certainly benefit from that.

Mr. TIERNEY. Anyone else?

Mr. SAGER. We then move toward one price for the same medication in every country, every wealthy country, and that's pretty close to the way things work for steel and bread and milk.

If we want to mimic what the free market will achieve, we will see one price.

Mr. TIERNEY. It's not a free market. Let's be serious on this. The NIH money owns 50 percent of what they get for research; tax credits, they're one of the lowest tax payers in the country; they get a patent. So I assume that none of us are laboring under the false notion that this is a free market.

Mr. SAGER. Absolutely and that's why I said mimic what the free market would achieve if we had one. I agree with each of your points, absolutely.

Mr. TIERNEY. Ms. Bascetta, Mr. Musslewhite, do you have any closing remarks you want to make? Comment on that last question?

Does anyone have any remarks they want to add as we wrap this up? Mr. Allen, Mr. Shays, any questions?

Mr. ALLEN. No.

Mr. SHAYS. No.

Mr. TIERNEY. Thank you very much. I just always like to know is there anything that you all, that you stayed up last night preparing to answer that we never asked you? I mean that seriously. Is there any question you want to put on the record that you think has not been put on the record that needs to be?

Thank you. In that case, thanks for coming here and enlightening us this morning. You've been very helpful. I recommend we take about 5 minutes and then we'll start with our second panel.

[Recess.]

Mr. TIERNEY. I think we'll get started on this second panel.

First, I do have to swear you in as we do to everybody. If you would raise your right hands and stand.

[Witnesses sworn.]

Mr. TIERNEY. Thank you. Let the record that the witnesses have responded on the affirmative.

Our witnesses on the second panel are Mr. John Ogden who is Chief Consultant to the Veterans Health Administration, Pharmacy Benefits Management, Department of Veterans Affairs. And our friend, Mr William Conte, Director of the Department of Veterans Affairs Medical Center in Bedford, MA who is a great friend of our Congressional District and the Commonwealth of Massachusetts particularly this area. He has worked with us in opening a number of community-based and outreach clinics and is a great ally to veterans in the area. We appreciate all that you do, Mr. Conte.

Mr. CONTE. Thank you.

Mr. TIERNEY. Mr. Ogden, would you care to start? We're going to give you 5 minutes, but if that's too restrictive, we'll——

Mr. OGDEN. No, I'm going to paraphrase my statement.

STATEMENTS OF JOHN OGDEN, CHIEF CONSULTANT, VETERANS HEALTH ADMINISTRATION, PHARMACY BENEFITS MANAGEMENT, DEPARTMENT OF VETERANS AFFAIRS; AND WILLIAM CONTE, DIRECTOR, DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER, BEDFORD, MA

Mr. OGDEN. Mr. Chairman, and members of the committee, I am pleased to have this opportunity to address the significant accom-

plishments that the Department of Veterans Affairs has made since 1988 toward effective and efficient management of pharmaceuticals and I refer you to the attachment to this statement that reflects those accomplishments over the past 14 years.

The Department organizational element that has been and continues to provide leadership for these efforts is the Veterans Health Administration, Pharmacy Benefits Management Program. The mission of VHA PBM is to enhance the appropriate use of pharmaceutical in the veteran population. Easy to say, difficult to accomplish.

The five major core functions of the PBM are utilization management, that is, development of pharmacologic guidelines, portions of clinical practice guides that include pharmacotherapeutics, a major part of our effort. No. 2, managing the distribution of drugs and related services. And Mr. Conte is going to talk about that in a few minutes.

No. 3, managing the cost of pharmaceuticals. No. 4, developing and conducting outcomes research that we've talked about and heard about earlier this morning. And No. 5, education. That's education of patients and education of providers regarding pharmacotherapy.

The business strategy for managing pharmacy benefits within VA is a simple one. Leverage national contracts are used whenever clinically possible in contracting for high volume, high cost pharmaceuticals. In addition, VA has a longstanding policy of using generic pharmaceuticals whenever they are the clinically acceptable choice. The contracting process is clinically driven with a goal of product standardization. The process is grass roots in nature, is driven by clinicians in the field, employs evidence based class reviews including data in the VA population where it exists and involves evaluating products and groups of products based on efficacy, outcomes, safety, compliance, VA patient needs and pharmacy factors.

VA has been very successful in these types of contracts and other similar contracting strategies.

Now I'd like to talk a little bit about utilization and expenditures. Our internal analysis inside VA shows that the increasing number of patients treated is the primary driver for increasing pharmaceutical expenditures in the veterans health system. In fact, when we analyze fiscal year 2001, 85 percent of the increase in outlays was because of new patients coming to VA and receiving pharmaceutical benefits. The increased utilization of pharmaceutical per patient or intensity of therapy and use of newer pharmaceuticals account for approximately 12 percent of our increase and 3 percent can be attributed to pharmaceutical or medical inflation, very small proportion of our increased outlays is caused by increased prices for existing products.

While our overall outlays for pharmaceuticals has increased, the cost for a 30-day equivalent outpatient prescription over the past 43 months remains relatively flat, essentially a little over $13. This fact demonstrates that a managed formulary process can serve as the framework for an affordable robust drug benefit.

Let me make a comment about a lack of a Medicare benefit and impact on VA expenditures. While it's difficult to quantify the impact on increased utilization and related expenditure pharma-

ceuticals due to the lack of a Medicare drug benefit, VA staff report anecdotal cases where dual eligible veterans have chosen to access VA for the drug benefit that is a part of our overall health care system. Some of these veterans indicate a desire to have VA serve as a pharmacy only. The Secretary has testified before the Congress and provided written comment to the Congress that VA should not be a pharmacy only, nor do we believe that Congress in enacting provisions of Title 38 contemplated that VA act only as a pharmacy.

We believe that when such veterans become aware of the positive patient outcome associated with VA's continuum of care delivery model and to safety and health risk inherent in a fragmented pharmacy-only benefit, they will want their care coordinated and managed by VA health providers.

From a financial and clinical perspective, the important lessons learned from VA's experience concerning pharmaceuticals is that effectiveness and efficiency can be achieved when providers who treat patients are actively involved in formulary decision when best clinical practices are employed, when volume based and committed use contracting are used when clinically feasible and when clinical pharmacists are fully integrated into the medication use process.

In conclusion, VA has many lessons learned to share in the area of drug contracting, drug utilization management, drug distribution and achieving positive clinical outcomes from drug therapy. While significant milestones have been reached in achieving cost avoidance through contracting activities within VA and jointly with the Department of Defense, even greater cost avoidance has been achieved by identifying and encouraging best practices, developing and promulgating drug treatment guidelines and through recognizing the value of pharmaceuticals in the treatment of diseases. It is gratifying to know that our cost avoidance efforts have been accomplished while improving the consistency of drug therapy across the VA health care system. Indeed, as a result of our clinically driven cost avoidance efforts, VA has been able to partially offset the cost of providing care to the large number of veterans enrolled in the veterans health care system.

This completes my statement and I'm prepared to answer questions.

[The prepared statement of Mr. Ogden follows:]

STATEMENT OF
JOHN E. OGDEN
CHIEF CONSULTANT FOR PHARMACY BENEFITS MANAGEMENT
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
COMMITTEE ON GOVERNMENT REFORM,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS
UNITED STATES HOUSE of REPRESENTATIVES
Boston, Massachusetts

JULY 22, 2002

Mr. Chairman and Members of the Committee:

I am pleased to have this opportunity to address the significant accomplishments that the Department of Veterans Affairs (VA) has made since 1988 towards effective and efficient management of pharmaceuticals.

BACKGROUND

In the 1980's, VA officials recognized the need to direct significant attention to the cost and utilization of pharmaceuticals within the system. In that decade, several forces converged on VA and led us to build an infrastructure that allows VA to successfully manage pharmaceutical procurement, delivery and utilization. First, the 1980's witnessed a steadily increasing prescription workload and expenditures for pharmaceuticals. Second, the demand for drugs was infinite in an era of finite resources. Third, the tradition and culture in the procurement and storage of pharmaceuticals within VA was no longer contemporary.

VA's pharmacy benefits management initiatives have resulted in significant enhancements in the quality, consistency, and cost effectiveness of pharmacy services provided to our patients. The attached chronology describes significant milestones achieved since 1988.

VETERANS HEALTH ADMINISTRATION'S (VHA) PHARMACY BENEFITS MANAGEMENT PROGRAM (PBM)

The mission of VHA's PBM is to enhance the appropriate use of pharmaceuticals in the veteran population. The five major core functions of the PBM are (1) drug use management, (2) managing the distribution of drugs and related services, (3) managing the costs of pharmaceuticals, (4) outcomes research, and (5) education.

The PBM facilitates VHA's National Formulary (VANF) Process through the use of a Medical Advisory Panel (MAP) and a Veterans Integrated Service Network (VISN) Formulary Leaders committee (VFL) representing each of the 21 Veterans Integrated Service Network (VISN) Formulary Committees. The MAP is composed of field-based practicing VA physicians, one Department of Defense physician, and a senior physician from VHA's Office of Quality and Performance. The VFL Committee is comprised of pharmacist and physician chairs and co-chairs of each VISN's formulary committee. These two groups are the primary decision-makers concerning the drugs listed on the VANF and are also responsible for identifying and fostering the development of pharmacologic treatment guidelines that reflect best practices associated with treating a particular disease state and the dissemination of that information.

The business strategy for managing pharmacy benefits within VA is a simple one. Leveraged national contracts are used whenever clinically possible in contracting for high-volume, high-cost pharmaceuticals. In addition, VA has a long-standing policy of using generic pharmaceuticals whenever they are a clinically acceptable choice. The contracting process is clinically driven with a goal of product standardization. The process is grass-roots in nature, is driven by clinicians in the field, employs evidenced-based drug class reviews (including data in the VA population where it exists), and involves evaluating products and groups of products based on efficacy, outcomes, safety, compliance, VA patient needs, and pharmacy factors. VA has been very successful in these types of contracts and other similar contracting strategies.

Utilization & Expenditures:

Outpatient prescription workload increased from 56 million prescriptions in FY 1990 to 98 million prescriptions in FY 2001. While the 56 million figure for FY 1990 is predominantly 30-day quantities, the 98-million figure for FY 2001 represents multi-month prescriptions, which actually equate to 167 million 30-day prescriptions. Thus, over 11 years, the number of 30-day equivalent prescriptions has increased nearly 200 percent.

Expenditures for pharmaceuticals for both outpatients and inpatients have increased from $715 million in FY 1990 to $2.5 billion in FY 2001. As a percent of VA's medical care appropriation, pharmaceuticals expenditures averaged 6 percent from FY 1980 through FY 1995. Beginning in 1996, the percent has increased each year and represented approximately 12.5 percent of the medical care appropriation in FY 2001. These percentages are less than those seen in health care organizations in the private sector even though the pharmacy benefit in VA is generally broader in scope than is the pharmacy benefit in most private sector plans.

The reasons for the increased utilization of pharmaceuticals in VA include an increased number of patients served by VA (700,000 more patients in FY 2000 than in the four prior years); a shift from treating patients in the acute care setting of the hospital to ambulatory care with a focus on disease prevention and amelioration; more aggressive therapy for common diseases among the VA population (e.g., hyperlipidemia and diabetes); medical inflation; and the introduction of new and more effective drug products. More patients treated and the introduction of new drug products stand considerably above the other drivers as reasons for increased pharmaceutical utilization and expenditures.

In VA, the increasing number of patients treated is the primary driver for increasing pharmaceutical expenditures. The increased utilization of pharmaceuticals per patient and use of the newer pharmaceuticals are only of minor importance as major cost drivers. From 1996 through June 2002, VA officials estimate $943 million in accumulated cost-avoidance has been realized from its formulary management activities. The increases seen in VA for average unit cost of outpatient prescriptions is not the key driver of increased

pharmaceutical expenditures. VA drug cost and utilization data show that the average cost per 30-day equivalent prescription in July 1999 was $12.68, increasing to only $13.50 through April 2002. The increased utilization of pharmaceuticals and the introduction of new drug entities drive prescription costs upward, while contracting and utilization management strategies help keep costs down. VA's average prescription costs demonstrate that a managed formulary process can serve as the framework for an affordable, robust drug benefit.

However, the financial impact of new drug therapies should not be completely overlooked as a cost driver. In fact, it is expected that new drugs are likely to have a more profound effect on drug spending in the future as compared to the present. An example of the impact of a new therapy on VA expenditures is the drug imatinib (Gleevec®). Imatinib is used in the treatment of Chronic Myeloid Leukemia (CML), which can occur at any age, but which more commonly affects middle-aged and older individuals. We have determined that there are currently 160 patients with this diagnosis enrolled in the VA healthcare system who potentially could be prescribed this medication. The estimated annual cost of treatment for patients receiving this therapy is between $20,000 and $30,000. Due to the high cost of the annual therapy, we plan to track the number of new patients who are being treated with this drug. In the absence of a Medicare drug benefit, eligible veterans over age 65 with a diagnosis of CML who have never accessed VA for medical care could be highly motivated to enroll in the VA health care system solely as a means to gain affordable access to imatinib.

Lack Of Medicare Benefit and Impact on VA Expenditures:

While it is difficult to quantify the impact on increased utilization and related expenditures for pharmaceuticals due to the lack of a Medicare drug benefit, VA staff report anecdotal cases where dual eligible veterans have chosen to access VA for the drug benefit that is a part of our overall health care system. Some of these veterans indicate a desire to have VA serve as a pharmacy only. We do not believe that VA should only provide pharmacy services, nor do we believe Congress, in enacting provisions of Title 38, contemplated that VA act only as a pharmacy. We believe that when such

veterans become aware of the positive patient outcomes associated with VA's continuum of care delivery model and the safety and health risks inherent in a fragmented pharmacy-only benefit, they will want their care coordinated and managed by VA health providers. From a financial and clinical perspective, the important lesson learned from VA's experiences concerning pharmaceuticals is that effectiveness and efficiency can be achieved when providers who treat patients are actively involved in formulary decisions; when best clinical practices are employed; when volume-based and committed-use contracting are used when clinically feasible; and when clinical pharmacists are fully integrated into the medication use process.

VA/DoD Joint Pharmaceutical Activities:

As of July 2002, VA and DoD have awarded 63 Joint National Contracts, 3 Joint Blanket Purchase Agreements, 36 pending Joint National Contracts, and 21 proposed Joint National Contracts. Additionally, VA currently has 30 unilateral contracts and DOD has four. Some of the unilateral contracts are for high volume/high dollar items and will be considered for joint contracting as they expire. VA and DOD have built the necessary clinical and logistic infrastructure to support ongoing joint contracting activities that will benefit taxpayers and most importantly, our nations veterans, active duty and dependent personnel. VA is committed to the goal of leveraging VA and DoD purchasing power whenever clinically feasible.

CONCLUSION

Mr. Chairman, one expert in pharmacy benefits management recently commented that prudent pharmacy benefit business practice suggests that pharmacy benefits provided by an organization answer four fundamental questions: (1) are patients receiving effective medications at competitive prices; (2) are benefits comparable to similar offerings within their respective industry; (3) are payors and their patients receiving value for their pharmacy benefit dollar; and (4) have all unnecessary expenses been avoided, including potential fraud and abuse?

VA has many lessons learned to share in the area of drug contracting, drug utilization management, drug distribution and achieving positive clinical outcomes from drug therapy. While significant milestones have been reached in achieving cost avoidance through contracting activities within VA and jointly with DoD, even greater cost avoidance has been achieved by identifying and encouraging best practices, developing and promulgating drug treatment guidelines and through recognizing the value of pharmaceuticals in the treatment of diseases. It is gratifying to know that our cost avoidance efforts have been accomplished while improving the consistency of drug therapy across the VA health care system. Indeed, as a result of our clinically driven cost avoidance efforts, VA has been able to partially offset the cost of providing care to the large number if veterans enrolled in the VA health care system.

Mr. Chairman, in closing, I believe VA is one of the leading health care providers in the United States in integrating the provision of pharmaceuticals in its patient treatment programs. In responding to the questions about an organization's pharmacy benefit I cited above, I can attest that VA is providing high quality health care at an affordable price by placing the highest priority on patient needs; emphasizing disease prevention; implementing best clinical practices; assessing validated evidence of a pharmaceutical product's effectiveness; and employing national procurement strategies whenever clinically possible. We are proud of our successes and the contribution these efforts are making to the Nation's understanding of health care delivery.

This completes my statement. I will happy to respond to questions from the Committee.

Attachment

Chronology of Significant Accomplishments in Pharmacy Benefits Management 1988 to present

- 1988 – National IV Solution Contract, VA's first large standardization contract.
- 1989 – Establishment of Veterans Health Administration (VHA) liaison with VA's National Acquisition Center.
- 1990 – Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) linked VA pricing to the best prices paid in the Medicaid program.
- 1991 – VHA established Drug and Pharmaceutical Product Management Working Group. VA developed the concept of Federal Pharmacy as it related to service delivery and contracting for pharmaceuticals.
- 1992 – Passage of Public Law 102-585, sections 601, 602, and 603 of which addressed the higher prices paid by VA and other government buyers as a result of OBRA '90. VA began the Consolidated Mail Outpatient Pharmacy (CMOP) pilot program.
- 1993 – Full conversion to the Pharmaceutical Prime Vendor drug distribution system.
- 1994 - Accelerating change: commitment of the USH as described in the Vision for Change. Full activation of VA's first automated CMOP facility.
- 1995 – Establishment of VHA's Pharmacy Benefits Management Strategic Healthcare Group.
- 1996 – Commercial Practice Initiative for National Contracts. Drug Treatment Guidelines in development.
- 1997 – Implementation of VA's National Formulary Process. Additional drug treatment guidelines developed.
- 1997 –VA receives Vice President's Hammer Award for Reinventing Government for its Bar Code Medication Administration system.
- 1998 – VA/DOD Joint Procurement Activities. Establishment of the Federal Pharmacy Executive Steering Committee (FPESC). PBM database links prescription utilization to patients and providers. Enhanced PBM website.

- 1998 – CMOP Program receives Vice President's Hammer Award for Reinventing Government
- 1999 – PBM recognized as a Finalist in the annual Rochester Institute of Technology/USA Today Quality Cup Competition for its overall contribution to quality movement. GAO published study "VA HEALTHCARE: VA's Management of Drugs on Its National Formulary," GAO/HEHS-00-34.
- 2000 – Institute of Medicine Report analyzes the VA National Formulary process ("Description and Analysis of the VA National Formulary").
- 2000 – Potomac Forum and Market Access International recognized the Department and Bar Code Medication Administration Team for Outstanding Achievement & Innovative Medical Management Solution – Business Applications for Mobile and Wireless Computing in Government
- 2000 – ChampVA Meds-by-Mail program received VA's Scissors Award for intra-agency partnership assisting eligible veterans and their families in receipt of prescription benefits
- 2001 – Data mining capability of the PBM's national utilization database made available to all VISNs. GAO reports validate the VA National Formulary Process ("VA DRUG FORMULARY: Better Oversight Is Required, but Veterans Are Getting Needed Drugs," GAO-01-183; "DOD and VA Pharmacy: Progress and Remaining Challenges in Jointly Buying and Mailing Out Drugs," GAO-01-588).
- 2001 – Department is publicly recognized for effective management of the its pharmacy benefit by members of the Senate Veterans Affairs Committee. VA issues updated policy on the VA National Formulary (http://www.va.gov/publ/direc/health/direct/12001044.pdf)
- 2002 – American Pharmaceutical Association recognizes the Department and the Bar Code Medication Administration Initiative for Achievement as a Health System in Improving the Quality Process.
- 2002 - Data mining capability expanded to each VA Pharmacy Manager. GAO validates VA's guidance on the use of atypical anti-psychotic medications (VA Health Care: Implementation of Prescribing Guideline for

Atypical Antipsychotic Drugs Generally Sound. GAO-02-579 April 29, 2002).

VA / DoD Joint CMOP Pilot planning is begun.

Mr. TIERNEY. Mr. Conte.

Mr. CONTE. I want to thank you for that nice introduction and I want to thank the chairman and members of the committee for the opportunity to testify on "Lessons Learned by VA" and for providing an effective and efficient management of pharmaceuticals. The key component in providing these services has been the creation of the Consolidated Mail Outpatient Pharmacies. This is a service we provide for our veterans, to provide timely, accurate and cost-effective mail out prescriptions.

Mr. Ogden highlighted the entire Department's success and the overall pharmaceutical management program. I'd like to concentrate on the CMOP production concept and its ability to deliver these cost-effective services to the veterans we serve.

It's pretty tough to do in a very short period of time, but first, I'd like to explain the CMOP operations. These systems are really quite unique and complex. A CMOP is a Federalized operation utilizing a assembly line techniques, robotics and software interfaces and automated filling systems to produce an accurately filled prescription with an acceptable pharmaceutical practice and packaged for delivery. And along with that good management practices to include inventory management, quality assurance and accounting practices and these are all the core of that operation. Patient specific information is sent daily from the individual facilities or we call them host sites to the CMOP via a software interface. The CMOP processes the request and mails the package containing the prescription to the veteran. All labels and patient information reflect the host facility, not the CMOP information, which makes the entire CMOP process transparent to the patient. It is as if the prescription were mailed from the host facility. One could view the operation as a vending service for the host facility. Information on cost, lot numbers, dates of fill, everything is electronically returned to the sending station upon completion of the order and placed in the patient's electronic medical record.

Next, I'd like to underscore a few of the critical elements that were addressed by the VA over a long period of time to make this happen. And we've heard this before: creation of a national formulary. A strong commitment to provide appropriate drugs for use by the local medical staff with an emphasis on best value was historically predominant in all VA hospitals. In 1992, the VA created a national utilization data base of actual dispensing actions system-wide. This forms the basis for national contracts for high volume, high cost pharmaceuticals. I mentioned our current Secretary was the Under Secretary at the time when we did this and this was really a major initiative in the VA.. The VA National Formulary system is a product of centralized coordination of grass roots process, which reflects evidenced-based medicine at the patient/provider interface.

Next came along the computerized pharmacy software. The VA clearly, currently possesses the most sophisticated automated medical record system I think in the country, in most countries. Standardized software gave the VA the opportunity to link these facilities to these CMOPs and we can download these prescriptions to the CMOPs in minutes. And Bedford currently downloads data from 50 sites across the Northeast.

Then came the national contracting of pharmaceuticals and use of generics when efficacious, has been a contributing factor of holding down overall drug costs. Without this national approach, we'd not be able to achieve these results. Use of national contracts and a strong, clinically based National Formulary allows local medical centers to maximize the utilization of resources. As John referred to earlier, we can take those resources and maybe buy staff.

Creation of the CMOP operation was another key milestone in us being able to provide this as centralized highly automated prescription operation. The first systems were in Bedford, Los Angeles and Leavenworth. The new system fills 60,000, 80,000 prescriptions a day. We're currently filling 26,000 to 28,000 a day.

The national average CMOP dispensing cost, that includes light, heat, this is truly a business operation within government. It's about $2.15 a day per prescription. That includes everything, plus the cost of the drug. So you're looking at—except for $2.15 a major savings.

Another significant factor the VA looked at was the creation of a prime vendor concept. This enabled us to order drugs just in time, reduce our inventory. CMOP currently in Bedford turns its inventory over 60 times a year which is an amazing factor. You're looking at a couple million dollars a day that comes in and out of that place.

So with that kind of coordinated ordering, we've been able to do a lot of things to drive our costs down.

Mr. TIERNEY. That was a day you were talking about?

Mr. CONTE. Yes, a day. This brief description of CMOP, I'd like to highlight a few advantages. This coordinated system decreases error rate. This is a totally bar coded system and it's got numerous balances and checks in it. CMOP was accredited by the Joint Commission on Hospitals. It received a 100. There was a maximization of pharmacist expertise at the facility because we have taken the burden of filling these prescriptions away from the facilities. This has enabled the facilities to put pharmacists on the front line and have them interface with a clinical staff which is a key component to holding your prices down because they can then interact with the clinical staff and pick the best drugs with them.

Maximization of production of staff. Right those pharmacists in that CMOP fill between 1500 and 2000 prescriptions a day. Meeting demands for service, I don't think without that we could recruit enough pharmacists in the Northeast to keep the operation going with the workload we've got, so because we've automated, we've been able to do that.

In summary, there's five things, six things or five things we really do: an extremely efficient system for the effective clinical review of pharmaceuticals; a distribution system of pharmaceuticals of CMOPs; a data system which is your software interface; a method to procure pharmaceuticals nationally and the software necessary to effectively enable the coordination of these efforts.

Thank you for your time.

[The prepared statement of Mr. Conte follows:]

STATEMENT OF

WILLIAM A. CONTE

DIRECTOR

EDITH NOURSE ROGERS MEMORIAL VETERANS ADMINISTRATION

MEDICAL CENTER, BEDFORD, MASSACHUSSETTS

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM,

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND

INTERNATIONAL RELATIONS

UNITED STATES HOUSE of REPRESENTATIVES

Boston, Massachusetts

JULY 22, 2002

Mr. Chairman and Members of the Committee:

I want to thank you for the opportunity to testify on lessons learned by VA in providing effective and efficient management of pharmaceuticals. A key component in providing these services has been the creation of Consolidated Mail Outpatient Pharmacies (CMOPs) to provide timely, accurate and cost effective mail out prescription services. While Mr. Ogden highlights the entire Department's successes in the overall pharmaceutical management program, I would like to concentrate on the CMOP production concept and its ability to deliver these cost effective services to the veterans we serve.

First, I would like to explain the CMOP operation since these systems are quite unique and complex. A CMOP is a centralized operation utilizing assembly line techniques, robotics, and software interfaces and automated filling systems to produce an accurately filled prescription, within accepted pharmaceutical practices, packaged for delivery. Good management practices, including inventory management, quality assurance and accounting, are the core of the operation. Patient specific information is sent daily from the individual facilities or "host sites," to the CMOP via a software interface. The CMOP processes the request and mails the package containing the prescription(s) to the veteran. All labels and patient information reflect the host facility information, which makes the entire CMOP process transparent to the patient. It is as if the prescription were mailed from the host facility. One could view the operation as a vending service for the host facility. Information on cost, lot numbers, date of fill, etc. is

electronically returned to the sending station upon completion of the order and placed in the patient's electronic medical record.

I would like to underscore a few critical elements that were addressed by VA over a period of time, which enabled this highly efficient CMOP network to become a reality and achieve its goals. They are as follows:

Creation of a National Formulary system.
For years VA Hospitals operated with local Pharmacy and Therapeutic Agents Committees. These committees reviewed and recommended for inclusion or deletion pharmaceutical items on the local formulary. A strong commitment to provide the appropriate drugs for use by the local Medical staff, with an emphasis on best value, was predominant in all VA Hospitals. In 1992, VA created a national utilization database of actual dispensing actions system-wide. This forms the basis for national contracts for high volume, high cost pharmaceuticals. The VA National Formulary system is a product of centralized coordination of grass roots process, which reflects evidenced-based medicine at the patient/provider interface.

Computerized Pharmacy software
VA, as judged by many, currently possesses the most sophisticated automated medical record system. This order entry system was created in various stages over the past 16 years. As various software packages, including a comprehensive pharmacy program, were implemented locally, it gave VA a significant advantage in terms of transferring data among facilities. Standardized software gave VA the opportunity to link facilities to the CMOP's. With minimal software development requirements, facilities were able to download mail prescription workload to the CMOPs in minutes. Currently, the Bedford CMOP downloads data from over 50 sites and returns the information (e.g. date filed, lot number, etc.) to the sending facility on a daily basis.

National contracting of pharmaceuticals
For years, VA has worked diligently to accumulate data and bid competitively for the best price on pharmaceutical items. This has enabled the system to remain cost effective in terms of cost per prescription. Use of generics, when efficacious, has been a contributing factor in holding down overall drug costs. Without this national approach VA would not be able to achieve these results. Use of these National contracts and a strong, clinically based National Formulary allows local medical centers to maximize resource utilization.

Creation of the CMOP operation – Linking of technology to achieve

a centralized production system that provides accurate and timely prescription filling and mailing.

In the late 1980s, VA envisioned the automation of the mail out prescription services to be provided at each Medical Center as a centralized, highly automated prescription-filling operation. The first systems were at the Leavenworth, Los Angeles and Bedford facilities. These sites were experiments in linking production technology (assembly line techniques) with known automated counting devices. Within 2 years, the three sites reached their estimated capacities and, with innovative staff ideas, pushed the systems beyond estimated production potentials. Clearly, they were extremely cost efficient in terms of labor and timely in terms of service. Turnaround times were less than 2 days, and in many instances, were within 24 hours. These initial systems eventually exceeded production levels of 15,000 prescriptions per day. The national average CMOP dispensing cost (labor, light, heat, supplies, mailing etc) is approximately $2.15 per prescription. The newest systems at Hines, Leavenworth, Murfreesboro, and Charleston are now capable of producing over 60,000 prescriptions daily with a goal of over 80,000 daily. All CMOPs are Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) accredited. Many have won numerous awards. The Bedford facility is the recipient of the VA's Scissors Award, the Vice President's Hammer Award, and the local Federal Executive Board Achievement Award.

Prime vendor contract

In 1993, the full conversion to a prime vendor concept enabled the facilities to reduce inventories size and manage more efficiently. CMOPs quickly utilized this advantage since large volumes of items were being turned over daily. The inventory turnover rate at the Bedford CMOP is 60 times a year. The prime vendor, over a period of time, has been able to accommodate the rapid growth, deliver items on a daily basis, automate the billing with the CMOP inventory system, and provide a significant discount for prompt payment. The just-in-time inventory system now used by the Bedford CMOP has reduced the need for large inventories, decreased out-dated and return items, and improved service to veterans due to the decreased numbers of out of stock situations.

This is a brief description of the CMOP and the VA national system that contributes to the quality, cost effective pharmaceutical services we provide to our veteran users. I would like to highlight a few of the advantages of this coordinated system:

- Decrease in error rate: With the automated systems utilizing bar code technology, the human element of filling high volumes of prescriptions has been reduced significantly. Use of digitized pictures and bar code validation have reduced the error rates to almost an un-measurable level.

Use of automated packaging equipment will reduce packaging errors. A full quality assurance monitoring system using statistical process control (SPC) is in place to identify and eliminate any errors at all CMOPs.

- Maximization of Pharmacist expertise at the facility level: As the burden of filling prescriptions is removed form the local facility, local Pharmacists have been able to provide clinical services in areas that demand their expertise. At the same time, their intervention at the point of service can provide additional cost savings by promoting and contributing rational prescribing practices.
- Maximization of production of staff: The use of automation to bring the product to the Pharmacist in the CMOPs (vs. utilizing professional staff to stock and retrieve products) has enabled CMOP professional productivity to exceed rates of 1,500 – 2,000 prescriptions daily.
- Improved service to the patient: In the past, mail out functions within local facilities were not automated and tended to fall behind in timely service to the patient. In the Northeast (to include VISN 1 and VISN 3), the Bedford CMOP has been able to accept and complete mail out workloads within 36 hours. This greatly reduces patient inquiries at the local level concerning status of the prescription refill request, maintains continuity of Medicare and enables numerous staff in the clinics to focus on hands-on care.
- Meeting demands for service: This coordinated system enables VA to meet the rapidly increasing demands for prescriptions due to the expansion of access via Community Based Outpatient Clinics.

In closing, I want to underscore that, through a nationally coordinated effort over the past 15 years, VA has been able to achieve:

- An extremely efficient system for the effective clinical review of pharmaceuticals,
- A distribution system of pharmaceuticals to patients in a timely, efficient and cost effective manner,
- A data system to gather information on the use of pharmaceuticals,
- A cost efficient method to nationally procure pharmaceuticals, and
- Developed the software necessary to effectively enable the coordination of these efforts.

I will be happy to respond to any questions from the Committee.

Mr. TIERNEY. Thank you for your testimony.

Mr. Allen, why don't we ask you to go first?

Mr. ALLEN. Thank you, Mr. Chairman. Thank you both for being here.

Mr. Ogden, let me begin with you. I've heard so much about PBMs and how now Medicare benefit program could be designed with private sector PBMs to be operating the program, that it's nice to hear about a Veterans Administration PBM, even though it's a little different, but you're not contracting that work out to a private entity, I take it?

Mr. OGDEN. No sir, we are not.

Mr. ALLEN. You do it in-house?

Mr. OGDEN. Yes.

Mr. ALLEN. Tell me in connection, you facilitate this national formulary process. In the private sector, of course, formularies are a key component holding down costs to the major buyers of prescription medication in this country, the major insurance companies, for example. And I was wondering if you could describe a little bit of the interaction between the industry and your organization as industry tries to get one of its drugs on a formulary and you try to evaluate the comparative effectiveness of drugs, how does that work?

Mr. OGDEN. I'll try to be succinct. I'll try to speak a little louder. This is a long story. Formularies in the VA go back, at least as far as I can determine, back to the early 1950's. I've seen a copy of the formulary dated 1951, so I can make that statement.

And I've got to tell you, up until about 10 years or so ago, I did not believe that we could move to a national formulary in our organization and the reason I believed that is because we have these affiliations with the medical schools across the Nation, that local practice customs would prohibit us, because of those two factors and ever moving to a national formulary.

As Mr. Conte indicated, when Mr. Principi, our present Secretary was the Deputy Secretary back in the early 1990's, he used to ask me repeatedly, what is happening the VA health care system? And my comment would be we all have to go to Austin. We would have to meet an army of people and we could give you a snapshot after working feverishly for many, many, manhours and come up with a picture at that point in time and that would be the best that we could do.

With his support, we established the National Drug Utilization Data base which captures the actual dispensing actions across our systems and we collect and collate and analyze that data in Chicago and in my offices in Chicago. That step, that program change has helped us change our mindset and allowed us to move toward the national formulary. When Ken Kaiser, our former Under Secretary for health came on in 1994, 1995, one of the first questions he asked me was why don't we have a national formulary? I explained our situation, the historical issue, the cultural issues, the different medical school affiliations, etc., and he said I want a national formulary and I want it next week. I said well, boss, it would be better if we kind of do it in a timed approach if you will, a tiered approach as opposed to going right to a national formulary. So what we did was we went to Network, the 22 VISN, the Veterans

Integrated Service Network first in 1995, 1996. A year later, we went to the national formulary and the key here for us again is that data base and that grassroots involvement. People in Washington don't make decisions about the drugs that are used to treat veteran patients. The people who make the decisions are two groups, basically. The first group is what we call our medical advisory panel and that's a group of 12 physicians who are field-based. They see patients. One of those 12 physicians is a Department of Defense practitioner. The second group that makes decisions is our VISN, our network and formulary leaders. These are individuals who are agents, if you will, of the network director regarding pharmaceutical matters in the particular VISN and a subset of that group is the number of clinical pharmacists who work in my office who do most of the staff work to prepare an issue for debate by the Medical Advisory Panel and the VISN formulary leaders. So those two groups make the decisions. So it's grass roots. It reflects the care that is being provided veterans.

I know the title of this hearing concerned lessons learned in our drug procurement. It's really not drug procurement. It's lessons learned in managing a benefit. And as I said in my statement, yes, we have been very successful in contracting, but that's not where the return on the investment comes. The return on the investment comes in being an aggregate of all of the factors that we would describing including one Mr. Conte described in how we distribute drugs, but the use and embracement, if you will, of those clinical practice guidelines and those pharmacologic treatment guidelines by our providers has to be one of the foremost factors in why we've been successful.

So the formulary is important, absolutely important. It's driven by what's actually happening out there at the front line.

Mr. ALLEN. When you say it's driven by what's actually happening, you're talking about patterns of prescribing by the VA physicians in the field.

Mr. OGDEN. Yes.

Mr. ALLEN. What is the role of the outcomes research that you referred to in your testimony? What kind of research is it? How does it use—does it get to the kind of research I mentioned before the earlier panel and just by way of background, let me explain that for one moment. Right now for drugs to get approval from the FDA it has to be proven that it is safe and that it is effective, that is, it treats the condition for which it is being prescribed. The two missing components are how comparatively how effective it is to other drugs on the market, No. 1, and No. 2, is it cost-effective? That is, does it treat the condition for which it's prescribed in a way that makes financial sense to whomever is paying the price. So my question to you is with that said, can you talk about your research, your outcomes and how, if at all, what your research is connected to the formulary and the decisions about the formulary?

Mr. OGDEN. Our intent is exactly what you just described. Our efforts inside the PBM regarding outcomes research, those efforts are in their infancy, but I can tell you that our colleagues in the research portion of VA are very interested in this issue as well and we get more and more interest in conducting these types of studies as time goes on and as the outlays for pharmaceuticals increase.

After we are absolutely interested in head to head studies inside therapeutic classes where these kinds of questions are being asked by our providers and by our managers and in some cases by our patients, let me just come over here to the chart that you have over here. On the right hand side of that chart you show two drugs, Prevacid and Prilosec and a few years ago when we decided clinically that one of those two drugs would meet the clinical needs of most veteran patients we competitively bid them with the idea in mind that marketshare would go to the formulary listed produced.

I'm going to tell you at the time, the drug on the right, Prilosec which has the generic name of omeorazike, it had 97 percent of the marketshare in the Department. They lost. Prevacid received the bid. Because that happens to be a therapeutic class——

Mr. ALLEN. Excuse me 1 second, Mr. Ogden, did they win the bid on a lower price or something else?

Mr. OGDEN. Yes, they did. They won the bid on a lower price because we determined clinically that they were both efficacious. They delivered similar clinical outcomes, so cost becomes a greater consideration. You can't say that for every drug or every class of drugs, but in this case there were only two drugs at the point in time and we made that clinical decision. Based on the evidence that was available, not only in the United States but worldwide at the time.

Well, as I just indicated, Prilosec had 97 percent or 98 percent of the VA business at the time. They lost the bid. This happens to be a class of drugs where again, clinically, they produce very similar clinical outcomes. So to convert patients, you don't have to titrate the patient. You can just make a conversion which is what we did.

The turnaround in market share from Prilosec to Prevacid, the generic name is Lansoprazole, was almost overnight, almost overnight. Again, that doesn't happen in every therapeutic class that we made that decision, but Prilosec's marketshare went like this. Lansoprazole's market share went like this. And obviously, the veterans that we treat benefited because we can treat more veterans because we're treating veterans who used this product and it is a highly prescribed product. It allows us to treat more veterans. So that happens to be a good example. You can't do that in every class of drugs or with every drug, but when we can do it, we can make a clinical call, we will do it and do do it as evidenced by the successes that we have demonstrated over the years.

Mr. ALLEN. Thank you very much.

Mr. TIERNEY. Mr. Shays.

Mr. SHAYS. Mr. Ogden, just refresh me. You're a consultant to the VA, not an employee?

Mr. OGDEN. In statute, I'm the Director of Pharmacy Services for the Department, but in the re—reformation, if you will, the reinvention of the veterans health system in 1995, they changed the title of people like myself, Director of Nursing, Director of Optometry, Director of Prosthetics to Chief Consultants. So I had been the Director of Pharmacy Services by law, but our title is Chief Consultant.

Mr. SHAYS. I think that's weird. [Laughter.]

Mr. OGDEN. We can talk about that. That would probably take a couple of hours.

Mr. SHAYS. OK. See I think of consultants as having less authority but getting paid more.

Mr. OGDEN. I'm a Federal employee.

Mr. SHAYS. Fair enough. That's why I asked the question. I want you to help sort out a few things. The Department of Veterans Administration charges $7 co-pay and that the average cost per veteran in the 30-day period is $13.50.

Mr. OGDEN. Ingredient cost, yes.

Mr. SHAYS. Pardon me?

Mr. OGDEN. That's ingredient cost. I neglected to say that $13 is a cost of the drug ingredients, not any labor, not any other—it's just the cost.

Mr. SHAYS. It's the cost of the drug?

Mr. OGDEN. Yes.

Mr. SHAYS. That surprised me. I thought it was going to be higher. I think it's going to have to change significantly because what I've seen in my part of the country, the greater New York area, it's still part of New England, closer to New York, I've had some very well to do constituents telling me almost with some bit of embarrassment that they are joining the VA system to get prescription drugs because they feel like they are taking $300 a month and throwing it in the waste paper basket by not taking advantage of it because they say their drug costs are hundreds of dollars and for a small co-payment they can buy into the system. But they have the ability to pay it on their own. They're fairly—I come from a fairly—overall, they have the ability to pay for it.

And so is there anything statistically that you had that tells us that $13.50 cost is going to go significantly—because frankly they're not pulling in my wealthier constituents are going to save $7 a month. They're coming in because they can save hundreds of dollars a month. So is there any projection that $13.50 goes to $26.50 goes to—over a short period of time?

Mr. OGDEN. I don't think it's going to go in a short period of time. It's going to increase dramatically. I think we can all expect that the average price is going to increase for a lot of reasons.

Mr. SHAYS. What that says though is that veterans pay half the cost.

Mr. OGDEN. But that $7 co-pay does not include—I think by statute does not include any amount. The $7 is for the ingredient cost.

Mr. SHAYS. So the $7 is basically the—well, how much, if you looked at costs, how much of the $13.50 represents the full cost?

Mr. OGDEN. You mean labor, depreciation, etc?

Mr. SHAYS. The full cost of providing the service. Tell me we know that cost.

Mr. OGDEN. Pardon me?

Mr. SHAYS. Tell me we know that cost.

Mr. OGDEN. I'm going to tell you it's probably under $13, under $20.

Mr. SHAYS. Do we know how much it costs to provide a prescription service to our veterans, the total cost? If we don't know, tell me, but——

Mr. OGDEN. I think what I told is pretty representational. We know that the average ingredient cost for a 30-day supply is right around $13.

The cost to deliver that product, including this facility, the CMOP facilities and the up front processing is another $7.

Mr. SHAYS. How do you know that?

Mr. OGDEN. Its cost on average $2.50 to process a prescription. That includes the mailing costs, all the overhead, everything to run those facilities.

Mr. SHAYS. The employees?

Mr. OGDEN. Yes. The professionals involved, the pharmacists, the technicians, the lights, the overhead.

Mr. SHAYS. So basically you're saying that the entire drug costs is paid for by the government?

Mr. OGDEN. Yes, for the veterans who are accessing our system for service connected. There is no co-pay as you know.

Mr. SHAYS. You were generous. I wasn't aware of that. There is no co-pay for the service connected.

Mr. OGDEN. Let me back up for just a second. If, in the Department, the pharmacy co-pay is not the type of co-pay that you or I would pay in an outside—those co-pays are generally based upon generic, brand, formulary, nonformulary. When Congress that legislation back in the early 1990's, the co-pay was based on eligibility. So if a veteran was rated 50 percent or greater service connected, they pay no co-pay, whether it's drugs or otherwise.

Mr. SHAYS. Mr. Conte, do you agree that the nonmedical, the nonprescription sole cost is $7?

Mr. CONTE. It's pretty close. I know that $2.15 is right on the target because the CMOPs have costed it very, very effectively. As far as the balance of that $7, that would depend on each facility and what the staff is. So John has a good handle on that. He's darn close.

Mr. SHAYS. It's hard for me intuitively and sometimes when I bring my intuition it gets me into trouble. But intuitively, based on moccasins that I wear, it strikes me that your costs have got to go up significantly—well, first off, we're allowing queuing and if you're in the line, you may not be part of the system. So let me just parenthetically ask how many people are waiting to be part of the pharmaceutical program in Massachusetts?

Mr. CONTE. In Massachusetts, I think the last figure we looked at was around 3,000, but these tend to be categories that are nonservice connected.

Mr. SHAYS. Right, and I predict to you that they're the ones who a good number of them will be the ones who are joining because they see significant savings. And I don't believe that they are going to go through the hassle of joining the system if they're just going to save $75 a month—excuse me, $13, a net of $7 a month. I think they have to basically see that there's significant savings by joining.

Mr. CONTE. I think what they're doing now is paying to a large amount their prescriptions through the private sector and they're coming in and paying $7 also.

Mr. SHAYS. But the cost to you will not be $13 per average. That average cost will go up significantly.

Mr. CONTE. That's a tough thing for me to answer. If a drug costs $50 and we pay $50, you're right. They're paying $6.

Mr. SHAYS. Do you want to say something, Mr. Ogden?

Mr. OGDEN. Yes, I was just thinking about your question and if a nonservice-connected veteran presented with a prescription written by a private doctor, we would simply fill that prescription, the cost could go up significantly, if that prescription was for an item not in a formulary process. It was for an item in our formulary process, then, in fact, it could be the—the price wouldn't go up because it would be—that's the average—those are the problems we use to dispense to all veterans who currently access our system.

Mr. SHAYS. But frankly—right, and the formulated would be they buy this drug. No, but they don't care—does the veteran care if it's in the formulary or not because they still get the drug at just a copay cost. You care, but the veteran doesn't.

Mr. CONTE. Yes, they do. Veterans in our system realize that the pharmacy benefit is, in fact, an integrated benefit as far as VA providing health care.

Mr. SHAYS. Let me just interrupt, just so I can follow the rest of your—I make an assumption that when a veteran goes, if he needs the drug that's not in your formulated list, they're entitled to that drug?

Mr. CONTE. If the veterans is enrolled for care and he presents and the physician orders that drug that doesn't happen to be on our formulary, we do provide that drug.

Mr. SHAYS. Sorry to interrupt you.

Mr. CONTE. Let's don't discount here the power of direct consumer advertising. When the patient is sitting home watching the evening news and they see every commercial has to do with the purple pill or for arthritis of the knee, etc., what do you think happens when they present in the exam room? They mention that commercial to the provider and for those veterans who have not been in our system very long, it's hard for them to appreciate that the pharmacy benefit is an in-bred part of our health care delivery system. We do have a formulary process and we do analyze products and we do when the evidence suggests and that's the type of product we use.

Mr. SHAYS. But that's irrelevant to them.

Mr. CONTE. It's irrelevant to them. It's hard for them to understand.

Mr. SHAYS. All I'm saying to you is that your point is well taken. If they get the formulary product, it is going to be a lot less. They say it's not a big cost to you because you got it at a lot less, but maybe this should be my last question, I see my red light, how much of your products end up being formulated and how much aren't? In other words, when you add up all what the veterans bought, how much is formulated and how much——

Mr. OGDEN. I don't have the figures of what we bought, but I can tell you what that is in the context of what we dispense. Last year, in fiscal year 2001, we dispensed approximately $98 million prescriptions, actual prescriptions. Of those $98 million, approximately 90 percent or 91 percent were for items listed on the VA National Formulary.

Mr. SHAYS. Let me ask you one last question. Of that 91 prescriptions, what was the cost? Was it 91—it wouldn't be. The 9 percent remaining, not part of formulary turned out to be how much of your expense.

Mr. OGDEN. Let me just finish by saying another 6 percent is listed on our network or VISN level formulary, so when you have 3 or 4 percent nonformulary, you use—the nonformulary use, as far as a percent in dollars, of total outlays would be insignificant.

Mr. SHAYS. It would be interesting to know—I mean I think this is great news, but it is surprising to me. My prediction intuitively would be that 3 percent will start to soar, but I could be wrong and if it doesn't, then we are truly on to something quite significant.

Mr. CONTE. I will tell you there are challenges and Mr. Allen asked a while ago about the interface between the industry and ourselves. It really should be about the interface between the industry, ourselves and you all just because we're a public institution. And that interface is constant and when we make these decisions in some cases we have for lack of a better way to put it, winners, and you have perceived losers. They are not happy about that. The ones who don't have the formulary listing, if you will. So it's a constant—maybe what I really want to say is a tug of war.

But I think as long as we're patient, we have been validated by the Institute of Medicine. We have been validated in our process that Cindy mentioned from the General Accounting Office. Again, it's a public institution. What we're trying to do here is to do the best we can——

Mr. SHAYS. I get that. Let me just say to you, it strikes me and thanks, Mr. Chairman, for having a long red light, but it strikes me as a very positive story and it's—I'm grateful one member of the press is here, but this is a story that more people need to hear. They're hearing a lot of negative stories. Thank you.

Mr. TIERNEY. I think all the Members here share the idea that what we really want to do is get the information and we don't really care who asks the questions, as long as we get answers, the credible answers that you're giving.

Mr. Ogden, can you envision this type of a process that you have at VA being enlarged to cover a larger population to include Medicare people?

Mr. OGDEN. I have thought about this a lot and I don't think it has to be a Federal program for Medicare to be successful and I'm going to digress a minute here, but I've spoken to Mr. Allen in the past and his staff in the past, for example, linking Medicare pricing to be a pricing and we have, as the Department testified, that's not in our interest to do that and as Cindy mentioned, the GAO has looked at that. The reason that we feel that way and it's not because we're parochial, we're trying to just provide a service to veterans and everybody else who doesn't get that opportunity is because when you think about the population, the size of the Medicare population and we're all going gray, that Medicare has the potential to achieve much greater pricing than we do. The VA and DOD combined, the Coast Guard and Indian Health Service for that matter, I think we comprise like 3 percent of the U.S. market in terms of outlays. Medicare is huge. The current population in Medicare, I think it's like, the dollars out there now are like 42

percent. And it's just going to get greater as the boomers age. But I think that again, Medicare through emulating the kinds of strategies that we have emulated that they can get far better pricing than we receive. And I'm going to go back to this example here. If Medicare can deliver the marketshare and that's the key, it's what was mentioned earlier, what will the market bear? If Medicare can deliver the marketshare, they will, in fact, receive better pricing. But another key area is the patients, of course, when the patients buy in, they get total free choice, because they get total free choice about all drugs and all drug facets that causes—it's a higher price.

Mr. TIERNEY. What if they put together a formula in process much like the one that you've got?

Mr. OGDEN. I think it could work and as long as we've got the providers, the physicians in this part of the country to make those decisions and drive it, it can work and it can work very successfully.

Mr. TIERNEY. But you need a data base?

Mr. OGDEN. And that's where the Department comes in and services the public good and the patients we treat are very geriatric. They're mostly male at this point in time, but there are a greater number of female patients that we're treating, but we have an excellent research and longitudinal, if you will, research base that can demonstrate people like yourselves, the types of public policy that will best serve in this case, the Medicare population and affordable cost. I think the difficult thing for us and Mr. Shays mentioned our costs are going to go and everybody's costs are going to go up is we're sitting here today, and pharmaceutical outlays are going up. But I don't think anyone will argue that pharmaceuticals aren't a good value. Because we all know they are a good value. The problem for all of us is with pharmacogenetics and genomics and biotechnology is the percent of our health care dollar that we outlay as a society for pharmaceutical has the real potential, in a very short period of time to climb dramatically. This is going to involve all of us to design a system that integrates pharmaceuticals much more so than we have up until this point in time.

Mr. TIERNEY. Excuse me, it seems like an interesting exercise would be to have somebody who does just that, design a system that could be laid over the Medicare population using what we've learned from the VA in setting it up and plainly is the direction to go. And I would suspect whatever cost that would be to do that design and get everything ready to go would be reasonable to consider what the benefits in the long run would be and maybe that's something we can all think about up here.

Mr. Conte, I'm curious to know your consolidated outpatient mail pharmacies, that network, how would you compare your CMOPs to the distribution systems used by private sector people like Pharmco, Merck and Expresscrips?

Mr. CONTE. Well, you know, they all visited us. I think we've been the model for that as far back as the early 1990's and I think we have some significant advantages in that we use technicians more than they do in the private sector and we've been able to automate our system using technicians and maximizing the pharmacy output. I can't give you exact figures, but I know our pharmacist to technician ratio is very different than what you see in the

private sector. It's still a very accurate system because of bar coding the way we support those pharmacists.

The system itself has got a history of being extremely cost effective versus those companies you mentioned. I have no figures on their actual cost, but we've seen their operations and they tend to have a lot more pharmacy staff and a lot more of staff than we do. I think the VA has demonstrated unequivocally that it's been able to produce the most cost-efficient mail out system for pharmacy. It's a service that we provide. The clinical aspects are sort of linked, the host facilities. We can't just mail it out. This is linked with those facilities on the clinical side.

Mr. TIERNEY. How long did it take the VA to get its architecture for this pharmaceutical program together from the concept to actually implementing it where you get to the point where you're comfortable and you feel that you're getting the maximum benefit from it?

Mr. OGDEN. The architecture has been in development during the past 12, 13 years or so. It's an evolving architecture. These facilities that we have are in laboratories and for example, Bill mentioned what the capacity of the current Bedford facility is and by the way it was one of the first generation facilities.

I was just in Chicago Thursday and Friday and they just added some technology at the Chicago facility and they anticipate, when it's debugged, that they'll be around 25,000 prescriptions per day. It's evolving not only in VA, but it's evolving in the private sector as well. Merck has some very excellent technology. Our people have been into their plant in New Jersey and have looked at it and it's very good, we all have very good technology, but it's an evolving situation. I think that ours is totally different than what you'd see in the private sector because we're a mail service pharmacy, not a mail order pharmacy.

Our intent was to have the patient talk to the doctors, nurses, the pharmacists, etc., when they access the VA system. What we designed over here far, far away, if you will, is an economies of scale distribution facility to maximize productivity dispensing the actual prescription. I have to give you credit to our IT people, information technology, people. Think about moving massive amounts of patient data day in and day out. We hand it off to commercial software processes who fills the prescription. We hand it back to put it back over the wires and we print the patient's medical record. It's absolutely phenomenal what our IT people have done over the past 12 years. It's evolving. It's a very good success story.

Mr. TIERNEY. If we supposedly thought about setting up a parallel system for Medicare patients and we wanted to learn what you were doing and we decided we're just going to take and replicate what you've done using what benefits we think we would learn on that, set it up with the Medicare and move forward, what cautionary notes would you give us on that?

Mr. OGDEN. Well, I think my primary cautionary note was it has to be gradual. If for some reason we decided to make a national decision what the formulary was, I don't think it would be successful.

Mr. TIERNEY. How do you envision that a grassroots operation——

Mr. OGDEN. I'm a proponent of allowing States to form consortiums.

Mr. TIERNEY. To do what?

Mr. OGDEN. Allowing States to form consortiums or a State like Maine that doesn't have a big population, if you will, with regards to New York, could partner with large other potential buyers and so that when they did determine what a formulary was, that they could actually affect better pricing in the marketplace just because of the numbers. So I think that's the key. I don't think we're ready for a national program under—and I'm not saying I'm a proponent—I'm obviously talking for myself and not for the Department.

Mr. TIERNEY. Right.

Mr. OGDEN. We're not a proponent of that. Again, our whole process has been in effect since 1995. We've been evolving this process. The buy-in is superior to the buy-in yesterday, superior to the buy-in 6 years ago. And we don't bat 1,000, but we're batting pretty good and it causes me to appreciate that unless it's grass roots, it won't work.

Mr. TIERNEY. I have some legislation that basically would give States, grants to States or regions to devise a system by which they could deliver health care services and then a second grant if they did that would let them implement that. Of course, part of that would be dealing with prescription drugs and there are some State efforts, particularly here in New England, where people are looking to have consortiums with States that do just what you're talking about and so there's nothing that you see that would stand in the way of doing what—state consortiums, getting together and deciding that they're going to establish formularies, maybe model it in a way that you've done yours and then go about their business in that respect.

Mr. OGDEN. I would certainly like to see that.

Mr. TIERNEY. Well, maybe we'll hear some of our gubernatorial candidates talk about it.

Mr. Conte, do you agree with that assessment, that it's worth it?

Mr. CONTE. Absolutely. I'm sitting here as John as talking, it really comes down to getting your providers on board because they're the ones who are actually going to do the prescribing and getting the software up and going, a formulary and an automated process, and that's what we've done.

Mr. TIERNEY. Mr. Allen, any more questions?

Mr. ALLEN. Just a couple, some comments. I'm struck by how much, at least up here, how much progress we've made during the course of this hearing. I hear two things that seem to me of great significance. Aside from the fact that VA has got a system that is moving along and that really does shed some light on where we're going. One of the points is and this is not acknowledged in the debate over a Medicare prescription drug benefit by either side of the aisle. One is that if you're going to save money, you need to do it as the private sector does and as the Veterans Administration does and accept the formulary. This is something that those who want a Medicare prescription drug benefit based on the insurance industry and the private sector say they don't want to go close to that and on our side of the aisle people say you can get any drug you

want under our plan, any drug you want. Again, a rejection of the formulary.

The second component is that if you have a formulary in order to hold that price, you have to have an independent way of doing the research that will allow you to conclude that Prevacid and Prilosec are equivalent effectiveness and without that research capability you're basically sunk and it has to a research capability that is not tainted by the pharmaceutical industry itself. And so to me what you've been saying is very helpful in sort of shaping that conclusion.

I want to give you both a chance to say is there anything that I've said that concerns you, troubles you or is incomplete? That was an effort to summarize sort of how, where my mind has been going as a result of what you've been saying and I don't want to take away a lesson that you didn't mean to convey.

Mr. CONTE. I think that we could have a formulary process, but I think we also could have access to any product on the market. And so they're not oxymorons. And the way to do that is to decide what clinically reflects the clinical care of most patients who are going to receive that benefit and then if patients want above and beyond, then you could just make the co-pay, make it co-pay, so if they want that particular product, then they could acquire it just with co-pay. Let's leave it open to allow any drug to be accessed, but do that through co-pay.

Mr. OGDEN. I hear what you're saying and absolutely, when I was the Chief of Pharmacy, how drugs came on the formulary, clinical people in that facility where I worked needed that drug for a particular reason and we would make a decision on putting a drug on the formulary based on cost, based on dosing, like you've heard and many times we made a decision to keep that drug and make it available for a specific clinical reason, an individual may be not able to take pills twice a day. Maybe that person needs—we can make exceptions. Give the purchaser the option to buy up if they want.

Mr. ALLEN. Mr. Conte, I have a smaller question and I just wanted to know and you may have covered it, but I missed it, if you could just talk about the impact on your facility of more veterans signing up for—to get the prescription drug category, veterans signing up for their prescription drug benefits. How big an influx have you had and how have you dealt with it?

Mr. CONTE. As Congressman Tierney knows, we were fortunate enough to enforce—John was working with us on this—and because of that our veteran population went from around 9,000 to 16,000 a year, so we've had a tremendous increase in veterans coming. Service has been good, yet it generates a large prescription volume. I would say we're probably going to expend just on volume alone. It doesn't increase costs. We have $2.5, $3 million in the budget for prescriptions for those patients that come in. That's really the impact, the volume of people coming to the VA because we do provide something more than just prescriptions. I think John's alluded to that. If you come to the VA system, we're asking you to join that system to provide continuity of care, not just prescriptions. I as a—my pharmacy had the honor—a friend of my is a physician—would not want to be just a writing service and not

have any responsibility, yet legally, he's responsible for the medical care of that individual by dispensing the prescription and/or writing that prescription. So when people come in to join our primary care clinic and then you become part of the VA system, so that alone also has impacted us because we need more staff to do that and I think you've talked about, someone on the committee talked about the funding mechanism where the VA system gives you a couple years later, so there's a lag in terms of that. We're constantly stressing the system trying to deal with those people who are on the waiting list, but it's had a major impact on the staff and I'm lucky enough that I have staff who is able to adapt and change.

The other thing is centralized mail out pharmacy. I mentioned it briefly. We've never been able to recruit pharmacists for other issues, partly pay. We'll stay out of that area, but the issue becomes how will you take care of this large volume to bring in new patients and this mechanism has helped us to do that.

Mr. ALLEN. Thank you very much.

Mr. TIERNEY. With the indulgence of my colleagues here and panel members, we're going to break protocol a little bit. If there's anybody out in the audience area that has a question for members of this panel or a question for members of the committee, provided that you're willing to share with us your name, we're willing to open the microphone to give you that opportunity for a brief period of time. We still have some time. And if we could get an idea of how many people might be interested in that opportunity, we'll be able to judge how much time each person would have. Is there anybody that today has a question, a comment? That saves us a lot of time.

I want to thank both of you, gentlemen, very much for your testimony. I'm sure that you'll be hearing from us and we'll try to work together. I thank Mr. Shays, again for his generosity, Mr. Allen for his work in the area. I thank all of you.

Mr. SHAYS. I thank the chairman, again for your encouraging us to come up here. I would just take the liberty to thank Michael McEneamy, State Administrator and Mr. Anthony Lopez, the Court Officer and Marilyn Franklin, the Court Reporter. I thank all three for their help and I obviously thank our staff for their work on both sides of the aisle, and again, thank you, Mr. Chairman.

Mr. TIERNEY. Thank you also and we'll look forward to working with you on this issue.

[Whereupon, at 12:30 p.m., the hearing was concluded.]