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PRESCRIPTION DRUG PRICE INFLATION:

ARE PRICES RISING TOO FAST?

TUESDAY, DECEMBER 8, 2009

House of Representatives,
Subcommittee on Health,
Committee on Energy and Commerce,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:39 a.m., in Room 2123, Rayburn House Office Building, Hon. Frank Pallone, Jr., [chairman of the subcommittee] presiding.

Present: Representatives Pallone, Dingell, Eshoo, Green, Capps, Schakowsky, Matheson, Harman, Barrow, Christensen, Castor, Sarbanes, Space, Sutton, Waxman (ex officio), Deal, Shimkus, Buyer, Pitts, Murphy of Pennsylvania, Burgess, and Gingrey.

Also Present: Representative Welch.

Staff Present: Brian Cohen, Senior Investigator and Policy

Advisor; Jack Ebeler, Senior Advisor on Health Policy; Karen Lightfoot, Communications Director and Senior Policy Advisor; Earley Green, Chief Clerk; Bruce Wolpe, Senior Advisor; Bobby Clark, Policy Advisor; Virgil Miller, Professional Staff; Jeff Wease, Deputy Information Officer; Erika Smith, Professional Staff; Katie Campbell, Professional Staff; Sharon Davis, Chief Legislative Clerk; Allison Lorr, Special Assistant; Lindsay Vidal, Press Assistant; Elizabeth Letter, Special Assistant; Mitchell Smiley, Special Assistant; Justine Italiano, Staff Assistant; Matt Eisenberg, Staff Assistant; Ryan Long, Minority Chief Health Counsel; Clay Alspach, Minority Counsel; Brandon Clark, Minority Professional Staff; Melissa Bartlett, Minority Counsel; and Chad Grant, Minority Legislative Analyst.

Mr. Pallone. The meeting of the subcommittee is called to order. And today we are having a hearing on "Prescription Drug Price Inflation: Are Drug Prices Rising Too Fast?" And I will first recognize myself for an opening statement.

Every day in America, a life is saved, an illness is averted, or the effects of a disabling condition are mitigated thanks to the innovative medicines produced by the pharmaceutical industry.

And I also think that it is important to mention the constructive role that the pharmaceutical industry and individual companies have played over the past few years amid various health care debates. The industry was an early and active proponent for the reauthorization and strengthening of SCHIP, which we were finally able to achieve earlier this year. In addition, I want to recognize their efforts to ensure comprehensive health reform is enacted this year. While I know that we all have not seen eye to eye on every issue, I appreciate the fact that the industry acknowledged very early on that they have a stake in making sure health-care reform succeeds and they are willing to make a contribution towards paying for it.

Unfortunately, for all the good the pharmaceutical and biotech industry do, it is often overlooked or eclipsed by reports of behavior designed to maximize profits at the expense of individual patients, employers, and American taxpayers.

Indeed, according to a 2008 public opinion poll conducted by the Kaiser Family Foundation, negative views of the pharmaceutical industry appear to be driven by perceptions about the cost of prescription drugs and pharmaceutical company profits. The Kaiser poll shows that seven in 10 adults say pharmaceutical companies are too focused on profits and not enough on helping people. And nearly eight in 10, 79 percent, believe that high profits are a major factor in the price of prescription drugs, and the same proportion feels that drug prices are unreasonable.

The poll further suggests that these opinions about prescription drug prices are driven by people's real-life struggles paying for drugs. Four in 10 adults report some serious problem paying for medication, either that it is a serious problem for their family to pay for drugs they need or not filling a prescription or skipping doses because of cost.

And new evidence suggests that prescription drug prices are increasing rapidly. Most recently, the New York Times reported on November 15th that drug prices had increased by approximately 9 percent over the last year. And, by at least one analysis, it is the highest annual rate of inflation for drug prices since 1992.

At the same time, general inflation, as measured by the Consumer Price Index, has fallen over the past year, which means that, while people are paying less for other types of goods and services, they are paying more for brand-name prescription drugs at a time when they are least able to afford to do so. And, as

you know, millions of Americans are out of work, millions are losing their homes, millions are without health care coverage. So it should come as little surprise that Members of Congress would be alarmed about the idea of drug companies raising prices at a time when so many of our constituents are already unable to afford the medical care they need.

Now, some researchers, including Dr. Schondelmeyer, who we are going to hear from today, has suggested there is a link between spikes in prescription drug prices and when there is legislation pending that impacts the pharmaceutical industry's bottom line, such as the various health-care reform bills currently moving through Congress.

I know that the pharmaceutical industry disagrees with this claim and has suggested that any increases in drug prices are a result of investments in research and developments that are necessary to keep new and innovative drugs moving through the pipeline. And I would be unfair if I didn't point out the industry -- you know, that this is not, you know -- how should I say it -- one broad stroke. I mean, there are companies that are increasing prices, and there are others that are not. But, according to Dr. Schondelmeyer's research, some drugs saw no increase, some increases were below the average, but other drug prices increased by almost 20 percent, such as Flomax, which appears excessive, in my opinion.

Furthermore, these surveys on drug prices are unable to

account for discounts and rebates provided by manufacturers to wholesalers or purchasers. Hence, there is a level of uncertainty that is inherent in these numbers, and that is why we are basically supportive of better price transparency. And when it comes to prescription drugs, I think that that is something that we really need, more transparency. And I have been advocating that for a long time.

I think that better reporting and more transparency will help us make sure that drug prices are not rising arbitrarily or to maximize profits and that every American has access to affordable prescription drugs. And that is a goal that we all share.

So we are here today to try to get to the bottom of this latest price increase. And we obviously have people that will be talking about some of the reports that have come out, and also from the industry. And so I want to thank our panel of witnesses in advance for being here today.

I do have to mention, though, that I know there is some issue with regard to Dr. Schondelmeyer because we just received his testimony this morning at 9:30. And I am very upset by that because the rules actually provide that we have to have the testimony much sooner. I think it is 2 days' notice. When we get it at the last minute -- you know, it literally is the last minute -- I know there are some Members here that are going to suggest that he shouldn't testify at all.

I was sort of inclined initially to say that, as well,

because I haven't had anybody that submitted their testimony so late. But I would ask -- I guess it is my prerogative to make the decision, and I am going to ask him to speak this morning, only because a lot of this hearing came about because of his initial survey. And I think if we don't have the opportunity to hear from him, the panel and the hearing this morning won't be as productive.

But I don't want to sound like a teacher chastising a student or something, but it is a problem when we get the testimony this late.

Mr. Shimkus. Would the chairman yield for 1 second?

Mr. Pallone. Yes.

Mr. Shimkus. Just trying to understand the historical aspect of this, did this happen last year with another health care briefing from Dr. Schondelmeyer, where we didn't get the briefing but all we got was a PowerPoint?

Mr. Pallone. You know, I am not sure. I know that -- look, let's be honest -- and I don't want to get into an argument with anybody, because I agree with you. Unfortunately, we are getting testimony late. Like, I know that one of your witnesses, I think we got it yesterday, which, you know, is not as bad as getting it at the last minute. But it is getting to be a pattern that, you know, we are getting some of this testimony a day earlier rather than 2 days. And so I think we need to be a little more -- I don't know what the word is -- tough on the witnesses and remind

them that we need it, you know, 48 hours in advance.

Mr. Shimkus. If the chairman would yield just for 1 more second.

Mr. Pallone. Sure.

Mr. Shimkus. It is my understanding that last year in the Government Reform Committee the same thing happened.

Mr. Pallone. I am just told he hasn't testified before.

Mr. Shimkus. And so my issue is, it is a pattern now. It is not a one-time mistake.

Mr. Pallone. Well, not in his case.

Mr. Shimkus. I am just making a point that it might be a pattern, and we ought to be a little bit more --

Mr. Pallone. Well, he has not testified before so I don't want to say that it is a pattern on his behalf.

But I do want to mention that it is important for both Democrat and Republican witnesses to try to get the testimony in, not just even 24, but 48 hours. The rules provide for the 48.

But, anyway, let me yield to our ranking member, Mr. Deal.

Mr. Deal. Thank you, Chairman Pallone. Thank you for holding this hearing on the cost of prescription drugs.

If the subcommittee is intent on addressing the high cost of pharmaceuticals, I believe that approval of the follow-on biologic legislation, which fairly balances consumer access with strong incentives to innovate, is essential to achieving this goal.

In 2007, global sales of these drugs reached \$75 billion.

Current estimates suggest that half of all drugs, both small- and large-molecule-based, will be biopharmaceuticals last year, while statistics further indicate that spending on biologic drugs is expected to grow 20 percent annually.

It is very disappointing that this committee, during markup of health reform legislation earlier, fell short on its commitment to achieve this goal. Unfortunately, provisions which aim to truly encourage competition, reduce cost, and, most importantly, increase access to critical drugs that currently fall out of the reach of countless Americans every day were not included as a part of the bill, as Chairman Waxman and I both tried to get done.

Instead of government price controls, which have a proven track record of declining research-and-development spending among those nations who have adopted it, appropriate incentives which spur research and development and enhance access to cutting-edge drugs is essential. As we all know, incentives to invest in R&D projects are highly dependent upon legislation this Congress puts into place. We must ensure appropriate provisions are put in place which continue to promote world-class pharmaceutical research and development in the fight for new cures here at home and abroad while ensuring continued access to these drugs by the American people. It is, indeed, a delicate balance.

I also look forward to AARP's testimony and appreciate the opportunity to discuss their decision to support H.R. 3962, particularly in light of significant cuts which are prescribed by

the legislation within the Medicare program. I look forward to learning more about the reasons that led them to endorse this health care bill, which, as Chairman Waxman and I would probably say, did not embrace some of the cost savings in the pharmaceutical area that perhaps it should have included.

Again, thank you, Chairman Pallone, for holding the hearing today. I yield back my time.

Mr. Pallone. Thank you, Mr. Deal.

Chairman Waxman?

The Chairman. Thank you, Mr. Chairman, for holding this hearing.

This is an important hearing. We are in the process of reforming health care, and one of our goals in doing so should be to hold down costs.

Well, our economy is in a slump. The Consumer Price Index has actually gone down. Yet, for pharmaceutical prices in the last year, there has been a 9 percent increase. I must say that, when it comes to prescription drugs and the drug industry, nothing surprises me anymore, but increases of this magnitude is really pretty shocking.

Our Nation sees that when drug prices are raised by 9 percent or more over a year, that increases the out-of-pocket cost for drugs, it drives up insurance premiums, it increases the cost of the Medicare D program, means more and more citizens -- some with insurance, some without -- are forced to go without the drugs they

need to remain healthy.

And reports indicate that this problem is getting worse, not better. The drug price increases over the last year are the biggest we have seen in a very, very long time. It is hard to escape the conclusion that the industry is positioning itself -- positioning its pricing for enactment of the new health reform legislation. They were met with great acclaim when they announced with the White House and the Senate that they were going to take an 80-percent reduction in their the profits over the next 10 years, \$80 billion. Well, a 9 percent increase in prices over this last year comes to \$20 billion that they are getting in just 1 year. So let us keep this in perspective.

When Americans hear about these soaring drug prices, they are absolutely right to demand to know what Congress is doing about it. In the House, led by members of our committee, we are trying to tackle this problem. Last month, the House passed historic health-care reform legislation, and I am confident the Senate is going to follow our example in a very short period of time.

In our legislation, we provided that health insurance, including drug coverage for 36 million citizens who would be otherwise without it, and we closed the Part D donut hole, meaning that seniors would no longer have to stop taking drugs when their coverage runs out. What we did in the pharmaceutical area is that these companies will not just get a blank check as we form our health care system. We tried to strike an important balance that

put consumers and taxpayers first.

We require the drug industry to provide additional discounts for the Medicaid program. We end the multi-billion-dollar windfall that the industry received when dual-eligible enrollees were switched from Medicaid to Medicare Part D drug coverage. We are requiring that discounts be provided when the government pays for low-income people to get health care coverage.

The House bill uses this money that would otherwise go to the drug companies to help millions of Americans afford health care coverage and to close the Part D donut hole. That is a good policy outcome. It is good for America, and it is the right prescription for PhRMA.

The drug industry made over \$50 billion in profits in 2008 -- \$50 billion in profits. Some of that went to increase their research and development. Most of it -- or let's put it this way -- more of it went to marketing drugs than into R&D.

So when we look at a drug price increase of 9 percent over the last year, it is the highest increase in recent memory. And as we try to climb out of our massive recession, as more and more Americans struggle with the loss of health care coverage and high insurance costs, everyone has to pay more costs for drugs. This is not right. We can't afford it.

The drug companies are playing a shell game when they tell us they are going to take reductions in government expenditure, yet they are going to get millions of new customers paying for drugs,

and yet what we see is, at the same time, they are increasing their drug prices at a record rate. I hope this hearing will help us inform the people who are working on health care reform so that we don't let them get away with this blank check.

Thank you, Mr. Chairman.

Mr. Pallone. Thank you, Chairman Waxman.

The gentleman from Illinois, Mr. Shimkus.

Mr. Shimkus. Thank you, Mr. Chairman.

And I do appreciate the chairman of the full committee's letter requesting a CBO analysis. I just wish we had that in hand prior to having this hearing, which bespeaks of the timing of this hearing for the purposes of whatever the majority wants to deem without having a proper analysis.

Having said that, Medicare D has been one of the most successful Federal health care programs. Originally scored in first-year costs at \$49 billion; it came in at \$41 billion. Overall, since its inception, it is 40 percent under projected cost. Seniors have more choices.

And it is a distinct difference in the direction that we are heading in 3962, where Medicare D incentivizes private insurers to provide access to prescription drugs so people can choose, and you let the market work, which is just the opposite of what we plan to do when we eventually move to a government takeover of health care in 3962.

Every health care hearing that we are going to have is going

to be, as the chairman of the full committee says, in the parameters of the health care bill that is moving through both chambers. And rightly it should be. So there will be a lot of great questions because of the calling of this hearing, and we look forward to discussing those.

Let me end on just talking about comments made last week which was disparaged but was been proved correct by a paper called The Californian. Last week we had the breast cancer decision from 40 to 49. And a lot of us said, this will start the road down to the government making determinations based upon cost. And the headline here, "State Ends Subsidy for Mammograms to Low-Income Women Under 50." And they also say, "The State's decision, announced December 1st and effective January 1st, follows a controversial Federal recommendation last month that mammograms before the age of 50 are generally not needed. However, the private health care system has rejected the Federal task force recommendations."

So here you have the public health agency say, we are going to accept these to save costs; the private insurers are going to keep them, which is an incentive for us to stop disparaging private insurance and really be concerned about government-run.

Here is what Dr. Klausen says. "What makes me really worried is that the California Department of Public Health wants to save money by taking away a cancer detection program," Klausen said. "That discriminates against a gender, also discriminates against

an income level, and it also discriminates against how community clinics can practice medicine."

That is the road we are heading. I reject this path. It will be harmful to public health. And we will get a chance to ask questions of those people who are in the room, the closed-door meetings with the White House and other leaderships, on their role in H.R. 3962.

And I yield back my time.

Mr. Pallone. The gentlewoman from California, Ms. Eshoo.

Ms. Eshoo. Thank you, Mr. Chairman, for holding this very important and timely hearing today.

Like most of my colleagues, I, too, am very concerned to see reports of artificially increased drug prices on the heels of a promise made by the drug manufacturers to decrease prices for consumers.

Last month, the AARP released a study which found brand-name drugs increased by 9.3 percent, the highest drug inflation since 2002. Just a few months earlier, a much-touted announcement by the White House and PhRMA promised \$80 billion in savings on drug costs, most notably to help seniors who are struggling to pay for medications in the donut hole.

At a time when everyone in the health care industry is being asked to put something on the table to contribute something to the reform effort, the drug companies were some of the most vocal in touting the, quote, "sacrifice" they were making for the cause of

health-care reform.

Last April, IMS predicted that drug sales might actually go down. But IMS Health, a consulting firm paid for by the drug companies to advise them, reported a significant increase in prices.

I certainly understand the need to couple profits with innovation in order to promote science and encourage new therapies and treatments. I think that that is essential, not only to advance what we want to advance but that we retain an American position where we are first in the world, because our people benefit from it. But, as I understand it, the House PhRMA agreement called for reduced drug costs to support comprehensive health-care reform and not discounts from jacked-up prices.

I know that we are going to be hearing from PhRMA, who I understand will testify that reports of rapidly increasing drug prices are false and that the increase was based solely on the listed price of drugs, not the discounted prices most Americans or the government pay. I am eager to hear their explanation and be able to report these explanations back to my constituents, if they are worthy of being reported, if they really hold something.

I am also eager to hear from AARP, which fueled much of the drug pricing debate with their recently released report. As both an interest group for seniors and an insurance company, their report may have different implications.

I would just like to add, too, that the gentleman from

Georgia made some comments about biologics. And I know that he is not pleased with the outcome of what is in the bill. I do believe very, very firmly that by treating biologics in a new way, bringing them into biosimilars, that this will make biologics -- move them into generics. And, thereby, more and more Americans will be able to not only afford them, but that that pathway is a very robust one, a smart way to go.

I don't want to lose this to other countries. I think that America is in a position today where it can ill-afford that. And, most frankly, we have two major biologics companies today. We have to do this the right way so that this can reach patients. And it really represents, I think, the most hope in medicine. Because, as good as pharmaceutical drugs may be, they only treat symptoms, they don't go to the cause of a disease. So biologics are really where the most hope lies.

So I thank you again, Mr. Chairman, for holding this hearing. I look forward to the testimony, the important testimony of the witnesses. And I yield back.

Mr. Pallone. I thank the gentlewoman.

The gentleman from Indiana, Mr. Buyer.

Mr. Buyer. I thank the chairman for the hearing today.

And I don't mind receiving input from anyone, at this point, because there is such great uncertainty out there, especially regarding your very aggressive health agenda. And it is an agenda that I think is on the verge to hurt the industry and which we are

going to discuss here today, and there, in turn, hurting the health of America and to the world.

I think it is important to look at what we know about drug prices and their relationship with regulations, such as price controls, which are supported by the majority. It is what is included in their health reform legislation that was passed by the House and is being debated by the Senate.

What we ought to be doing is we ought to be looking at the effect of price controls. And we can look at the model that is by European countries between 1986 and 2004. During this time, these countries strengthened their price controls, and the controls had a devastating impact upon research-and-development spending. And all of that investment then began to shift to America.

Before the strident price controls were implemented in the mid-1980s, spending in Europe for research and development of the new life-saving drugs exceeded that of the United States by 24 percent. By 2004, spending in Europe on research and development of drugs trailed the United States by 15 percent. So what did this dramatic decline in research-and-development investment in Europe amount to? Well, they have 50 fewer new drugs approved in Europe and about 1,700 fewer scientists employed in Europe.

Europe's pharmaceutical industry research and development grew at merely one-half of the rate of that here in the United States. As economists John Vernon and Joseph Golec found, quote,

"Whereas European Union firms introduced about twice as many new medicines as U.S. firms between 1987 and 1991, they introduced about 20 percent fewer than U.S. firms between 2000 and 2004."

So here we sit, with potential price controls that will be similar to Europe. I think America ought to pause -- actually, I think America ought to wake up. Because there is a wave of socialism that is truly coming to the shores of America. And we better wake up.

Now, all of us either have friends or someone or a family member that has a narrow disease. So when you think of types of narrow disease -- adenoid cystic carcinoma, Alpers' disease, Bell's palsy, Dandy-Walker malformation, Hodgkin's disease, sickle-cell disease, sudden infant death syndrome -- there is a very long list. And so, what is the demand when someone has a narrow spectrum of a disease? Well, they want the pharmaceutical companies to find that drug that can help.

Well, if it is very narrow and there is not any ability to have a profit, what is the incentive for industries to go? So government tries to provide the incentive. If we are going to wipe out and move to price controls and wipe out incentives in R&D, then many of these disease groups, people are going to be left on the outside. And that is not how we define compassion for public health for America.

I yield back.

Mr. Pallone. Thank you.

The gentleman from Texas, Mr. Green.

Mr. Green. Mr. Chairman, thank you for having this hearing on prescription drug prices.

We have seen many reports on the high cost and rising prices of prescription drugs. The most recent report released by AARP Policy Institute in November found that, between October 2008 and September 2009, the brand-name drug prices increased 9.3 percent, the highest drug inflation since 2002. Prices for specialty drugs used by Medicare beneficiaries increased even more, by 10.3 percent. Over the same time, prices for generic drugs declined by 8.7 percent. The high cost of these prescription drugs has an impact on Medicare, due to the increased taxpayer expenditures and increased premiums.

I am also concerned that every member of this committee has heard from seniors in their district who are enrolled in Medicare Part D who have fallen into the donut hole, which is a result of the Medicare Modernization Act of 2003. This forced Medicare Part D enrollees to pay 100 percent of drugs between \$2,700 and \$6,154. Each year, 4,400 seniors in our district hit the donut hole and are forced to pay their full drug costs despite having Part D drug coverage.

Throughout the country, seniors pay thousands in out-of-pocket expenditures they are unprepared for with fixed incomes. The donut hole often causes seniors to choose between purchasing medication and food, which is not something they should

ever have to do. This is not the kind of benefit seniors deserve, and it needs to be corrected by Congress.

The House passed a health reform bill, H.R. 3962, which makes several major changes in prescription drug programs to ensure seniors and low-income individuals receive the prescription drug medication they need at an affordable cost. H.R. 3962 increases current Medicaid drug rebates that manufacturers pay to the government and closes a program loophole that prevent full rebate payments.

It also ensures the drug prices for dual-eligible and other low-income enrollees are no higher for Medicare Part D than they are under Medicaid. H.R. 3962 reduces the donut hole by \$500 immediately and institutes a 50 percent discount for brand-name drugs in the donut hole upon passage. It actually eliminates that donut hole over a period of years by 2019.

The legislation gives the Secretary of HHS the ability to negotiate with pharmaceutical manufacturers to get the best deal possible for Medicare Part D beneficiaries. This allows the Secretary to obtain large discounts and rebates on drugs used by seniors, passing on that savings to Part D enrollees and to the taxpayers.

The Senate is working on their health care bill right now, but their bill does not allow the Secretary to negotiate the lower Part D prices and does not create new Part D drug rebates and does not close the Part D donut hole. If we want to make real

health-care reforms, we must address the problems that exist in Medicare, particularly those that cost our seniors thousands of dollars each year.

And, again, I want to thank the witnesses and appreciate them for appearing before our committee, Mr. Chairman.

Mr. Pallone. Thank you.

The gentleman from Georgia, Mr. Gingrey.

Dr. Gingrey. Mr. Chairman, I will waive my opening statement in the interest of having more time for questions. Thank you.

Mr. Pallone. Thank you.

Our vice chair, the gentlewoman from California, Mrs. Capps.

Mrs. Capps. Thank you, Chairman Pallone, for holding this hearing on such a timely and urgent situation.

As we move forward with health-care reform efforts, we need to ensure that we aren't just providing access to health care services in theory, but we need to actually make it affordable, both for individuals and for the government. With prescription drugs accounting for 10 percent of medical expenditures, it is imperative that we assure affordability for the people who rely on them.

I am particularly concerned with the impact of rising drug costs on our seniors, who, for the most part, live on fixed incomes. I am sure all of our colleagues have heard from constituents who have literally had to decide each week between medication and groceries because the costs are so prohibitive; or

other constituents who decide to take only half of their prescription, their dosage, because they can't afford to pay for the entire amount.

While there are assistance programs to help individuals pay for their medications, they aren't always reliable, and they don't always apply to the particular medication that the senior needs. And that is why it is so important that we have this hearing today to look into the possible reasons for the rapidly increasing costs of medication.

I certainly understand that drug manufacturers must recoup the expensive costs of research and development. But, at the same time, isn't it unconscionable for us to be watching as drug companies' profits rise the way they are, while more and more of their patients with chronic disease lose their ability to afford life-saving medications? I look forward to hearing our witnesses' thoughts on why these price increases are occurring and how we can address the costs as we move forward.

And I yield back. Thank you.

Mr. Pallone. Thank you.

The gentleman from Texas, Mr. Burgess.

Dr. Burgess. Thank you, Mr. Chairman.

I am sure if there are people watching this hearing this morning, they are wondering what in the world is the purpose of what we are doing here this morning. If it is to answer the question, "Are prescription drug prices rising too fast?" then

they probably have a couple of concerns.

And the first is, why have we not waited until the report requested by Chairman Waxman from the General Accountability Office on this very question was received? We really can't debate the proper increase in prices, what they should look like, until we know the facts -- not the facts as reported by the New York Times or an advocacy group with a policy agenda, but that provided by an independent entity which has the responsibility of providing Congress with information.

And the second concern is, why in the world did we not initiate this in the Subcommittee on Oversight and Investigations where we have subpoena power if necessary and can take testimony under oath? If the concern is that prices are being manipulated and causing harm to Americans on programs under this committee's jurisdiction, then that would seem to be the natural place to hold that hearing.

Maybe this is all about that monstrosity of a bill that we passed late in the night a couple of Saturdays ago. Again, it is just hard to know. But you do have to ask the question, where is the General Accountability Office, where is the Congressional Budget Office, where are the actuaries at the Center for Medicare and Medicaid Services that could make sense of some of this for us? None of those people are testifying today. Mr. Chairman, why is that?

Now, I know some people look at drug prices and say, "All

drug companies are evil, and they shouldn't make a profit, and we need to take those away from them." This government's history, in the past year, of manipulating in the market is wrong on so many principles. I don't think we should encourage that type of behavior in this committee today.

But you know what we really don't know? If this manipulation does exist, what part of it was fostered by those secret negotiations that occurred down at the White House in May and June? And why has this committee had absolutely no curiosity about what was going on in those secret negotiations in May and June? And why is it that so many of these things were stumbled upon in the workup of the legislation in this committee and on the Senate Finance Committee? Why is it that pharmacy prices can't be changed? Why is it that the American Hospital Association has some of the things that it has brought to the table that are judged to be pretax? What other deals were struck? What deals with the AMA? What about AHIP? What about the Service Employees International Union?

We know nothing about that because this committee has had no curiosity about what might have been happening down at the White House under the cloak of darkness. This was supposed to be a transparent process available to the American people on C-SPAN from start to finish. And we can't get the most basic information about what was given up and what was given away during those secret negotiations in May or June.

Now, we can also do a lot of stuff on Medicare Part D. I have to tell you that the fact that we decided in 2006 to work with the market rather than dictate to the market has been responsible for a significant amount of success in the Part D program.

But I suspect we will hear some of the same arguments that we have heard for years about why that program is not working, despite the fact that 90 percent of Americans aged 65 and over have access or have prescription drug coverage today compared to 75 percent before we started in 2004 and that the satisfaction with that program is at an all-time high. I am not going to say that the program can't be improved, but it has worked and it has exceeded expectations. And I think we need to be careful before we start tinkering around the edges with that program.

Thank you, Mr. Chairman, for holding this hearing. And I yield back.

Mr. Pallone. Thank you.

The gentlewoman from California, Ms. Harman.

Ms. Harman. Thank you, Mr. Chairman, for holding this hearing.

Let me say to Dr. Burgess that I sat through the tens of hours of markups of the health care bill, and I heard people on our side complain fiercely about the so-called deal that the White House struck with PhRMA, the \$80 billion deal. And I remember voting for parts of the health care bill that were reported by

this committee that scuttled that deal and that required, for example, negotiations for better drug prices under Medicare Part D. So I think whatever it is that the White House did, I want to applaud this committee for looking independently at some of those deals.

And I think the reason we are here today is because we are still enormously concerned about the escalation in drug prices. According to the AARP, the wholesale prices, not the retail prices, of brand-name drugs have risen by 9.3 percent in the last year, the highest annual increase since 1992. And this comes at a time when the Consumer Price Index has dropped by 1.3 percent.

As we head into the holidays and people are strapped to buy anything for their families over the holidays, I think it is just unconscionable and immoral that a basic necessity of life, which is drugs, is having this unexplained escalation in prices.

We already spend nearly \$300 billion a year on prescription drugs. It is one of the fastest growing areas of health-care spending. And, frankly, since the very beginning, I have maintained that reducing the cost of prescription medications is the one reform that will have the biggest impact on people.

So I am very glad that we are holding this hearing. And I just want to say to our witnesses and to others who are looking at this problem that consumers are watching, and right now what I think they are seeing is price gouging.

I yield back.

Mr. Pallone. Thank you.

The gentleman from Pennsylvania, Mr. Murphy.

Mr. Murphy of Pennsylvania. Thank you, Mr. Chairman.

This is a hearing that we have long awaited, as with many other hearings of this type, to find out accurate information with regard to pharmaceutical companies and what they do. I am particularly concerned here about making sure that we are not having hearings on why drug companies are not inventing drugs to cure disease. That would be a sad state of affairs, indeed.

Many of my constituents are senior citizens, and we know they struggle to pay their high medical bills. We know that we have had opportunities, sometimes squandered, with regard to how we could reduce medical bills by reducing costs of health care through preventative services, through making sure that we maintain disease management, by making sure we reduce waste in health care.

However, one thing we don't want to do is eliminate drugs that can help cure problems. After all, drugs that are not affordable offer little consolation, and a drug that is not invented offers little cure. And, as a combined thing, we have to make sure this committee does not stand in the way of coming up with those cures.

It is easy to go after companies that make money -- oil companies, pharmaceutical companies, anybody else who makes a profit -- as a for-profit or nonprofit company and say that they

should not be making that kind of money if the cost is passed on to the consumer. I understand, and we need to be sensitive to that area and make sure that these prices of any item is not inflated to the point that people cannot afford them.

However, it is also important that this committee, nor this Congress, nor this country stands in the way of coming up with these cures to treat diseases. There was a -- certainly, other things that we have done here. We have looked after the consumers. We want to make sure we continue to look after the consumers and making sure that these are things that they have.

Generic drugs also are a critical function. They have grown massively in their use. They provide some good choices for people. And we need to continue to support generic drug use. However, they are not involved in the research-and-development sector, and we have to make sure that the research and development continues on.

Congress funds much of that through NIH, through NIMH, through a lot of studies that take place, and we need to continue to do that, as well. And somehow we have to look at how combining these efforts to fund research and development, to fund all levels of research continue on so that this country leads the way in coming up with ways that we can find affordable prescription drugs.

And, to that end, I am looking forward to hearing the testimony of the panelists here and seeing if they can offer us

some solutions that is based upon how we can maintain this search for cures as well as search for affordable costs.

I yield back.

Mr. Pallone. Thank you.

The gentlewoman from Illinois, Ms. Schakowsky.

Ms. Schakowsky. Thank you, Chairman Pallone. I appreciate your having this hearing today to better understand why prescription drug costs are rising exponentially at a time when millions of Americans are struggling to make ends meet.

I assure you my constituents applaud the fact that we are having this hearing today. A recent AARP survey of Illinois seniors confirmed the concerns that I hear from my constituents every single day. Sixty-three percent of AARP members in Illinois said they were concerned about affording their prescription drugs. Close to 20 percent reported having to cut back on necessities to pay for prescriptions. Twenty-one percent reported not filling or delaying a filled prescription because they simply couldn't afford it. And one in five said they took less than the prescribed amount to make their medicines last longer.

Facing a severe budget deficit, our State took the bold step of expanding its prescription drug program, called Illinois Cares Rx, designed to benefit seniors and people with disabilities. When asked about the reason for the expansion of the Illinois -- when asked for a reason, we asked Barry Maram, who is head of the Illinois Health Care and Family Services Division, and he said,

quote, "The cost of prescription drugs has escalated to the point of being unaffordable for many of the people who rely on them most, especially seniors and people with disabilities. No one should have to go without medication that keeps them healthy," unquote.

The cost of brand-name prescription drugs are rising at a pace that far exceeds price increases for other consumer products. My constituents, both as consumers and as taxpayers, want to know whether the pharmaceutical industry is preparing for health-care reform by trying to squeeze every bit of profit they can now.

Health consumers are desperate for health-care reform, and there are many provisions in H.R. 3962 that would lower drug prices, including the language that I had the honor of offering to this committee to eliminate the ban on Medicare negotiating for drug prices. But they can't afford to have the drug industry use the time between now and the implementation to artificially raise prices and profit at their expense.

Again, I thank you, Mr. Chairman. And I yield back.

Mr. Pallone. I thank the gentlewoman.

Next is the gentlewoman from Ohio, Ms. Sutton.

Ms. Sutton. Thank you, Mr. Chairman. And I appreciate you holding this hearing today.

I would like to be able to say that I am shocked that we are here talking about this, but, sadly, I am not. Americans pay the highest drug prices in the world. We pay between 35 percent and

55 percent higher than people in other developed countries. And we have been paying these exorbitant prices for a long time. Drug prices account for 10 percent of all health-care spending.

Over the past year, we have been working hard in this committee and in Congress to make health care more affordable for families, businesses, and individuals. And the "Affordable Health Care for America Act" health care bill contains a number of initiatives aimed at curbing the out-of-control drug prices for America's families and seniors.

And yet, during this period, drug companies increased prices by over 9 percent at a time when inflation was negative. Increased drug prices hurt us all. They hurt older Americans on fixed incomes, who saw their drug bills increase by \$550 last year. They hurt people who have insurance and who now have higher co-pays. They hurt taxpayers and the government, who are now paying higher drug prices. And, more than anyone else, they hurt the uninsured, who do not have anyone to negotiate on their behalf.

There is something wrong when Americans are paying record-high drug prices and drug companies are reporting such high profits. The CEO salaries at some of the largest drug makers are evidence enough that something is seriously wrong. At Abbott Laboratories, the CEO made over \$28 million last year. At Merck, the CEO made over \$25 million. And at Pfizer, the CEO made over \$15 million.

And it does not end there. Drug companies often claim that they must charge higher prices in order to fund research and development for new drugs. But the truth is, drug companies spend more on advertising than they do on R&D. It is time for some answers. It is time for the drug companies to explain why they are raising prices, especially right now.

And I yield back.

Mr. Pallone. Thank you.

The gentleman from Pennsylvania, Mr. Pitts, waives.

The gentleman from Georgia, Mr. Barrow.

Mr. Barrow. Thank you, Mr. Chairman. I will waive.

Mr. Pallone. Thank you.

I think that concludes our opening statements from the Members, so we will now turn to our witnesses. We have just one panel today, and I would ask the panel to come forward at this time.

Welcome. And thank you for being here today.

Let me just introduce each of you. Starting on my left is Professor Stephen Schondelmeyer, who is professor and head of the Department of Pharmaceutical Care and Health Systems and director of the PRIME Institute at the University of Minnesota. Second is Mr. Rick Smith, who is senior vice president for policy, research, and strategic planning at PhRMA, which is the Pharmaceutical Research and Manufacturing Association. And then we have Kathleen Stoll, who is deputy executive director of Families USA. And Dr.

John Vernon, who is a professor, Department of Health Policy and Management, at the University of North Carolina at Chapel Hill, and he is a faculty research fellow with the National Bureau of Economic Research. And finally is Ms. Bonnie Cramer, who is Chair of the Board of Directors of AARP.

Thank you all for being here today. We have 5-minute opening statements. They become part of the record. And you may, of course, with our discretion, submit additional statements in writing. And you may get some additional questions after the hearing, too, to respond to in writing.

And I will start with Dr. Schondelmeyer.

STATEMENTS OF STEPHEN SCHONDELMEYER, PROFESSOR AND HEAD,
DEPARTMENT OF PHARMACEUTICAL CARE AND HEALTH SYSTEMS, DIRECTOR,
PRIME INSTITUTE, UNIVERSITY OF MINNESOTA; RICHARD I. SMITH, SENIOR
VICE PRESIDENT FOR POLICY, RESEARCH, AND STRATEGIC PLANNING,
PHARMACEUTICAL RESEARCH AND MANUFACTURING ASSOCIATION; KATHLEEN
STOLL, DEPUTY EXECUTIVE DIRECTOR, FAMILIES USA; JOHN VERNON,
PROFESSOR, DEPARTMENT OF HEALTH POLICY AND MANAGEMENT, UNIVERSITY
OF NORTH CAROLINA AT CHAPEL HILL, FACULTY RESEARCH FELLOW,
NATIONAL BUREAU OF ECONOMIC RESEARCH; BONNIE CRAMER, CHAIR, BOARD
OF DIRECTORS, AARP

STATEMENT OF STEPHEN SCHONDELMEYER

Mr. Schondelmeyer. Thank you, Mr. Chairman.

And my apologies for being late with my testimony. I was rather pressed with time and short notice on this particular hearing.

I am here to speak on my own behalf as a researcher and one who has studied this marketplace for more than 30 years. I am not here representing AARP or even the University of Minnesota other than the fact that I am a professor there and that is where I do my research.

And, also, let me comment that the Medicare Part D drug program has expanded coverage for prescription drugs for people

who would not otherwise have had such coverage, and it has provided many benefits, and we have made some progress in that area.

Realizing that drugs and drug prices and drug expenditures were an issue, the AARP and others, such as myself, researchers in the marketplace, determined that we need to, kind of, follow the advice, for example, of President Reagan when he said, with respect to nuclear disarmament, "Trust and verify." One, let's trust that there is a reason for the price changes, but let's track them and see what they are and report that and reflect those price changes in the marketplace. And so, individuals at the AARP Public Policy Institute had an interest in tracking drug prices, and I had been doing that for a number of years in the marketplace, and we decided to get together and collaborate.

That collaboration has led to a series of studies of drug prices over the last 5 or 6 years with AARP, one of which was the study that got reported in the New York Times back about a month ago. The details of that study and how we conduct our reports can be found in the reports that are available on AARP's Web site. And so the detailed methodology, I would refer you to those reports rather than take time today to go through them, but I would be happy to answer any questions.

Just to put it in perspective, though, we used actual Medicare Part D prescription data and identified the most frequently prescribed, the highest expenditure drugs, and the

drugs that accounted for the most days of therapy. And, with 548 individual drug products in our market basket, we were able to account for over 81 percent of all prescription expenditures under Medicare Part D, over 79 percent of the prescriptions dispensed, and over 91 percent of the days of therapy. So this market basket represents virtually all of the Medicare Part D market with the exception of a very small set.

The data that we use is a price called the wholesale acquisition price. And let me remind you that wholesale acquisition price is a price that is set by the manufacturer and reported to the price databases such as Blue Book, Red Book, or Medispan, and these prices are the manufacturers' set price. On the one hand, even the wholesale acquisition cost is, in a sense, a type of a list price, but this list price very directly affects the price that is paid for prescription drugs at the retail level for virtually all third-party programs in the U.S., including the Medicare Part D plan which is in the private market as well.

So let's get down to the meat. What has the trend been for prescription drug prices in the past year? And here we are comparing prices from October of 2008 up through September of 2009, so I am talking about annualized prices, a 12-month period. And we use a rolling average which actually levels out and actually pulls down, in some cases, the price increase that is reported.

Brand-name drug prices -- that is, largely patented

single-source drugs -- increased on average from this Medicare market basket 9.3 percent in the 12 months ending in September 2009. That 2009 increase of 9.3 percent was the highest that we have seen in at least 7 years prior to this for that same market basket of drugs. The previous years, we saw 5.3 to 8.7 percent increases, nothing to brag about, but now we are up to 9.3 percent.

The average cost of just one brand-name medication if a patient is taking it on a chronic basis would be over \$2,000. And this 9.3 percent increase then means that the individual taking just one chronic medication experienced a \$200 increase in the cost of that medication last year. The average elderly person is on two to three medications, so they would have experienced a \$400 to \$600 increase in expense.

Ninety-six percent of the brand-name drugs that we tracked experienced a price increase. None had a price decrease.

The annual price increases of individual brand drugs that were notable -- and there were many, and I will only give a few examples: Ambien CR, a heavily advertised drug, increased 20.8 percent; Aricept, an anti-dementia drug with generic competition, increased 17.2 percent; Zetia, a drug with a questionable value and efficacy, increased 14.3 percent; Nexium, a heavily advertised drug with a patent until 2020, increased 7.1 percent.

That is brand-name drugs. We also pulled out specialty drugs. These are often the drugs you are talking about in terms

of biologicals or biosimilars. Not all of them are, but the vast majority of specialty drugs are biologicals. The biologicals and specialty drugs experienced a 10.3 percent average increase in 2009. And there, we can look -- for example, the drug Betaseron, used for multiple sclerosis, had an increase of 28.2 percent.

There were five drugs -- actually, four drugs and five different presentations of those drugs in our market basket. All five of the multiple sclerosis drugs increased more than 17 percent, ranging from 17.5 up to 28.2 percent increase in price. There were 12 cancer drugs in our specialty database. They ranged from a low of 4.9 percent up to 20.8 percent. And, again, remember, inflation overall was negative last year.

The bright spot is we also tracked generic drugs, and generic drugs actually went down 8.7 percent. This is one of the few --

Mr. Pallone. I am going to ask you to summarize because you are, like, a minute and a half over.

Mr. Schondelmeyer. Okay, I will.

Generic drugs are one of the few sectors that truly has a marketplace and has economic competition, and generics have continually gone down in price. The question isn't what do we use to measure price inflation, the Consumer Price Index for Rx drugs or the AARP index? Each of them provides information that is unique and different. Our index was created to show the difference between brand names and specialty and generic, not just the aggregate index. And my full report -- and I would be glad to

answer in questions the role that rebates and discounts that other methodological issues have in how we viewed this.

The bottom line, though, is the average senior last year got a zero percent cost-of-living increase for Social Security income.

RPTS CALHOUN

DCMN MAYER

[10:36 a.m.]

Mr. Schondelmeyer. They experienced an 11 percent increase in the premiums they had to pay for their Part D plans. That is for the drug benefit plan. They also face a 9.3 percent for brand name and 10.3 percent increase for specialty drugs. The only bright spot there is the 8.7 decrease in generic drug prices.

These prices are real. They are felt by your constituents.

Mr. Pallone. Thank you.

[The prepared statement of Mr. Schondelmeyer follows:]

***** INSERT 2-1 *****

Mr. Pallone. Mr. Smith.

STATEMENT OF RICK SMITH

Mr. Smith. Thank you, Mr. Chairman, Ranking Member Deal, members of the committee; thanks for the invitation to testify today.

CBO reports that the pharmaceutical research sector is one of the most research-intensive industries in the United States. Companies' investment in discovering new medicines is yielding results. Also, according to CBO, many examples exist of major therapeutic gains achieved by the industry in recent years. The rapid increases that have been observed in R&D spending have been accompanied by major therapeutic gains. Extensive research also reports that medicines often reduce spending on other health care services.

The committee requested that I provide information on prescription drug pricing. As a trade association, PhRMA maintains a strict antitrust compliance policy. We can neither obtain nor discuss our members' proprietary information related to prices, negotiations, or discount strategies. My testimony, therefore, reflects only aggregate market data and publicly available information.

Recent government reports demonstrate that prescription drug

cost growth has slowed dramatically. Findings about drug costs in the government's most recent national health expenditures data are summed up in the CMS report's title, national Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998.

According to CMS, prescription drug cost growth in 2007 was 4.9 percent, the lowest rate since 1963, and slower than health care overall. 2007 was not a 1-year blip; between 2003 and 2007, the average annual growth rate for prescription medicines dropped by half compared to the 1998 to 2002 period, and CMS's most recent 10-year projection reduced expected growth in prescription drug spending by \$515 billion, or 14 percent, compared to 3 percent for the rest of health care. Likewise, CBO reports, from 2004 to 2007 drug expenditures grew by an average of just 3.2 percent per year, slightly less than the rate of growth in overall health care spending.

Since 1964, IMS Health has found that the U.S. market grew by less than 5 percent only twice -- 2007 and 2008 -- and it now projects that growth will remain at historically low 4.5 to 5.5 percent in 2009, and will be 5 percent or less in each of the next 5 years.

At the same time the drug cost growth has slowed sharply; reports like those issued by AARP reach conclusions that conflict with government data and is skewed toward finding high price growth. These reports exaggerate drug price trends by failing to

reflect the way public policy and the prescription drug market function. Our system is designed to fund the next generation of medical advances through innovator drugs that have a limited time on the market before going generic and to achieve cost savings through the high use of generics. Large, powerful payers use a variety of tools such as tiered formularies to negotiate lower brand prices while driving high use of generics, which now account for about 70 percent of all prescriptions.

We don't believe that each tool used by a purchaser always yields the best possible outcome, and we are encouraged by forward-looking purchasers who are looking at alternatives that make better use of medicines to improve care and control costs. Nonetheless, under the current system, drug costs as a whole are growing slowly, not fast, and consumers use drugs that were once innovator molecules as generics in large volume for many years with little or no return to the innovator.

The importance of understanding how the market operates when interpreting pricing data is evident in AARP's most recent report. Eight of the drugs on AARP's list of the top 25 brand drugs are sold as generics. These drugs are counted in AARP's brand price calculation as though patients continue to use them at brand prices, even though brand drugs typically lose nearly all of their sales after going generic.

In one example, for a statin, 99 percent of the utilization for that statin on AARP'S list of top-used brand drugs is now

generic, and the cost per day of therapy has dropped by 58 percent over 3 years, not reflected in the AARP report.

The Federal Government CPI data on prescription medicines includes a market basket of brand and generics that reflects what consumers actually buy. In the 3 years ended October, 2009, drug prices rose by an average of 2.3 percent per year, compared to 3.8 percent for all medical care. For the most recent year, the government's measure of drug price growth was 2.7 percent.

The implicit message of reports on brand prices seems to be that the pharmaceutical research companies stand to be in a uniquely favorable position. In fact, the sector is currently characterized by slow growth, rapid substitution of generics for brand medicines, a projected \$90 billion in sales facing generic entry over the next 5 years, and the exceptional challenges inherent in discovering new medicines that safely and effectively treat disease.

Through October of this year, 58,000 job cuts have been announced in the industry, on top of cuts in 2007 and 2008. Nonetheless, there is reason for optimism that new medicines will continue to improve medical care in the future. Investment in pursuing these objectives accounted for by the 10 percent of health spending going to medicines is repaid to society in longer, healthier, more productive lives.

Mr. Chairman, in conclusion, I will note that the National Economic Council recently published a document titled Strategy for

American Innovation: Driving Towards Sustainable Growth and Quality Jobs, which identifies new treatments such as smart anticancer therapeutics and personalized medicine as among the 21st century's grand challenges. Achieving these challenges is viewed as important to improving the quality of life and establishing the foundation for industries and jobs of the future. The biopharmaceutical research sector looks forward to its role in bringing these goals to fruition.

Again, Mr. Chairman, Ranking Member Deal, thank for the invitation to testify.

Mr. Pallone. Thank you, Mr. Smith.

[The prepared statement of Mr. Smith follows:]

***** INSERT 2-2 *****

Mr. Pallone. Ms. Stoll.

STATEMENT OF KATHLEEN STOLL

Ms. Stoll. Thank you, Chairman, and thank you, Ranking Member Deal, members of the subcommittee. My voice isn't quite as loud as the previous gentleman.

I think we have heard a lot of numbers. I am going to actually give us a little pause from the numbers. I have got a few stats, but I also want to paint a picture of what it means to have rising prescription drug spending and prices for consumers. Let me just give you a few numbers, but let me mix in some stories.

Increasing access to affordable prescription drug coverage is a top issue for Families USA. We have seen prescription drug spending by consumers more than double in the last 10 years.

Now, it is fair to say that that spending is driven by more than just price increases. People are using more drugs, and in many cases that is a good thing. Prescription drug use has increased 72 percent while the population is only growing by 11 percent. That is a pretty good business proposition, I think.

Utilization has also changed. That means the kinds of drugs people take has changed. And some of the drugs, the new drugs on the market, the biologics, are more expensive. That is not

necessarily a bad thing because many of them are real breakthrough drugs. But we do see statistics that show that spending on biologic drugs is growing nearly twice as quickly as other traditional chemical drugs.

And the third element of why consumers are spending more on drugs -- or are trying to spend more on drugs -- is the cost of prescription drugs, and that is what this hearing is about; and drugs are becoming more expensive.

We can go back and forth with stats. I think we should be careful that we understand that reduction in the rate of growth still means you have a rate of growth. What we have seen is that between 1997 and 2007, retail drug prices, which is what counts for consumers, have increased an average of about 6.9 percent a year. That is about 2-1/2 times faster than general consumer inflation. It seems like that trend might be accelerating; it is really hard to say, and I leave that to Steve.

So what does this mean for consumers? If you look at uninsured consumers, uninsured adults, half report that they don't get their prescription drugs filled. They don't get their prescriptions filled and don't seek needed refills. And I pause here now to tell you a story, and I'm not going to tell you a story of a dramatic disease -- perhaps a rare disease with a dramatic cure.

Let me just tell you about a single mom that came to our attention. She has a severe problem with migraines. They are

debilitating. Her vision is impaired by them. And she is really left unable to function. And because of her migraines, she misses many days of work and many days with her son.

She doesn't have insurance. She does work full time. And she finally went to a headache specialist and they went through a couple of different drugs. He had some samples. After three or four, they found one that works. It is actually like a miracle drug for her. So we do thank the pharmaceutical industry for this breakthrough drug. I am not going to name it. The problem is that this brand name drug that provides her tremendous relief for debilitation migraines is very, very expensive. So you know where the story is going.

She can get the prescription filled. She gets six at a time. And it really takes hundreds of dollars to fill this prescription for six pills. So what she has told us is that she saves her pills and if she gets a real severe migraine, her doctor said, Take it right away, don't wait; but she holds on to those pills because they are so expensive. And she will go ahead and have a migraine because she doesn't take it early when she should.

The end of the story is what she shared with me, which is she had one pill left 1 month, and she knew it was very expensive, she wouldn't be able to replace it, and her son pays the trumpet and he had a recital coming. So she held on to that pill, went through three severe migraines, missed time at work, missed paychecks, in order to be able to take that pill on the day of the

son's recital. She ended up not having a headache that day, but she wanted the insurance.

So that is what we are dealing with at the consumer level. If we could bring down the name of that brand drug, it would mean a tremendous difference for this woman who is uninsured.

She's uninsured. Many Americans who have health insurance are still unable to afford prescription drugs. You all know that as premiums go up, people are buying plans with higher deductibles, higher copays. They may have special deductibles and copays just for prescription drugs. So they end up underinsured when it comes to prescription drug coverage. They, too, make difficult decisions. They paid for coverage; because they are underinsured or may not have prescription drug coverage at all, two out of five of these folks underinsured actually go without filling their prescriptions as well. So, a problem of the uninsured and the underinsured.

Of course, some folks don't have coverage through their employer. They are in the individual market. I would just point out that in the unregulated individual insurance market consumers are four times less likely to have prescription drug coverage at all. Certainly, for people with chronic conditions, that is where we see the most impact in terms of high prescription drug spending. A person with a single chronic condition can spend -- about 36 percent of their out-of-pocket costs will be for prescription drugs. If it is a person with two or more chronic

conditions, their out-of-pocket spending for drugs can be six times higher than their hospital costs.

Now that is not necessarily a bad thing. I am just giving you a sense of the impact on consumers. It may be those prescription drugs are keeping them out of the hospital. Certainly, we know that there is a toll in terms of reduced quality of life, reduced productivity; and sometimes it means death not to have access to prescription drugs. It also means that our health care system has higher costs long term.

I will tell you one more story. It is a story of a child with asthma. Both of this child's parents work full time. They have pretty good insurance coverage for themselves. They have no dependent insurance coverage. So their kid is not covered. Their son has asthma. He needs a maintenance drug that costs a couple hundred dollars a month. Because they don't have dependent coverage for their son -- and they don't qualify for CHIP, by the way -- their son doesn't get the asthma medication on a regular basis. They can't afford it. It is hundreds of bucks a month. These are low-wage working parents.

They have tried things like making their fifth-grade son wear a mask when he goes to school to help with the maintenance and the management of the asthma. If you have ever tried to send a fifth-grade boy off to school with a mask, you know that is probably not going to work too well.

So the end of the story is, obviously, the child without regular asthma medication to maintain and monitor his asthma to keep it under control, he ended up in the emergency room and he had a very high-cost hospitalization, and it had a very hard financial impact on the family.

Mr. Pallone. I appreciate it. I am going to ask you to stop now because you are almost 3 minutes, but thank you.

[The prepared statement of Ms. Stoll follows:]

***** INSERT 2-3 *****

Mr. Pallone. Professor Vernon.

STATEMENT OF JOHN A. VERNON, Ph.D.

Mr. Vernon. Mr. Chairman and members of the committee, thank you for the invitation to testify today. My name is John Vernon and I am a professor in the Department of Health Policy and Management at the University of North Carolina at Chapel Hill and a Faculty Research Fellow with the National Bureau of Economic Research.

In addition to discussing the issue of rising drug prices, I will also discuss the role drug prices pay in firm- and industry-level R&D investment. The latter is of critical importance because considering drug prices in isolation is not useful. The tradeoff between drug prices, industry profits, and innovation is what is relevant. My research on this point is based on unfunded research published in the peer-reviewed economics literature.

Regarding the issue of rising drug prices in the U.S., the conclusions drawn by the AARP report are based on flawed methods and, thus, are misleading. Some of the more serious flaws with the analysis are:

The AARP report is based on wholesale prices, not retail prices or transaction prices, which are often substantially lower

than wholesale prices. This is because PBMs and insurers negotiate discounts, often steep discounts, and rebates with manufacturers.

Second, the AARP report is an analysis of branded products only. The burden to U.S. consumers of prescription medications associated with access to prescription drugs should also consider generic drugs, which in the U.S. have among the lowest prices in the world and the highest utilization rate.

For example, approximately 70 percent of all prescription drugs dispensed are generic drugs. So we have both the highest utilization rate and the lowest prices. Much of this credit goes, of course, to the 1984 Waxman-Hatch Act, which did a nice job of balancing innovation with generic competition.

Three, in the AARP report, 10 of the top 25 branded pharmaceuticals in their study actually have generic versions currently on the market. Mandatory generic substitution laws in most States implies that the lower-cost generic versions of these 10 brands drugs are dispensed to consumers, not the branded versions.

In my opinion and based on my experience as both an academic journal editor and peer-reviewer for academic journals, this study, as it stands, does not meet the peer-review standard for economic publication -- and that is the hallmark of academic research. A better measure, in my opinion, of drug price trends in the U.S., one that is based on retail

prices, not wholesale prices, and which also captures the cost savings from generic competition and substitution, is the prescription drug Consumer Price Index reported by the U.S. Bureau of Labor Statistics. The BLS prescription drug inflation rate for 2009 is approximately 3 percent, or roughly one-third of the 9 percent inflation rate reported by the AARP.

Moreover, the change in drug price inflation was approximately half that in the most recent year of the change in the inflation rate for nonprescription drugs and medical supplies. This suggests a small increase in prescription drug prices may reflect broader health sector market dynamics and not an isolated increase in prescription drug prices.

As previously mentioned, the consideration of prescription drug prices in isolation is an incomplete and misleading exercise. What must be considered are the costs and the benefits of higher or lower prescription drug prices and, specifically, the economic tradeoff between access to existing medicines and access to future, yet-to-be-discovered medicines.

The expected returns on individual R&D projects are directly related to expected pharmaceutical prices and profitability; price controls or indirect price controls via such mechanisms as reimportation or technology assessment rationing lower expected net returns for firm shareholders. The result will be a decline in the rate of pharmaceutical innovation, fewer drugs developed, and it will take a longer time to find cures for many diseases.

Unlike the benefits of the price control policy, which clearly would be to improve access for today's consumers and seniors -- implicit price controls, which will produce immediate and observable cost savings through lower drug prices -- the costs of a price control policy in terms of forgone innovation is much more difficult to appreciate and quantify.

What might we have discovered? How much more quickly would we have found a cure for Alzheimer's disease? These are very nebulous and difficult to appreciate and certainly to quantify, but that does not justify not considering these very important costs. A full economic analysis considers both the costs and benefits of any policy or health care reform.

The sensitivity of R&D spending to pharmaceutical prices and profits has been studied with variety of different research methods, including standard retrospective statistical analyses of industry- and firm-level data, protective simulation analyses, and financial event studies. The research findings have been strikingly consistent and robust. I will summarize the results from two recent studies published in the economics literature that I authored by myself and with coauthors.

The first study utilized publicly available firm-level financial data and exploited observable differences in the U.S. and non-U.S. pharmaceutical profit margins. Outside the U.S., most countries have some form of price regulation, explicit or implicit. Using established economic models and statistical

techniques, we estimated that a new policy that reduces pharmaceutical profit margins in the U.S. to non-U.S. levels will cause firm R&D spending to decline by between 25 and 35 percent, all things considered.

A policy that regulates prices in the U.S. -- for example, reimportation from foreign markets with forced sale clauses, those foreign markets, of course, having price regulation -- will theoretically have this effect on U.S. profit margins.

The second study adopted a slightly different approach and utilized publicly available industry-level data to study the direct link between U.S. drug prices and industry-level R&D spending. In this study, we estimated that for every 10 percent reduction in U.S. prices, industry R&D spending will decline by approximately 6 percent. We call that an elasticity estimate of R&D with respect to real drug prices in the U.S. this finding is also consistent with an earlier study by Harvard economist, F.M. Scherer.

In sum, the empirical evidence suggests that firm R&D spending is very sensitive to pharmaceutical prices and profits and to prices, as the economic theory would predict and the empirical literature supports. The key point is that the benefits associated with lower drug prices -- and it cannot be argued that there would be benefits and improved access to medicines that are currently on the market and available -- would unequivocally come at a cost: lower levels of R&D investment and a reduced rate of

pharmaceutical innovation. It is critical that these costs be balanced carefully against the benefits of associated regulation, explicitly or implicitly, that regulates drug prices. This is particularly true in light of the recent evidence on the significant contributions of pharmaceutical and medical R&D to human health and life expectancies in the U.S., research that suggests the U.S. is currently underinvesting in medical and pharmaceutical research based upon the benefits that we enjoy in America as a result of improved quality of life and extended life expectancies. Thank you very much.

Mr. Pallone. Thank you, Professor.

[The prepared statement of Mr. Vernon follows:]

***** INSERT 2-4 *****

Mr. Pallone. Ms. Cramer.

STATEMENT OF BONNIE CRAMER, MSW

Ms. Cramer. Thank you, Mr. Chairman and members of the Health Subcommittee. I am Bonnie Cramer. I am chairman of AARP's all-volunteer board of directors, and on behalf of our 40 million members, thank you for including AARP in this discussion of brand-name prescription drug prices.

As you know, AARP is deeply committed to making prescription drugs affordable for our members and for all Americans; and whether we are ready to admit it or not, the United States is aging at an unprecedented rate. Starting on January 1, 2011, 10,000 people will turn age 65 every day, and this will continue for the next 20 years. When combined with the rapidly escalating brand-name prescription drug prices and the fact that older Americans use prescription drugs more than any other segment of the population, it seems evident that many Americans will soon find themselves unable to access the drugs they need at a price they can afford. And that, we believe, is not acceptable.

As part of these efforts, AARP's Public Policy Institute, working with Dr. Schondelmeyer, has been reporting on manufacturer price changes for prescription drugs. Since 2004 we have done our prescription drug

watchdog report. Our latest report found, as you have heard, that average manufacturer prices for widely used brand-name and specialty prescription drugs continued to increase substantially between October of 2008 and September of 2009, rising by 9.3 percent and 10.3 percent respectively.

Now it has been twice said that 70 percent of all prescription drugs are generic, but you need to know that 76 percent of all spending is for brand drugs.

Rising prescription drug prices are a source of concern for many of our members and it can impact their health. The inability to afford needed prescription drugs has been shown to negatively impact patient adherence to drug regimens. Many consumers report that they have not filled prescriptions, they skip doses, and they cut pills in half as a result of high prescription prices. These are stories that we hear from our members every day. This type of behavior in turn can lead to more expensive health care needs in the future.

Problems paying for prescription drugs are more common among those taking a larger number of medications, such as older adults. Approximately 20 million AARP members are over the age of 65 and eligible for Medicare. The Part D benefit, which AARP fought very hard to enact, provides much-needed prescription drug coverage for Medicare beneficiaries, but unfortunately, the Part D benefit currently contains a doughnut hole, where the beneficiary must shoulder the entire cost of the drug as well as continuing to pay

their premiums. More than 3 million Americans are at risk of falling into the doughnut hole each year and feeling, firsthand, the impact of rising prescription drug prices.

Unfortunately, because the doughnut hole is indexed to prescription drug spending, the doughnut hole is growing larger each year; as a result, more people will fall into the doughnut hole in the future. And that is why we at AARP have made closing the doughnut hole one of our top priorities as part of health care reform.

But price increases also impact Medicare Part D enrollees. It impacts their cost sharing for their brand-name prescription drugs.

A recent AARP Public Policy Institute analysis of most national Part D plans shows that in 2010, more plans will require copayments of close to \$100 per drug for certain brand-name drugs. Other plans will use coinsurance or a percentage of the drug's cost for brand-name medicines as high as 65 percent of the drugs cost.

We are greatly concerned about the future of Medicare's Parts D and B, which are financed through premiums and general revenues. As prescription drug prices continue to increase, spending will grow correspondingly, which means that all Medicare beneficiaries as well as all taxpayers will be required to pay more in order to keep the program solvent.

Now, AARP was pleased to endorse the Affordable Health Care

for Americans Act, H.R. 3962, that recently passed the House of Representatives. For years, AARP has been fighting to make sure that our members and all Americans have access to affordable health care coverage. Key to our endorsement was provisions that would close the doughnut hole, which the House would begin to do next year, and fully close the doughnut hole by 2019.

We also support the House health bill's provisions that would grant the Secretary of Health and Human Services the authority to negotiate on behalf of Medicare beneficiaries. We have also supported provisions that would promote medication therapy management services.

So, Mr. Chairman, thank you for your continuing efforts to improve the Nation's health care system. At AARP we look forward to continuing to work with you to ensure that prescription drugs remain affordable for our members and all health care payers.

I appreciate the opportunity to be with you today, and I look forward to your questions.

Mr. Pallone. Thank you, Ms. Cramer.

[The prepared statement of Ms. Cramer follows:]

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Mr. Pallone. We are going to have questions now from the members, and I am going to start with myself. I am going to try to get in two topics here with you, Mr. Schondelmeyer.

When we passed or when we finalized the health care reform legislation, it will mark the second time in 6 years Congress has passed important legislation affecting the prescription drug market. In 2003, we passed the legislation creating Part D; and you have analyzed drug prices before and after Part D went into effect.

So what happened in the months before Part D went into effect, and are we seeing the same thing happening now with this health care reform legislation?

Mr. Schondelmeyer. Well, I would respond by providing observation and pointing you to figure 5 in the testimony that I prepared. Basically, it shows in the time period prior to Medicare Part D being first passed and then later enacted -- remember, there was a delay time between when it was passed and when Part D actually got implemented, 2003 to 2006 -- prescription drug prices did increase during that time period substantially. They leveled out, if 6-plus percent is leveling out, in terms of price increases for a brief period, and then after last fall's elections in November when it appeared that health care reform might be a topic that comes into play again, we saw an increase.

Now, this is not a cause-and-effect relationship, but if one

looks at the graphs, it is pretty apparent there is an increase.

Mr. Pallone. So you don't think it is a coincidence, obviously.

Mr. Schondelmeyer. I don't think it is. There are multiple factors that affect the drug companies' choice to raise their prices, but I think this is certainly one that weighs in.

The mentality that may be going into effect is, if R&D is as important to them as they say it is -- and I believe it is; and I want, we as a society want, the innovation and R&D and other factors. So if they rationalize, if they are going to start controlling or affecting my prices by having a more effective market in some way, and I have a less controlled market right now, I am going to push the price as much as I can so when they start squeezing, I am at a higher point on the mountain when they are trying to bump me down a little bit. So it makes sense to do that.

Mr. Pallone. Mr. Smith, I will let you have an opportunity to respond, but I have to go back to him. So if you could just spend about a minute or so.

Mr. Smith. Mr. Chairman, thank for the opportunity to respond.

Unlike Dr. Schondelmeyer, I am not going to speculate about motives. As I made clear in my statement, I can't discuss pricing decisions and so forth. But what I can say is that, number one, the Consumer Price Index, as has already been discussed, has, for

the year ended with the period that AARP looked at, was up about 2.7 percent.

I can also tell you that the prices are negotiated with purchasers who are large, sophisticated and powerful and have many tools. My guess would be, and I have to underline guess, my guess would be if a company went to one of these purchasers and said, We need you to pay us more because health reform is coming, they would be laughed out of the room.

Mr. Pallone. Okay. Now I am going back to you, Dr. Schondelmeyer.

At some point -- I don't know if it was in your testimony or in your written statement -- you mentioned that the wholesale acquisition cost does not include discounts or rebates that are provided by the manufacturers to wholesalers. When these discounts were factored in, it has the effect of lowering the price paid.

You stated in your footnotes that there are no consistent comprehensive and publicly reported data sources for this discount and rebate information. That gets to the issue of transparency. That is my question.

How would better drug pricing transparency help patients? I mean, what would you suggest in terms of trying to create more transparency?

Mr. Schondelmeyer. First, if we are really talking about an economic market and making wise decisions, we need to avoid

asymmetric markets, where the seller knows a whole lot more about their product than the buyer. Asymmetric markets were defined by Nobel economists who described the market for lemons, or used cars.

In a sense, drug companies, thankfully, know a lot more about our drug product than we do, but that gives them extreme economic power in the marketplace. Rebates and discounts are out there, and they may lower the actual price, but they don't lower the rate of increase unless the rebates and discounts are increasing as a proportion.

Mr. Pallone. What do you suggest in terms of what we could do on transparency?

Mr. Schondelmeyer. Well, one, for example in Medicare Part D, you could require that Part D plans disclose the amount of rebates that they get. Apparently, the committee in the past couple of years has done studies of the Part D plans. The Part D plans have reported that they get rebates on about 10 to 14 percent of the drugs; and they may get some rebates, but they have admitted they don't pass them on to the consumer. And, apparently, it doesn't lower the premiums, because this last year Part D premiums went up 11 percent, and last year they went up 17 percent.

So the only two places I can see that rebates can benefit either the Medicare beneficiary or the taxpayer would be in lower premiums or lower prescription prices. And they don't appear to

show up in either of those.

I don't know where they went.

Mr. Pallone. Thank you.

Mr. Deal.

Mr. Deal. Ms. Cramer, I am told that 52 percent of AARP's annual revenues come from royalty fees from insurance company profits, and less than 20 percent of it comes from your membership dues. In 2008, I am told that AARP generated \$414 million in royalty fees from United Health Care Corporation.

Could you tell me what percentage of those revenues came from the sale of AARP Medicare supplemental insurance plans that were offered by United Health Care Corporation?

Ms. Cramer. I don't have that figure with me. I will be glad to get it for you. Those numbers you cited are approximately correct.

But let me just say that AARP is not an insurance company; we contract with United Health Care to provide insurance to our members, and we provide market-changing policies. We make sure that our members have the best policies that we can have under State and Federal law.

Providing insurance to AARP members is the reason AARP was formed over 50 years ago, when our founder -- the private market was not serving older people, and it was not serving retired teachers. Our founder was a retired teacher. It is the beginning of our organization.

But I do want to say one other thing, which I have heard said in Congress numerous times, especially over the weekend. I am the chairman of the all-volunteer board. We had over 15 to 20 meetings on health care reform -- detailed meetings. Not once, not once, did the AARP board talk about the money we might make on our insurance products or the money we would lose. We would gladly forgo --

Mr. Deal. You will get us information to the question that I have asked.

Ms. Cramer. I will get the information on what portion is related to Medicare supplement.

[The information follows:]

***** COMMITTEE INSERT *****

Mr. Deal. When you announced your endorsement of the immediate health care reform plan, you cited the fact that preexisting conditions would be excluded under that legislation, yet the supplemental plan that you sell has a 6-month waiting period. And the way the legislation has been crafted is that your supplemental insurance plan will still continue to have the opportunity for a 6-month waiting period as an exclusionary period.

Was that a condition that was negotiated with the White House as a condition of endorsement?

Ms. Cramer. It was not a condition that was negotiated with the White House. And AARP has been on record for a long time of supporting guaranteed issue for Medicare beneficiaries.

Mr. Deal. But do you think it is fair for your supplemental plan to have a preexisting condition exclusion, whereas other plans in the basic coverage would not?

Ms. Cramer. That is something that we can look at. It was not a deal with anyone. And certainly we do support guaranteed issue.

Mr. Deal. All right. Let me ask the panel, and this would be something that any of you could address.

We are concerned here about trying to figure out how to get consumers in the United States the best value for the dollar they are paying for prescription drugs. Do you believe that U.S.

consumers are paying a disproportionate share of R&D costs compared with the rest of the consumers in the world?

Does anyone want to take a shot?

Mr. Smith. Mr. Deal, I will note that other countries clearly underfund their R&D. They are not paying their share of R&D, particularly other developed countries, and I believe the result is, less R&D occurs and fewer new drugs are discovered, and that is a loss to Americans as well as people in their own country.

Mr. Deal. Aren't you shifting those costs to American consumers?

Mr. Smith. Mr. Deal, I can't speculate about how pricing might occur cross-nationally.

Mr. Deal. Dr. Schondelmeyer, do you have an observation?

Mr. Schondelmeyer. Well, again, in terms of the individual decisions of companies and specific decisions, it is hard to say. But if you look at the market, and as described by Mr. Smith, if other countries are underfunding and we are paying a substantially higher price and we are getting R&D, which we value, we are overpaying; we are essentially letting other countries be free riders on the R&D that we are paying.

What we do with that is a different issue. I think we probably need to look for a new model of funding R&D. Rather than funding 10 years from now the new drugs based on the high price of drugs today to the degree that some people can't afford them, I am

not sure that model is working today.

Mr. Deal. I want to go to your analysis that brand-name drugs increased 9.3 percent in your study. Specialties, which you say were primarily biologics, increased by 10.3 percent.

Isn't it logical that in the brand names, where their patents will expire, that those prices will drop in the future; whereas if we grant, in addition to patent protection, some 12 or more years of market exclusivity on biologics, that you are going to see that increase in the biologic arena continue to be an escalation?

Mr. Schondelmeyer. I don't recall more than two or three brand-name drugs that I have ever seen drop their price, and those were under political pressure. It was pointed out that some of the drugs in our index have generic competitors in the market, and yet those brand-name drugs continue going up in price, sir.

Mr. Deal. Yes. But if you build in a 12-year exclusivity period that prolongs any ability for follow-on biologic, don't we compound that problem?

Mr. Schondelmeyer. Not necessarily. I think one has to do an assessment of what is an appropriate time for recovering that innovation cost and R&D cost. I think if you make it too short, you can stifle innovation. I think if you make it too long, you can stifle innovation. If you make it too long, you allow companies to rely on cash cows, which is much of what we see now, products they just keep hanging on to and riding, rather than -- what they find is Nexium instead of Prilosec, which isn't a new

drug, it's just a right-handed version; or Ambien CR instead of Ambien, which isn't a new drug, it is just a manipulation.

So if we let the period be too long, it can be just as damaging as too short. I think the period that is currently in the bill at 12 years is on the long side.

Mr. Pallone. Chairman Waxman.

The Chairman. We have heard the estimate that the amount of prescription drugs over a 10-year period has increased 72 percent. That is a big increase in people using drugs, or at least a number of prescriptions. So the market for drugs has increased over the last 10 years.

Dr. Schondelmeyer, you say that the drugs in the past year have increased, on an average, 9 percent; is that a correct statement?

Mr. Schondelmeyer. It is, but we need to parse out increased expenditures from increased prices. Expenditures go up because of increased utilization and increased price and increased changes in the mix.

The price index I report with AARP is a pure price index. Price only. The actual utilization of prescription drugs in the last year to 2 years has flattened out or even decreased slightly in some therapeutic markets, yet the prices keep going up. And the private payers, the large PBMs, report price increases similar to the 5.4 percent that we show for our aggregate composite index, rather than the 2.7 percent that CPI has.

Dr. Vernon commented that my study only looked at brand-name drugs. Apparently, he has only read the New York Times version of my study, because if you read the full study, you will see that we look at brand names and specialties and generics, and we calculate a composite index.

The Chairman. So you have a composite index of all those drugs. Let's parse them out.

Are brand-name drugs where the drug manufacturer still holds a patent, which means it has a monopoly, going up faster than the increase for the prices for those drugs than generic drugs competing with a brand-name drug?

Mr. Schondelmeyer. In our index, brand-name drugs can be either patented, single-source products or it can be brand-name drugs. The originator, the original NDA holder, they may not have discovered the drug at all; they may have licensed it in. But the original NDA holder, even after the drug is off patent, may still be in our index, in some cases, because those products are still on the market and the prices are going up.

So we track those prices and then we track generics, and they are going in opposite directions -- 9.3 percent up and 8.7 down for generics.

The Chairman. So where there is competition from generics, the generics are going down in price? And where there is no competition, the price of drugs is increasing?

Mr. Schondelmeyer. It is increasing. And even the brand

name, when it has generic competition, doesn't enter into the economic competition by lowering its price. It may lose volume, but it doesn't lower its price.

The Chairman. This seems to be happening whether the economy is booming or in a recession, whether the number of uninsured is going up or down; it doesn't make any difference.

Mr. Schondelmeyer. It doesn't appear to have done so over the last decade, and we have had both of those periods, some booms and some busts.

The Chairman. Over the last decade, I assume that the increases are every year. Are they pretty level or is this 9 percent higher than the general increase over the last 10 years, let's say?

Mr. Schondelmeyer. The rate of increase is the highest, at least from the data I have done with AARP I have seen in the last 7 years. When I look at other similar data going back even 15 years or more, this is the highest level we have been at for quite some time.

The Chairman. Now let me go back to the question Mr. Deal asked you. The specialty drugs, which really biologic, these are the new breakthrough drugs, but they are very expensive drugs, aren't they?

Mr. Schondelmeyer. Yes. These, on average, cost thousands to tens of thousands of dollars, if not in some cases, hundreds of thousands of dollars per year.

The Chairman. For the most part, these drugs have no competition?

Mr. Schondelmeyer. They do not have competition directly and in an economic sense.

The Chairman. In an economic sense? What does that mean?

Mr. Schondelmeyer. In a sense it would lower their price. There may be two drugs for multiple sclerosis, and the drug companies may very vehemently compete through advertising and through calls on the doctors that treat those patients, but it hasn't had an effect on the price, an appreciable effect on the price.

The Chairman. Is that because one is not substitutable for the other?

Mr. Schondelmeyer. Substitution has been a major mechanism to bring about economic decline of generic prices in the regular drug market, and that is not available for the biological products. There is no equivalent of an ANDA for a biological license applicant.

The Chairman. Now there is a bill that promises the developer of a generic drug 12 years of exclusivity and then there can be competition. But that competition may not be a substitutable competitor. So we are not guaranteed a reduction in prices even after 12 years; isn't that right?

Mr. Schondelmeyer. That is probably correct. It depends on the terms of how that bill would bring about or allow other

products in the marketplace.

What you need is an equivalent of the FDA therapeutic equivalence evaluation for normal pharmaceuticals to be developed for the biological markets.

The Chairman. They claim they have to have a 12-year exclusivity because competition is going to drive down the price of that drug so dramatically. But, in effect, they are going to have much longer than 12 years to be recouping a huge amount for their drug.

So what we are really talking about is not just a 12-year period, but a much longer period of time in which this drug will have market dominance; isn't that correct?

Mr. Schondelmeyer. That is quite likely. In addition, they are likely to come out with alternate dosage forms and remarket the drug in a different dosage form that has a new patent, has a new exclusivity.

The Chairman. We have "evergreening" in the bill that passed the House and the Senate, which means there is no end to the monopoly control they are going to have over these biologic drugs.

Monopoly control, is it fair to say, in your experience, means higher prices?

Mr. Schondelmeyer. Yes.

The Chairman. Thank you, Mr. Chairman.

Mr. Pallone. Thank you, Chairman Waxman.

The gentleman from Illinois, Mr. Shimkus.

Mr. Shimkus. Thank you, Mr. Chairman. I think we are developing more questions through this hearing, but that is a positive thing.

Ms. Stoll, I would just request that if you have these constituents' stories, one, I would ask if they have gone to their Member of Congress to ask for assistance. We deal with folks in many of these similar situations.

I would also highlight the fact that if that Member is not willing, if you provide those names to my office, we will try to intervene. Because I know the pharmaceutical companies have options in which they can provide discounted or low-cost or drugs for free; and we use those operations frequently in my congressional service.

I have limited time, but I want to throw that out as an option for these stories that you have given us today.

To Mr. Smith, we have heard a lot about the "deal" between PhRMA and the White House. Can you explain what that deal is?

Mr. Smith. Congressman, what I can do is -- I wasn't asked to come and explain the deal today. I can try to give you sort of --

Mr. Shimkus. I have been told it is pretty well public knowledge.

Mr. Smith. There have been public announcements by the White House. I believe AARP attended a public announcement of the initiative at the White House. There are public announcements

from the Finance Committee.

Our board concluded that in line with its longstanding support for moving forward health reform, that was mentioned by the chairman in his opening comments, that we wanted to support moving forward --

Mr. Shimkus. I am actually looking for more of the specifics.

Do you know if the Senate health bill reform reflects the negotiations?

Mr. Smith. The Senate bill is so much in flux, it would be hard for me to make an assessment.

Mr. Shimkus. I would like for you all -- these are questions that I would like to get answered. I would hope that you would. My concern is H.R. 3962, there are negotiations behind closed doors, and I want to know if those have negotiated, which then turns me to AARP.

Ms. Cramer, you said that -- Mr. Chairman, I would like the consolidated financial statements from December 31, 2008, and 2007, and the IRS form 990 for 2008 submitted for the record, with your approval.

Mr. Pallone. Can I just take a look at it, because I am not sure I know what you are talking about.

Mr. Shimkus. It will be followed up with these questions.

Ms. Cramer, you stated that you all don't have an insurance plan, but on the 990 you list one. On the IRS Form 990, it says

"the AARP insurance plan." So my question is, do you have an insurance plan or do you not?

Ms. Cramer. What I said is that we contract with United and other health insurers to provide insurance to our members. We also contract with Aetna for the 50- to 64-year-old product.

We contract with Genworth to provide long-term care insurance to our members. We even provide homeowners insurance and car insurance to our members.

Mr. Shimkus. Reclaiming my time, what it says on the IRS Form 990, At the direction of third-party insurance carriers, the plan pays AARP, Inc., a portion of the total premiums collected for the use of its intellectual property, which is reported as royalties in the consolidated statements of activities. Is that correct?

Ms. Cramer. It is correct that we make royalties off the sale of insurance plans.

Mr. Shimkus. So you are acting as a grant or trust. And, in essence, when these profits are made through the selling of this insurance, the net then goes back to you all. In fact, AARP benefits from selling the most costly insurance because that portion then goes to operate AARP at a major profit; is that correct?

Ms. Cramer. It goes back to support the advocacy and education efforts of AARP, yes.

Mr. Shimkus. And I would say in about current operations

that is about \$653 million in annual revenue, based upon this portion, which was stated by Mr. Deal as. What, three-fourths of the operating budget?

Ms. Cramer. The budget is about \$1.3 billion, but that amount is approximately correct, yes.

Mr. Shimkus. Fifty-two percent of your fees or annual revenues come from these insurance fees, and 20 percent of AARP's annual revenues come from membership dues, correct?

Ms. Cramer. About 24 percent.

Mr. Shimkus. Could you operate without this \$653 in annual revenue?

Ms. Cramer. I have already answered that question. We were founded on providing --

Mr. Shimkus. Can you operate currently without this revenue that you all receive based upon selling insurance, yes or no?

Ms. Cramer. We have never looked at that. I don't know how to answer that.

Mr. Shimkus. So if you are without \$653 million, you don't know if your operations will change?

Ms. Cramer. Well, obviously, it would change if it is 52 percent of the revenues.

Mr. Shimkus. Thank you. I yield back.

Mr. Pallone. The gentleman from Illinois has asked for unanimous consent to enter into the record AARP's consolidated financial statements from December 31, 2008 and 2007. Without

objection, so ordered.

[The information follows:]

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Mr. Pallone. Next is the gentlewoman from California, Ms. Eshoo.

Ms. Eshoo. Thank you, Mr. Chairman. I can't help but observe the following. It is always interesting around here when advocacy organizations endorse legislation. I remember not that many years ago when my friends on the other side of the aisle had their arms wrapped around AARP, hugging them so tight, because they were supporting Medicare Part D and all that came with it.

Today, they are attacking the hell out of AARP because they have endorsed this side of the aisle's health care -- universal health plan for the American people. So I guess, as Kurt Vonnegut said, "And so it goes."

But I can't help but make the observation; I guess that is the way it goes around here.

Thank you, each one of you, for coming to testify. I think if we could stay away from good guys and bad guys, we would just be much better off. What we need to do is to scratch below the surface and see what it is that is causing the prices to be what they are, which we all know is a burden to the American people and especially older citizens in our country.

I believe in research and development. I believe in science. It is at the heart of all of the work that I have done here in Congress. Some say that favors some and doesn't help others. I think that that is a source of pride to our country, and I want to

keep that and innovation alive. But I also think we can do a much better job with what the costs are.

Now, the House has already passed the health care reform legislation, and hopefully the Senate is going to do the same. As we go to conference, I think it is important we get some perspective in how provisions in these bills will help to reduce drug costs. The House bill has numerous provisions to protect taxpayers and all citizens from increasing drug prices. It increases Medicaid rebates; it provides drug coverage with 36 million citizens; it requires pharmaceutical manufacturers to give a 50 percent rebate for drugs in the doughnut hole; it closes the Part D doughnut hole, which the other side all created, together with AARP, and thought it was terrific then. Now it is costly and we are being attacked for what it costs to plough back and fill this hole, but fill this hole we must do because of what it is doing to senior citizens. It allows the Secretary to negotiate for lower Part D drug costs.

Now the Senate bill contains some of these provisions, but not all. It doesn't close the Part D doughnut hole, doesn't allow the Secretary to negotiate, and it doesn't create new Part D rebates.

So, to Dr. Schondelmeyer, let me ask you generally, do you believe the provisions in the House bill or the Senate bill will do a better job of protecting seniors and taxpayers from rising drug prices? I mean, it is a softball question, but I think we

need to get the answer on the record.

Mr. Schondelmeyer. I believe there are many useful provisions in the House bill that would assist in that goal. As with many tools that we have in society, it all depends on how they are implemented.

Ms. Eshoo. Ms. Cramer, do you agree?

Ms. Cramer. We have strongly supported the House bill. We are working every day in the Senate to try to get the doughnut hole closed completely.

Ms. Eshoo. Let me ask about a specific provision in both bills. It is a provision that requires manufacturers to provide a 50 percent discount on brand-name drugs in the doughnut hole. My understanding is that this offer was made by the drug manufacturers as part of their negotiations with the Senate and the White House.

Now this is not a bad provision. We have it in the House bill as well. But it seems to me that it has some problems. What manufacturers give, which in this case is a 50 percent discount, manufacturers can take away by increasing the base price of their drugs.

So, to Dr. Schondelmeyer, am I understanding this correctly? As manufacturers increase prices, can they also wipe out many of the benefits of this 50 percent discount?

Mr. Schondelmeyer. I believe they can, and they have the market power to do so. Their current price increases for this

year may have come close to wiping out the whole \$80 billion over the next 10 years.

Ms. Eshoo. Let me ask the panel, whoever would like to step up and answer this, what do you think is the best way to protect us from what I just described?

Mr. Smith. Congresswoman, thank you for the opportunity to answer.

Ms. Eshoo. Keep it short.

Mr. Smith. I will, absolutely.

Part D, as you know, has come in at much lower cost than expected. That is because of the competition and the negotiation that goes on. Contrary to Dr. Schondelmeyer's point, of course, the 50 percent discount that will be provided in the coverage gap is a 50 percent discount off of the negotiated price. So I think that there is a real benefit to seniors there.

Ms. Eshoo. Dr. Schondelmeyer, do you want to respond?

Mr. Schondelmeyer. You tell me how much discount you want, and I will tell what you the price is. That is kind of the way the market works today. Yes, there is some negotiation, but it is at the margins. It is mostly about retail prices, not about meeting the retail margin and the retail dispensing fees. It is not much about brand-name, single-source drug product negotiations.

I work with major buyers in the marketplace with my own university, and we don't get discounts on those brand-name prices.

Mr. Smith. Congresswoman, can I get 5 seconds of your time, please?

Ms. Eshoo. You have to ask the chairman, not me.

Mr. Pallone. Yes, and then we are going to finish.

Mr. Smith. I will simply note, contrary to Dr. Schondelmeyer's assertions, if you look in the Medicare trustees' report, they will note that while generics don't carry rebates, I believe their phrasing is many brand-name drugs carry rebates, often 20 to 30 percent.

Mr. Schondelmeyer. Generics are priced so low, a rebate still doesn't get the brand name close to the generic price.

Ms. Eshoo. Mr. Chairman, I think this whole issue of the increase of the prices says to us that we need to get socks on this octopus. Because if the rate continues to rise as much as it already has, and the predictions of the industry itself underscoring that, then by the time the entire national plan for universal health care takes place, then that whole new floor -- a whole new floor is established.

This is about bringing prices down across the board so we have affordability for people. I think that we have got to press hard, look hard on a provision that will be placed in the bill.

You know what I would be willing to do is to say that by such and such a date this is what you have to do, and a hammer comes down by that year. If you haven't, then the prices are just going to drop.

Thank you.

RPTS MERCHANT

DCMN HOFSTAD

[11:39 a.m.]

Mr. Pallone. Thank you. And I apologize for turning the clock off. I wanted to make sure Mr. Gingrey got his 8 minutes, since he didn't have an opening.

I recognize the gentleman from Georgia.

Dr. Gingrey. Mr. Chairman, thank you very much, and thank you for allowing me the extra time for questions.

I am going to direct all my questions to AARP and to Mrs. Cramer.

Ms. Cramer, my first question, to your knowledge, has AARP been contacted by the Justice Department concerning alleged large kickbacks -- well, actually, you call them "royalties" -- that you receive from insurance companies for your Medigap plans, a matter that, as you know, Chairman Rangel suggested he would be referring to the Justice Department during the Rules Committee hearing on H.R. 3962 last month?

Ms. Cramer. To my knowledge, today, no.

Dr. Gingrey. Well, if you do hear of that and have that information, that the Justice Department is looking into that, would you be willing to let the committee know that you have been informed by the Justice Department?

Ms. Cramer. Surely.

Dr. Gingrey. Good. Thank you.

The second question: Today, roughly a million customers purchase Medicare Advantage plans, roughly 8 percent of the market, and 2.8 million Medigap plans, representing roughly 30 percent of the Medigap market, bearing the AARP logo. Under the House and Senate health reform bills, Medicare Advantage plans would be cut -- again, I am sure you know this -- by as much as \$160 billion, yet Medigap plans do not endure these same cuts. Under the House and Senate bills, Medicare Advantage plans would be forced to pay 85 percent of revenues received for medical claims, yet Medigap would only be subject to pay 65 percent of its revenues on claims.

Are you aware that Medigap plans are not held to the same 85 percent standard as all other insurance products but Medicare and non-Medicare policies under the House or the Senate health reform bills, yes or no?

Ms. Cramer. No, I was not aware of that.

Dr. Gingrey. Would AARP be willing to forego this sweetheart exemption that clearly favors AARP and their Medigap plans in order to help reduce the cost of health care for its members who receive their insurance from the Medicare program?

Ms. Cramer. I can't answer that on Medigap. I can say that on Medicare Advantage we have supported the reduction. We also contract for Medicare Advantage plans and --

Dr. Gingrey. Well, reclaiming my time, I don't understand

how you could say that you are not sure or that you wouldn't support that.

Ms. Cramer. I am just telling you, we have not discussed that and so I just can't answer that today. I don't have that information. We haven't even discussed that among the board.

Dr. Gingrey. Well, Ms. Cramer, in the interest of your 40 million AARP beneficiaries, including myself, don't you think it would be your responsibility as a board, all-volunteer board, to discuss things like that?

Ms. Cramer. As I indicated, I would be glad to get back with you on that.

Dr. Gingrey. Well, I am glad to hear that.

My third question: Representative Deal mentioned Medigap plans would not be subject to preexisting-condition coverage like every other insurance product sold in this country if H.R. 3962 were to become law.

Considering that an AARP member in New York has actually brought suit against you in January on this very issue, would you be willing to tell this committee today that AARP would like that provision changed in order to ensure that your members who currently receive their health care from the Medicare program would not be forced to purchase a Medigap plan with a preexisting condition?

Ms. Cramer. As I indicated previously, we have for years supported guaranteed issue of Medicare policies.

Dr. Gingrey. Well, then your answer is, yes, you would be --

Ms. Cramer. I believe I answered that we would discuss that within our board. I can't answer that today, but we do support guaranteed issue.

Dr. Gingrey. Well, I certainly would hope so, and I thank you for that response.

Next question: The House and the Senate health reform bills would cut Medicare Advantage plans by as much as \$160 billion, cuts that CBO figures will force 3 million seniors to lose that coverage and then revert to the traditional Medicare, and 8 million more if insurance companies are forced to stop selling altogether by the health choices czar, if he or she chooses.

As we all know, Medicare Advantage plans offer seniors benefits that traditional Medicare doesn't, services like dental, hearing, and vision, just to name a few. Therefore, seniors will be forced to purchase a Medigap policy to make up for those lost services, policies for which AARP has a significant market share and would stand to gain substantially.

I see a significant conflict of interest in your support of legislation that would allow you, AARP, to gain customers, and therefore further royalties, from a product in which you have a significant market share, namely Medigap plans, because seniors are being forced off of Medicare Advantage plans, plans for which AARP products do not have a particular market advantage, as I think you said in your testimony.

In light of these concerns, would AARP be willing today to rescind its support of H.R. 3962, of the Pelosi health reform act, if changes to bring Medigap policies in line with all other insurance products are not made, yes or no?

Ms. Cramer. We have supported the House bill. We have also supported the cuts to the Medicare Advantage. We also contract for Medicare Advantage. And we would willingly forego any revenue to get those changes in place to get affordable health care for our members.

Dr. Gingrey. Let me ask you one last question in my remaining time.

I have seen recent reports that AARP supports the Senate Democratic version of health-care reform. One of the ways in which a Senate health reform bill pays for the reforms it seeks is through a payroll tax on all those making \$250,000 or more each year.

Unfortunately, this payroll tax is not pegged for inflation, meaning that it will negatively impact your members, including myself, aged 50 to 64 today, and over time cause those making well below \$250,000 a year to pay this additional payroll tax of .5 percent, increasing the Medicare payroll tax from 2.9 to 3.4.

Does AARP support the use of a payroll tax to pay for health care reform?

Ms. Cramer. We have not endorsed the Senate bill. We are working to get the age rating provision in the Senate bill. It

does not meet what we would like to have. It is 3 to 1. We do not support that. And the Senate bill does not fully close the donut hole, which is our top priority. We have not --

Dr. Gingrey. Ms. Cramer, reclaiming my time, are you saying that you do not support the version of health-care reform in the Senate bill that raises a payroll tax a half a percent?

Ms. Cramer. I am saying that we have not endorsed the Senate bill as of this time.

Dr. Gingrey. Again, I want to ask you specifically a yes-or-no question. As the chairman of the board of AARP, do you or do you not support increasing the payroll tax 0.5 percent to help pay for health-care reform, whether that is in the Senate version, the House version, or in a conference report that comes back to us later in the year or the 1st of the year?

Ms. Cramer. We believe that revenues will have to be raised to provide all Americans affordable health care.

Dr. Gingrey. Last point in my remaining few seconds: Would you support a change in the final bill indexing this tax for inflation if, indeed, that increased payroll tax is in there?

Ms. Cramer. We have not discussed that. I cannot speak to that today.

Dr. Gingrey. Well, I am disappointed that you can't speak to that as being a responsible board member, volunteer board member, advocating on behalf of 40 million seniors to try to keep costs down. Because, clearly, this is not a partisan question; this is

just an issue of doing the responsible thing on behalf of your membership.

Mr. Chairman, with that, thank you for the additional time, and I will yield back.

Mr. Pallone. Thank you, Mr. Gingrey.

Next is the gentleman from Texas, Mr. Green.

Mr. Green. Thank you, Mr. Chairman.

And, Ms. Cramer, I appreciate AARP's support for the House-passed bill that doesn't have the payroll taxes the Senate does.

But, Dr. Schondelmeyer, you conducted the study that found the brand-name drug prices increased 9 percent in the last year. We heard a lot of criticism of that study by Dr. Vernon and Mr. Smith in your testimony. How do you respond to that criticism? Does your study present a true picture of what is going on with prescription drug prices?

Mr. Schondelmeyer. I believe it does.

First of all, the price data we used are prices actually reported by the drug companies. And I would ask, if they are so concerned about those prices not being accurate, why are they reporting inaccurate prices in the market and to the price databases?

Second, the Consumer Price Index is a very useful measure, but it measures a market aggregate only for the retail market. The CPI doesn't even include most specialty drugs in the

marketplace. And the CPI -- and, by the way, I would correct another number people have thrown around, that drugs are 10 percent of our health-care expenditures. That is retail outpatient prescription drugs are 10 percent. Drugs in all settings -- in hospitals, in physician's offices, and every other setting -- are about 17 percent of the total national health expenditures. And yet we keep fooling ourselves saying they are only 10 percent.

So I think our market basket reflects the full spectrum of drugs in the marketplace, in the places where they are used, and it is based on prices reported by the manufacturers.

Mr. Green. They also say that your study does not take the discounts and rebates provided by drug manufacturers into account. Does that skew the results?

Mr. Schondelmeyer. I have offered opinions that I don't think it appreciably skews the results because I don't see in the marketplace where consumers get the benefit of either those rebates or discounts. I have never met a consumer nor have I, myself, directly received a rebate from a drug company, and I have never met a consumer who says they have.

Supposedly, the Medicare Part D plans do negotiate rebates, and it is supposed to either lower the premiums or the drug product price. But when the Office of the Inspector General for HHS evaluated Medicaid prices versus the Medicare prices back in 2007, he found that for brand-name drugs the Medicaid price was

actually on average 0.6 percent lower than the Medicare prices before rebates were taken into account. When rebates under Medicaid were taken into account, it would have reduced the price by about 30 percent, but those rebates don't exist and aren't paid to the government on the Medicare side.

So they can have an impact, but the way they are implemented under Medicaid Part D, they don't appear to get passed to the consumer or the taxpayer.

Mr. Green. Well, I know we can look at the big picture, but prescription drug prices have increased at rates beyond the inflation rate in the last few years.

Mr. Schondelmeyer. Absolutely. I have no doubt of that.

Mr. Green. Okay.

Mr. Smith, your testimony states that Medicare Part D costs are not as high as projected, and I tend to think just because we created the donut hole, forcing seniors to pick up that majority of the tab of their prescription drug medications. Additionally, Medicare Part D plans -- the Secretary of HHS cannot negotiate drug prices with manufacturers. This forces seniors in the Part D to pay much higher drug prices. Under H.R. 3962, the health care bill, we close that donut hole by 2019.

A PhRMA statement from Senior Vice President Ken Johnson following the release of the AARP report on prescription drug prices states, "What is more, AARP fails to mention that 50 percent discount that companies will provide to most seniors and

disabled Americans who hit the so-called donut hole in Medicare Part D. That provision alone is expected to save beneficiary spending in the coverage gap as much as \$1,800 in 2011."

My office has contacted many companies on behalf of our seniors who have entered into the donut hole, and these discounts are not guaranteed and should not be advocated as a benefit to seniors as a way to curb the cost of drugs. Now, we try to work with individual drug companies because we see the ads on TV just like our seniors does, but oftentimes they are not qualified for those discounts when they fall in that donut hole.

Do you have information on how many companies provide such discounts to seniors in the donut hole and the average discount they provide?

Mr. Smith. Congressman, thank you for the question.

I do not have information about the number of companies that provide discounts in the donut hole. I can say that, under the initiative that we undertook, all companies would be providing the 50-percent discount on brand drugs in the donut hole.

Mr. Green. Well, I know the quote I gave you from Vice President Ken Johnson talked about \$1,800. Believe me, I have seniors I talked to Friday in Houston that would love to have that because they fell in that donut hole.

If you could get us more information from PhRMA on where they came up with that \$1,800, I would really appreciate it, because I think all of us would like to make sure our seniors -- because we

do constituent casework, and that is our next option when they hit that donut hole, outside of eliminating the donut hole, as our health care bill does.

Thank you, Mr. Chairman. I know I am out of time.

Mr. Pallone. Thank you, Mr. Green.

The gentleman from Texas, Mr. Burgess.

Dr. Burgess. Thank you, Mr. Chairman.

I think Mr. Shimkus's questioning just a few moments ago really showed to us why this hearing should be on the Subcommittee of Oversight and Investigations where we can, indeed, swear people in, get them under oath, so that we get answers that we can depend upon, because we have heard some conflicting information today.

I still remain troubled by the fact that we had PhRMA, AMA, AHIP, SEIU, AdvaMed down at the White House in May and June doing these deals, some of them, to be sure, part of the public record, but we don't have the phone logs, we don't have the e-mails, we don't have the minutes from those meetings, and we are in the dark as to what was struck.

So what I read in the newspaper is that PhRMA created an \$80 billion deal to help the health care bill get through. Okay, that sounds like a good thing, but I don't know what PhRMA gave up, I don't know what the White House gave up. It is just difficult to evaluate that.

And then, of course, you do have the Congressional Budget Office sitting back there and saying, "Wait a minute, if you are

doing something you should have been doing in the first place, we don't actually score that as a savings." So does that \$80 billion decline?

I would just like to point out, since I was criticized about the aspect of negotiation from the Secretary of HHS with Part D, I mean, the Congressional Budget Office -- who we should have at this hearing, by the way; they should be here -- but they sat at that very table last fall in a secret meeting that we had that wasn't open to the press. The Congressional Budget Office reiterated that direct negotiation from the Secretary of Health and Human Services on Part D prescription drugs would not result in any significant savings. They have said this over and over again. I don't know what we need to do to kill that notion, but it is one that certainly deserves to die.

On the issue of the donut hole, Ms. Cramer, I will just ask you, if we did away with that, what would be the effect, the practical effect, on those very low-priced policies that are available to people? Now, in my State of Texas, I think there are some 40 policies that are available for Medicare Part D. What is the practical effect of those very low-cost policies if the donut hole goes away and essentially everything is the same?

Ms. Cramer. If I understand your question, I believe only about 20 percent of the Part D drug plans provide coverage in the donut hole. And I believe, at that point, it is primarily for generic drugs.

Dr. Burgess. But a person does have that option to buy coverage that would provide coverage in the gap if they so chose. Is that correct? I mean, that happens today. There is no donut hole for that individual, is that correct?

Ms. Cramer. Well, that is correct. And, as I said, 20 percent --

Dr. Burgess. But a person who doesn't use much in the way of medications is free to purchase one of these very low-cost policies that costs a minimal amount each month. And if something happens during the course of that year, yes, then their out-of-pocket expenditure may not be covered, but they also do have a maximum catastrophic coverage above which their drug costs are covered.

But because the way Part D is set up, next year in the open enrollment period, they may switch to one of those programs that provides coverage in the gap. Will we lose that flexibility if we go down this road of closing the donut hole, as has been outlined in the House bill?

Ms. Cramer. Well, I don't believe so, Congressman. You know, our top priority is to completely close the donut hole because 26 percent of people enter that donut hole; only about 3 to 4 percent really exit that. And during that coverage gap, you have heard the stories about what people do with their drugs when they don't follow their drug regimen. So we think it is extremely important to --

Dr. Burgess. Now, I need to interrupt you there for just a moment because there are other options. And my office certainly works with individuals on an individual basis, as Mr. Shimkus pointed out. There is the option, though -- next year, during the open enrollment period, you don't have to stay on that particular policy under which you have been covered previously that has allowed you to end up in the donut hole. There are policies that provide coverage in the gap which would be available to that individual in the years ahead.

I am going to have to move on because there is some other things that I just need to get asked. And, first off, Ms. Stoll, I have to ask you the name of that medicine for migraines, because I am just dying of curiosity.

Ms. Stoll. Of course I won't be telling you the name of that product. Maybe we can have a private chat later.

Dr. Burgess. See, this is why this has to be on Oversight and Investigations, because we could put Ms. Stoll under oath and she would be required to tell me the name of the medicine and I wouldn't be left in the dark here.

Ms. Stoll. I will leave my colleagues to do the paid advertising for specific drugs. But, you know, I just want to raise an issue about --

Dr. Burgess. Well, hold that thought. We will talk about that privately, because I do have to get one last thought in to our two participants at the end.

We talk about what may be a causal relationship and what may be a casual relationship. I do think it is important, and one of the things we can't know at this hearing, because we don't have access to all the information, we can't know what is just a casual relationship between the \$80 billion that PhRMA said they are going to give up and a causal relationship, "Hey, if we give up \$80 billion, then we are going to be able to have price flexibility to make up some of that ground on something else." We just don't know.

So where is the line drawn between what is a casual relationship and what is causal?

Mr. Schondelmeyer. Well, that is more of a scientific or statistical question. But I think, just from a policy observational perspective, we have never seen drug prices go up this high in the last decade and a half. And this is a time when there is the most risk for drug companies -- that is, having either price controls or a change in the market structure in a way that affects their prices. And so, it would be logical that they are looking for ways to buffer their revenue for as much as they can and as long as they can.

Dr. Burgess. Well, again, that is speculation. It would be better if we were all on the record and under oath.

Let me just ask you one last thing. You said you have not seen a drug price go down. We did have Prevacid which went over-the-counter this past month, and the price drop has been

dramatic, and it still sold under a brand name.

Mr. Pallone. Can we ask you to respond in writing? Because we have a number of Members, and we have a vote coming up.

Dr. Burgess. Mr. Chairman, with all due respect, I sat here while many of our panelists -- and I appreciate them being here -- went significantly over time. This is an important issue.

Mr. Pallone. I understand that the panel went over time, but I am trying to keep the Members to the minute. We are going to have a vote at 12:15. We have a lot of Members, so respond to us in writing, if you will.

Next is Chairman Dingell.

Mr. Dingell. Thank you, Mr. Chairman.

This question is to Mr. Schondelmeyer.

Mr. Schondelmeyer, I am not sure you or the panel members remember years ago but we made some changes in the food and drug law which banned the imports of pharmaceuticals which could not be certified as safe by the Secretary of HHS. Do you remember that?

Mr. Schondelmeyer. Yes. I think that was back in the 1980s.

Mr. Dingell. So the law now says you cannot import pharmaceuticals unless they can be certified as being safe. Is that right?

Mr. Schondelmeyer. I believe the law says that. It has not been implemented.

Mr. Dingell. That is what the law says. So pharmaceuticals can be imported, but they have to be certified as being safe. Is

that right?

Mr. Schondelmeyer. I believe that is the case.

Mr. Dingell. Okay. Now, we have the nice problem that, if we change that, unsafe pharmaceuticals could be imported. Is that right?

Mr. Schondelmeyer. It depends on your certification process and how good it is.

Mr. Dingell. Well, if the Secretary can't certify that they are safe, they can't come in. Isn't that right?

Mr. Schondelmeyer. Well, they may not be able to certify for political reasons or for practical reasons.

Mr. Dingell. Dear friend, I wrote the legislation. It didn't say political reasons. It just says you can't import them unless they are certified and safe. Are you in accord with that?

Mr. Schondelmeyer. In what sense?

Mr. Dingell. Do you agree that that is good public policy?

Mr. Schondelmeyer. I believe there are processes by which an appropriate certification process could be undertaken.

Mr. Dingell. Well, and I have no objection. But, up until now, they have not been able to do it. And I don't want to engage in a great big toe dance here, I just want to get the record clear, because everybody is trying to reimport, and I am keep trying to tell them, "You can do so if the pharmaceuticals are safe and the Secretary can so certify." And I just want to get that into the record.

Am I correct in my appreciation on this matter or not?

Mr. Schondelmeyer. I believe you are, but, again, I am not a lawyer.

Mr. Dingell. Okay. Thank you very, very much.

Now, I note several things here, and very quickly I would like to get them. There is no trap here, so just please give me a yes-or-no answer.

H.R. 2962 will provide assistance for millions of other Americans to ensure that they can afford prescription drugs. This would have a substantial impact on medical adherence. Is that correct?

Mr. Schondelmeyer. I don't know the bills by their number, as you have quoted it, so I can't answer that, sir.

Mr. Dingell. All right. Now, H.R. 3962 will also close the donut hole. Is that not so, yes or no?

Mr. Schondelmeyer. Again, I don't recall the specific provisions of the bill.

Mr. Dingell. I am not trying to trap you, I am just asking you facts. You are my expert here, and I would like to get your help on this thing.

All right. Let's go to Mr. Smith.

With regard to H.R. 3962, it will provide financial assistance for millions of other Americans to ensure that they can afford their prescription drugs. Is this so or not?

Mr. Smith. Congressman, it provides assistance.

Respectfully, as you know, we oppose the bill.

Mr. Dingell. Thank you.

H.R. 3962 will also close the donut hole. Is that not so?

Mr. Smith. Same answer, Congressman.

Mr. Dingell. Okay.

Now, Ms. Stoll, if you please, we sometimes overlook the problems that confront millions of Americans with insurance that fails to cover adequate benefits and protection from financial bankruptcy. These are the underinsured.

You mention a 60 percent increase in the number of underinsured from 2003 to 2007. Could you tell us what are the major causes for this jump?

Ms. Stoll. Well, there are about 25 million underinsured. As we figure it, a major cause of that is lack of solid prescription drug coverage. A lot of plans in the individual market don't cover prescription drugs. We will fix that with H.R. 3962, so I applaud that.

Mr. Dingell. Now, we include a number of important provisions in H.R. 3962 such as the minimum benefit package that includes prescription drug coverage, elimination of the annual and lifetime caps, assistance for premium and out-of-pocket costs. Would these provisions help address the problems of the underinsured?

Ms. Stoll. Absolutely.

Mr. Dingell. Thank you.

Ms. Cramer, if you please, I would like to highlight your comments on Medicare Part D, the donut hole, the point at which beneficiaries are responsible for the full cost of their prescription drugs. You state, "Under current law, the donut hole is projected to almost double by 2016 to more than \$6,000. This means that Part D beneficiaries can find themselves paying the full cost of their drugs far longer in the future." This is quite unsettling to me.

H.R. 3962 provides a 50-percent discount on brand-name drugs in the donut hole, reduces the donut hole by \$500 in 2010, and eliminates the donut hole entirely by 2019, and authorizes the Secretary to negotiate on behalf of seniors for lower drug prices in Part D.

Give me your judgment. Are these steps sufficient to avert the substantial donut-hole growth that you have referred to by 2016 and to provide necessary and needed relief for our seniors?

Ms. Cramer. Yes, Congressman, it completely closes the coverage gap.

Mr. Dingell. Thank you.

Mr. Chairman, my time has expired, and I thank you for your courtesy.

Mr. Pallone. Thank you, Chairman Dingell.

The gentleman from Pennsylvania, Mr. Murphy.

Mr. Murphy of Pennsylvania. Thank you, Mr. Chairman.

Dr. Schondelmeyer, do you have any research that is funded by

NIH? Are you involved in any of the research funded by NIH?

Mr. Schondelmeyer. No, I have not conducted research in the lab, which is primarily the type of research conducted by NIH.

Mr. Murphy of Pennsylvania. NIMH, National Science Foundation, anything of that sort?

Mr. Schondelmeyer. I have had research funded by the Centers for Medicare and Medicaid Services.

Mr. Murphy of Pennsylvania. Okay. When that is done, what percentage of that research is there to cover overhead costs?

Mr. Schondelmeyer. What percentage --

Mr. Murphy of Pennsylvania. What percentage of your research grant just funds overhead costs, do you know?

Mr. Schondelmeyer. The University of Minnesota has a negotiated rate with the government --

Mr. Murphy of Pennsylvania. How much?

Mr. Schondelmeyer. -- that is like 51 percent, I believe.

Mr. Murphy of Pennsylvania. So 51 percent is not involved in the actual research but it goes to the overhead?

Mr. Schondelmeyer. That is negotiated between the government and the university.

Mr. Murphy of Pennsylvania. That is a standard, actually, for NIH grants, too, across the country, about 51 percent. As a matter of fact, I found it interesting that some universities, such as Harvard, have a 71 percent overhead rate; MIT, 67 percent; University of Minnesota is around 50 percent. It concerns me that

so much money is set out to do actual research but over 50 percent goes to things that have nothing to do with research.

Should we stop giving universities money for their overhead at these outrageous rates of nearly two-thirds or half or more that doesn't even go to taking care of the things they are supposed to do? What do you think?

Mr. Schondelmeyer. Well, first, as a mischaracterization, the 51 percent overhead means about a third of the money goes to overhead. It is 51 percent on the direct --

Mr. Murphy of Pennsylvania. With facilities and administrative, yeah, we are paying for buildings. But I am just asking, should we cut that so that universities should only use their research money to go directly to research and not go to pay the things to run the university? What do you think?

Mr. Schondelmeyer. No. Those overhead costs do pay direct costs that are -- or indirect costs that are related to the cost of conducting that research. In fact, the University of Minnesota estimates --

Mr. Murphy of Pennsylvania. A lot of the costs that the universities get in these things are not necessarily going to the research, which is helping save lives and develop new drugs, things like that, but we should keep paying that when it is not really going? I mean, some of it goes to a university president's salary. Some of them make quite a bit of money, I understand. Should we stop doing it?

Mr. Schondelmeyer. I am not a university president, so I don't know what --

Mr. Murphy of Pennsylvania. Okay. All right. Well, we will just keep you within your line.

Ms. Cramer, on the AARP board of directors, you have responsibility of oversight over the insurance plans that AARP contracts with, some of these companies. Does AARP have a Medicare Part D plan?

Ms. Cramer. Yes, we do.

Mr. Murphy of Pennsylvania. And who do you contract that with? Or do you run it yourselves?

Ms. Cramer. With United Health Group.

Mr. Murphy of Pennsylvania. How much do they pay AARP in royalties or whatever you would call it to offer that plan?

Ms. Cramer. I don't have that number with me.

Mr. Murphy of Pennsylvania. You are a member of the board. You just told me you have oversight over that. You tell me that something that is a massive amount of the income for AARP, you don't know how much it is?

Ms. Cramer. I don't know what portion is for the Part D plan.

Mr. Murphy of Pennsylvania. A dollar amount, you don't know.

Ms. Cramer. Congressman, I have answered. I don't know what portion is for the Part D plan.

Mr. Murphy of Pennsylvania. No, you haven't answered my

question. You said that over half of your income comes from insurance plans but you have no idea how much it is and you are on the board? I think you are chair of the board. And you are telling me you don't know what kind of money AARP makes? I don't understand that.

Ms. Cramer. Well, I have answered --

Mr. Murphy of Pennsylvania. No. Well, let me ask another question because I am trying to get an answer to that. So do you have a donut hole in your plan?

Ms. Cramer. I am sorry?

Mr. Murphy of Pennsylvania. Do you have a donut hole in your Medicare Part D plan?

Ms. Cramer. Yes, we do.

Mr. Murphy of Pennsylvania. You do. And yet you make millions and millions and millions of dollars out of your Medicare Part D plan. Why don't you use that money to fill the donut hole?

Ms. Cramer. Our plans operate under Federal and State laws just like any other plan does.

Mr. Murphy of Pennsylvania. But I am asking you, if Federal or State law allows you to have a plan that does not have a donut hole, why don't you fill the donut hole with the profits you make? After all, you are a nonprofit organization. Why don't you use that money -- I understand your executive director makes how much money for AARP?

Ms. Cramer. I am sorry?

Mr. Murphy of Pennsylvania. How much does your executive director get paid per year at AARP?

Ms. Cramer. He doesn't get paid what the Senate said he got paid.

Mr. Murphy of Pennsylvania. How much does he get paid?

Ms. Cramer. I would be glad to answer that offline.

Mr. Murphy of Pennsylvania. I don't understand why we can talk about everybody else's salaries but AARP's. And you are here criticizing other companies.

Ms. Cramer. It is around \$800,000.

Mr. Murphy of Pennsylvania. It is my time. The drug companies -- I am concerned about the cost of drugs, and I am concerned how much it costs people. But I want to get to the bottom of this. And so you have the cost of manufacturing the drug. You have the profits companies make. You have research and development for those drugs. You have advertising. I want to get to the bottom of that. But there is also the cost of administering plans.

And AARP is not an innocent partner in this, because you also make a lot of money from this. And when I ask you how much your director makes, suddenly that is off limits. But we can talk about --

Ms. Cramer. It is around \$800,000.

Mr. Murphy of Pennsylvania. -- how much money pharmaceutical companies make. I don't know how much money AARP is putting into

your pockets and how much is going to doing such things as eliminating the donut hole or reducing prices. What this committee needs to do is look at all of these levels.

And I think it is disingenuous for AARP to come in here and say, "When it comes to AARP, we are not telling you how much money we make or what we do with it," or, for some reason, the chairman of the board doesn't understand that stuff. When it comes to talking about --

Ms. Cramer. Congressman, I believe our --

Mr. Murphy of Pennsylvania. No. When it comes to talking about these prices, everything should be on the table.

I am deeply concerned about senior citizens who cannot afford drugs. I am deeply concerned about members of AARP who cannot afford drugs. But you are telling me a lot of this goes into your profits, you won't tell me how much your executives make in salaries, and you won't close your own donut hole.

And I yield back the balance of my time.

Ms. Cramer. Congressman, I believe our --

Mr. Murphy of Pennsylvania. I yield back the balance of my time. If you are not going to answer my questions, you don't have a right to answer.

Ms. Cramer. And the executive director's salary --

Mr. Murphy of Pennsylvania. Mr. Chairman, she is not going to answer my questions.

Mr. Pallone. Look, if she wants to answer the question --

Mr. Murphy of Pennsylvania. Mr. Chairman, she has told me she doesn't have the answers to these questions that I have asked.

Mr. Pallone. Ms. Cramer, if you would like to answer, you can.

Ms. Cramer. Well, as I said, I believe our audited report moments ago was entered into your record, which would include the information the congressman is asking. And also the 990, which is public document, would include information on our executive director's salary. I also said that it is around \$800,000 per year.

Mr. Murphy of Pennsylvania. Why don't you use that money to close the donut hole?

Mr. Pallone. She tried to answer your questions as best she could, and we do have the documents that were entered into the record by Mr. Shimkus.

We have about -- I guess we still have another 13 minutes or so, so I would like to get a couple more people in. Mrs. Capps is next.

Mrs. Capps. Thank you, Mr. Chairman.

And I want to spend most of my precious 5 minutes on the topic of medications used to treat cancer. But I want to give you a chance, Ms. Cramer, to talk 1 more minute or less, hopefully less, on the donut hole. Because, in your written statement, you reference AARP's donut hole calculator. Just to get it on the record for today's discussion, would you very briefly tell us what

that is?

Ms. Cramer. It is a new online tool that became effective in July. It is found at donuthole.aarp.org. It helps individuals calculate and track their out-of-pocket expenses. It helps individuals locate cheaper alternatives for their condition. It provides a personal medication record. And it also provides personalized letters; if individuals decide they want to pursue cheaper generics, it helps them begin the conversation with their doctor.

It is extremely popular. We have served over 180,000 people since it came online in July. That is a thousand people a day.

Mrs. Capps. Thank you very much.

There was an article in the New York Times this weekend, a pretty disturbing one, about the high cost of drugs treating cancer. And it reported that a new medication called Folutyn is going to be sold for about \$30,000 a month.

Now, for the record, drug companies should be able to make a profit. We need a profitable and successful domestic pharmaceutical industry.

But I am going to ask you, Mr. Smith, what good do breakthrough treatments do when they are unattainable for almost all the people who need them most? Is there any point at which your industry simply says, "No, we can't charge this much"?

Mr. Smith. Congresswoman, drugs absolutely need to be accessible for them to do good. That is one of the reasons that

we are trying to, you know, help support a health reform bill.

So, you know, in terms of this particular issue, I don't know anything about this drug, I don't know this company. But what I can say is that there are certainly cases where there are high-cost drugs, and these medicines -- you know, patients need high-cost medicines at times, just like they need high-cost hospitalization --

Mrs. Capps. Let me ask you -- go ahead.

Mr. Smith. And part of what we do with insurance is spread the risk across the entire population for the few people who need high-cost services.

Mrs. Capps. Well, this is a pretty big risk for a few people whose lives are hanging by a thread.

Here is the shocking part of the story, as it was reported in the newspaper. The drug hasn't even been shown to increase the life expectancy of those who take it. If a manufacturer is going to charge \$30,000 a month for a drug, I would think that they would want to be able to show that it at least helps patients live a little bit longer.

Now, you have answered, and I want to use whatever time, and it is only 2 minutes, to see if others on the panel would like to respond to this particular issue, either using this story or one other one. But I am focusing particularly on life-threatening diseases that are lumped together as cancer and the way the cost of treatment has gone up.

Dr. Schondelmeyer, you might want to speak to it or maybe Ms. Stoll, too, as well.

Mr. Schondelmeyer. Sure, I would. First of all, I did not see that article in New York Times this weekend. I will go back and look for that.

In our own study, the 12 cancer drugs that we had in the specialty area, those 12 drugs all went up in price, and the price increase in 1 year ranged between 4.9 percent up to as much as 20.8 percent increase in price in a single year. And then that compounds over time, of course, as prices keep going up.

I think the point you raise is one of, we have to assess what is the real margin of value that a drug adds to society. And I am going to shift away from a cancer drug, but I think it is the same principle. A drug called Zetia, which is supposedly used for cholesterol, we recently found that that drug really is not as effective as we thought and not as effective as an old drug that is very inexpensive even though it has a slight, small convenience-type side effect perhaps. But Zetia, itself, was able to raise their price dramatically in the marketplace even though it is not even effective.

Mrs. Capps. Let me see if Ms. Stoll -- what do you think we should do now? How can this legislation of health reform address this particular egregious issue?

Ms. Stoll. Well, there are a number of drugs that are expensive like this one in the New York Times article. I think

part of the answer is, again, we need to get everyone into the system; we need to have a pooled program where we are sharing costs. Not everyone is going to need these expensive drugs. We need prescription drug coverage with annual and lifetime limits. And we need special and lower limits for low-income people to protect them so that their access to this drug and other drugs like it are not limited.

And I think that is where you find, in this sort of back and forth between good and bad today, some common ground among all of us in wanting to see that everyone is in the system and has out-of-pocket protections so they can have access to drugs.

Now, drugs should be evaluated to make sure they bring more value and new value to what is already on the marketplace.

Mrs. Capps. Thank you very much.

I yield back.

Mr. Pallone. We have 7 minutes left. I would like to get Mr. Buyer in, if that is okay. I am assuming that the other Members will come back after the votes. We have four votes.

Mr. Buyer?

Mr. Buyer. I have two questions of two different witnesses, one of Professor Vernon. I want to you think about this. And then I have some questions of Ms. Cramer.

In my opening statement, I made some comments regarding the impact of price controls in the European Union that has been part of your studies. And now that you have had a chance to examine

H.R. 3962 and some of the price controls and the comparative effectiveness that is in that bill, I want you to talk a little bit further about the potential impact of those controls upon drug pricing and whether it has a positive or negative impact upon public health. Okay?

Secondly, Ms. Cramer, I would like for you to respond -- number one, I would like to know whether AARP, whether your organization has produced requests or received any estimates about how much additional revenue per annum will be created to your organization by H.R. 3962. That is number one.

Number two, I also would like to know whether your organization had any contact with this committee, any contact with this committee, or their staff relative to the sweetheart deal that you have in Section 102 of H.R. 3962. Most insurance plans are required to have a medical loss ratio of 85 percent. However, this bill that passed the House allows Medicare supplemental insurance plans, such as AARP's Medicare supplemental insurance plan, to have a medical loss ratio of 65 percent. I would like to know whether or not your organization had any contact in the advocacy of that. And I will give you a chance to respond.

Professor?

Mr. Vernon. Thank you, Congressman.

I would begin by saying, you had referenced my study with Professor Golec at the University of Connecticut regarding the exodus of R&D investment from Europe to the U.S. That is

certainly true. I mean, we have seen regulations of pharmaceutical prices in the EU become more stringent, the U.S. now being largely the only price-unregulated market for pharmaceuticals in the world. And, certainly, you know, the prize in terms of both basic research, which could be done globally, but specifically later-stage research, large clinical trials, and, you know, marketing networks, as well as a familiarity with how to get through the FDA process has resulted in a lot of R&D leaving Europe and coming to the U.S. And, as a result, we have seen a dramatic change in the levels of R&D comparing the two markets.

And then, also, generally speaking, regarding the legislation, any attempt, implicit or explicit, to control drug prices -- there have been bills on reimportation, technology assessment, and perhaps negotiated drug prices -- does represent a very serious threat to the incentives to undertake R&D. And, to be frank, it is remarkable, research by economists at Yale and the University of Chicago have shown that the benefits of pharmaceutical innovation and medical innovation have been astounding and far exceed the levels of investment and the cost of that investment, suggesting we should be doing more medical research, more pharmaceutical research, because the benefits exceed the costs.

Now, that being said, I am not denying the fact that cost-containment measures would benefit consumers of existing medicines that are on the market. It would make them more

affordable, improve access and utilization, and improve health. But I think we have to consider that cost and that benefit, and specifically that benefit of lower-cost medicines today, with what it would mean for the rate of innovation in the future. And I think the latter is an order of magnitude greater than the former, based upon the empirical research out there.

Mr. Buyer. All right. Thank you.

Ms. Cramer?

Ms. Cramer. The answer to both of your questions is no. We have not, to my knowledge, had any estimate of revenues that AARP would lose or gain under House bill 3962. And I have checked with staff; to my knowledge, there has been no contact with the committee looking at the medical loss ratio we advocate on behalf of members.

Mr. Buyer. The Congressional Budget Office has said that H.R. 3962 will result in fewer people enrolled in Medicare Advantage -- "fewer" really is 3 million -- and more people enrolled in Medicare Part D.

Isn't it true that the vast majority, probably up to 80, 90 percent, of people enrolled in Medicare Part D by a supplemental insurance policy, such as the AARP Medicare supplemental insurance plan offered by United Health Care?

Ms. Cramer. Are you asking me?

Mr. Buyer. Wow. Who else would I be asking?

Ms. Cramer. Well, Congressman, I don't work for United

Health Care, so I don't know that I can answer that question.

Mr. Buyer. Well, I find it really hard to believe -- well, first of all, there is going to be a tremendous shift to supplementals which you offer. And I cannot believe that you run an organization that you have never really calculated what the potential income flow to your organization will be. That is really, really surprising to me.

I guess you are just trying to guard yourself in exchange for questions about why you endorse the overall packet, but I think it is now obvious.

I yield back.

Mr. Pallone. Thank you.

Now, we are going to have four votes on the floor, maybe half an hour, a little more. I am assuming that some Members are going to come back. So, if you would wait, we would ask you to wait. And the subcommittee will stand in recess.

[Recess.]

RPTS CALHOUN

DCMN MAYER

[1:13 p.m.]

Mr. Pallone. The subcommittee will reconvene, and I will ask the witnesses to come back to the table. I don't think we will be much longer. Thank you for bearing with us.

Next is the gentlewoman from the Virgin Islands, Ms. Christensen.

Ms. Christensen. Thank you, Mr. Chairman. I didn't have an opening statement, so let me thank you for holding this hearing.

As a physician, I am, of course, well aware of the key importance that pharmaceutical companies have made to the advances which have made and will continue to make in our health and health care. Overall, Americans, including the patients I have served over my lifetime, are living longer with better quality lives because of the products that the companies have created.

Unfortunately, that is not true for all. Although Medicare Part D has made a substantial improvement, people of color, the elderly, disabled and the poor continue to not be able to afford medications that they need to keep them healthy, despite some of the free and discount programs.

I know that medication costs are not the only cause of increasing health care spending. I am also not against profits. And most definitely I support the research and development which

has resulted in better lives for all of us. But I do not discount the AARP report either, as it tells a true story of people across this country who cannot afford to take all their medications every day as prescribed. So I don't think we should make light of that report at all.

I will start with Ms. Cramer on my first question. AARP plays a critical role in advocating for its membership for seniors and really for everyone one in health care, retirement security, and things that all of us care about. I would assume the membership dues alone don't support these activities.

Is it safe to say that the royalties we have heard so much about this morning are used to make important services available to your members and to fund advocacy efforts on issues that even some of those companies that are paying with those royalties may not agree with AARP on?

Ms. Cramer. Yes, that is safe to say. We often have disagreements with the providers, but the royalties do support AARP -- our education, our advocacy, our member engagement -- not only in Washington, D.C., but as you know, with the 53 State offices in the Territories and the States.

Ms. Christensen. And we thank you for the support that AARP has given to the Virgin Islands.

Mr. Smith and Professor Vernon, this is on pricing, so I can understand this better. At the point at which generics come on the market, has the brand-name producer generally recouped their

cost to research and develop those products, and if so, why then do the costs continue to go up after that point, especially in excess of what the inflation is?

I ask that because when we see the new technologies come on the market, they are usually really expensive. And after a few years their prices go down. But it is the opposite for pharmaceuticals. Can you explain that for me?

Mr. Vernon. Madam Congresswoman, first, I would say that recent research undertaken by myself suggests that only two out of every ten pharmaceutical products that reach the market generate after-tax present value returns in excess of average R&D costs. I would also say we have very intense generic competition at patent expiration for very large, successful products.

The price of generics is driven very rapidly down to the marginal manufacturing cost of pharmaceuticals. We have the most competitive, lowest price, highest utilization rate of generics in the world, very successful as a result largely of the Waxman-Hatch Act.

I would also say that there is some uncertainty whether pharmaceutical prices have indeed been rising as fast as has been purported in this hearing.

And also I would add one more point, and that is that the suggestion that firms are raising prices in anticipation of health care reform is not at all clear. Certainly, the most comparable recent legislation to the current legislation was the Clinton

Health Security Act, where we saw firms pledging publicly -- that got them in trouble with the FTC -- to restrain drug prices.

There are other factors like compressed product lifecycle cash flows as a result of patent challenges, intensified generic competition, that could be driving what we are observing in the pricing of pharmaceuticals, as well as the mix of biologics and pharmaceuticals, a shift towards more-costly-to-develop biologics, which have higher prices, versus fewer pharmaceuticals.

Ms. Christensen. Well, it may be 12 years, we hope, but wouldn't you expect to get back what you have put into R&D and begin to make a profit in that period of time? That is what we are assuming.

I just wonder why the prices keep going up when a product has been on the market for years; technology has the same kind of competition, but their prices go down.

Mr. Vernon. Well, I think there are a lot of dynamic factors, and certainly the market is very different now. As I said, we have much more intensive generic competition; we have a higher rate of patent challenges; we have lower productivity with respect to pharmaceuticals; and we are seeing more biologics on market, which have a higher financial cost of capital and higher manufacturing costs. So we are seeing that mix shift between pharmaceuticals and biologics.

Ms. Christensen. Let me try to get another question in to

Ms. Stoll and Dr. Schondelmeyer.

I will acknowledge that our health status in this country would not be where it is were it not for the investment in research and development that the pharmaceutical countries make, although it would be a lot higher and better if all of us were able to participate in access to those drugs.

Do you believe there has to be a tradeoff between research and development and lowering the cost to consumers? Research and development always is what comes up when you talk about lower costs.

Mr. Schondelmeyer. I believe there is a tradeoff we are making already, but we are not doing it very consciously. We are doing it more implicitly rather than explicitly.

In America we may generate much of the R&D for the world that finds new medicines, but we probably have a higher percentage of our population as a developed country who don't have access to medications than any other developed country, and so that is why our health status overall is down around 20th instead of at the top of the list.

So we are making that tradeoff already and some people are paying the price. Others derive the benefit of the wonderful medicines that are discovered.

Mr. Pallone. We are going to have to stop, only because I can't allow the others.

All right.

Ms. Christensen. Thank you.

Mr. Pallone. Thank you.

The gentleman from Maryland, Mr. Sarbanes.

Mr. Sarbanes. Thank you, Mr. Chairman, and I appreciate you all coming back or staying while we came back.

Dr. Schondelmeyer, is the cost of R&D something that is accounted for before the profit numbers or something that happens with the profits?

Mr. Schondelmeyer. As I understand the way drug companies keep their books and the profits they report to Wall Street, R&D has already been costed out at that point.

Mr. Sarbanes. Right. So we are looking at profits of \$51 million in 2008 and a 19 percent return on revenue, and since 2005, \$180 billion in profits. This is after the R&D. So that makes this kind of R&D justification for where the pricing is less compelling to me, if I am understanding sort of how the books are kept on that.

I have to say, Mr. Smith, I know you can't comment on the motives, but I have no doubt that the pharmaceutical companies are running up the price in anticipation of health reform, based on past experience with them doing that. We see it also happening with the health insurance industry. There is evidence that the premiums for next year's renewals have been sky high with the recent notices that have gone out.

The disappointing thing with the -- I guess it cuts both

ways. I am disappointed maybe that the health insurance industry didn't make a deal the way PhRMA did, but I am disappointed that PhRMA, having made a deal, appears to be price gouging in anticipation of what is coming so they can establish a new baseline.

My question was, "the deal," as it is referred to, I guess, was about \$80 billion. Is that represented by the 50 percent discount that is expected to be offered to people in the doughnut hole, or does that account for some other things as well?

Mr. Smith. Congressman, as I mentioned earlier, I didn't come prepared today to testify about "the deal," but at a broad level the industry's contribution towards the cost of health reform would include the 50 percent discounts in the coverage gap.

As you know, both bills -- both House and what we see in the Senate -- include very substantial increases in the Medicaid rebate, very substantial extensions of the Medicaid rebate across to much broader a population than it applies to today, beyond the currently uninsured population that would become eligible for Medicaid.

As you know, the Senate bill includes some other fees, and as you know, both bills include provisions to create a pathway for follow-on biologics. It also comes with a pretty sizable government score.

Mr. Sarbanes. I would hope the contribution that PhRMA is willing to make would increase in relationship with the change in

the baseline on the drug pricing that is appearing to occur right now. In other words, if at the time the deal was made, the pricing was here, and that meant that a 50 percent contribution to the cost in the doughnut hole at that pricing represented this amount of money, then if the pricing is going up substantially, then the amount needed to cover a 50 percent discount would also go up; and beyond that, the amount needed to get you back to the anticipated discount for the consumer would even be more.

So I just hope that PhRMA is ready to stick with the deal it made in terms of the effect or the benefit it would have on the consumer in relationship to the increase in the baseline that seems to be occurring as a result of, again, what I view as a kind of price gouging scheme in these last few weeks and months.

With that, I will yield back.

Mr. Pallone. Thank you.

Let me thank all of you for coming today. This is not an easy issue. The way it works is, members can still submit written questions through the clerk. I think the clerk is supposed to get back to you within 10 days or so.

So we still may get additional written questions. I know that a number of you said you were going to respond in writing to some of the questions that were asked by the members as well. But, in any event, we do appreciate you coming.

Dr. Burgess. Mr. Chairman, can I ask unanimous consent -- we are up against the clock here at the end of the

year, and to the extent possible, could we have these written responses within 5 days so we would have an opportunity to evaluate those before we get into this ping-pong match with the Senate with whatever they are going to do at the end of the year?

Mr. Pallone. The way the rules are, we usually have 10 days for Members to submit the questions and then we send them to the witnesses. I don't think 5 days is enough time.

I would ask that you get back to us fairly quickly, but I don't want to put a date on it because I think it depends on how complex they are. But please get back to us as quickly as you can, once you get the questions.

Dr. Burgess. Mr. Chairman, further inquiry: I think you would acknowledge it is unlikely this health care bill is going to go to a conference.

Mr. Pallone. If it is passed by the Senate by the holiday, we will probably go to conference in January. It all depends on when the Senate passes it. But the intention is to go to conference. I don't know how we could avoid that, given there are probably going to be major differences.

Dr. Burgess. The way we would avoid it is, your Speaker would say we simply have to accept what the Senate does, and we acquiesce to the Senate bill by the end of the year.

Mr. Pallone. You know, Dr. Burgess, I can't predict that. Everyone is saying there will be a conference. I think it is likely that there will be.

Dr. Burgess. Well, I am depending upon you as my subcommittee chairman to advocate that there be a conference and that it be a real conference.

Mr. Pallone. You do not have to worry about my advocating for a conference. I will advocate for a conference, I assure you.

Dr. Burgess. The same way you advocated for a subcommittee markup.

I yield back.

Mr. Pallone. I guess we are done. Without objection, this subcommittee is adjourned.

[Whereupon, at 1:28 p.m., the subcommittee was adjourned.]