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THE OBAMA ADMINISTRATION=S MEDICARE DRUG EXPERIMENT: THE PATIENT AND DOCTOR PERSPECTIVE

TUESDAY, MAY 17, 2016

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Joe Pitts [chairman of the subcommittee] presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Green, Engel, Capps, Schakowsky, Butterfield, Castor, Sarbanes, Schrader, Kennedy, Cardenas, and

Pallone (ex officio).

Also present: Representative Welch.

Staff present: Mike Bloomquist, Deputy Staff Director; Sean Bonyun, Communications Director; Rebecca Card, Assistant Press Secretary; Karen Christian, General Counsel; Paul Edattel, Chief Counsel, Health; Tim Pataki, Member Services Director; James Paluskiewicz, Professional Staff, Health; Graham Pittman, Legislative Clerk, Health; Chris Sarley, Policy Coordinator, Environment and the Economy; Jennifer Sherman, Press Secretary; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Sophie Trainor, Policy Advisor, Health; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Jessica Martinez, Minority Outreach and Member Services Coordinator; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; and Arielle Woronoff, Minority Health Counsel.

Mr. Pitts. I will ask all members to take their seats. The time of 10:00 has arrived. The subcommittee will come to order. The chair will recognize himself for an opening statement.

Today=s hearing will take a closer look at a recent proposed rule from the Centers for Medicare and Medicaid Services, CMS, on a Part B drug payment model. This proposal represents the biggest change in Medicare drug reimbursement in years.

There are several aspects that are concerning to many, including the mandatory nature of this so-called demonstration project, the breadth of the experiment essentially across the nation in virtually all primary care service areas and the timing.

These major changes would take place as early as July and on top of the current implementation of MACRA, the new payment structure for physicians that replace the SGR, the sustainable growth rate.

But perhaps the most concerning aspect of this proposal is that it came from unelected bureaucrats in this administration who made the decision behind closed doors affecting our seniors and their health care.

What happened to the transparency in regard to stakeholders that we expect when considering proposals of this magnitude? In fact, these concerns over provider reimbursement under the Medicare Part B program are so considerable that recently 242

bipartisan members of Congress wrote to the Administration and asked that the rule be withdrawn.

Several others letters from both the House and Senate have been sent detailing numerous and serious concerns. Moreover, our Health Subcommittee colleague, Dr. Larry Bucshon, recently introduced legislation that would stop this proposal from advancing.

So today, we=re going to hear from doctors and patient advocates about their views on this proposed rule. I want to make it clear at the outset that we are not opposed to demonstration programs and in fact have supported a number which tests certain models in limited areas to determine positive or negative outcomes and whether such demonstrations should be advanced in a larger context.

However, the health and well-being of seniors is nothing to be experimented with. This particular rule could result in grave consequences for our seniors. CMS is proposing to reduce reimbursement for physician-administered drugs with half of the country=s providers seeing dramatic cuts.

The other half will retain current reimbursement levels but half of those will be used to test out vague value-based purchasing arrangements and after a very long five years CMS will see what happened.

Keep in mind Medicare is the largest payer of provider-administered drugs. The Part B program covers provider-administered injectables and certain other drugs for physician offices and outpatient clinics the provider purchases and administers the product before submitting a claim to Medicare.

After purchasing a drug from a wholesaler or a specialty distributor, the provider will store the product at its location.

The provider then administers the drug to the patient and after the patient receives the drug and any other medical care, the provider then submits a claim for reimbursement, hence term buy and bill, because the medical claim is submitted after the provider has purchased and administered the drug.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 -- MMA-requires Medicare to use a drug=s average sale price -- ASP+6 percent for reimbursing provider-administered injectable drugs.

ASP is based on the manufacturer=s actual selling price minus all price concessions. CMS asserts this system somehow gives incentives for physicians to prescribe more expensive drugs and therefore has proposed this nationwide two-phase experiment which would allow half of the providers to continue to be reimbursed at ASP+6 percent while the other half would receive the lower ASP+2.5 percent rate plus a fixed $16.80 payment.

However, with the impact of sequestration calculated in the reimbursement falls to nearly ASP+0 percent. This proposal is so far reaching and has caused so much concern it is difficult to imagine any meaningful conclusions can be drawn because marketplace realities will undermine the integrity of this massive and unprecedented experiment on patients and providers.

My time has expired so I yield back the balance of my time and now recognize the ranking member of the subcommittee, Mr. Green, five minutes for his opening statement.

Mr. Green. Thank you, Mr. Chairman. Good morning. I thank our panels for being here today.

As we know, CMS, through the Centers for Medicare and Medicaid Innovation, recently proposed to test value-driven payment models for prescription drugs under Medicare Part B.

This proposal has garnered significant reaction and response from the provider, patient, and the pharmaceutical communities.

I appreciate the chair for having this hearing today and hope this committee will take the opportunity to examine the proposals, merits and drawbacks.

While the loudest voices have been oppose to the model outright, it is important to thoroughly evaluate the issues CMS is attempting to address and look at the proposal with calm and reason, and I appreciate CMS= consistent goal of strengthening the

Medicare program. However, I have some concerns about the size and scope of the proposed demonstration and its potential impact on Medicare beneficiaries= access to physician-administered drugs now and in the future.

I also question how the demonstration may affect physicians= participation in existing and upcoming delivery and payment reform models.

Currently, Medicare Part B pays physicians and hospital outpatient departments the average sales price, or ASP, of a drug plus the 6 percent add-on on payment commonly referred to as ASP+6.

Medicare pays ASP+6 for drugs regardless of the price paid to acquire the drug. MedPAC and others have raised concern that the 6 percent add-on may create incentives to use higher priced drugs when lower priced alternatives are available and appropriate for the patient.

It=s difficult to know the extent in which a percentage add-on to ASP influences drug-prescribing patterns because few studies have looked into this issue.

Prescription drug spending in the United States was about $457 billion in 2015 and roughly 17 percent of the overall health spending. In 2015, Medicare Part B spent $20 billion on outpatient drugs administered by physicians and hospital outpatient departments, which has doubled the amount spent in

2007.

Beneficiary cost sharing under fee for service Medicare Part B is 20 percent with no out of pocket limit. According to the GAO, some seniors and people with disabilities have faced catastrophic expenses amounting to as much as $100,000. The median income -- annual income for Medicare beneficiaries is less than $25,000 a year and one in four have less than $12,000 in savings.

There=s a national conversation occurring about the cost of prescription drugs. I appreciate CMS for attempting to address this issue in part by proposing to test tools that reward value in Medicare Part B similar to the efforts in the private sector.

Congress should not ask seniors to pay 20 percent of increasingly expensive therapies without due consideration of whether their money is being well spent. Health care delivery systems are rightfully changing and Medicare should not be left behind.

I=m confident that providers will fulfill their calling and practice medicine, delivering the best care for their patients rather than pad their bottom lines.

Yet, on behalf of seniors and the sustainability of the health care system at large we cannot put our heads in the sand and ignore trends. This proposed model is far from perfect and I have serious concerns about the aspects of it.

Recently, I joined members of this committee in sending a letter to CMS outlining our concerns with the demonstration and urging the agency to address them.

I ask for unanimous consent, Mr. Chairman, to submit this letter for the record.

Mr. Pitts. Without consent, so ordered.

[The information follows:]

**********COMMITTEE INSERT 1**********

Mr. Green. I look forward to hearing from our witnesses about their perspective of the model and concerns we=ve outlined to the agency.

Taking a step back, I=m going to bring up a related issue that has become part of the conversation around the demonstration which is that of prompt pay.

I have long had an interest in preserving seniors= access to quality care by ensuring Medicare pays at a rate that will retain a robust network of providers.

H.R. 696, also know and the Prompt Pay bill, is a piece of legislation I=ve introduced with my colleague on our committee, Mr. Whitfield, for several Congresses.

The bill excludes the prompt payment discounts offered by manufacturers to wholesalers from the average sales price for drugs and biologics covered under Medicare Part B.

This became an issue when the Medicare Modernization Act was enacted in 2003. It reduces the amount doctors are reimbursed for administrative treatments and as a result patients are pushed to more expensive settings for their care.

Reducing the number of options for patients, diminishing the access drives up the costs in both short and long term and is bad policy. The Prompt Pay discount has negatively affected patients for many years before sequestration and whether we adopt

legislation repealing, replacing or otherwise authoring the sequester without adopting H.R. 696 the underlying issue will still exist.

Thank you, Mr. Chairman, and our witnesses here today and I look forward to a robust discussion about the proposed demonstration and I yield back my time.

Mr. Pitts. The chair thanks the gentleman and now recognizes the vice chair of the full committee, Mrs. Blackburn, five minutes for opening statement.

Mrs. Blackburn. Thank you, Mr. Chairman, and I do want to say welcome to our witnesses. I think that you can tell from the chairman=s statement and from -- you=ll find out from the questions that you hear we are all very concerned about a couple of things that are happening with the demonstration project.

Number one, rural areas -- they=re already challenged and I have 19 counties in my district in Tennessee and some of the more rural counties are quite concerned about this and health care providers are very concerned about this and fear that this may be the type component that pushes some of these providers to the brink and out of the business in service areas.

So we are very concerned about that, especially when it comes to things like cancer and getting the appropriate treatments. And Mr. Chairman, I would like to include for the record a letter that

is dated April 29th from Senator Grassley to Secretary Burwell.

Senator Grassley has made specific inquiries of the secretary if CMS -- if this model is in fact a clinical trial but without the typical patient safeguards.

And I understand that clinical trials are important. In my district we have a lot of physicians and researchers who participate in this when it comes to oncology treatment.

I have had the opportunity to visit with some of them and they are quite concerned about the way this is moving. So I ask permission to submit the letter.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 2**********

Mrs. Blackburn. Thank you, Mr. Chairman, and to each of you again, we=re going to look forward to digging a little deeper on this. Access to the right type care at the right time is essential for positive outcomes and so we will be seeking your guidance and with that I will yield to any other member of the committee seeking time or will yield back.

Mr. Pitts. All right.

Mrs. Blackburn. Yield back.

Mr. Pitts. Without objection the lady yields back and now the chair recognizes the ranking member of the Full Committee, Mr. Pallone, five minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman, and thanks to the witnesses who will be testifying today. I think we would all agree that it is critical we continue to transform our health care system into one that incentivizes value over volume.

That is the theme we heard time and again when we worked together to repeal the SGR and replace it with a payment system that rewards doctors for the quality of care they give to seniors and we were all in agreement that more care must be replaced with better care. The status quo, we said, was unsustainable.

The success of this kind of delivery system reform, however, is not possible if we do not give Medicare the tools to stay in business.

Medicare must be able to innovate just like the private sector is doing and that=s why I support the innovation center that was authorized in the Affordable Care Act because it allows Medicare to test new models that improve care and save money.

Now, we=ve all heard loud and clear that there are concerns with the center=s most recent proposal to change the way we reimburse doctors for drugs administered in their offices under Part B. I look forward to hearing more from our witnesses today about the rule. I don=t think anyone here would claim this proposal is perfect.

I=m particularly interested in hearing about how to ensure that seniors have access to necessary drugs. I=m also interested in better understanding how we can assure that the evaluation of this proposed model is robust and thorough before it=s expanded.

To date, there has been widespread engagement ranging from comments from stakeholders to letters from members of Congress.

This feedback is an important part of the process, and I believe the Administration will take into account these concerns and make changes to address them in the final rule.

So I=d like to now yield the remainder of my time to Congresswoman Schakowsky.

Ms. Schakowsky. I thank the gentleman for yielding. I strongly believe that lowering drug prices is imperative to the sustainability of our health care system, especially our public

insurance programs like Medicare, and I support CMS= proposal to create a demonstration project for drugs paid under Part B.

Luckily, I=m not alone. Many organizations that represent beneficiaries, insurance companies and consumer organizations including AARP, Aetna, the AFL-CIO, the Alliance for Retired Americans, ASME, the American Federation of Teachers, Center for American Progress, Center for Medicare Advocacy, Doctors for America, Consumers Union, Families USA, Justice and Aging, Kaiser Permanente, Medicare Rights Center, National Committee to Preserve Social Security and Medicare, the National Education Association, the National Partnership for Women and Families and the Boilermakers, among others, support this proposal, and I=d like, Mr. Chairman, to enter their letters of support for the Part B demonstration project into the record.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 3**********

Ms. Schakowsky. I=d also like to enter into the record several additional statements of support from many of those same groups as well as the United Steelworkers, the Public Sector Health Care Roundtable, United Auto Workers and the Academy of Family Physicians supporting CMS= proposal.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 4**********

Ms. Schakowsky. And I -- thank you -- and I=d also like enter into the record a letter signed by 20 members of the House and a letter signed by 11 Senators supporting CMS= proposal.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 5**********

Ms. Schakowsky. Yet, every time we attempt to do anything to rein in drug costs we are met with fierce opposition. We are actively reforming every other aspect of our health care system to pay for value except pharmaceuticals.

In fact, drug manufacturers are the only one entity that can charge Medicare anything they want for their products. We would never accept that from any other entity in our health care system and we should no longer accept it from pharma.

The proposal from CMS is not final. They have committed themselves to working with stakeholders to address their concerns. In fact, CMS has indicated that they would be open to changes including the scope of the proposal and exceptions for small and rural providers.

But all we hear today is no. With no alternative ideas on how to realign incentives and reduce drug costs for beneficiaries and that is not good for anyone anymore.

We cannot continue on this unsustainable path where drug costs rise faster than overall health costs and patients are bankrupted in order to pay for the lifesaving drugs that they need.

You know, in some ways I would rather find out that there is no cure for a certain disease that I have than know that that cure is right there in front of me but I simply cannot afford it. Because I don=t have the dollars to pay for it, I can=t get that cure. This is unconscionable. I think it=s also un-American,

and I yield back.

Mr. Pitts. The gentleman=s time has expired. As usual, all opening statements of the members will be made a part of the record.

I have a UC request as well. I=d like to submit the following documents for the record: statements from the National Council on Disability, Health Care Leadership Council, American College of Rheumatology, Academy of Managed Care Pharmacy, letters from the ASP Coalition, two dozen members of the patient community, Partnership to Improve Patient Care, the American Association of People with Disabilities and over 80 other patient advocacy organizations, Senate Finance Democrats, Representative Scott Peters, 25 Democratic members, Senate Finance Republicans and we also completed a review of 218 comments from state and national groups as well as over 800 individuals. The vast majority of comments express concern and urge withdrawal.

[The information follows:]

**********COMMITTEE INSERT 6**********

Mr. Pitts. So at this point, I=ll introduce the witnesses in the order that you will present testimony. First of all, we have Dr. Debra Patt, MD, MPH, MBA, Vice President, Texas Oncology Medical Director, the U.S. Oncology Network Chair, Clinical Practice Committee of the American Society of Clinical Oncology, Editor-in-Chief, Journal of Clinical Oncology, Clinical Cancer Informatics and Board Member of Community on Oncology Alliance. Welcome.

Then Dr. Michael Schweitz, MD, FACP, MACRNational Advocacy Chair, Coalition of State Rheumatology Organizations, CSRO; Ms. Marcia Boyle, President and Founder, Immune Deficiency Foundation; Ms. Heather Block, a patient advocate and Mr. Joe Baker, President, Medicare Rights Center.

Thank you for coming today. Your written testimony will be made a part of the record. We ask that you summarize. We=ll give you each five minutes for your summary. So at this point the chair recognizes Dr. Patt five minutes for your opening statement.

STATEMENTS OF DR. DEBRA PATT, MD, MPH, MBA VICE PRESIDENT, TEXAS ONCOLOGY, MEDICAL DIRECTOR, U.S. ONCOLOGY NETWORK, CHAIR, CLINICAL PRACTICE COMMITTEE, AMERICAN SOCIETY OF CLINICAL ONCOLOGY, EDITOR IN CHIEF, JOURNAL OF CLINICAL ONCOLOGY, CLINICAL CANCER INFORMATICS, BOARD MEMBER, COMMUNITY ONCOLOGY ALLIANCE; DR. MICHAEL SCHWEITZ, MD, FACP, MACRANATIONAL ADVOCACY CHAIR, COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS; MARCIA BOYLE, PRESIDENT AND FOUNDER, IMMUNE DEFICIENCY FOUNDATION; HEATHER BLOCK, PATIENT ADVOCATE; JOE BAKER, PRESIDENT, MEDICARE RIGHTS CENTER

STATEMENT OF DR. DEBRA PATT

Dr. Patt. Chairman Pitts and Ranking Member Green, thank you for the opportunity --

Mr. Pitts. Make sure your button is on. Is that on? The red light=s on?

Dr. Patt. Yes, sir.

Mr. Pitts. Okay. There you go.

Dr. Patt. Chairman Pitts and Ranking Member Green, thank you for the opportunity to testify today on behalf of Texas Oncology, the U.S. Oncology Network, the Community Oncology Alliance and the American Society of Clinical Oncology regarding the oncology community=s grave concerns with the proposed Medicare Part B drug payment model.

My written statement provides numerous arguments against the CMS-proposed model but with the limited time I have today as a physician I will tell you why this is bad medicine for patients.

I am Dr. Deborah Patt and for 13 years I have been providing care to cancer patients in Texas. As a physician, quality care and value are the standards by which I practice every day.

My patients often face life and death situations and my responsibility is to help them choose and then deliver the personalized treatment for their disease. Increasingly, the time I have to spend with patients is consumed with overcoming a complex maze of administrative obstacles to provide treatment.

But the CMS-proposed model is not just another hurdle. It=s an experiment that is simply unworkable in cancer care. Let me explain.

CMS has proposed an experiment that randomizes physicians by zip codes into test and control groups. The study hypothesis is that financial disincentives for use of newer more expensive drugs will cause physicians to choose less expensive treatment alternatives.

In my world, this is clinical research. Unlike the CMS experiment, however, my patients have to volunteer their participation in a clinical trial. But there is no opting out of this mandatory national experiment.

There is no informed consent for patients, no monitoring for

adverse events and no ability to evaluate impact on quality and outcomes. These are central requirements of any ethical research.

In this experiment, Medicare beneficiaries in certain zip codes won=t have access to treatments that have a known survival advantage. This is simply unacceptable.

More fundamentally, the underlying hypothesis for this experiment that these incentives will result in reduced Medicare spending is simply unfounded. I will let my written testimony explain how United Health Care Project has already disproved the CMS hypothesis.

Today, I=d like to focus on how few opportunities there are to select therapeutic alternatives based solely on drug price. Ten years ago when I met my patient Karen, who has metastatic breast cancer, she couldn=t walk. She couldn=t stand without pain. Her bones were riddled with disease and she was told there was no hope. Within a year of meeting Karen she developed metastatic breast cancer to her brain. Ten years ago, we knew that patients with metastatic breast cancer to their brain lived an average of a few weeks. Karen had an option of a different treatment because he disease amplified a receptor called HER2 and she was given a novel and targeted therapy that we know would change her course dramatically.

In the last ten years, Karen has had some disease progression

in her brain. But she=s lived to see her son get married and she danced at his wedding. She=s lived to see her first grandchild be born and grown into school age and she continues to receive targeted treatment today and enjoys a good quality of life.

These targeted therapies are expensive but the alternative treatment to these expensive medications would lead to an early death. Premature death is not a treatment alternative.

When I started my fellowship at the MD Anderson Cancer Center in 2003, myeloma patients lived an average of three years. Usually they were three years of toxic therapy.

Today, an average myeloma patient lives greater than seven years due to new novel therapies and they live better because myeloma has become a chronic disease where many patients have remission for many years.

The treatment is expensive but the lower cost alternative would shave years off their life and diminish their quality of life as well. I remind the committee that Medicare covers 60 percent of cancer patients and the number of Medicare beneficiaries are growing every day.

The CMS experiment has the potential to affect treatment options and outcomes for the most significant and vulnerable segment of the population fighting cancer. Interfering with the physician=s ability to act in the patient=s best interest is counter to our core values and certainly inconsistent with the good

work Congress has done to advance high quality, high value care to every American.

It is not who we are. Like everyone here today, I am very concerned about the increase in cost of treating cancer, especially rising drug prices.

However, as I outlined in my written testimony, the CMS proposal will not only fail to reduce drug prices but in fact it will likely increase costs.

In closing, I want to thank the members of the committee for their extraordinary support of community-based cancer care. Many on this panel and even more on the Full Committee have introduced legislation, authored amendments and wrote letters to improve cancer care and access for our patients.

Most recently, thank you to Congressman Bucshon for introducing H.R. 5122. On behalf of oncologists nationwide, thank you for holding this hearing to highlight the serious concerns around the CMS proposal.

I know we share the common goal of providing high-quality medical care to Medicare beneficiaries and thank you for your work on their behalf. When it=s appropriate I=m happy to answer any questions.

[The statement of Dr. Debra Patt follows:]

**********INSERT 7**********

Mr. Pitts. The chair thanks the gentlelady and now recognizes Dr. Schweitz five minutes for your opening statement.

STATEMENT OF DR. MICHAEL SCHWEITZ

Dr. Schweitz. Thank you, Chairman Pitts and Ranking Member Green, for inviting me to testify today on behalf of the Alliance of Specialty Medicine and the Coalition of State Rheumatology Organization.

The alliance is a coalition of national medical societies representing specialty physicians in the United States. The CSRO is a group of state and regional rheumatology societies primarily made up of community practitioners formed to ensure access to the highest quality care for rheumatologic disease.

I am a practicing physician and I spend the vast majority of my time taking care of patients. I am here today to discuss our concerns regarding the Part B demonstration project and to support Dr. Bucshon=s bill, H.R. 5122.

I note for the committee that our concerns track those expressed in the letter CSRO signed together with more than 300 stakeholders urging withdrawal of the demo.

We have expressed our procedural concerns in my written testimony. But today I will focus on our substantive concerns including prescriber behavior, patient access and sustainability.

First, clinical decision making is not influenced by the add-on cost. We take issue with the underlying premise of the rule which is the belief by CMS that clinical decision making is driven

by the opportunity to maximize revenue.

Data supporting this premise is not existent. In fact, in a recent report by Magellan it looked at utilization of rheumatoid arthritis medications and found that physicians are not routinely prescribing the most expensive product.

In fact, in 2014 in the physician=s office the most expensive product was one of the least prescribed. Second, many rheumatology practices will be unable to absorb this reduction. The current 6 percent add-on already results in practices without volume purchasing power, being underwater on several products.

A reduction from 6 to 2.5 percent plus a nominal flat fee will result in unsustainable cuts, especially considering that CMS did not incorporate the impact of sequestration in its calculations.

Specifically, the current reimbursement level is actually ASP+4.4 percent. Accounting for sequestration, the new rate will be ASP+0.86 percent with a flat fee.

Rheumatology is a specialty of small practices. For example, in my state there are only a few practices with seven or more doctors. Many practices with one or two rheumatologists do not have the purchasing power to buy at ASP.

Third, and most importantly, is the impact on our patients. As a result of these unsustainable cuts, if the demo moves forward patients will lose access to office-based infusions.

CSRO surveyed its members to ascertain the behavioral

response to the CMS proposal and 73.08 percent of respondents said that infusible Part B biologic options would no longer be available for Medicare patients in their offices -- 44.87 percent of respondents noted that they would refer to hospitals or external infusion centers to continue therapy.

Hospital referrals will create challenges for patients with rheumatoid arthritis including the distance to an outpatient center and increased personal cost to beneficiaries, especially those in rural areas.

It also runs counter to the goals of the model as costs of the Medicare program will be higher when patients must receive therapy in the outpatient department instead of the physician=s office.

Fourth, value-based purchasing cannot be one size fits all and will require significant stakeholder input through pre-rulemaking engagement. One of the concepts in phase two are interesting to explore while we believe they are not developed enough yet to even be in a proposed rule since they do not contain enough detail for comment meaningfully.

In addition, in rheumatology we don=t have comparative affecting this data to compare treatments. There are very few studies that do that. On average, it takes two or more drugs in sequence before finding the one that the patient responds to.

And finally, the cost of these drugs are closely grouped so

there is little reason to apply tools such as reference pricing.

In conclusion, the alliance and CSRO appreciates CMS= concern about high drug prices and would like to work with the Congress and the administration to find solutions.

However, we must oppose the Part B drug payment model as it suffers from serious procedural and substantial flaws that we believe render it unworkable and it does nothing to actually address the issue of drug costs.

As such, we have requested that CMS withdraw the model and we urge the committee to do the same. The alliance and CSRO thank the committee for its attention to this critical topic and for the opportunity to provide the views of practicing rheumatologists on the Part B model.

[The statement of Dr. Michael Schweitz follows:]

**********INSERT 8**********

Mr. Pitts. Chair thanks the gentleman and now recognizes Ms. Boyle five minutes for her opening statement.

STATEMENT OF MARCIA BOYLE

Ms. Boyle. Well, thank you, Chairman Pitts, Ranking Member Green and all members of the subcommittee for inviting me to testify today on behalf of the Immune Deficiency Foundation, or IDF.

IDF is the national patient organization founded in 1980 dedicated to improving the diagnosis, treatment and quality of life of people with primary immunodeficiency diseases through advocacy, education and research.

Primary immunodeficiency, or PI, represents a group of more than 250 rare chronic genetic diseases in which part of the body=s immune system is missing or functions improperly, resulting in decreased ability to fight infection.

Approximately 250,000 people are diagnosed with PI in the United States. Many require lifelong lifesaving treatment with immunoglobulin replacement therapy, or IG therapy, to replace antibodies needed to fight infection.

When patients cannot access IG, their lives are threatened and they experience more doctor visits, hospitalizations and time away from work and school.

I=m here today representing IDF and patients of PI, including my own son, who was diagnosed as an infant. We have serious issues with the Part B model and have asked CMS to withdraw it.

In addition, we signed a letter expressing these concerns led by the Arthritis Foundation and 24 groups representing millions across the country with wide ranging conditions such as lupus, mental illness, cancer and the health care needs our veterans face.

Our concerns are rooted in our experience with the previous Medicare reimbursement change that resulted in many of our Medicare patients losing access to their lifesaving treatment.

Starting in 2005, there was significant reductions in reimbursement for IG products as a result of the Medicare Modernization Act, which changed Part B drug reimbursement from the average wholesale price to ASP+6 percent.

In 2007, two studies by HHS reported on the difficulties physicians and specialty pharmacies had obtaining IG at the Medicare reimbursed price and the impact on patients= ability to obtain their infusions.

One noted the 61 percent of responding physicians that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment.

But the problems were even bigger than that. Many patients lost access to IG not only in the physician=s office but in the home as well. Thankfully, Congress responded by passing the Medicare IVIG Access Act with overwhelming support including support from every member of this subcommittee who was in Congress

at that time.

This demonstration is currently underway and IDF anticipates it will lead to a permanent fix in the current Medicare home infusion benefit for IVIG.

We are not crying wolf. Patients with PI have personally experienced the unintended consequences of major payment changes, which is why we wish CMS had engaged in more pre-rulemaking dialogue with stakeholders before issuing such a sweeping proposal that will dramatically impact beneficiaries.

In addition, our fear is that the proposed Part B model which explicitly includes the ongoing Medicare IVIG access demonstration will undercut this demo. Some specialty pharmacies report that they are already close to underwater with ASP+6 and low payment for their items and services.

With regard to the so-called value-based purchasing tools contemplated by CMS for phase two of the model there is insufficient detail on the concepts proposed to comment one way or the other and this is particularly troubling because we have never seen any definition around what value actually means particularly to patients.

Our patients have extensive experience with private insurers using the word value as a guise for implementing cost cutting tools that deny or delay access to needed treatments.

This experiment needs significant stakeholder input and

requires true dialogue with those who will be affected, especially patients. We also have procedural concerns with the model. The innovation center is authorized to test innovative delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

However, the model is not a test. It contains a Medicare program change. In addition, we are concerned that this policy change does not preserve or enhance the quality of care for beneficiaries. In fact, we are convinced it will reduce quality and access for our patients.

In conclusion, IDF has urged CMS to withdraw the Part B drug payment model and request the Congress do everything in its power to stop this harmful experiment from moving forward. It jeopardizes beneficiary access to needed medications, is the result of an opaque and poorly thought out process and may actually increase costs to the Medicare program.

I thank the committee for its attempt to create accountability in the CMS process and for the opportunity to present the potential implications of the model for patients with PI.

[The statement of Marcia Boyle follows:]

**********INSERT 9**********

Mr. Pitts. The chair thanks the gentlelady and now recognizes Ms. Block five minutes for your opening statement.

STATEMENT OF HEATHER BLOCK

Ms. Block. Good morning. Thank you, Chairman Pitts, Ranking Member Green and distinguished members of the Subcommittee on Health for inviting me to testify today.

I rarely share my cancer story as I find every cancer story is unique to the person and often frightening or boring to everyone else. But due to the importance of this hearing, I=d like to share my story.

I found a lump in my own breast while managing aid projects for the State Department and the U.N. in Afghanistan. I was mystified as no one in my family had ever had cancer before.

I returned to the U.S. for a diagnostic mammograms, and it was negative, so I returned to Afghanistan. My doctor suggested it might be a mastitis infection due to an injury. There was a chance I had bruised myself when I fled an attack that May. Running and jumping into a police truck will leave some bruises.

I ignored worsening symptoms as the mammogram had been conclusively negative. Within three months, I returned again to the U.S. for a second mammogram, and it was invasive breast cancer.

I continued to work through a mastectomy and six months of chemo, by then managing the monitoring and evaluation of aid projects in Iraq.

A year after my oncologist said I was cured, I learned that

the cancer had returned. It was now in my liver. There was a chance to surgically remove the cancer from my liver but cancer cropped up in my lungs within days of a pretty brutal liver resection.

Stage IV, no cure -- I was reeling with the news and my oncologist told me that 50 percent of women survived two years and only 20 percent approximately survive five years and that I would remain in treatment for the rest of my life.

At four and a half years, I=m living beyond most projections.

But this isn=t a feel good story. My personal catch-22 is that while drugs are keeping me alive I=m also going through my savings at an alarming rate.

I spend a ridiculous amount of time and energy trying to cut costs and drafting budgets based on living longer with less money and rising drug costs and trying to figure out how to move closer to my cancer center -- I do live in a rural area -- when I cannot sell my house.

It is the only asset that cannot be taken from me if I end up declaring medical bankruptcy.

I was so relieved when I found out that I qualified for Medicare, even though I=m well under 65. For those unaware, one can qualify for Medicare after 29 months on Social Security disability income if you=re unable to work.

My drugs are billed through Part B, as most cancer treatment

drugs are, but my relief was short-lived when I realized that the drugs are exceedingly expensive, and I am always on the hook for the 20 percent co-pay.

Medicare right now pays about $2,000 a month for my monthly treatment. There=s no out-of-pocket maximum for Medicare Part B. This means I=m responsible for paying 20 percent of ever cancer drug that I receive forever more.

This is why I was pleased to hear about the demo. The CMS demo proposes to address rising drug prices in a five-year evaluation, not an overhaul of Medicare Part B. It=s a way for the government to begin to shift pricing incrementally based on what they learn.

By evaluating payment models over a five-year period CMS can determine best practices without forcing me to change doctors, hospitals or affecting my drug coverage.

How else can Medicare continue to ask me to pay for 20 percent of increasingly costly prescription drugs without any evaluation of whether my money is being well spent.

I want to know that the drugs that are being used to treat my cancer are the ones that will do the best job and not just make my doctor the most money.

Every patient deserves that. In all of the uproar over this proposal I have yet to hear anyone say that the current system is working. Where did the payment formula of +6 even come from and

why would anyone push to keep a system where prescribing choices could be motivated by money?

It seems common sense to remove any possibility of financial incentive and instead create an appropriate handling or storage fee.

I also think it=s worth mentioning that my 20 percent co-pay is based on whatever Medicare pays. My provider may receive rebates or discounts. I=m still paying full freight.

I=m betting also that most patients don=t know that one component to be studies reduces or even waives the 20 percent co-pay and I=m hoping that my zip code is selected for that part of the demo.

These proposals simply put new options on the table to evaluate tools that are already being used in the private sector.

As a taxpayer and a patient, this is exactly what I want our government to be doing -- getting the best value for our money. Frankly, we need to start somewhere. The price of drugs is not sustainable.

CMS needs to test ways to hold down prescription drug spending. Patients like me should not have to choose between getting lifesaving drugs or paying our mortgage. No one should have to fear bankruptcy as much as cancer.

Finally, I=d like to share America=s dirty little secret. We already have drug rationing. It=s called affordability. Drug

innovation is meaningless without affordability.

Thank you for the opportunity to address the subcommittee and I look forward to answering any questions that you might have.

[The statement of Heather Block follows:]

**********INSERT 10**********

Mr. Pitts. The chair thanks the gentlelady and now recognizes Mr. Baker five minutes for your opening statement.

STATEMENT OF JOE BAKER

Mr. Baker. Thank you. Chairman Pitts, Ranking Member Green and distinguished members of the Subcommittee on Health, thank you for the opportunity to testify on the Part B drug payment model.

As president of the Medicare Rights Center, I lead a national nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counselling and advocacy, educational programs and public policy initiatives.

The Medicare Rights Center supports the proposed model. The model seeks to realign perverse payment incentives while ensuring that health care providers can continue to prescribe the medications best suited to the individual needs of patients.

The model also brings innovative value-based payment strategies being used in the private market to the Medicare program. Transitioning Medicare to a system that reimburses on the basis of value is an aim supported by diverse voices including patients and consumers, physicians, hospitals, health insurers and others.

This objective will not be realized if pursued only in silos, meaning the prescription drugs including Part B medications, must be part of these reforms.

Beyond improving the quality of care delivered to

beneficiaries, the proposed model may help the Medicare program by promoting more efficient use of program funds. Last year, Medicare spent $22 billion on prescription drugs, double the amount spent in 2007.

The Medicare Rights Center answers nearly 17,000 questions on its national help line and provides educational resources to over 2 million individuals each year through medicareinteractive.org and other means.

Challenges affording needed health care are a common theme heard on our help line. Sky-high cost sharing for Part B drugs is a notable concern most often for cancer and immuno-suppressant medications.

Many of these cases involve beneficiaries with original Medicare who lack adequate supplemental coverage. Estimates suggest that between 10 to 14 of beneficiaries only have original Medicare, making them responsible for a 20 percent coinsurance on all Part B services with no out of pocket maximum. These beneficiaries can be exposed to catastrophic costs which can reach as high as over $100,000.

Calls to withdraw the Part B payment model fail to acknowledge the very real and unrelenting beneficiary access challenges that exist under the current payment system, not merely hypothetical ones.

We commend the Centers for Medicare and Medicaid Services for

proposing to test solutions that have the potential to alleviate calamitous cost burdens which cause too many older adults and people with disabilities to forego care, and we urge members of Congress to support and strengthen the proposal.

The Medicare Rights Center engage in this very process. Our comments on the model focus on the need for enhanced monitoring and oversight.

Among the topics we addressed were concerns raised about how the model might shift how care is provided such as from community practices to hospital settings. Though we note that such shifts are already occurring and that shifts predicted in the past were not as draconian or dramatic as projected.

We identified practical solutions that we believe can address this and similar concerns. Such is the creation of a dedicated ombudsman for this payment model.

We encourage CMS to carefully weigh comments submitted by diverse stakeholders and we urge members of Congress to ensure that the proposal moves forward with refinements that reflect concerns identified through the comment process.

Prohibiting the payment model from moving forward would perpetuate a system that allows patients with less to go without needed care and halt progress in how -- in transforming how Medicare pays for care and saddle taxpayers and saddle taxpayers with the unrestrained costs of prescription drugs. People with

Medicare and taxpayers deserve a Medicare program that pays for high value innovative health care.

We believe the Part B drug model -- payment drug model presents an important opportunity to ensure that Medicare meets this high bar.

Thank you.

[The statement of Joe Baker follows:]

**********INSERT 11**********

Mr. Pitts. The chair thanks the gentleman, thanks each of the witnesses for sharing your expertise with us. The chair would like to note the presence of a former member of this subcommittee, a very valued member.

Dr. Phil Gingrey of Georgia is with us, sat for many years here with us on the dais. So welcome, Phil.

I=ll begin the questioning and recognize myself for five minutes for that purpose. There may be a misperception by some that the drugs we=re talking about being impacted in this proposal amounts to an issue of simple generic substitution -- that patients can be easily switched to lower cost treatments without consequences.

However, I know that many of these drugs do not have alternatives that are clinically interchangeable -- that even treatments that may appear similar can have different effects on individual patients. Many other patients only have one effective treatment option.

So, Dr. Patt, we=ll start with you and go to Dr. Schweitz. What have you seen in your own practical experience? What are some of the adverse effects that could occur if patients aren=t able to access their most appropriate prescribed treatment?

Dr. Patt. Thank you. I think there are many intended consequences of this policy. When Avalere did an analysis of the proposed Part B payment model, they demonstrated that for drugs

that cost more than $480 that many practices would be underwater. We know that even in the ASP+6, which is not really ASP+6 model today, that 25 commonly used oncology drugs are in fact underwater.

So high cost drugs would commonly be underwater and this is a disproportionate burden on oncology practices because we have a higher percentage of more expensive drugs.

Unfortunately, many of the new innovative products that we have that are very effect don=t have generic treatment alternatives -- don=t have interchangeable options that are a lower cost. And so by not allowing practices to use or not having practices be able to purchase drugs and give them to their patients it diminishes the Medicare beneficiary=s access to care.

An example of that is pembrolizumab, which is an immunotherapy in melanoma. So we all probably know about Jimmy Carter=s story with melanoma-that in August he was diagnosed with a metastatic melanoma to his brain.

Because of the advent of targeted therapy this immunotherapy pembrolizumab he informed his Bible school class in December that he was in remission. He would not have access to this treatment in Medicare under this new model.

Mr. Pitts. Dr. Schweitz?

Dr. Schweitz. In rheumatology we have a limited number of agents, some with different mechanisms of action. Unfortunately, we have no way to predict response. It=s pretty much trial and

error.

The average patient goes through at least two drugs before we find one that is effective for that patient and one of the tenets we like to follow is you don=t change a patient who=s doing well.

We have concerns about the phase two that may dictate that we change medications into, quote, Ahigher value meds" and we don=t have a definition of that in rheumatology.

In the private world -- in the commercial world -- there are, quote, Avalue programs" which are really only directed at cost and don=t take into account the patient=s individual responses.

So it=s a difficult problem to try to change medications to a, quote, Amore effective" or a, quote, Amore value-based medicine" when it doesn=t exist.

Mr. Pitts. Ms. Boyle, did you want to add anything?

Ms. Boyle. Well, I agree with the sentiments because I=ve seen my own son, for instance, be on a 5 percent immunoglobulin product change to a 10 percent and collapse on the floor twice when they were trying to get used to it.

He is now in his late 30s and has been on a wonderful immunoglobulin product for years and he=s all of a sudden having reactions. He=s having high blood pressure and trying to control the reactions, and thankfully there=s a subcutaneous option out there that he=s able to take -- a higher percent solution.

I have seen, again, private payers say well, we=re just going

to use the least expensive. Their value is expense. It=s not patient reactions. If my son or other patients have to change to that least expensive option du jour they will have reactions. Their well-being will be compromised and it=s unconscionable.

Mr. Pitts. One more question. There=s a lot of speculation about what drives a doctor=s treatment of diseases using injectables. It appears that there=s speculation that decisions are made based of the ASP.

So Dr. Patt or Dr. Schweitz, would you please tell us what=s more important to you? Is it your patients= need or preferences, your clinical evidence? Do you decide based on which drugs have a better reimbursement?

Dr. Patt. Obviously, as a physician I practice -- I provide the care and prescribe the care for my patients that is a mutual shared decision in their best interest and that is solely what drives our decisions about patient care.

Mr. Pitts. Dr. Schweitz?

Dr. Schweitz. I concur 100 percent. The appropriate choice of medication is based on what=s best for the patient. I can tell you in our practice of seven rheumatologists if you ask any one of the doctors what the drugs actually cost or what the reimbursement is they will not know.

Mr. Pitts. Thank you. My time is expired.

The chair recognizes the gentleman, Mr. Green, five minutes

for questions.

Mr. Green. Thank you, Mr. Chairman.

Mr. Baker, the Medicare Rights Center is a trusted and respected organization that advocates on behalf of American seniors. The Medicare Rights Center has come out in support of the proposed demonstration.

Can you explain to the committee how your organization came to this conclusion?

Mr. Baker. Well, I think, once again, as I said in my spoken and my written testimony, we see in a daily way the consequences of these high drug prices, which Ms. Block detailed I think so clearly as well in her own experience where folks just cannot afford the rising prices of these drugs.

The 20 percent co-insurance, if they don=t have supplemental coverage -- even those that do have supplemental coverage that might cover all or part of that 20 percent they are facing rising premiums for that supplemental coverage.

And then, of course, all people with Medicare see increases in the Part B premium based upon the rising cost of Part B medications as well as other services under Part B. And so we see the proposal as an attempt to, one, restrain those prices and provide relief to those individuals that are -- cannot afford these drugs and cannot get access to them all at all.

You know, these are patients in effect that are under water,

if you will, and cannot afford the care that they need. Secondly, we think it will help the program overall, once again get at high and rising --

Mr. Green. Let me -- let me ask another question.

Mr. Baker. Of course. Of course.

Mr. Green. In both your comments of CMS in testimony before the committee the Medical Rights Center identified ways the organization believes the model could be improved to ensure access is maintained and care is not disrupted. Can you elaborate on these and did CMS adopt any of your suggestions on the model?

Mr. Baker. Well, as you know, the comments were just recently submitted and now CMS has an opportunity to review all of the comments that they received. So we don=t know yet whether they=ve adopted them.

But what they have done is said up front that there will be claims monitoring in real time so if there are dislocations they can be fixed, hopefully in real time. That=s what they said they want to do.

We also have said that we think there should be an ombudsman as part of this program. So an ombudsman has been used in the DME purchasing project.

It has been very helpful in identifying problems quickly, helping individuals with those problems, also helping suppliers and others with those problems and also bringing systemic problems

to the attention of not only CMS but to you all here in Congress.

I think the other thing that we=re really looking for CMS to do is engage multiple stakeholders ongoingly and be very transparent with that monitoring that they=re doing of claims with all stakeholders including Congress, not only transparent with that monitoring and what they=re finding but also with any corrective action or corrective steps that we=re taking.

So we really think that this has to be done transparently. If there are not -- it needs to be shown that there=s clinical effectiveness here. I mean, if there aren=t clinically equivalent drugs they won=t move into this value-based purchasing kind of system that CMS wants to set up in phase two of the -- of the program.

We think that certainly physicians and other providers with clinical knowledge, pharmaceutical manufacturers with clinical studies, need to come to the table, need to work with CMS to show that there is clinical equivalence.

If there is not there=s nothing in this proposal that would prevent coverage for a prescription drug for someone that needs it regardless of price. This is --

Mr. Green. The proposed demonstration project -- I only have five minutes and if you talk for four of them I can=t answer.

Mr. Baker. I=m sorry about that.

Mr. Green. The proposed demonstration result in changes in

Medicare payments is going to be all Part B medications over a five-year period and require 75 percent of the providers to participate in either one or both of two phases.

Patients, providers and other stakeholders raised concern about the scope and size of this demonstration, recognizing the demonstration would affect care for our sickest seniors that=s being treated for serious illness I have concern -- I have concerns and urge CMS to reexamine the size of the proposed model. Is that one that they share? Because this is a pretty large model --

Mr. Baker. Right.

Mr. Green. -- to do and I know that we need to have enough to get good information.

Mr. Baker. Right.

Mr. Green. But it seems like they=re actually -- the model is impacting the whole system.

Mr. Baker. Well, I do -- we share that concern and many of the consumer organizations that we work with do share the concern and have questioned CMS about that.

I know that there is concern about rural providers has been mentioned and something that I think CMS needs to take a close look at as well as providers that are represented here at this table and the switch between facility type of -- the types of facilities that are providing this care.

So I do agree that that size and scope needs to be examined

and needs to be questioned. I also agree that the scope needs to be large enough to really test these models for payment.

Mr. Green. Thank you. My time is expired.

Mr. Baker. Thank you.

Mr. Pitts. Chair thanks the gentleman. I now recognize the vice chair of the Full Committee, Mrs. Blackburn, five minutes for questions.

Mrs. Blackburn. Thank you, Mr. Chairman, and Dr. Patt and Dr. Schweitz, I want to come to you first. And I mentioned Senator Grassley=s letter to HHS and concerns with the -- with this demonstration project and the fact that in the rule you have two different terms used, and I=ll just read from Senator Grassley=s letter. It=s more succinct. AI=m concerned that throughout this proposed rule two terms are repeatedly used -- study and test. These terms seem to indicate there is a component of research going on in this proposal."

So what I want to ask you -- each of you to weigh in on because you=ve got oncology, rheumatology. When you have read this rule do you see this as being clinical research or do you just see it as being a test that they have thrown out there? And Dr. Patt, I=ll come to you first.

Dr. Patt. Representative Blackburn, thank you. I do see this as an experiment but we conduct clinical research in our cancer center and patients have informed consent. They have to

electively consent to clinical trials. They can opt out if necessary and we follow adverse events and outcomes of those patients.

In addition, clinical trials are to investigate potential enhancements. We know that this experiment would decrease the availability of some treatments that have a survival advantage.

So this is an experiment that would never pass an institutional review board. You know, as you mentioned your concerns about rural clinics, as you know, average sales price is an average. Some large groups like hospital systems and large practices are able --

Mrs. Blackburn. Okay. Dr. Patt, let me just interrupt you there for the sake of time. So you say it wouldn=t pass an IRB. So should they be forced to go in and get an IRB before they embark on this?

Dr. Patt. I think that=s not a bad idea.

Mrs. Blackburn. Okay. All right. Dr. Schweitz?

Dr. Schweitz. You know, when you look at the goals of this plan, initially it appeared that it was to direct a way to save costs. But in meeting with CMMI, we realized -- we were advised that this is budget neutral and if you look at the rule it=s budget neutral.

So the goal of the program then is to collect information, which makes it a study -- a test. So if the goal is to collect

information and the patients are part of that process they should be signing informed consent. They should be notified this is going to impact their treatment. There may be changes in their treatment directed by phase two and they should be part of the process of consent.

Mrs. Blackburn. Okay. Thank you for that.

Dr. Patt, I want to come back to you. As I mentioned in my opening, we are very concerned about access and the impact that this demo is going to have on access in the rural areas.

And I have talked with so many of my health care providers and I want you just to lay out what you see as being the impact on rural Medicare access for oncology services.

Dr. Patt. I think that -- thank you for that opportunity. I think that this will be a burden disproportionately hitting small practices in rural areas and the reason for that is because average sales price is by its very nature an average.

Some people will pay higher amounts for procurement than that average and some people will pay lower amounts. Larger hospital systems and larger practices have the ability to have contracting arrangements where they purchase at a lower price. What this means is that smaller practices disproportionately pay a higher amount.

You can imagine if in the new model, which is ASP+.86 percent, given Prompt Pay discounts, sequestration and the six-month delay

in increasing prices that if you have a 1 percent difference in smaller practices they will lose money on all the drugs that they buy.

And so, you know, it will be impossible for smaller practices in rural areas to be open. What I think that you=ll see is a natural unintended consequence of this policy is that you=ll have a shift inside of service to hospital outpatient departments and you=ll have decreased access where patients in rural areas will have to travel further distances to receive care.

I think that that=s not in our best interest as we already have deficiencies in service in rural areas today.

Mrs. Blackburn. I thank you for that and I agree with you.

I think what we=re going to see this type of disruption in the health care marketplace is going to lead some people to feel that they have to abandon a certain protocol or therapy or course of care and go to something that maybe is not as fitted to them.

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

Mr. Pitts. Chair thanks the gentlelady. Now recognizes the ranking member of the Full Committee, Mr. Pallone, five minutes for questions.

Mr. Pallone. Thank you, Mr. Chairman. My questions are of Mr. Baker. The Medicare Rights Center=s mission is to advocate for access to health care for Medicare beneficiaries.

In addition to public policy initiatives, Medicare Rights

Center helps beneficiaries on the ground through educational programs and counselling including a national help line that provides direct assistance to Medicare beneficiaries and their friends, family and caregivers, and with beneficiary access as Medicare Rights Center=s sole focus, we in Congress should take seriously your recommendations to ensure the patient access is not disrupted by the proposed Part B drug payment demonstration project.

In your testimony you mentioned some monitoring and oversight ideas for the proposed demonstration that CMS should adopt in its final rule.

Could you just please discuss these proposals a little further and how they can help ensure that patients are getting the care they need and when have similar provisions worked or have they worked in other programs in Medicare?

Mr. Baker. Of course. Thank you.

First of all, you know, in the proposal as written there is claims monitoring so that -- and CMS is saying that they can fix problems that arise in real time with that claims monitoring.

The thing that we=re asking CMS to add to that protection for both providers and for patient is an ombudsman and an ombudsman, an ombudsman office was -- should be created for this program, we believe.

The idea actually comes from one that Congress enacted with

bipartisan support with the durable medical equipment comparative bidding program -- competitive bidding program.

The ombudsman would serve both beneficiaries and providers, as I said, by tracking complaints, troubleshooting appeals, monitoring beneficiary and provider experiences and reporting to CMS and Congress on a regular basis.

We also, as I said earlier, think that CMS should regularly engage multiple stakeholders as part of the demonstration both in phase one and then, of course, in phase two they need to do that in order to find these clinically effective drugs and alternatives.

So that monitoring of claims about how care is received, where it is received and then publicly release the monitoring that they are doing and the corrective action that they may have taken or they will be taking.

So that can be, once again, commented on by all the stakeholders and, of course, by you in Congress.

Mr. Pallone. Now, I was going to ask, unless you think you=ve already answered this, what should CMS do to evaluate the results of the demonstration projects to ensure that if they move forward and expand it that Part B drug payment policy best suits the needs of Medicare beneficiaries?

Mr. Baker. Yes, I think the claims data monitoring is something that is already in there that will help evaluate it. We

also think there should be additions to that.

So we think that there should be patient experience surveys and focus groups of patients and providers as part of the evaluation to track the beneficiary experience with differing payment models.

I think the -- they=ve also suggested that they might develop patient-reported outcome measures, particularly in phase two of the -- of the model. And so we strongly support that and we actually think that should be part of the phase two model.

And I think there should be multiple metrics that CMS uses. We don=t have a patent on what those metrics are. It may be an iterative process as it moves forward.

But it should definitely be metrics that focus on patient access, access to particular sites as well as care quality and the access to particular medications.

Mr. Pallone. All right. Thank you, Mr. Baker.

You did mention in your testimony I noticed a concern that has been expressed to me by some of the physicians in my district about shifting from community practices to hospital settings.

Did you want to talk a little bit more about why that might happen and whether that=s a good or bad thing?

Mr. Baker. Sure. First of all, I would say, you know, we certainly want to see Medicare beneficiaries have access to care in whatever setting is appropriate for them and the most convenient

setting to them so, you know, that is important to us and I think that=s why we urge CMS to monitor any unintended consequences vis-a-vis settings.

I think what we saw when we moved from AWP to ASP was a lot of concern about settings and moving to different settings and some of those concerns were -- proved not to be that significant.

That movement from physicians= offices to patient -- hospital outpatient is happening regardless of this model and so it is something that we need to be concerned about and that has a larger causation from a consolidation that=s happening across the health care market.

Mr. Pallone. Thank you very much. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman. I now recognize the vice chair of the Health Subcommittee, Mr. Guthrie, five minutes for questions.

Mr. Guthrie. Thank you. Thank you all for being here to testify and thank you for your service overseas. I often talk about the experience I had in Yemen when I -- not as a service person but in my role here and talk about the men and women in uniform over there serving and then I always point out -- I said there are a lot of people in civilian clothes that are serving too from the Department of State and putting themselves in harm=s way as well. So thanks for what you do in serving.

But I do have a couple of questions for the physicians here.

I know a couple of you said you view this as a test. Some of us believe this is a way -- the rule actually amends what we think is a statutorial set formula, which is the price plus 6 percent and subject to sequestration, so it=s really quite less -- 4.2 percent, I believe. But and so the concern is they=re using this process to amend the statute.

So wherever you are on what the policy should be I think all of us on this dais up here, both sides, should be concerned that our essential authority -- our legislative authority is being, I think, infringed upon.

But one thing that we did all agree on was MACRA last year. We all wanted to put MACRA in place because we all realized that people are in situations like Ms. Block and we need to come up with a system that takes care of patients, that=s sustainable, that works.

And I=ve often said when I=m talking about MACRA if we don=t have everybody together -- patients, providers -- if it just comes from Washington it=s not going to -- and goes out into the -- where I think Mr. Baker was talking about, unintended consequences that could come needs to be monitored -- you know the way that you eliminate those the most is that you have everybody involved going forward and because I don=t know what happens in rheumatology practice.

I mean, people who practice it tell me but I think if we all

sit down -- fortunately, I haven=t had -- been through an oncology practice as well.

But so I just want to look at the way this rule came about and we were troubled that unlike other CMMI initiatives it was negotiated behind closed doors, mysteriously placed on a website and then taken down, as far as I can tell without any input from providers, patients or other affected stakeholders and can the physicians here -- can you speak to CMMI=s engagement with stakeholders prior to issuing this rule?

Dr. Patt. Thank you, Representative Guthrie.

So I=ll say that this proposal, unfortunately, did not have stakeholder input prior to it being air dropped and, to your point, was put out without stakeholder input during a time of tremendous system change.

So with the advent of MACRA we=ve had to infuse tremendous resources in infrastructure and systems changes. For me as an oncologist to do things like providing a standard treatment plan, standards survivorship counselling, patient navigation, ways to collect patient reported outcomes, ways in which to collect data for the merit-based incentive payment system, it=s been a tremendous infrastructure investment.

Not only has that been a tremendous infrastructure investment but my practice, which treats half of Texans, will participate in the oncology care model and that has been a tremendous

infrastructure investment.

Mr. Guthrie. Okay. I have a question. Now I=m going to get Dr. Schweitz next. But so my next question to you was how is the way this proposal has come forward different than the way that you worked on the oncology care model -- how that came forth?

Dr. Patt. We worked in collaboration with three years. They got oncologists= input. We were collaborating on how that model was formulated and many individuals from the U.S. oncology network and Texas oncology participated. This CMS-proposed drug proposal had not input. It was put out there without any stakeholder input whatsoever.

Mr. Guthrie. The oncology care model was a collaborative effort to try to --

Dr. Patt. Yes.

Mr. Guthrie. -- look at costs to people in oncology care and try to lower the costs for people in oncology care.

Dr. Patt. Right. And for us in Texas oncology it brings in parts of that value because within the U.S. oncology network we have a system of value pathways where we take into account efficacy, toxicity and cost, looking at the incremental cost effectiveness in comparison to the next nearest comparator.

So when you have interchangeable drug opportunities we will always pick the lower cost alternative. And so that=s incorporated in this value-based system that we collaborated with

CMS on.

Mr. Guthrie. There was a big effort legislatively to put forth last year.

Dr. Schweitz, I only have a minute left. I=d like for you to comment on.

Dr. Schweitz. We did have extensive involvement with MACRA pre-rule, pre-law. So we were not involved in the development of this policy.

In fact, I believe that there was guidance to the -- to the MACs even before the rule was released. So this was being developed without any knowledge or input of the stakeholders.

Mr. Guthrie. And I think that=s a frustration from our side who are involved along with all of you and patients and MACRA is that, you know, we put a lot of -- that took a lot of time. The SGR finally went away.

We got MACRA in place and we=re looking at accountable care organizations value based. How do we have sustainable systems where people get caught in situations like Ms. Block and how do we avoid that and then all of a sudden this rule comes out when we=re in the middle of that process and that negotiation that we=ve all worked so hard on and it came from nowhere and we -- or came from above without any input and we really appreciate your testimony. My time has expired.

Mr. Shimkus. Gentleman=s time has expired.

The chair now recognizes the gentleman from New York, Mr. Engel, for five minutes.

Mr. Engel. Thank you very much, Mr. Chairman.

I want to give a shout out to our colleague, Phil Gingrey, who served on this committee for many years. Good to see you, Phil.

Let me say to Ms. Block I was quite moved by your testimony and I would like to ask you to talk a bit more about why your personal experiences led you to support this demo even in the midst of so many voices saying that the demo that would be harmful to patients.

Ms. Block. Thank you.

I think, first of all, that we need to all remember why this demo was even put out. With all the talk about drugs being under water and doctors being under water, patients are already under water.

We=re already there, and I talk to patients all the time because that=s what I do. I end up sitting in chemo rooms talking to other cancer patients and everyone is struggling. We=re struggling to stay alive.

We=re struggling to pay for our drugs. We=re struggling to pay for our mortgage and take care of our kids and do everything else. We have to start somewhere.

You know, as many times as -- as many things as I=m hearing

all of you say that you don=t like about this demo I say okay, then let=s work together and get a better finished product.

But you don=t throw the baby out with the bathwater, as my mother would have said. We need to start somewhere and this is a start.

I have read the regs through and through and I don=t see any issue with access to drugs -- my getting access to the drugs. So what I see is an attempt to figure out how to support patients. That=s what I=m seeing. So thank you very much.

Mr. Engel. Well, thank you. I think your testimony was very, very --

Mr. Shimkus. Eliot, would you get a little bit closer to that mike so --

Mr. Engel. Yes. Sure.

Mr. Shimkus. We want to make sure we hear you.

Mr. Engel. Bring two microphones then. Okay. Again, thank you, Ms. Block. You know, I also want to thank Ms. Boyle for talking a little bit about her son and they=re all so very courageous when we=re asking people to come up and tell personal stories. It=s really helpful to us and very, very courageous for the witnesses.

I have been a great supporter of infusion therapy and I=d like to talk about how the model that we=ve been discussing would impact patients who rely on such therapy.

Administering infusion therapies is very much more involved than administering oral medications.

Infusion therapy necessitates specialized equipment, supplies and professional services including sterile drug compounding, care coordination and patient education and monitoring.

And currently Medicare fully covers infusion therapy when it=s administered in a hospital, a doctor=s office or a nursing home. Medicare=s coverage of infusion therapy in the home though is fractured and does not adequately cover the services needed to provide home infusions. That=s the patient=s home.

Not only does this coverage gap force patients into expensive institutional settings but it also puts patients at risk of developing additional infections in these environments and on top of that this coverage gap prevents patients from receiving the treatment they need in the most comfortable setting possible -- their homes.

In 2003, Congress opted to exclude infusion drugs from the average sales price, or ASP pricing methodology, put in place for other Part B drugs, and as I mentioned Medicare does not reimburse for the services needed for home infusions and ASP pricing is insufficient to cover those necessary services. It just doesn=t make sense. I want to highlight it because I think it=s important.

Unfortunately, we still have not corrected this coverage gap

and that=s why Congressman Pat Tibiri and I have introduced H.R. 605, the Medicare Home Infusion Site of Care Act, which would expressly provide coverage for infusion-related services, equipment and supplies.

Given that this coverage is still not in place though I think we need to be cautious when considering changes to the reimbursement structure for infusion drugs.

While CMS has excluded DME infusion drugs from the phase one of the Part B drug payment model, these drugs have not been excluded from phase two.

So let me ask Mr. Baker, would you agree that more work is needed to ensure that Medicare beneficiaries can get the infusion therapy they need in the comfort of their homes?

Mr. Baker. Yes. I think that certainly Medicare doesn=t provide, as you said, adequate coverage right now for home infusion services and we would agree that this problem could be resolved outside of the demonstration.

It=s not necessarily affected one way or another by the demonstration, and certainly in part two this could be part of the resolution where there could be additional legislation that would bolster this benefit for beneficiaries and make it more available to them.

Mr. Engel. This is something that, obviously, is better for the patient but ultimately would involve a savings of money, it

would seem to me. So it seems like a win-win.

Mr. Baker. If the setting is as safe as you=re saying and it=s at least a less expensive setting and more convenient to the patient and that would certainly be a win-win.

Mr. Engel. Okay. Thank you. Thank you, Mr. Chairman.

Mr. Shimkus. Gentleman yields back his time.

The chair now recognizes myself for five minutes for questions.

And first of all, before we start, I ask unanimous consent that the letter on May 2nd signed by 241 Republicans and one Democrat in opposition to this rule be placed into the record. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 12**********

Mr. Shimkus. And the -- I want to go on, first, to Mr. Baker. Are you at all concerned that this proposal will force large numbers of Medicare beneficiaries into a mandatory test?

It was kind of talked about that this is not voluntarily. No one is signing consent forms. It=s a mandatory -- so does that have some -- are you concerned about that? I mean, that=s not really how tests are operated.

Mr. Baker. Well, we have a number of demonstrations that are going on throughout the country and, for example, ACOs --

Mr. Shimkus. Yeah. But I mean we=re talking about size too. I mean, this is really not a test. This is in actions a rule, you know, promulgated because it dwarfs -- the test dwarfs the remaining control group.

Mr. Baker. Right.

Mr. Shimkus. Significantly.

Mr. Baker. And we=ve done these kinds of, if you want to call them tests or --

Mr. Shimkus. Of this size, percentage wise?

Mr. Baker. We=ve changed reimbursement before. We were talking about a change in reimbursement. And so what I would posit is that we need to evaluate and monitor that change in reimbursement very carefully because whenever we do that there can be unintended consequences.

Mr. Shimkus. Okay. Let me ask another question. What=s a

larger expense to the individual patient? Twenty percent of a doctor office oncology service rendered or 20 percent of an oncology services rendered in a hospital setting?

Mr. Baker. Typically, the hospital settings can be more expensive than physicians.

Mr. Shimkus. Typically, like, if you find one that=s not please let us know. I just don=t think that=s possible, which is part of this debate, because especially in rural districts you=re changing really, in essence, a lifestyle in care of patients. We have great concerns.

I also, Ms. Block, want to -- thank you for your service to the country. Brats -- Army buy, I=m an Army guy so we=ve both done the deal.

But I don=t -- so you got Medicare based upon disability. When you entered Medicare were you given a choice of supplemental or a Medicare Advantage?

Ms. Block. Thank you for the question. I was not given the choice of a supplemental. Supplemental coverage for under 65 is a whole another issue. So I welcome a hearing on that.

Mr. Shimkus. Well, no. But were -- so you could have?

Ms. Block. I could not at that time, no.

Mr. Shimkus. And why?

Ms. Block. It wasn=t -- they didn=t offer policies in my state. That=s a state by state issue on whether insurers have to

offer policies for those under 65 that are disabled. Now, you could enter an Advantage plan but, unfortunately, I live in a rural area and the Advantage plan doesn=t cover any providers.

Mr. Shimkus. Right. Okay. Thank you. I wanted to clear that up. Appreciate it.

Dr. Schweitz and Dr. Patt, CMS continues to reiterate that, and I quote, nothing in this proposal will prevent doctors or other clinicians from prescribing the treatment that a patient needs.

Do you believe this proposal will impact your ability to prescribe and administer the most appropriate treatments for your patients in your office? Dr. Patt first.

Dr. Patt. Thank you.

Mr. Shimkus. And pull that mike close.

Dr. Patt. So I don=t believe that this will change my opportunity to prescribe the right therapy -- the appropriate therapy. It will alter my ability to deliver the appropriate therapy to my patients.

So I think that, you know, there are two alternatives. One, is that you either financially have a hazard for a practice that=s likely to have them closed by having them take money out of the practice to try to purchase a drug that they cannot afford or they=ll shift the patient=s care to a different site of service like the hospitals.

When we=ve seen the shift occur in the last decade, we know

that the hospital outpatient department increased 30 percent of the chemotherapy infusions that they have in the last decade and the reason for the shift are the financial changes.

We know that during that time period of that 30 percent shift that the hospital cost is a higher site of service care -- 30 percent higher -- and the patient outpatient cost is higher in the hospital outpatient department as well.

Mr. Shimkus. Because the co-pay will have to pay that 30 percent additional cost?

Dr. Patt. In fact, we recently conducted a study with the Community Oncology Alliance and the Millman Group that looked at the ten-year shift from 2004 to 2014, and if you take the drug -- if you take the costs in 2014 and attribute the cost only to site of service shift alone, it=s $2 billion in that one year.

Mr. Shimkus. Dr. Schweitz?

Dr. Schweitz. I agree with Dr. Patt. It won=t impact our ability to prescribe but our ability to deliver. If, as a business entity, we are unable to make ends meet we will not be able to provide the service.

That=s the central issue, and if we cannot provide the service in our office we=re going to have to move the patient to a different site of service, i.e. the hospital.

Mr. Shimkus. And I=ll just end on this. My time has expired. It doesn=t make sense to move people out of

doctor-center oncology services and move them into a hospital setting where they -- you have the chance of other infectious diseases that could occur and we all know of the risks that=s involved in that.

So with that, yield back my time and recognize the nurse, Ms. Capps, for five minutes.

Ms. Capps. Thank you, Mr. Chairman, and thank you all for being here today. I appreciate that this topic is brought up today and your expertise on it.

I believe we can all agree that the current system is not working. Providers have long noted that the ASP+6 drug reimbursement formula is inaccurate and some patients have struggled to come up with their 20 percent share of the cost of their share in these settings.

While the Part B program was intended to relieve our most vulnerable from catastrophic costs by providing access to important medications, for some -- many individuals, I would say, it has fallen short.

While the problems with the current system are well known, how to move forward to address it is more controversial -- complicated.

Through this -- though this demonstration project is an opportunity to explore strategies that could help transition Medicare into a more value-based system, I remain concerned about

some elements of the project.

Last week, my colleagues and I wrote a letter to CMS with concerns about certain components of the demonstration, particularly the nationwide scope of the project, the possible impact of it on small medical practices in under served areas and the potential shifting of patients of provider offices to expensive hospital settings.

As co-chair of the Cancer and Heart and Stroke Caucuses and as a nurse, my biggest concern is that CMS needs to find ways to address problems before they strike and have them place a strong mechanism or strong mechanisms to identify barriers to care that arise during the demonstration.

But and the very real fact that patients depend on drug therapies to extend and improve the quality of their lives is critical to this. But they and the system need to be able to afford it. In light of this, we must proceed thoughtfully and in the best interest of patients who will be most affected by this demonstration.

Ms. Block, you mentioned in your testimony the difficulties of paying the 20 percent co-insurance for vital drugs as a Medicare beneficiary.

And Mr. Baker, is Ms. Block=s experience common for Medicare beneficiaries? Should Medicare have an out of pocket maximum like the one in the Affordable Care Act to address this?

Mr. Baker. There=s about 10 to 14 percent of people with Medicare that do not have supplemental coverage, as Ms. Block does not, and they pay the full freight for that 20 percent.

As you note, there=s no out of pocket maximum in the Medicare program so that means that, you know, you=re paying that 20 percent up to infinity.

There=s never a place where Medicare takes over that coverage and provides you with 100 percent of coverage regardless of how much you=re spending out of pocket.

As you say, plans under the Affordable Care Act as well as plans available to employed individuals usually have some limit on out of pocket spending.

Ms. Capps. Okay. As we look at the plans for this demonstration program, my primary concern is for the patients and the tools they will have to address any barriers to care on the front end rather than afterward.

I know some of my colleagues have touched on this but it is a great concern to me. So Mr. Baker, as someone who works to ensure access to affordable health care for Medicare beneficiaries, are there aspects of the demo that will help protect patients from disruptions in care?

Are there any other protections that you would like to see? This is demonstration. This is the time --

Mr. Baker. That=s right.

Ms. Capps. -- to look at it. Any other protections you would like to see to ensure that patient care is not disrupted?

Mr. Baker. Once again, I think that the ombudsman program that was used so successfully and the Congress mandated for the durable medical equipment program is an important protection, would be -- would serve to protect consumers as well as this idea of getting shared decision-making tools out there for consumers and physicians to be able to work together and talk through clinical effectiveness as we move into phase two.

But I think the ombudsman is why I haven=t mentioned the pre-appeals process that would be used in the phase two and that would basically allow providers and/or consumers to do an appeal and to get relief if they feel that something is unavailable to them or not reimbursed at the right rate in the value-based phase of the program.

Ms. Capps. Thank you.

You know, just in concluding, in our efforts to improve the Part B program we have to keep our eyes on the goal of ensuring that patients have timely and affordable access to medications they need. That=s got to be the bottom line.

As we move forward, I urge CMS to pay special attention to the impact the demonstration project will have on our nation=s most vulnerable and to continue to work with affected stakeholders to address issues and unintended consequences before any changes are

implemented. This is the time to do that. So I yield back.

Mr. Shimkus. The gentlelady yields back the time.

The chair now recognizes the gentleman from Pennsylvania, Dr. Murphy, for five minutes.

Mr. Murphy. Thank you, Mr. Chairman, and I thank the panel for being here.

Before I start, Mr. Chairman, I just want to say I have a letter from the National Alliance on Mental Illness I=d like to submit for the record.

Mr. Shimkus. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 13**********

Mr. Shimkus. I=d also like to correct the record. There were four Democrats on my letter, not one. So --

Mr. Murphy. Thank you. That is recognized too.

Now, starting -- Dr. Patt and Dr. Schweitz, you both deal with chronic illnesses of cancer and rheumatoid disorders. I want to just point a couple of things.

In the area of mental illness you may be aware that 75 percent of people with severe mental illness have at least one chronic illness. Among them are ones within the areas you practice.

Fifty percent of people with severe mental illness have at least two and a third have at least -- have three or more other chronic illness and it is important we deal with those.

As a matter of act, Medicaid reports that they -- about 5 percent of Medicaid recipients are responsible for about 55 percent of Medicaid spending and nearly all of them have a mental illness.

So in the context of this, I want to ask a couple questions here. Both of you discussed in detail some of the concerns about the proposed demonstration, the negative impact on patient access to treat cancer and arthritis.

Hopefully, you=re aware that similar concerns are there also in the area of mental illness drugs, particularly long-acting injectables, anti-psychotic medications that treat schizophrenia and other psychotic disorders.

And, of course, when a person is more stable they are adhering to their other treatments for the diseases that you treat. When you=re not stable they=re not following through on this.

So with regard to this, I see that CMS= proposal is based on this idea that we should be paying for services based on the average patient under this phase two CMS proposal to provide, quote, Aequal payments for therapeutically similar drug products", unquote, and assuming the most clinically effective drug in a group can be identified.

But in practice -- and I need you to answer this both in about 15 seconds -- what impact will these one-size-fits-all value assessments have on patient access to individualized and personal medicine?

Can=t have a dissertation. Real quick.

Dr. Patt. I think that they will have decreased access to higher cost appropriate therapies.

Mr. Murphy. Thank you. Dr. Schweitz, would you so agree?

Dr. Schweitz. I agree.

Mr. Murphy. And so would you say with part of this is that, I mean, certainly you would agree that different people respond differently to the same medication with regard to effect and side effects. Would you both agree with that?

Dr. Schweitz. Right.

Mr. Murphy. And also that you need to adjust your

prescriptions in order to decrease side effects and increase effectiveness and therefore increase adherence. Is that correct too?

And now, the FDA said that medications not taken as prescribed occurs about 50 percent of the time and the Center for Disease Control tells that nonadherence causes 30 to 50 percent of chronic diseases treatment failures and about 125,000 deaths per year.

So I look at this then that -- an important safeguard in current law that says CMS cannot use cost effectiveness as a threshold to set Medicare average payments or payment policy.

However, in phase two of the proposal CMS intends to use cost effectiveness in its analysis to inform value-based pricing.

Now, would it concern you if CMS said that in order to implement this proposal they would ignore or waive this safeguard? Dr. Patt.

Dr. Patt. It would concern me.

Mr. Murphy. Dr. Schweitz.

Dr. Schweitz. Greatly. Greatly.

Mr. Murphy. And with regard to this, it also seems to me that, you know, obviously people more likely to take a medication that they -- that deal with the side effects -- some may actually take a certain medication because they find the side effects less objectionable and another one will say I=ll deal with the side effects but I=ve got to have the treatment for this too.

But these are all tradeoffs. But it seems to me that the way this proposal is coming through that it would limit the patient choice -- your choice -- and when a patient is not adhering to those drugs we saw from those statistics from FDA and CDC it may actually complicate the diseases tremendously and increase the cost. Now, can you elaborate on that, Dr. Patt and Dr. Schweitz?

Dr. Patt. So as I said before, I think that we would continue to prescribe the drugs we think that are appropriate. But this proposal would impact the patient=s ability to receive those drugs.

Mr. Murphy. And with that, isn=t it -- it=s best that -- I understand adherence works best if you actually have a conversation with a patient with regard to the drugs.

Dr. Patt. Absolutely.

Mr. Murphy. But if that -- and I know you=re saying you would prescribe it anyways -- but if there=s a difference in reimbursement or --

Dr. Patt. Well, I=m saying that I would prescribe the drug anyway. But you can imagine a scenario if someone was in a rural clinic and a drug is prescribed for them that they cannot receive in that rural clinic and they have to travel a distance to a hospital that may be two or three hours away to be able to receive that therapy. That would likely diminish compliance with a therapeutic regimen.

Mr. Murphy. Dr. Schweitz?

Dr. Schweitz. I would add to that. I=m in an urban area -- relatively urban area and there is no nearby hospital that I can send the patient to for an infusion.

Most of the hospitals are not treating our patients unless they=re 340Bs. So there is decreased access in that way as well and our fear is that our patients are going to drop out -- that compliance will drop and they won=t get treated.

Mr. Murphy. And my fear is they=re going to drop dead, according to statistics that CDC gives us and that=s pretty frightening. And so we may save a little money in the front end by not prescribing the drug but the complications of the overall cost increases need to be taken in account. I thank you for your insights, and I yield back.

Mr. Shimkus. Gentleman yields back.

At this time the chair now recognizes my colleague from the great state of Illinois, Ms. Schakowsky, for five minutes.

Ms. Schakowsky. Thank you, Mr. Chairman.

I want to make a couple of comments and then I want to get to Ms. Block and Mr. Baker with some questions.

But, you know, I just feel like if you are offended at all at the suggestions that physicians would prescribe higher cost drugs because you want to make more money then it seems to me that the suggestion of CMS, which is that there be a percentage plus,

a lower percentage, plus a flat rate would be something that would not be objectionable.

Also, I wanted to mention that I found it very curious in testimony of Dr. Patt as well that there=s over two pages within your testimony that are exactly the same language -- exactly the same language. Even the highlighted important parts are highlighted in the same -- in the same way. I thought that odd.

But I also wanted to mention that there was a difference. Dr. Patt and Dr. Schweitz touched -- both touched on something in their testimony.

Dr. Patt, you claimed that drug prices are not truly increasing faster than the rate of overall health costs. Yet, Dr. Schweitz, in your testimony you stated that you are keenly aware of unsustainable rise in drug costs and the effects of those costs on our patients= ability to adhere to treatment regimens. That=s your quote.

And I have to say, Dr. Schweitz, that I agree with you that spending on prescription drugs has risen significantly in recent years, driven by high and rising drug prices and recent IMS health report found that list prices for brand name drugs increased by more than 12 percent in 2015, representing the second year of double digit increases and on and on.

But I want to get to Ms. Block. Thank you so much for coming here today and telling your story. I know that there isn=t a

family including my own that hasn=t gone through the issue of -- related to cancer and treatments that are required and the issue of affording those treatments.

So you testified that your cancer treatment has been incredibly expensive. Can you detail some of the costs and how they=ve impacted your personal finances?

Ms. Block. I guess I can begin -- thank you, first of all -- I think I can begin to say that when you enter cancer world it=s a different world and no one talks about cost at first.

So it=s very interesting when costs -- when you start to ask questions and you have difficulty getting answers. I=ve had probably -- I think I=ve had six surgeries by now, including one with a long stay in the hospital.

I=ve had -- I=ve been through full ranges of chemo. This is the third type of drug that I=m on now. Having metastatic cancer what that means is you=re constantly changing drugs to keep up with the cancer so it=s always changing. And the future is stacking drugs, which means more than one drug at a time. So my expenses will only go up.

I make up budgets all the time. I think they=re probably meaningless because we don=t know how long I=m going to live. But you do the best you can to try and stay on top of it and that=s what life is like living with cancer in a country like ours where the drug prices just continue to rise.

I=ve actually done my own studies on what my drug costs in other countries as opposed to the U.S. I did it on social media. It=s an amateur study.

But I was able to find out that I=m paying much more than every other country that I found including Dubai, U.K., Denmark, you know, Norway, Sweden, on and on. Every other country that I have friends that were able to come back and tell me the monthly cost of their drug.

Again, it=s an informal amateur study but I keep looking at am I going to have to move eventually -- is that what my recourse is as the drug prices continue to rise and my savings dwindle.

Ms. Schakowsky. Thank you. I want to wish you the best, too.

Mr. Baker, why is it important that we work to reduce or eliminate cost sharing for beneficiaries? What impact would this have on one=s ability to access care?

Mr. Baker. I think, once again, the -- certainly for the folks that are -- that go bare, as it were, on the 20 percent it will increase their ability to access these treatments.

They=re disproportionately folks with lower incomes, anywhere from $10,000 to $25,000 a year, disproportionately African American.

Ms. Schakowsky. I want to tell you, I have talked to -- at my pharmacy. I said what happens when people are told it=s $1,000.

He says that most -- that often, not most, but often they just walk away.

Mr. Baker. They walk away. Right. Or they find a way to pay for it with family friends mortgaging their home and other situations like that.

So it=s an -- they are, as we were saying, underwater and unable to access the care.

Mr. Shimkus. Gentlelady yields back her time.

Chair now recognizes the gentleman from Missouri, Mr. Long, for five minutes.

Mr. Long. Thank you, Mr. Chairman.

We are in the 114th Congress which each Congress, of course, runs for a two-year period. During the 113th Congress, I did not miss a single vote in that two-year period, which there was about a half dozen of us that had that type of a voting record, and it=s tough when you catch flights, you miss flights, there=s connections, everything.

There=s two-minute votes. You have to be paying attention. And so voting is very important to me. In this Congress, the 114th Congress, I missed two solid weeks of votes.

Didn=t go to the floor for two weeks because our 25-year-old daughter, youngest daughter, was diagnosed with non-Hodgkins lymphoma and so I kind of realized what it=s like to go through that process. Thankfully, she=s doing great, had her 12 rounds

of chemotherapy, lost all her hair, got all her hair back, curls and all.

So we=ve been very, very fortunate with the -- what=s happened in oncology over this last 20-some years because I think that if it would have been 20 years ago we might not have had the same outcome.

So with that as a little background on my personal story with our daughter=s battle, Dr. Patt, supporters say this proposal will remove incentives to use higher-priced medications that are no more effective than alternative therapies. Can you talk about therapeutic alternatives in oncology?

Dr. Patt. Yes, sir. First of all, I wish your daughter the very best.

Mr. Long. She=s doing great.

Dr. Patt. I think most of us have a personal experience that we=ve been touched by at least someone with cancer. And so being able to deliver high-quality care close to one=s home is critical to maintain quality cancer care for Americans.

With regards to therapeutic alternatives, I=ll say that, you know, this proposal what it does is it disincentivizes utilization of high-cost options for treatment.

And so if there is a high cost alternative and a low cost alternative that=s equivalent in terms of efficacy and toxicity obviously --

Mr. Long. And they were closing the door. I didn=t hear -- in terms of what?

Dr. Patt. In terms of efficacy and toxicity. Then, you know, we would want to facilitate utilization of the lower cost alternative.

In fact, my -- the U.S. Oncology Network -- my network, which treats over 12 percent of Americans with cancer, we use a pathway system in the network which brings in drugs if there are alternatives that we only have the option of using the lower cost alternative. The problem is is there are actually few instances where a therapeutic alternative that is equivalent actually exists.

And so, like, my patient in my testimony who receives Recepten, or a monoclonal antibody, against HER2 there is not a therapeutic equivalent for that drug and it=s changed her survival from weeks to over a decade.

And so, you know, the therapeutic alternative would be to give no treatment because there=s not a low cost alternative to that drug.

So it=s either our sum scenarios -- you know, I think that the stage II non-small cell -- sorry, the stage two -- stage four second line treatment colon cancer drugs are a commonly discussed alternative where there are drugs that are of equal efficacy and similar toxicity profile that have a difference in costs.

Non-small cell lung cancer is also another area that=s frequently talked about.

But the truth is oncology is a collection of many different diseases and many of them don=t have equivalent therapeutic alternatives.

And so a decision to provide a lower-cost drug may convey a diminished survival benefit for patients and that=s not an alternative. We want patients to live better.

We want patients to live, you know, on chronic therapy -- to have even advanced cancer be a chronic disease where they can live a good quality of life and live a longer life.

Mr. Long. You sound like Michael Milken. That=s what he told me. He said he wanted to make cancer a chronic disease and they=ve done a lot of good work in that area.

Also, Dr. Patt, what impact will this proposal have on consolidation in the oncology space and the continued shift of care from the physician office to the hospital?

Dr. Patt. That=s a great question.

So as you know, in the last 11 years we=ve seen an over 30 percent shift from community clinics to the hospital outpatient department.

We recently conducted a study with Millman that demonstrated that community clinics gave about 84 percent of therapy in 2004 and only 54 percent in 2014.

We know that that site of service shift would be augmented with other financial pressures on community oncology practices and that the natural consequence of that action would be higher cost for payers and patients.

Mr. Long. Okay. Thank you, and I=ll yield back my four seconds, Mr. Chairman.

Mr. Shimkus. We appreciate that. Thank you very much.

Chair now recognizes our veterinarian from Oregon, Dr. Schrader, for five minutes.

Mr. Schrader. Thank you very much, Mr. Chairman. Appreciate it.

I, like many others, have submitted a letter to CMS regarding the scope of this demonstration project and also sympathy particularly for the special need groups and the types of medications you administer.

You just can=t go to a generic. I mean, oftentimes even in my little world of veterinary medicine there were brand names drugs that would work and only be the drug that would work for certain patients of mine.

So I=m hoping and based on past track record that CMS will be responsive to a lot of the concerns you=re talking about as we go forward and the trick is, as everyone I think has alluded here tonight or today, is get it right. You know, make sure we get it right.

I don=t think the appropriate way though is to just stop the rule altogether. I think we=re losing a little bit of focus and this is a proposed rule. CMS hopefully will be listening to this testimony and come back with something that is better than what we have seen so far.

I=d be probably not smart to legislate before I actually see the proposed rule. And the goal is to get to a value-based, you know, outcome and value-based purchasing is part of that.

I think there=s some alternatives that are being discussed. The second phase I think is pretty interesting. But aside just dealing with this individual drug or that individual drug, different incentives are probably very, very appropriate and I guess I=m hoping that as we talk through this that this -- we can -- it continues to be very constructive as we go along.

Shifting gear a little bit, I guess, Dr. Baker, you talk a little bit about phase two. We focused here pretty much on phase one but phase two offers some options and I=d be curious your take on that.

Mr. Baker. There are many physicians on the panel but I=m not one of them so --

Mr. Schrader. Mr. Baker, I do apologize.

Mr. Baker. So, first off, I think there are a number of value-based initiatives in phase two of this project, reference pricing, indication-based pricing, outcomes-based risk sharing

agreements and others and, you know, for example, Express Scripts is looking at implementing a system -- is implementing a system of indication specific pricing with some of its clients including with cancer drugs, several pharmaceutical companies and ensures health plans are partnering on outcomes risk -- outcomes-based risk sharing Novartis with Anthem and Cigna on Entresto for treating heart failure, others with other drugs around moving cholesterol range, United Health with Gilead on Harvoni for hepatitis C.

CALPERS, the large California insurer for public sector employees and Safeway are using reference pricing.

First Safeway used it for colonoscopies because of the differences in prices in the markets across the country that they were seeing and within markets where they were -- they had stores and now they=re expanding that to other aspects of health care.

So we see this in use in the private sector, these models being used -- being heavily evaluated and monitored once again in the private sector and we do believe Medicare in phase two of this project can take advantage of that experience but also needs to be very transparent, needs to be very engaged with stakeholders because as we=ve heard there are instances where there are not clinically equivalent pharmaceutical products. And so we went to make sure that there is access to all of the products and that an individual determination will still be able to be made with a

patient in a doctor.

That=s why the pre-appeals program is important that CMS has put in there with balance building protection to consumers which is very important as well to keep their access to all of the drugs that might be useful for their condition.

Mr. Schrader. Yes, and I do appreciate the tone of your response because the goal here is to treat the patient. I mean, we=ve heard everyone testify that is our goal and, you know, certainly, the -- historically we=ve seen that through the prism of our own particular specialty or practice mode and I think one of the goals of health care treatment going forward, whether or not we like the ACA or not, is to treat the whole patient.

And that usually involves, frankly, getting together as groups of doctors and hospitals and organizations, not necessarily giving up their private practice but working with your colleagues and having a relationship so that Ms. Block or whoever can get the right referral.

You come in for one issue and you discover another one maybe much more serious -- you want to make sure that that group takes care of you and I think the focus of this hearing has been on just a fee for service piece and the real goal, I think, is to get to bundle payments where different doctors with their patients get to make that particular choice of what type of treatment, what medication to get, if a medication is better than perhaps

psychological behavioral treatment.

There=s a lot of what we=re talking about here focussing only on a fee for service and I think that=s an old way of treating things. We need to be moving forward and value-based bundle payments would, I think, a lot of the concerns that have been expressed here.

And I yield back. Thank you, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman.

Now I recognize the gentleman from Virginia, Mr. Griffith, five minutes for questions.

Mr. Griffith. Thank you, Mr. Chairman.

I=ve heard from ophthalmologists about the proposed demonstration=s potential impact on access to sight-saving treatments for numerous blinding conditions including age-related macular degeneration -- AMD -- which is the leading cause of blindness in the United States.

Currently, there are three treatment options for AMD and other ocular conditions. Two are name brand drugs approved for ocular use and one is a cancer drug, Avastin, that is repackaged for off-label use by ophthalmologists for the eye.

The demonstration seems to assume that lower cost alternatives are always available. However, many ophthalmologists are experiencing increasing difficulties accessing the lower cost drug, in this case Avastin, due to new

federal and state regulations on the compounding and repackaging of drugs.

Also, notwithstanding the fact this committee worked very hard to allay fears -- the fears related to compounding drugs as a result of the New England Compounding Center scandal and tragedy has made many patients reluctant to receive a drug that is compounded and repackaged.

Both of these factors are leading to increased use of the more expensive brand drugs. Further, I am told that the continued access to Avastin for the treatment of AMD and other ocular decisions will effectively end if the FDA finalizes its pending February 2/15 draft guidance that calls for a maximum five day beyond use date for compounded or repackaged biologics.

So I know that it=s not directly on point with what you all have been testifying to this morning and you may not wish to comment on this.

But I=m just curious if you all would think that perhaps CMS ought to go back and take a look and instead of including all Part B drugs if the agency ought to give consideration to excluding certain classes and, obviously, the one that I just talked about are classes of drugs that include compounded repackaged drugs or drugs that are used off label for demonstration.

So do you think that -- and I guess I=ll ask you, Dr. Patt, although I understand it=s a little off your subject area.

Dr. Patt. Thank you, Mr. Griffith. So I=m not an ophthalmologist. But I will say that there have been discussions of many carve outs of carving out -- oncology of carving out in rural areas -- of carving out the oncology care model of carving out certain segments.

In my opinion, there=s not a right way to do the wrong thing. We need stakeholder engagement from the beginning to engage with CMS and value-based ways in which we can move forward like we did with the oncology care model. We want to participate.

In our oncology practices we have many value-based programs and have demonstrated pilots that have saved tens of millions of dollars. And so want to work with CMS on that kind of work. I don=t think that there=s a way to exclude certain segments from this pilot and make it make it better.

I think that we need to go back to the drawing board and look to projects like the oncology care model that are collaborative and value-based and have a better path forward. We would like very much in the oncology community to participate in that.

Mr. Griffith. Anyone else have a comment on that?

Okay. Sticking with you, Dr. Patt, I noticed on Page 11 of your written testimony -- I didn=t hear it in your oral testimony but in your written testimony you did talk about the era of hospital acquisitions and consolidation in the oncology space where doctors= practices are being taken over by the hospital and you

think this experiment by CMS will push more of that and then that makes it even harder for rural districts like my own and earlier one of the folks said they had a rural district -- they had 19 counties. I have 29 geopolitical subdivisions, most of whom are rural counties.

Dr. Patt. Yes, sir. So as we mentioned, the current model which is not really ASP+6, because you have to take out Prompt Pay sequestration and the six-month lag, has to take into account not only acquisition but also inventory storing of drugs, specialized handling of drugs and then -- and then disposal of drugs. So there=s a lot that has to go in there.

If you bring it down to ASP+.86 percent you have to know that average sales prices by its very nature an average. There are people that pay more than that average and people that pay less than that average.

Hospital systems in large practices are going to get preferential contracting to pay less than average on average and smaller practices are going to have less bargaining ability because of less volume-based purchasing and have to pay more.

So you can imagine if you=re at ASP+6 percent it has to pay for all of these other functions and you=re paying 1 percent higher. How will you be able to keep your doors open?

And so what we=ve seen with these financial pressures over the last decade is the natural consequence of the shift from

community practices to the hospital outpatient department and we know that that=s a 30 percent shift in the last 11 years.

We also know that that conveys on average a higher cost of over 30 percent and a higher co-pay for patients. And again, if we look at the cost of that shift in one year for cancer spending, just attributed to the distribution of site of service alone it=s about $2 billion.

Mr. Griffith. I do appreciate it. Thank you very much and I appreciate all of you being here today. Yield back.

Mr. Pitts. Chair thanks the gentleman and yields five minutes to the gentlelady, Ms. Castor, for questions.

Ms. Castor. Thank you, Mr. Chairman. Thank you to all of our witnesses for participating today.

Ms. Block, you=ve heard the testimony from the doctors on the panel that find the proposed model very problematic. They say that this will actually harm patient care, that oftentimes the doctors do not know the cost of drugs. They are focussed on what is best for the patient. How does this -- what=s your response to that?

Ms. Block. I guess I would start by saying in all of the work that I did in many countries around the world we were told that you could never even have the appearance of impropriety. So that we couldn=t take a cup of coffee from someone because there could never even be an appearance of impropriety.

So I guess what I would say is that if there=s a chance that there=s financial incentives involved here then we remove them and come up with an appropriate storage and handling fee.

But as long as there is an appearance of financial impropriety I=m going to question that, number one. And the second thing is I am just still not reading where there=s going to be a specific issue with access to any of the drugs.

I know my doctor is limited to what drugs I can get at this point too. But when I asked him he said he didn=t see any issue with access after reading this demonstration project.

So I understand that maybe in some areas there=s some drugs they=re saying that maybe they can=t afford to get. But is the 6 percent really making the difference?

So as a patient I really question some of this and just want to keep bringing the focus back to the patients are already under water. We already, you know, don=t have enough money to pay for this.

So when everyone=s talking about all these issues and obstacles in the way how do we get back to how to make the system work better for the patients.

Ms. Castor. And Dr. Schweitz, I mean, the cost of drugs now is astronomical for many families. You know, it just -- it does oftentimes push care out of reach for them and then when we have anecdotes about how costs are so much lower in other countries a

lot of my neighbours at home say why, why in America are drugs -- why do they cost so much more.

So what advice can you provide about how we better control drug prices and Medicare spending?

Dr. Schweitz. That=s a very good question. Unfortunately, I don=t have a clear answer. I do know that access to medications across all medications including generics is becoming problematic for our patients.

But it=s not an easy problem. There is no easy answer. I think we all have to sit down at the table -- patients, providers, payers and manufacturers -- to see how we=re going to work out that problem so that our patients have better access.

Ms. Castor. Dr. Patt, do you have any advice on how we address the high cost of drugs?

Dr. Patt. Ms. Castor, as you know, I=m very concerned and oncologists are very concerned about the increase in drug prices. I know you=ve heard from Dr. Diaz in your district with Florida cancer specialists and from others that this is a great problem.

Unfortunately, doctors don=t set the prices for cancer drugs, and when we look historically at what=s happened as a natural consequence of CMS decreasing reimbursement like the Prompt Pay discount and sequester, we see that during that time interval that costs went up tremendously.

And so what we see is that that=s not effective at controlling

drug prices. What I=d like to see -- what I think doctors can do and what we can partner with CMS to do within our realm is to change our system of care delivery to value-based systems and, again, like I=ve said before we would be -- we would like to be partners with CMS in that endeavor like we have been with the oncology care model and like we have done in our practice, the U.S. Oncology Network, that treats 12 percent of Americans with value-based pathways for a decade.

Ms. Castor. So Mr. Baker, you=ve heard what they=ve said. It=s -- gosh, it=s very difficult, they don=t have all the answers on drug costs. Dr. Patt says we can look at value-based and indeed the second phase of the model proposed to examine the impact of certain value-based and you=ve mentioned that.

What I haven=t heard is how we link this to outcomes as well. When you=re talking about value is there no -- is there no ling currently under Part B prescribing to outcomes? Do we not have the data and are you confident that this model is actually gathering that data?

Mr. Baker. I think that right now we don=t have a lot of that data. I think we=re starting to get this data in part of the private sector value-based experiments that I talked about earlier.

I think those models can lead to further outcomes-based information that we can use in this space to this model. But I

do think part of the challenge of getting to a good place on this phase two is making sure we have the right metrics, that we have the right feedback loop on outcomes.

And so we recommended that that definitely be a part of phase two.

Ms. Castor. Yield back.

Mr. Pitts. Gentlelady yields back. The chair recognizes the gentleman, Mr. Bilirakis, five minutes for questions.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it. I thank the panel for their testimony today as well.

Many conditions, especially within the rare disease community, lack treatment and those that have a treatment do not have multiple therapies to choose from.

Ms. Boyle and Dr. Patt, under the proposed rule it seems like it would encourage physicians to prescribe cheaper or generic alternatives to benefit from a flat fee in the reimbursement payment. Do many of the Part B drugs have interchangeable alternatives?

Ms. Boyle. Well, representing the Immunodeficiency Foundation we have a number of conditions that only have drug. There is not an alternative.

Whether it=s a generic or nongeneric, there=s only one drug and, again, if this experiment reduces the ability of the physician to provide that drug, when you=re talking rare diseases there are

very few physicians or hospitals around that have the ability to treat the patients.

It=s -- we experience this with intravenous immunoglobulin back in 2005, =06 and =07 with the change in the MMA and our patients were shifted from the physician office. Those that could find hospitals, and that was not always an easy thing to do to infuse immunoglobulin and where there are no generics but there are a number of products, we=re lucky to find a site of care.

Very often they had to change their product and there were many who could not find a site of care and had to go without. There were -- the OIG and the ASPE reports did report on adverse events for these patients -- sickness, hospitalizations -- and there just aren=t alternatives for the rare disease community. It=s not just our patients, it=s many other patients with rare disorders. So this is very frightening.

Mr. Bilirakis. Thank you. Dr. Patt.

Dr. Patt. So I=ll say in the oncology community there are a few examples of treatment alternatives with equal efficacy and toxicity that have differences in cost. And in those scenarios, you know, we think that utilization of the lower cost alternative would absolutely be appropriate.

The problem is is that these instances are few and far between. But in order to optimize the ability to give value-based prescribing, as I mentioned the U.S. Oncology Network had

pioneered value pathways.

ASCO, the American Society of Clinical Oncology, has come out with a pathways policy statement. There are other pathway systems which utilize this and the community oncology alliance has come out with a patient-centered oncology medical home also trying to utilize a pathway system really to facilitate appropriate utilization because most of the time there are not alternatives that are equally efficacious and toxic that are of different costs where a lower cost alternative is truly therapeutically interchangeable.

Mr. Bilirakis. Thank you. The second part of the question -- Ms. Boyle again and Dr. Patt-under the proposed rule one value-based tool is the use of reference pricing. This requires setting a standard payment rate for an entire group of drugs, usually using the most clinically effective drug in a group for therapeutically similar drugs.

Can you do reference pricing when there are no alternative drugs available?

Ms. Boyle. Well, for instance, in the immunoglobulin products there are 13 of them. There have never been any trials -- head on trials comparing them. They all are approved by the FDA but they=re all very different.

Some have high sugar content. Some have high salt content that would be bad for patients with heart conditions or diabetes.

They all have different formulations and patients react differently.

Some are appropriate for subcutaneous infusion which some patients need because they have poor venous access or they have other problems -- adverse events to IV.

Some patients cannot do subcutaneous. They are really not appropriate. So I don=t know how you would put these together. They -- patients react differently and when you look at the administration and talking precision medicine and let=s take best product for the individual patient this proposal runs counter to that.

Mr. Bilirakis. Dr. Patt, briefly, because I want to ask another question.

Dr. Patt. And I=ll say that we don=t today have a way to do reference and value-based pricing in oncology. But we would love to partner with CMS to do that instead of having a policy just drop down to us.

Mr. Bilirakis. Thank you very much. Mr. Chairman, I know I have seven seconds so more than likely I=ll yield back if you=ll give me a couple more. Can I have a few more seconds to ask another question? Yes? Okay. Thank you.

Ms. Boyle and Dr. Patt again, under the proposed rule one of the value-based tools would have CMS pay more for effective treatments. Does CMS actually define what an effective treatment

is?

In the world of oncology or IG where treatment is more personalized, as you said, is it wise to have an unelected bureaucrat declare what is effective for all seniors and I=ll start with Ms. Boyle.

Ms. Boyle. No, it=s not. Essentially, we want our trained immunologists who are specialists in treating our patients to make these decisions. Again, this is important for any condition.

Let=s not take the decision away from the physician that works with the patient in what is the best treatment and the best outcome for that patient.

Mr. Bilirakis. Thank you very much. Dr. Patt?

Dr. Patt. I completely agree. I think that think that this is not something that we want outside of our specialty=s hands -- outside of a physician=s hands and we would love to ask in partnership with CMS to think about a better path forward to try to institute value-based mechanisms for implementation of cancer care.

Mr. Bilirakis. Makes sense to me. Thank you very much. Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentleman and now recognizes Mr. Cardenas five minutes for questions.

Mr. Cardenas. Thank you very much, Mr. Chairman, and I appreciate all the panellists for sharing your expertise with us.

I=m not going to have enough time to ask all the questions that I=d like to ask. But at this time, Mr. Chairman, I have -- I request that I can submit two letters for the record. Request unanimous consent to submit the --

Mr. Pitts. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 14**********

Mr. Cardenas. One is by the American Cancer Society, Cancer Action Network, and the second is the California Life Sciences Association to the CMS on the proposed demonstration. Thank you, Mr. Chairman.

Okay. With that, my first question is the proposed demonstration would be made so that three out of four Medicare Part B providers across the country would have to participate once we entered phase two of the demonstration.

I have concerns about the nationwide scope of this demonstration. Mr. Baker, do you think it=s possible for CMS to modify and narrow the scope of the model and yield efficiently reliable results to evaluate with respect to the goal of the model?

Mr. Baker. Our understanding is that the breadth of the model is to -- in order to, you know, test the model and make the results generalizable or scalable. That said, I believe that they have been -- they have said that they=re open to suggestions about the scope and breadth of the model.

So I know folks have commented on that in this comment period and I hope and expect that CMS would take those comments into consideration in the comment period.

Mr. Cardenas. Dr. Patt, what do you think?

Dr. Patt. I think that, again, as I mentioned we need to do the right thing. There=s not a right way to do the wrong thing.

We want -- I think this proposal needs to be pulled back

completely. I think that we would really look forward to the opportunity to work with CMS on better value models. I sat with four of the leaders of CMS a month ago and gave them information on value pathways and how to work towards pathway systems or other alternative systems to reduce cost. I=ll meet with CMS again tomorrow.

The oncology community would really look forward to the opportunity to focus on value in a collaborative way and not have a proposal that=s bad medicine put down for patients that would decrease their access to care.

Mr. Cardenas. Okay. Thank you.

This next question is to Mr. Baker and Dr. Patt and also Ms. Boyle. I=m going to give you a scenario. If I am a senior who is seeing my doctor for a medicine that=s administered in his or her office and I disagree with the coverage or payment decision made by Medicare, it can seem daunting to file an appeal and many patients aren=t aware that there is even an appeal process.

CMS is proposing that a new pre-appeals process would be most applicable to phase two of this demonstration. Beneficiaries and/or providers can request a review of a claim before it=s submitted for payment, giving the provider the opportunity to discuss why a particular drug or treatment would be best for a particular beneficiary.

Currently, appeals are handled by the Department of Health

and Human Services Office of Medicine, Hearings and Appeals, otherwise known as OMHA. OMHA has a significant backlog in the processing cases.

Although beneficiary appeals generally can be expedited and the demonstration will establish a separate appeals process, apparently.

Mr. Baker, what=s your experiences been with the Medicare appeals process and do you think that there should be an expedited appeals process for patients established in the demonstration?

Mr. Baker. I definitely think there should be an expedited appeals process for the demonstration not only in the pre-appeals process but we=ve also recommended to CMS, as I=ve said before, that there be an ombudsman both in phase one and phase two. And I might add that in phase two a lot of the consultation that some of the other panel members are talking about will occur will regard to, you know, value-based payments.

So I do believe that consultation will ultimately occur before phase two value-based ideas are implemented.

Mr. Cardenas. Ms. Boyle or Dr. Patt, do you have any comments on that?

Dr. Patt. I would be concerned about an appeals processing causing inappropriate delays in patients receiving treatment.

Ms. Boyle. I would agree on that sentiment because our experience with appeals through the years have been people making

the decisions for the -- on the side of the insurers are not specialists, particularly when it comes to rare diseases, and we=ve just seen patients go through delays getting their lifesaving infusions.

Mr. Cardenas. Thank you all very much. I yield back.

Mr. Pitts. The chair thanks the gentleman. Now recognize the gentlelady from North Carolina, Ms. Ellmers, five minutes for questions.

Ms. Ellmers. Thank you, Mr. Chairman, and thank you to the panel. This is a very important subcommittee hearing and I appreciate all of the testimony I am hearing, especially from the personal side, and I want to take my congressional hat off for a moment and put my nursing hat on, and I do want to ask Ms. Block -- you have such a compelling story with your cancer treatments.

And I -- you know, I understand whether we=re talking about oncology, whether we=re talking about rheumatology or immunology, I know that the care that is provided is a multi-disciplinary education-based treatment where physicians and nurses, other health care providers are working with the patients and families to give the best care possible.

So I am -- I am very concerned about some of the issues that you have brought as patient, especially in your unique situation with Medicare and the inability to have basically a secondary or Medicare Advantage availability.

So my question is where are you getting your care? Are you getting your care at a hospital or are you getting your care at a community-based oncology clinic or independent physician?

Ms. Block. Sure. Thank you very much for the question.

First of all, for the record, I now have a supplemental plan only because I drafted a bill and passed it in my own state legislature.

Ms. Ellmers. Wonderful.

Ms. Block. The only way that I could get it.

Ms. Ellmers. Congratulations. That=s great.

Ms. Block. There=s more problems coming in the weeds since Congress last year did away with some of the -- selling some of the plans in the future. So I=m not going to be able to switch. But that=s, again, it=s trying to stay ahead of these bills.

Ms. Ellmers. That=s what we -- unfortunately, what we do so many times is try to keep putting out those fires.

Ms. Block. Right. So I=ve got problems that are going to be coming as my premiums rise to the point that I can no longer afford to pay them. I do -- I get my treatment now at a hospital outpatient location.

Ms. Ellmers. Okay. So but it is a hospital-based facility?

Ms. Block. That -- yes, and the irony is we don=t have any private oncology practices in the state so that I had great difficulty at one point because my co-pays would have been so much

less expensive to go to a private practice but there wasn=t one.

Ms. Ellmers. Right. Great. Okay. Well, I do -- I do think that it=s very important that we clarify that point because that gets back to the issue of cost based on site. The difference between the availability of having -- being a patient at a primary care or a private practice versus a hospital-based, I mean, because we=re talking about kind of two different beasts there when we=re talking about Medicare. So that is a very important point to make. But thank you for that because that was part of my concern.

I guess the next issue I would -- this last question for you as a patient have you had that conversation with your oncologist? Have you -- have you actually asked is there a less expensive treatment because of this issue that I=m faced with financially? Is there something else that I could be receiving?

Ms. Block. My oncologist is a rare bird and he -- when I was diagnosed with metastatic disease he sat me down and talked to me about my finances and I found when --

Ms. Ellmers. Wonderful.

Ms. Block. -- when I talked to other patients that that was unusual because he said, you know, things are going to be changing dramatically for you.

Ms. Ellmers. It=s an issue. Yes. Definitely.

Ms. Block. But that said, I ask -- every single time that I go for treatment I ask the nurses giving me the treatment, I ask

the doctors I talk to, do you know how much this costs.

Ms. Ellmers. Uh-huh. And they don=t, do they? I mean, the answer is usually no, right?

Ms. Block. For the most part. Especially the people the administering it.

Ms. Ellmers. Yes.

Ms. Block. No one -- no one knows and they=re all amazed when I tell them.

Ms. Ellmers. Yes. No, and that is typical because, you know, the health care provider is so concerned with providing for you the best possible care that you can receive that the issue of cost is not their focus.

It=s really the focus of us and for you and we want to do everything we can to make sure that you are getting that really good care and I just -- there again, I=ve only got 50 seconds left.

Thank you, Ms. Block, for your testimony today, and I just want to thank the physicians who are here -- Ms. Boyle and Mr. Baker as well.

I think we=re all in agreement here. Even though this is a possibility of moving forward, I think we really do need to put the brakes on this because there are other ways that we can achieve decreasing costs and I=m kind of a little amazed at some of my Democrat colleagues -- not all, because I think we all care about patients -- but I=m a little concerned because they seem to have

a little bit of amnesia.

And there again, I=ll ask Ms. Block -- are you aware of our 21st Century Cures Initiative that we passed here in the House?

Ms. Block. No.

Ms. Ellmers. This is actually an effort that we are putting forward. The Senate is working on their version right now and basically we are looking at all these issues and we have -- we have gone globally.

We have, you know, worked with other countries -- how are you providing care that=s less expensive. We=ve worked with our universities, our patient advocacy groups, our hospitals, our high-end universities, NIH, CMS, FDA, so that we can get drugs through the process in a more efficient less expensive manner that takes care of our patients.

So I think we need to stay on that front and move forward and give the best possible care we can and keep those drugs costs down as well. So thank you all again. I apologize, Mr. Chairman. I went over.

Mr. Pitts. The chair thanks the gentleman.

The chair now recognizes Dr. Bucshon five minutes for questions.

Mr. Bucshon. Thank you very much and thank you to all the panellists for coming and, you know, I=m reading the legislation to restart this discussion and let me tell you why.

First of all, one thing I want to -- I was a practising cardiovascular and thoracic surgeon for 15 years and to me discussing the and putting forth the premise of physicians out there basing therapy, whether it=s heart disease like I did or cancer therapy, based on how much they=re going to get reimbursed from Medicare is just -- it=s almost an insult to the medical profession, from my perspective, because are there bad actors?

There are in all fields. But I can tell you the doctors that I know and myself never consider that -- that we can make more money if we prescribe something else.

Now, that said, you also can=t have something like this that could force independent practitioners to lose so much money on these medications that it limits access and puts them out of business. So I think we have to address that. You know, but cutting provider reimbursement without addressing the ASP -- the actual costs of the drug in the first place is just the wrong approach.

And, you know, for the last 30 years CMS has tried to control health care costs by cutting provider reimbursement almost exclusively and look where we are today. It hasn=t solved the problem.

This is a big problem. I empathize with everyone including myself and my own family. I=ve got -- my father=s had all kinds of -- have had four different cancers. My mother has had problems,

and it is very expensive and costs are a real issue -- no doubt about that.

But it seems CMS proposed this without any stakeholder -- substantial stakeholder input other than MEDPac and threw mud at the wall and they=re now trying to figure out what=s going to stick and what isn=t and that=s just the wrong approach. This should be scrapped and we should start from scratch.

We do need to address costs, no doubt about it, but we should get stakeholder input and let=s all work together -- patients, patient advocates, physicians and CMS and Congress to address this issue.

You know, I=m going to ask a question of the physicians. First, say, for example, there are two practices within the proximity-in the same geographic area and for whatever reason their zip code isn=t picked.

How is that going to affect the local or regional care, potentially, of patients? Dr. Patt, do you want to -- I mean, that could potentially happen, right? You have an urban area -- half this town has this, half doesn=t and half the patients are at one place, half at the other. How is that -- how might that affect this?

Dr. Patt. I think that if I was in a zip code that was randomized to the experiment, having decreased reimbursement, that I would recommend my patient get the appropriate care not at

my center.

Mr. Bucshon. So you can see -- you have the federal government in Washington, D.C. affecting the local marketplace and health care and picking winners and losers.

Dr. Schweitz. In rheumatology it=s a little more problematic. There aren=t many of us and there is usually a significant backlog to get in to see a rheumatologist.

So if I=m going to refer my patient to the zip code across the county there=s going to be a delay in that patient being seen and a delay in that patient getting medication -- his treatment.

Mr. Bucshon. You know, and this is Washington, D.C. so I=ll say there very well could be politics involved in zip code selection, believe it or not. I just want to put that out there, and for anyone to think that there won=t be is just -- doesn=t know Washington, D.C.

And people that have substantial political pull in this town will not be selected to have their reimbursement cut. I=m just here to tell you. That=s what=s going to happen, and it=s going to substantially affect practitioners= ability in different communities to continue to treat their patients.

I mean, again -- I mean, the other thing is as it relates to alternative payment models, Dr. Patt and Schweitz, do you see this affecting the development and resources going into implementing APMs, for example? Do you see this as an issue?

Dr. Patt. It does. I can say that as a network, the U.S. Oncology Network will put 10 percent of Medicare beneficiaries with cancer on the oncology care model and it=s been a tremendous infrastructure investment.

How do you then account for having to not have patients receive care in your practice because all of a sudden they=re in this experimental arm of this experiment as well? I can=t imagine a foreseeable situation where that will work.

And I=ll just say that, you know, we, as a large practice, have bought into a lot of infrastructure investment in procuring for these alternative payment models. I cannot imagine how a smaller practice will buffer that change.

Mr. Bucshon. Yes. My time has expired but I just want to say this at the end is that I would urge CMS to scrap this proposal and come to the table with stakeholders and look at other ways that we can address patient medication costs.

They are -- it is an issue. We all know it. But cutting provider reimbursement, as I said in my opening, is not the solution to a very, very complicated problem that we all, I think, agree needs to be addressed.

I yield back.

Mr. Pitts. Chair thanks the gentleman. Now recognizes the gentleman from Massachusetts, Mr. Kennedy, five minutes for questions.

Mr. Kennedy. Thank you, Mr. Chairman.

In recent years, the cost of prescription medication has risen sharply, raising concerns for patients and their families about how to access and pay for needed drugs.

The Boston Globe has reported that prescription drugs represent the fastest growing component of health care and spending on prescription drugs increased 13 percent from 2014 to 2015.

Given that, in 2016 alone Medicare is expected to cover about 57 million people. This hearing on Part B could not be timelier, especially as the entire health care system of the United States moves toward quality and value-based systems.

Delivery system reform are a key part to the future of medicine and finding ways to reduce costs and ensure patients have access to affordable effective medications while spurring innovation is absolutely critical.

Ms. Block, thank you for sharing your deeply personal story in your testimony earlier this morning. As we know, Medicare Part B beneficiaries pay 20 percent co-pays with no out of pocket money. Can you tell us more about how your doctor decides what course of treatment is right for you?

Ms. Block. Thank you, sir.

Right now, I have limited options because I=ve already been through a range of drugs. So there are limits on what my doctor

can offer me, though he is very cognizant of the co-pay and we spend a lot of time talking about the co-pay and what I can do to afford it and how to make that work in my life.

Mr. Kennedy. Have you ever had to forego, Ms. Block, treatment because of those costs and if you have an idea of how this demo might affect you and patients like you?

Ms. Block. Okay. I have never foregone treatment under Part B. I still have a prescription under Part D sitting in CVS right now waiting for me to pick up since I can=t afford to get it. But under Part B I have not foregone treatment.

I don=t -- I believe this demo will enhance my life. I think that it=s going to reduce my co-pays. Number one, just off the bat, if they reduce that +6 percent after the -- you know, with ASP that=s a reduction in my co-pay right there. So that=s number one.

Phase two, if I=m lucky enough to be in an area that reduces or waives the co-pays then again I get a win-win. So I see this as a very positive move.

Mr. Kennedy. I appreciate that, Ms. Block.

Mr. Baker, in your testimony you highlight that Medicare paid $22 billion for prescription drugs last year, more than double the amount that was spent in 2007.

And as we all know, co-pays for beneficiaries aren=t decreasing either, which means that they already face access

problems. As CMS moves forward with the demo, how can they ensure that the demo doesn=t hinder access?

Mr. Baker. I think -- once again, I think the -- some of the key pieces are that real time claims monitoring that I=ve been talking about. The other piece is the ombudsman program that we recommended and that was used in the durable medical equipment area I think to such great effect.

And once we=re moving into phase two and the value based models that could be used in various specialities and with various drugs the pre-appeals process would be a way of, once again, getting access where access is needed and ensuring that it occurs.

And then finally, those kinds of outcomes measures that we were talking about earlier would be a way not only of protecting patients but also of gathering research and data. And finally, we believe focus group testing, patient engagement surveys as well as provider engagement surveys to make sure that CMS has a full range of information about the effect of the model.

Mr. Kennedy. And so I wanted you to clarify as well, sir, and I think you touched on it a little bit from your testimony earlier.

But can you clarify if this proposal would require to pick one drug over another or will doctors retain the ability to pick the most appropriate treatment for their patients?

Mr. Baker. The proposal -- the model as written would allow

doctors to prescribe, you know, whatever drug. This isn=t a formulary, a list of approved drugs or a limited group of drugs.

Doctors would be allowed to prescribe any drug that they felt was necessary for their particular patient and if there were some value-based program that indicated that maybe that drug wasn=t the most clinically effective drug, once again, that doctor or that patient could use the pre-appeals process to or an ombudsman program, we would hope, to make the case that no, this is the most clinically effective drug for this particular individual because of their particular health profile or clinical needs.

Mr. Kennedy. I appreciate that, and just before I run out of time I also want to echo some of the concerns raised by my colleagues that noted the similarities between testimonies today. I think that raises some important questions as well. I yield back.

Mr. Pitts. Chair thanks the gentleman.

Now, I recognize the gentleman from New York, Mr. Collins, five minutes for questions.

Mr. Collins. Thank you, Mr. Chairman. I want to thank all the witnesses. This has been very enlightening. And just to bring a couple of things up and Ms. Block, I know you said that you thought your co-pays would go down with this. Well, it doesn=t work that way.

I don=t want to be too contradictory but a $100 drug with a

20 percent co-pay is $20 whether it=s +6 or +2.5 because it=s -- the ASP doesn=t change. So your co-pay doesn=t go down.

But Ms. Patt -- Dr. Patt, in the big picture what I=ve heard is doctors don=t even know what the drugs cost, by and large. Maybe their office manager does.

They=re prescribing to treat their patients, as Dr. Bucshon indicated. So I kind of reject CMS= whole premise that nuancing the +6, which we know is really 4.3, or the 2.5 which is really .86, that would only make an impact in prescribing drugs if these doctors, before they treated a patient, would be bringing out the spreadsheet to figure that out, which I don=t see happening.

Now, let me go through the math as well. Let=s say you=ve got a drug that=s $1,000 and you go to the 2.5 percent but under sequester it=s .86 and you=re one of the randomized, you=re going to get $8.60 as your markup. Then you get $16.80 flat fee. So you get $25.40 for that $1,000 drug.

Now, if there was a $500 version you get $4.30 instead of $8.60. You get the same $16.80. So now you have $21.10. So if somebody said that switching it from six to -- you know, changing that would drive a physician to prescribe the lower cost, I guess I kind of reject that because under the higher cost you=re getting $25.40.

Under the lower one you=re getting $21.10. I don=t think either one is adequate. But I think a physician would rather have

$25 than $21.

So the whole idea of driving someone to a lower cost drug you reject it categorically because the practice is still going to get more money with a higher priced drug.

The co-pay to the patient may switch with a lower cost. I don=t know that doctors are facing that. So I guess -- I just don=t see in the big picture that any of this is going to impact the cost of drugs.

And I guess I=ll throw out there, because I=ve become the subject matter expert on 340B pricing, if there=s a problem in the cost of drugs and cancer drugs, it=s all the private oncology practices being purchased by hospital systems -- DSH hospitals who then get a 50 percent break from the pharmaceutical companies on these expensive drugs and you=re seeing oncology practices bought up every single day so that the hospitals can cheat and get their 50 percent discount, which goes to their bottom line, which comes out of the hide of the pharmaceutical companies.

And at the end of the day, you want to talk about why prescription -- why prices may be high? Every time one of these drugs is now getting a 50 percent discount, what do you think the pharmaceutical companies have to do?

I think the bigger savings is to stop the cheating on 340B pricing where fully covered patients the DSH hospitals are getting a 50 percent discount and yet the hospital is getting fully

reimbursed by Blue Cross/Blue Shield. I=m just venting a little.

But, you know, Dr. Patt, as I=m sure you=ve seen these oncology practices bought out and I=m sure you=ve seen them go to DSH hospitals where under 340B now there=s this huge discount which has to impact you. Would you care --

Dr. Patt. Yes, sir, and also imagine a scenario that=s different than the one that you gave. Imagine that you=re in a rural clinic where you purchased 1 percent above ASP, because again, ASP is an average.

Mr. Collins. Well, that=s the other thing. People think ASP is the price. It=s not. Some smaller practices pay more than ASP.

Dr. Patt. Right. So imagine you=re in a scenario where you purchased a drug for 1 percent more and let=s say it=s a high cost drug. Let=s say it costs $10,000 per month to administer.

You can imagine that that would be a substantial loss to the practice -- that if you transition that patient to the hospital outpatient department -- let=s say it=s an hour away -- where they may have the 340B preferred vendor program and the ability to purchase drugs at a 30 to 50 percent reduction in cost then you would, you know, transition that patient=s care. And I think that that trend is a trend we=ve seen over the last 11 years and we would see it continue to be propagated.

Mr. Collins. Well, and that=s -- you know, I=m concerned

about -- I have a very rural area -- access and it=s exactly what we=re seeing, that the private practices are being bought up for one sole purpose and that=s so the DSH hospitals can cheat.

Get the 30 to 50 percent discount on the most expensive drugs -- the $10,000 drugs -- driving that to their bottom line and disadvantaging health care systems in total, pharmaceutical companies and ultimately patients.

I yield back.

Mr. Pitts. Chair thanks the gentleman. Without objection, we have a member who=s not on the subcommittee present who would like to ask questions.

The chair now recognizes Mr. Welch five minutes for questions.

Mr. Welch. Thank you very much, Mr. Chair, and I thank my colleagues for allowing me to sit in.

I have some sympathy with the point that Dr. Bucshon made and Mr. Collins made about the cost and the complexities that are involved. But this is not a case of cutting provider reimbursement as much as it is about linking physician reimbursement to the cost of drugs they prescribe.

I share the concern about cutting to the bone the providers but there is no transparency whatsoever in what medical care costs are.

Nobody knows, and it=s really true with respect to

prescription drugs. And I have to say -- I=ve been in and out but I am very alarmed at the lack of sense of urgency about something that is absolutely intolerable -- prescription drug prices.

First of all, prescription drugs save lives. They alleviate pain. But the market is broken and the cost that the pharmaceutical companies are charging is starting to kill patients they=re trying to save, and no one=s in charge. The doctor, Mr. Collins says, doesn=t know how much the drug is. I think they should, like Ms. Boyle said.

That=s relevant to the everyday lives of people. And what I=ve heard Dr. Patt, from you, and Ms. Boyle is sort of the situation normal. It=s all complicated. We want to collaborate.

We have value pathways. But I don=t know what that means if I=m a patient. I literally don=t know what it means. What it sounds like to me is that let=s keep rolling.

The problem I have with the prescription drugs is that it=s not a value proposition. It=s a broken market. So the price is set by the pharmaceutical companies and it=s whatever the traffic will bear, and they=re protected by patent protection and they=re entitled to that because it=s intellectual property.

But should they be charging $1,000 a day to a patient or to the taxpayers that have no recourse whatsoever but have a desperate need for the medication? And where you have -- what we=re talking about here is not the global mess of pricing and health care.

We=re talking about this system where the prescriber makes more money when he or she prescribes a more expensive drug. Dr. Patt, is that true or not?

Dr. Patt. So I=ll say that in my practice that is not true because our physician compensation model is not in any way dependent upon the drugs that I write.

Mr. Welch. All right. But the --

Dr. Patt. But there is variability between practices. But I=ll say in my practice.

Mr. Welch. Right. So just -- if I=m -- if I am -- work at a car store -- you=ve rented a car and you=ve seen how much people try to upsell what it is you=re trying to rent and there=s an incentive for that sales person, right? Now, if a doctor=s going to prescribe something, let=s say a regular -- anybody who=s got -- and they=ve got their challenges, like Dr. Bucshon said.

They want to -- they=ve got to pay their assistants and they want to do the right thing. But the model by which they=re paid is affected by whether they prescribe the $50,000 drug or a $3,000 drug.

So just isn=t that an incentive that would make one question whether that affected their decision?

Dr. Patt. Mr. Welch, I think you make some very good points. But I=ll say again that my personal income from my practice that

treats half of Texans is not dependent upon the drugs that I write.

Mr. Welch. You know, that=s great and I=m talking just about the pricing model here.

Dr. Patt. Right. So I think there are limitations because when we talk about value pathways and when you have opportunities to exchange therapeutic alternatives, to use those opportunities for better value choices, that that=s really important.

But the issue of drug pricing --

Mr. Welch. But I mean, I don=t have much time so let me interrupt. But thank you.

In this proposal the medical provider is going to be in control of the final decision about what=s the most efficacious drug. That is agreed, because the patient=s entitled to that.

Mr. Bucshon. Will the gentleman yield real quickly? That depends, I would say, Peter, on whether or not the pricing results in a massive loss to the practice and then there may -- they may not be able to absorb that without closing their practice.

Mr. Welch. Thank you. Reclaiming my time.

Then that gets us to the heart of another problem. If we create this Rube Goldberg situation where you=ve got to do all of these maneuvers to try to get your practice to be solvent instead of paying fair value for the procedure you do but then not linking your bottom line to whether the prescriptions are the most expensive drugs then we=re going to get a chance to deal with this.

But I just want to say this is -- this is a disaster looming. The taxpayer can=t afford it, employers can=t afford it and patients like -- my first wife had cancer nine years. We had a fantastic oncologist.

Drugs extended her life. They alleviated her pain. They made our family much stronger. But you know what? That=s out of reach for more and more Americans in this economy can=t support it.

I really was upset about the lack of urgency on the part of some of the witnesses here to what I think is a very urgent problem.

Thank you, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman and recognizes Dr. Bucshon for UC request.

Mr. Bucshon. Yes, I just want to ask unanimous consent to introduce an article from the New York Times from an oncologist from New York describing how this type of thing may limit their ability to properly treat cancer patients.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 15**********

Mr. Pitts. Mr. Welch.

Mr. Welch. I=d like to introduce into the record an article examining congressional comments regarding Medicare=s Part B pilot proposal.

Mr. Pitts. Did you get that? You want to repeat it slowly? Turn on your mike.

Mr. Welch. I apologize. I=d like to introduce into the record an article examining the congressional comments regarding Medicare=s Part B pilot proposal.

Mr. Pitts. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 16**********

Mr. Pitts. That concludes the questions of the members present. We will have some follow-up questions. We=ll send those to you in writing. We ask that you please respond.

Thank you very much. This is a very important hearing, very timely, lots of good information. Members have ten business days to submit questions for the record. So they should submit their questions by the close of business on Tuesday, May 31st.

Without objection, this hearing is adjourned.

[Whereupon, at 12:42 p.m., the committee was adjourned.]